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HOUSE OF REPRESENTATIVES
REPORT
114–531

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017

APRIL 26, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. ADERHOLT, from the Committee on Appropriations, submitted the following

R E P O R T

together with

DISSENTING AND ADDITIONAL VIEWS

[To accompany H.R. 5054]

The Committee on Appropriations submits the following report in explanation of the accompanying bill making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for fiscal year 2017.

CONTENTS

OVERVIEW

The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee has jurisdiction over the U.S. Department of Agriculture (USDA), except for the Forest Service, the Food and Drug Administration (FDA), the Commodity Futures Trading Commission (CFTC), and the Farm Credit Administration (FCA). The Subcommittee's responsibility covers a vast and diverse group of agencies responsible for such things as promoting

the production of a plentiful food supply; assisting farmers and ranchers across the country with sound production practices; improving the quality of life and vitality of communities in rural America; assisting indigent populations in the U.S. and abroad with basic nutritional needs; research and development in agriculture to improve productivity and stability; overseeing commodity markets that provide confidence for businesses, traders, investors, and the public; supporting a safe food supply; and safe and effective drugs and medical devices. The activities of these agencies impact every American every day of the year.

The fiscal year 2017 discretionary spending in this bill totals $21,299,000,000, which is $451,000,000 below the fiscal year 2016 enacted level and $281,000,000 below the President's budget request for fiscal year 2017.

The funding levels provided in this appropriations bill continue to demonstrate how seriously this Committee takes its responsibility to fund the highest priority programs and activities while helping to address the Nation's debt, deficit, and economic challenges.

The Committee does not include funding to begin new programs and, except where specifically noted, does not provide additional funding for pay increases. The Committee identifies savings of almost $1,000,000,000 at USDA, provides relief for excessive leasing costs at the CFTC, and reins in regulatory overreach at the FDA, USDA, and CFTC.

OVERSIGHT AND HEARINGS

Consistent with the Committee on Appropriations Oversight Plan, as approved and transmitted to the Committee on Oversight and Government Reform and the Committee on House Administration in January 2015, the Subcommittee began the fiscal year 2017 process committed to maintaining the Committee's focus on comprehensive oversight of federal discretionary spending under the Subcommittee's jurisdiction. In order to thoroughly review the President's budget request for fiscal year 2017 and examine how funds appropriated in previous years had been managed, the Subcommittee held 11 hearings for the mission areas, agencies, and programs of the USDA, the FDA, and the CFTC. The hearings included:

Commodity Futures Trading Commission—February 10, 2016
Secretary of Agriculture—February 11, 2016
USDA Inspector General—February 12, 2016
USDA Food, Nutrition, and Consumer Services—February 24, 2016
USDA Food Safety—February 24, 2016
Food and Drug Administration—February 25, 2016
USDA Natural Resources and the Environment—February 26, 2016
USDA Marketing and Regulatory Programs—March 3, 2016
USDA Rural Development—March 15, 2016
USDA Research, Education, and Economics—March 16, 2016
USDA Farm and Foreign Agricultural Services—March 17, 2016

As stewards of the taxpayer's dollar, the Subcommittee is responsible for ensuring that the funds under its jurisdiction are wisely

invested and properly used. As such, the Subcommittee established four objectives to guide its hearings, oversight activities, and the development of its bill and report recommendations for fiscal year 2017. These objectives include increasing oversight, efficiency, and the need for effective outcomes; keeping rural America vibrant; supporting American farmers, ranchers, and producers; and protecting the health of people, plants, and animals.

Through its oversight activities, the Subcommittee can accomplish the goal of improving the management of agencies and programs by identifying and reducing waste, fraud, and abuse. It is joined in this effort by USDA's Inspector General, CFTC's Inspector General, and the Inspector General's Office of the Department of Health and Human Services. During the hearing with USDA's Office of the Inspector General (OIG), the Subcommittee focused on USDA financial statements, improper payments, and how well USDA's agencies are managing their programs.

The Subcommittee questioned the Secretary of Agriculture about spending reductions included in USDA's budget request that are proposed for some of USDA's most popular and successful programs, such as crop insurance, Animal and Plant Health Inspection Service (APHIS) pest and disease programs, and Rural Development loan and grant programs. The Subcommittee also discussed ways in which USDA can assist U.S. producers struggling to recover from citrus greening, highly pathogenic avian influenza (HPAI) and declining market prices.

When it convened to review CFTC's increased budget request, the Subcommittee questioned the need for a 123 percent increase since the Financial Crisis of 2008 and continued to identify wasteful spending in the agency's excessive leasing costs. The Subcommittee made clear that it does not tolerate fraud, waste, or abuse in any program, knowing that these actions undermine support for all programs. The Subcommittee also examined the CFTC's regulations regarding the Swap Dealer de Minimis level.

When the Subcommittee heard from the FDA, it focused on preventing burdensome regulations for producers and the American people, in addition to ongoing discussions of how the FDA is implementing the Food Safety Modernization Act (FSMA), the motivation for the generic drug labeling rule, and regulation of tobacco products. The FDA regulates over 20 percent of every consumer dollar spent on products in the U.S., and so the Subcommittee reminded the FDA to be aware of the comprehensive economic impact of their regulatory decisions.

The Subcommittee heard from USDA's Food, Nutrition, and Consumer Services mission area and reviewed implementation of school meal regulations as well as waste, fraud and abuse within nutrition programs. The Members discussed potential ways to identify and help beneficiaries of nutrition programs who showed indications of illegal drug use.

During the hearing to review the USDA's Rural Development (RD) mission area, the Subcommittee focused on the shocking spike in the cost of the Rental Assistance program and support for rural broadband programs. Members also questioned the Administration on proposed funding cuts for rural housing programs necessary for the continued well-being of rural communities.

During the hearing to review the USDA's Research, Education, and Economics mission area, the Subcommittee focused on the efficient use of limited research dollars and coordination of research efforts within USDA. The Subcommittee also expressed its interest in USDA's ongoing investigation of animal care at the Agricultural Research Service's (ARS) Meat Animal Research Center (MARC) in Clay Center, Nebraska.

The Subcommittee discussed implementation of the 2014 farm bill and international, in-kind food aid during its hearing with USDA's Farm and Foreign Agricultural Services mission area. The Subcommittee also received an update on the farm bill directive to create an Under Secretary for Trade and Foreign Agricultural Affairs within USDA.

During the hearing with USDA's Marketing and Regulatory Programs mission area, the Subcommittee focused on USDA's response to emerging threats to animal and plant health, particularly the recent outbreak of HPAI.

Because the Subcommittee knows that it cannot fulfill all requests for funding, it focuses on those areas that are most effective, broadly supported, and capable of delivering positive outcomes and a substantial return on investment. The Subcommittee will monitor the issues identified by its constituents and other stakeholders, those issues discussed at the hearings, and other high priority matters relevant to the management of USDA, FDA, CFTC, and FCA. The Subcommittee will maintain its oversight efforts throughout the 114th Congress to ensure taxpayer dollars are wisely and prudently used on behalf of the American people.

TITLE I

AGRICULTURAL PROGRAMS

PRODUCTION, PROCESSING, AND MARKETING

OFFICE OF THE SECRETARY

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$45,555,000
2017 budget estimate	64,403,000
Provided in the bill	44,555,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	19,848,000

The following table reflects the amount provided by the Committee for each office and activity:

OFFICE OF THE SECRETARY

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Office of the Secretary	$5,051	$10,178	$5,051
Office of Tribal Relations	502	755	502
Office of Homeland Security and Emergency Coordination	1,496	1,592	1,496
Office of Advocacy and Outreach	1,209	11,220	1,209
Office of the Assistant Secretary for Administration	804	807	804
Departmental Administration	25,124	27,420	24,124
Office of the Assistant Secretary for Congressional Relations	3,869	3,919	3,869

OFFICE OF THE SECRETARY—Continued

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Office of Communications	7,500	8,512	7,500
Total	$45,555	$64,403	$44,555

COMMITTEE PROVISIONS

For the Office of the Secretary, the Committee provides an appropriation of $44,555,000. The Committee recommendation includes the following offices under the Office of the Secretary: immediate Office of the Secretary; Office of Tribal Relations; Office of Homeland Security and Emergency Coordination; Office of Advocacy and Outreach; Office of the Assistant Secretary for Administration; Departmental Administration; Office of the Assistant Secretary for Congressional Relations; and Office of Communications.

Pay Cost.—The Committee does not include requested funding for a civilian pay increase across the Department. Should the President provide a civilian pay increase for fiscal year 2017, it is assumed that the cost of such a pay increase will be absorbed within existing appropriations for fiscal year 2017.

Commodity Credit Corporation (CCC) Obligations and Commitments.—The Secretary is directed to notify the Committees on Appropriations of the House and Senate in writing 15 days prior to the obligation or commitment of any emergency funds from the CCC.

CCC Report.—The Committee directs the Secretary to provide a report on November 15, 2016, and May 16, 2017, on planned uses of funding under the authorities of Section 4 and Section 11 of the CCC Charter Act.

Crop Biotechnology & Biotech Ingredients.—Plants, food, and food ingredients developed using genetic engineering were introduced into the U.S. food supply in the 1990s. Public and private sector scientists knowledgeable in genetic engineering, toxicology, chemistry, nutrition, and other scientific areas have carefully evaluated and assessed the safety of these products and have determined that such products are safe for human and animal consumption. The Committee provides a total of $3,000,000 for the FDA to coordinate with USDA to provide education and outreach to the public on the safety and benefits of crop biotechnology and food and animal feed ingredients derived from biotechnology. The Committee expects this educational information to be posted on both agency websites and through other social media and communications platforms within 60 days of enactment of this Act.

Federal Employee Conduct.—The federal government grants federal employees with tremendous responsibility and trust to carry out their duties. They must do so free from conflicts of interest and without seeking private gain. Employees are public servants charged with implementing federal programs in a legal and ethical manner. Federal employees are reminded that they shall not advance a personal agenda or give preferential treatment to any outside organization or individual within the government programs which they administer. Information that is received by the em-

ployee, including information from the employees, offices, or Committees of the Congress of the United States, should be handled in a professional and confidential manner according to the federal government's code of conduct, standards, regulations, and statutes. The Committee is aware of recent conduct in violation of these principles, and the Committee believes that it is incumbent upon agency officials to take immediate disciplinary action when they confirm such behavior.

Nutrition Research Coordination.—The Committee seeks to bring more transparency and coordination to nutrition research and evaluation projects conducted by the Department. The Secretary is directed to ensure both the Research, Education, and Economics (REE) and the Food, Nutrition, and Consumer Services mission areas coordinate and finalize the Food and Nutrition Service (FNS) Research and Evaluation Plan submitted in fiscal year 2017 to prevent duplication of efforts and resources. The plan submitted for fiscal year 2017 shall include a brief description of the projects FNS expects to pursue and whether or not it was mandated by law.

Section 732 states that FNS shall not receive any funding for new research and evaluation projects in fiscal year 2017 until the Committees on Appropriations of the House and Senate receive the fiscal year 2017 Research and Evaluation Plan that has been developed in coordination with REE. In submitting the fiscal year 2018 budget justification, FNS is directed to provide its Research and Evaluation Plan simultaneously with its budget request. There is an expectation that this process will be followed in the future.

Improper Payments, Unachieved Savings, and Financial Management.—The Committee remains concerned with the Department's overall management of crucial financial issues that result in savings and efficiencies for taxpayers. This includes its consistent lack of compliance with mandatory improper payments reporting information, failure to complete OIG recommendations that would total $801 million in savings, and delaying the submission of financial statements for the second consecutive year.

The Department has made gradual progress on some of these issues. USDA has reduced the amount of unachieved savings identified by the IG slightly since fiscal year 2015, and certain agencies, including the Risk Management Agency (RMA), have reduced their improper payment rates. The Committee directs the Department to properly report information related to improper payments and continue to work to reduce unachieved savings. Finally, the Department is directed to work with the Office of Management and Budget to submit financial statements on schedule for fiscal year 2016 and correct deficiencies identified for fiscal year 2015.

Avian Influenza.—The Committee appreciates the Department's response to the recent outbreak of HPAI, which caused considerable devastation to America's poultry industry and cost the economy well over $1,000,000,000 between the public and private sector. The Committee encourages the Department to continue its work with trading partners to reopen trade for poultry and poultry products to the greatest extent possible. The Committee will continue to closely monitor the situation and directs USDA to keep the Committee apprised of future developments.

Congressional Relations Allocation Notification.—Within 30 days of the enactment of this Act, the Secretary shall notify the Commit-

tees on Appropriations of the House and Senate on the allocation of the funds provided to the Assistant Secretary for Congressional Relations by USDA agency, along with an explanation for the agency-by-agency distribution of the funds.

State Office Co-location.—The Committee continues to direct that any reallocation of resources related to the co-location of state offices scheduled for fiscal year 2017 and subsequent years is subject to the Committee's reprogramming procedures required under law.

Administrative Provision.—The Committee directs the Secretary to advise the Committees on Appropriations of the House and Senate, through the Office of Budget and Program Analysis (OBPA), of the status of all reports requested of the Department in this bill at the time of submission of the fiscal year 2018 budget request and monthly thereafter. The Department needs to improve its timeliness in adhering to this requirement as stated in the fiscal year 2015 and 2016 House Appropriations reports. The Committee reminds the Secretary that all correspondence related to the directives in this bill must be addressed to the Committee on Appropriations.

Loan and Grant Programs.—The Committee directs the Department, through OBPA, to provide quarterly reports to the Committees on Appropriations of the House and Senate on the status of obligations and funds availability for the loan and grant programs provided in this bill.

The Committee further directs that if an estimate of loan activity for any program funded in Titles I and III of this bill indicates that a limitation on authority to make commitments for a fiscal year will be reached before the end of that fiscal year, or in any event when 75 percent of the authority to make commitments has been utilized, the Secretary shall promptly notify the Committees on Appropriations of the House and Senate through OBPA.

Communication from USDA.—The Department is reminded that the Members of the Committee must be informed of the activities, pending and proposed actions, and expenditures made by USDA and its respective agencies so that Congress can determine whether laws and programs are being implemented and carried out in accordance with the intent of Congress. A collaborative working relationship between the Committee and the agencies is necessary to ensure efficient and effective implementation of Congress' funding decisions. USDA is directed to ensure the Committee is notified of major changes to existing policies and any significant developments in its operations prior to providing non-governmental stakeholders such information.

Late Reports.—The Committee reminds the Secretary that the timelines specified by the Committees on Appropriations of the House and Senate for fiscal year 2016 reports are deadlines that must be met. While the Committee notes that the Department has made progress since 2014, the Department still has several outstanding reports that are delayed due to long reviews and clearances, especially in the immediate Office of the Secretary. The Committee directs the Secretary to submit these overdue reports.

Decentralized Rent and Homeland Security.—In fiscal year 2015, the Committee provided the Department with authority to decentralize rent from the General Services Administration (GSA) and the Department of Homeland Security (DHS). The Secretary sub-

mitted this request "as part of USDA's implementation of the President's 'Freeze the Federal Footprint' initiative" and to encourage efficiencies across the Department at individual agencies. On the contrary, USDA did not freeze, but expanded, its footprint by approximately 141,000 square feet. Meanwhile, the Secretary has claimed savings of $25,200,000, while there will be a projected increase of $9,900,000 since fiscal year 2015.

The Secretary is directed to find actual savings within the total estimated costs for fiscal year 2017, in accordance with the President's "Reduce the Footprint" initiative. If USDA does not find ways to reduce its physical footprint or the cost of its existing footprint, such increased costs will need to be absorbed by the agency to the detriment of the core missions of these agencies. Further, the Committee in fiscal year 2015 directed that "any future requests for increases to rent and security costs will need to be accompanied by detailed justifications." USDA has not provided such justification. The following table shows the increased costs, with the most recently available data as provided by USDA:

[Dollars in Thousands]

Year	GSA Rent and DHS Costs	Change
2015	$209,436	– – –
2016	216,657	+7,221
2017	219,328*	+2,671
Total	.....	+$9,892

*Amount does not include the Administration's request for $17,700,000 to support a move in FNCS.

FSMA Implementation and Interagency Coordination.—The Committee provides the full amount requested, $5,000,000, for the National Institute for Food and Agriculture (NIFA) to be the sole agency providing education and technical assistance for farmers in implementing new requirements resulting from FSMA. The Committee commends NIFA's extension programs for the relationship they have built with our nation's producers, and hopes that they will continue to build this trust through FSMA implementation. However, USDA must clearly communicate their lead role in the collaborative partnership with the FDA to administer and manage the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program. The Secretary is directed to work with the Commissioner of the FDA to ensure that there is no duplication of efforts and resources for FSMA education and training at the farm level.

Design-Build.—The Committee encourages the Department to use the design-build method of project delivery when appropriate.

Invasive Species.—The Committee recognizes the threats posed by invasive plant species and the need to protect, restore, and enhance native plants, including those that are endangered or threatened. The Committee encourages ARS, the Natural Resources Conservation Service (NRCS), and NIFA to support the research, education, and conservation of native plants.

Flexibility in Loan and Loan Guarantee Levels.—The bill includes language to exceed the limitation on loan and loan guarantee levels by up to 25 percent without budget authority upon written notification to the Committees on Appropriations of the House and Senate.

Scientific Integrity.—Pursuant to the President's 2009 memorandum and as directed by the Office of Science and Technology Policy, USDA adopted a scientific integrity policy in 2011. It appears to conform to the President's directive by requiring the use of information based upon well-established scientific processes, including peer review where appropriate, making the Department's scientific findings and conclusions publicly available and ensuring a mechanism is in place to resolve disputes regarding scientific processes or the integrity of scientific information. The Committee directs the Secretary to ensure all USDA agencies are complying with the policy and using it as a requirement in their policy and regulatory decisions.

Rural Poverty.—The Department has statutory authorities and programs designed to help break the multi-generational trap of poverty in rural counties. The Committee recognizes that USDA may utilize existing programs and funding within RD and FNS in order to assist families, create jobs, and develop a path towards independence and self-sufficiency. Other existing resources such as the extension service and public universities can be used for coordination and outreach activities. As of April 2016, the Committee has not received the detailed plan required to be submitted by the Secretary which would detail all funding resources and bundled services to combat rural poverty.

StrikeForce Initiative.—The Committee appreciates the Department's efforts to target assistance to at-risk communities through the StrikeForce Initiative for Rural Growth and Opportunity. USDA, in collaboration with public and private partners, helps rural counties experiencing chronic poverty improve economic opportunities and quality of life for local residents. The Committee encourages USDA to place special emphasis on persistent poverty counties and continue to utilize a strategy of partnering public resources with local expertise to grow rural economies and create jobs in these poverty-stricken areas.

Administrative Savings.—The Secretary has repeatedly stated that USDA has achieved $1,400,000,000 in savings through the Blueprint for Stronger Service initiative. The Committee acknowledges that the Department has taken positive steps to cut costs and modernize operations, but USDA must also acknowledge that a majority of cost savings were made necessary by funding limitations instituted by Congress and at the direction from Congress. The Committee is still awaiting a detailed report describing each of the specific cost savings and the actions taken to achieve such savings for each agency in order to arrive at the estimated total.

U.S.-Mexico Cooperation.—The Committee directs the Secretary of Agriculture to work with his Mexican counterpart to develop a U.S.-Mexico working group to increase cooperation between the two countries in a similar manner as the "Beyond the Borders Initiative" between the United States and Canada. The working group shall develop proposals and create potential solutions aimed at facilitating commerce through improvements in the efficiency of the inspection process on both sides of the border, integrating small and large producers into the trade supply chain, and improving border wait times and transportation costs, among others. In addition, the Secretary shall work with his Mexican counterpart to develop a program for U.S.-Mexico academic exchanges for students

in agriculture related fields of study and professional agriculture specialists. The Secretary shall brief the Committee within 180 days of the date of enactment on efforts in these areas.

Urban Agriculture.—The Committee acknowledges the need for an expanded USDA role in support of urban agriculture in American cities. Support from the Department is lacking for urban producers who often have different needs than rural producers. Therefore, the Committee directs USDA to evaluate policies and programs and deliver a report to the Committees on Appropriations of the House and Senate explaining how to further advance urban agriculture.

Conflict of Interest.—The Committee is aware of concerns within Congress and the agricultural community regarding conflict of interest issues with the consultants, academics, and other personnel contracted out by the Department. Such contracts may include parties in multiple roles who receive funding from the Department for legitimate activities who are simultaneously employed by advocacy or partisan-leaning research institutions. Such situations are particularly harmful to the Department's credibility when parties employed in advocacy or other roles opine on similar topics or products as those involved in the Department's contract. The Committee directs the Secretary to avoid such conflicts of interest in order to protect the credibility of the Department and the integrity of the programs and policies under the Department's purview.

Cottonseed as an Oilseed.—Section 8702(10) of Title 7 of the U.S. Code states the Secretary of Agriculture may choose to define "any oilseed as designated by the Secretary." The Committee notes that this law is explicit in its intent. The Secretary has publicly chosen not to exercise such authority regarding cottonseed, even given significant demand from Congress and its constituencies. The Committee recognizes the significant obstacles facing cotton producers who are in need of financial assistance and encourages the Secretary to use the authority he has in law, and has used recently, to provide such assistance.

Under Secretary for Trade and Foreign Agricultural Affairs.—The Secretary is directed to complete the report regarding the establishment of an Under Secretary for Trade and Foreign Agricultural Affairs required by the 2014 farm bill, the 2015 Agriculture Appropriations Act, and the 2016 Agriculture Appropriations Act. This report is two years overdue.

USDA and EPA Cooperation.—Interagency Consultation.—The Department has a robust history of collecting and analyzing data related to agricultural economics and the environmental impact of farming practices upon the environment, including crop protection and pest management. Although several provisions in the Federal Insecticide, Fungicide, and Rodenticide Act require USDA and US EPA to consult and coordinate together, there has been a recent notable disconnect. Given the Department's expertise, the Committee directs the Secretary to ensure USDA experts consult with the US EPA on regulatory decisions impacting America's farmers.

EXECUTIVE OPERATIONS

OFFICE OF THE CHIEF ECONOMIST

2016 appropriation	$17,777,000
2017 budget estimate	17,592,000
Provided in the bill	16,777,000
Comparison:	
2016 appropriation	−1,000,000
2017 budget estimate	−815,000

COMMITTEE PROVISIONS

For the Office of the Chief Economist (OCE), the Committee provides an appropriation of $16,777,000.

Drought Resilience.—The Committee is concerned about the extent and severity of the drought in the U.S. and recognizes the importance of understanding and being prepared for drought. The Committee encourages the OCE to continue research and work with partners on drought resilience efforts to better address the serious threat posed by drought in the U.S.

Policy Research.—The Committee includes $4,000,000 for policy research under 7 U.S.C. 3155 for entities with existing institutional capacity, including staff, databases, models, and long-term, well-documented experience, to conduct complex economic and baseline analysis for the benefit of USDA, the Congressional Budget Office, and the Congress.

NATIONAL APPEALS DIVISION

2016 appropriation	$13,317,000
2017 budget estimate	13,481,000
Provided in the bill	13,317,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−164,000

COMMITTEE PROVISIONS

For the National Appeals Division, the Committee provides an appropriation of $13,317,000.

OFFICE OF BUDGET AND PROGRAM ANALYSIS

2016 appropriation	$9,392,000
2017 budget estimate	9,525,000
Provided in the bill	9,392,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−133,000

COMMITTEE PROVISIONS

For the Office of Budget and Program Analysis, the Committee provides an appropriation of $9,392,000.

OFFICE OF THE CHIEF INFORMATION OFFICER

2016 appropriation	$44,538,000
2017 budget estimate	65,716,000
Provided in the bill	44,538,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−21,178,000

COMMITTEE PROVISIONS

For the Office of the Chief Information Officer (CIO), the Committee provides an appropriation of $44,538,000. This includes $28,000,000 for cybersecurity activities.

IT Purchases and Oversight.—The Committee directs the CIO to comply with the spirit and letter of the Federal Information Technology Acquisition Reform Act and incorporate its principles into future planning and current oversight of IT activities across the Department and the performance plan required in H. Rpt. 113–468.

OFFICE OF THE CHIEF FINANCIAL OFFICER

2016 appropriation	$6,028,000
2017 budget estimate	9,119,000
Provided in the bill	6,028,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,091,000

COMMITTEE PROVISIONS

For the Office of the Chief Financial Officer (CFO), the Committee provides an appropriation of $6,028,000.

Digital Accountability and Transparency Act (DATA).—The Committee supports the work of the CFO to bring the Department into compliance with the DATA.

Shared Costs Report.—While the Committee notes that the Department did not find any increased costs in its Shared Costs Programs per the report required by the 2015 Appropriations Act, the Department also did not identify any savings. The Committee continues to direct the production of the report required in Public Law 113–235 and directs the agency to identify areas of savings and efficiencies.

OFFICE OF THE ASSISTANT SECRETARY FOR CIVIL RIGHTS

2016 appropriation	$898,000
2017 budget estimate	901,000
Provided in the bill	898,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Assistant Secretary for Civil Rights, the Committee provides an appropriation of $898,000.

OFFICE OF CIVIL RIGHTS

2016 appropriation	$24,070,000
2017 budget estimate	24,750,000
Provided in the bill	24,070,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−680,000

COMMITTEE PROVISIONS

For the Office of Civil Rights, the Committee provides an appropriation of $24,070,000.

AGRICULTURE BUILDINGS AND FACILITIES

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$64,189,000
2017 budget estimate	84,365,000
Provided in the bill	84,189,000
Comparison:	
2016 appropriation	+20,000,000
2017 budget estimate	−176,000

COMMITTEE PROVISIONS

For Agriculture Buildings and Facilities, the Committee provides an appropriation of $84,189,000.

Report on Headquarters Modernization.—The Committee directs the Department to provide the report required in H. Rpt. 113–468. The Committee requests the report include an update on the establishment of the Nonrecurring Expense Fund through the authority provided in Public Law 113–235. This authority was provided to enable the Secretary to use funding from expired accounts to invest in the Department's infrastructure. The Committee is concerned the Department has failed to utilize this previously provided authority.

HAZARDOUS MATERIALS MANAGEMENT

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$3,618,000
2017 budget estimate	3,633,000
Provided in the bill	3,618,000
Comparison:	
2016 appropriation	–––
2017 budget estimate	−15,000

COMMITTEE PROVISIONS

For Hazardous Materials Management, the Committee provides an appropriation of $3,618,000.

OFFICE OF INSPECTOR GENERAL

2016 appropriation	$95,738,000
2017 budget estimate	100,998,000
Provided in the bill	96,040,000
Comparison:	
2016 appropriation	+302,000
2017 budget estimate	−4,958,000

COMMITTEE PROVISIONS

For the Office of Inspector General, the Committee provides an appropriation of $96,040,000. This amount includes an increase for GSA rent.

OFFICE OF THE GENERAL COUNSEL

2016 appropriation	$44,383,000
2017 budget estimate	49,599,000
Provided in the bill	44,383,000
Comparison:	
2016 appropriation	–––
2017 budget estimate	−5,216,000

COMMITTEE PROVISIONS

For the Office of the General Counsel, the Committee provides an appropriation of $44,383,000.

OFFICE OF ETHICS

2016 appropriation	$3,654,000
2017 budget estimate	4,617,000
Provided in the bill	4,556,000
Comparison:	
2016 appropriation	+902,000
2017 budget estimate	−61,000

COMMITTEE PROVISIONS

For the Office of Ethics, the Committee provides an appropriation of $4,556,000.

OFFICE OF THE UNDER SECRETARY FOR RESEARCH, EDUCATION, AND ECONOMICS

2016 appropriation	$893,000
2017 budget estimate	901,000
Provided in the bill	893,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−8,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Research, Education, and Economics, the Committee provides an appropriation of $893,000.

Administrative Reorganization.—The Committee does not concur with the agency's proposal to combine NIFA Research and Education Activities, Extension Activities, and Integrated Activities into one account. While the Committee supports greater efficiency in the management of limited federal research dollars, the proposal fails to demonstrate that such reorganization would result in significant savings or the improvement of programs offered through NIFA.

Biological Research Stations.—The Committee directs USDA to provide a report within 120 days of enactment of this Act on the feasibility of establishing a new biological research station in association with a Historically Black College or University that has previously established partnerships in the conservation field. The report should examine the need for such a station, the economic and educational benefits, and associated costs.

Coffee Plant Health.—The Committee appreciates ARS and NIFA's work to address existing and emerging challenges to coffee production in the United States and commends the agency's work with research partners and coffee grower groups. The Committee encourages ARS, NIFA, and its partners to maintain support for coffee plant health research.

Office of Pest Management Policy.—The Committee commends the Office of Pest Management Policy for its work providing the Department, federal agencies, producers, and other interested stakeholders scientifically sound analysis of pest management issues important to agriculture, especially methyl bromide transi-

tion, pesticide resistance management, and the development of antimicrobials to combat citrus greening. The Committee encourages the Under Secretary to better utilize this office and directs ARS to continue to support its vital work.

Pollinators and Colony Health Research.—The Committee recognizes that Colony Collapse Disorder and related colony health issues are a significant concern to beekeepers, honey producers, farmers, researchers, policymakers, and the public. It appreciates USDA's logical, scientifically based approach to studying these issues and directs the Department to continue to focus on the challenges facing pollinators.

Potato Research.—The Committee supports research efforts to combat crop-threatening pest and disease pressures, including the potato cyst nematode. The Committee also recognizes the importance of research initiatives to identify and improve desired traits for new potato varieties and directs the Department to continue working with universities, industry and potato growers on these projects.

Screening Technologies.—The Committee encourages the development of technologies that will provide rapid, portable, and facile screening of food fish species at port sites and wholesale and retail centers.

ECONOMIC RESEARCH SERVICE

2016 appropriation	$85,373,000
2017 budget estimate	91,278,000
Provided in the bill	86,000,000
Comparison:	
2016 appropriation	+627,000
2017 budget estimate	−5,278,000

COMMITTEE PROVISIONS

For the Economic Research Service, the Committee provides an appropriation of $86,000,000, including $627,000 for cooperative agreements on groundwater modeling and drought resilience.

NATIONAL AGRICULTURAL STATISTICS SERVICE

2016 appropriation	$168,443,000
2017 budget estimate	176,639,000
Provided in the bill	168,443,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−8,196,000

COMMITTEE PROVISIONS

For the National Agricultural Statistics Service (NASS), the Committee provides an appropriation of $168,443,000, of which $41,871,000 is for the Census of Agriculture.

Pecan Data.—The Committee encourages NASS to restart surveys and reports for pecans, including publication of the 2016 Noncitrus Fruits and Nuts Preliminary Summary.

AGRICULTURAL RESEARCH SERVICE

SALARIES AND EXPENSES

2016 appropriation	$1,143,825,000
2017 budget estimate	1,161,340,000
Provided in the bill	1,151,825,000
Comparison:	
2016 appropriation	+8,000,000
2017 budget estimate	−9,515,000

COMMITTEE PROVISIONS

For Salaries and Expenses of the Agricultural Research Service, the Committee provides an appropriation of $1,151,825,000.

The Committee does not concur with the agency's proposed redirections of research programs or increases for fiscal year 2017.

Agriculture Research Stations.—The Committee is concerned about the continued trend towards reductions in on-the-ground agriculture research through proposed cutbacks and consolidations without a clear plan to ensure that research which reflects the local needs and growing conditions continues. The Committee directs the ARS to prioritize funding for field stations and work directly with local growers as changes in local research offerings are considered.

Animal Research.—The Committee expects the Department to keep the Committee informed on the progress of implementing changes to policies and procedures as a result of the January 19, 2015, *New York Times* article titled "U.S. Research Lab Lets Livestock Suffer in Quest for Profit" about MARC in Clay Center, Nebraska.

The Committee understands that some specific instances mentioned in the article may have been taken out of context and that others may have been exaggerated. It also believes that ARS scientists sincerely care about the animals they work with. The Committee recognizes the need for and value of animal research, but it demands that all animals be treated humanely and that the risk of premature death will be limited wherever possible. No type of abuse or mistreatment will be tolerated.

Aerial Application Research.—The Committee recognizes the importance of the ARS Aerial Application Technology Program. The program conducts innovative research making aerial applications more efficient, effective, and precise. Research for aerial application serves the public good as a vital tool for the future, as agriculture strives to meet the food, fiber, and bio-energy demands of a growing population.

Alfalfa Research.—The Committee supports research into alfalfa seed and forage systems, which hold the potential to maximize crop yields, increase milk production, and improve genetics.

ARS Field Stations.—The Committee recognizes the successful utilization of authorities granted in previous annual appropriations Acts to further cooperation between industry and the ARS Canal Point, Florida Sugarcane Field Station. However, the Committee is concerned that this partnership is jeopardized by requirements that are outside the scope of the functionality of the facilities. The Committee directs ARS to resolve these issues, thus allowing this model partnership to continue. Additionally, the Committee recognizes Florida's importance as a sentinel state in studying invasive pests and diseases. With new species entering ports every week, it

is critical that ARS devote attention to the need for research facilities to study these threats.

Aquaculture Industry Coordination.—Nearly half the seafood consumed across the world is the product of aquaculture, and the aquaculture industry is a critical and growing part of the U.S. economy. However, less than one percent of worldwide production comes from U.S. producers. In January 2016, the National Oceanic and Atmospheric Administration's National Marine Fisheries Services issued a final rule to open the federal waters in the Gulf of Mexico to development of aquaculture. The Committee is concerned that vital seedstock required to implement this initiative will be sourced from foreign aquaculture producers. The Committee encourages the agency to support and protect the U.S. aquaculture industry by working collaboratively with U.S. aquaculture producers and research institutions that specialize in the development of aquaculture technologies.

Aquatic Animal Health.—The Committee supports ARS' work with land-grant universities and other federal partners to develop solutions to aquatic animal pathogens including *Aeromonas* in catfish and viral *hemorrhagic septicemia* in finfish. ARS is encouraged to collaborate with industry stakeholders on the development of potential vaccines and therapeutants.

Citrus Greening Disease Research.—The Committee commends ARS' research efforts on citrus greening disease and encourages the agency to continue working to develop methods to reduce transmission and enhance immunity in citrus trees and to work with industry, universities, growers, and other partners to develop effective control mechanisms. The Committee also encourages ARS to coordinate its efforts with the Huanglongbing Multi-Agency Coordination (HLB MAC) group.

Co-Location of Researchers.—The Committee encourages ARS to develop a plan to maximize its investments in plant science facilities and research by taking advantage of the synergies and efficiencies realized through the co-location of USDA researchers in state-of-the-art facilities with university and other stakeholders.

Cotton Ginning.—The Committee recognizes the importance of pollution abatement, improving fiber quality, ginning efficiency, cotton seed and other byproducts, and remains committed to expanding research in cotton ginning and innovation by existing laboratories.

Cranberry Research.—The Committee recognizes the ongoing research needs of the cranberry sector, ranging from disease control to pesticide use to responsible management of water resources. The Committee urges ARS to continue these efforts.

Domestic and Bighorn Sheep.—The Committee recognizes the challenges caused by infectious disease problems arising from wildlife-domestic animal agriculture interactions, particularly between domestic sheep and wild bighorn sheep. The Committee encourages ARS to work to determine the role of domestic sheep in causing die-offs of bighorn sheep from respiratory disease and to develop methods to reduce transmission and enhance immunity.

Emerging Cereal Rust Diseases.—The Committee continues to be concerned about emerging cereal rust diseases, particularly Ug99, and the threat they pose to domestic and world food supplies. The

Committee encourages ARS to continue its work on these diseases, including the development of Ug99-resistant wheat varieties.

Forest Products Research.—The forest products sector is an important part of the U.S. economy. The Committee supports research on wood quality, forest product evaluation standards and valuation techniques, and ARS' continuing work with the Forest Products Laboratory.

FOV Race 4 Cotton Research.—The Committee recognizes the serious threat that *fusarium oxysporum f. sp. Vasinfectum* (FOV), particularly the strain FOV Race 4, poses to the U.S. cotton industry. The Committee encourages ARS to continue research efforts to combat FOV Race 4 and to work with industry and other partners to develop effective control measures to eradicate this disease and prevent its spread nationwide.

Germplasm Enhancement of Maize.—The Committee supports the germplasm enhancement of maize project and encourages continued cooperation between ARS and industry.

Greenhouse Technology Research.—The Committee recognizes the importance of advancing greenhouse technology and exploring its capabilities to address the energy and water challenges inherent in four-season production systems, beginning in food insecure communities across the country. The Committee encourages ARS to work with the Department of Energy (DOE) for greenhouse technology research that explores how to integrate ongoing research projects at the various DOE National Labs to develop affordable, deployable, and energy- and water-efficient food production platforms for undernourished regions of the country. By working together, ARS and DOE can bring their respective strengths and resources to designing the most desirable, low-cost, and efficient production system.

Horticultural Research and Education.—The Committee recognizes the importance of the U.S. National Arboretum and its role as a center for discovery and education, as well as a destination for more than 500,000 visitors every year. The Committee encourages the agency to continue to support the Arboretum.

Human Nutrition Research.—There is strong evidence that nutrition plays a vital role in how a person ages, particularly its significance for preventative health care and degenerative and age-related diseases. Research is needed to address the needs of the rapidly growing number of older Americans. The Committee encourages ARS to continue research relating to the effect of nutrition on aging.

Long-Term Agro-ecosystem Research Network.—The Committee recommendation includes an additional $1,000,000 above fiscal year 2016 for the Long-Term Agro-ecosystem Research (LTAR) network.

Lower Mississippi River Basin.—The Committee recognizes the groundwater problems in the Lower Mississippi River Basin and encourages ARS to continue research to quantify how conservation practices and technology affect water quality and quantity.

National Agricultural Library.—The Committee encourages ARS to maintain a focus on agricultural-related legal issues within the National Agricultural Library. The Committee notes that as the agriculture sector faces increasing financial stress, there is a necessity that agricultural-related legal issues be addressed on an in-

creasingly frequent basis. Further, agricultural-related legal issues are increasingly complex, and the impact of these legal issues continues to broaden in scope. The Committee recommends that the National Agricultural Library play an important role in assisting all stakeholders with understanding these issues.

Porcine Virus Research.—The Committee is aware of ongoing research to identify mechanisms of viral pathogenesis, transmission, and immunity to porcine epidemic diarrhea virus (PEDv) and encourages ARS to continue its efforts to identify the genetic virulence factors of PEDv, identify a protective immune response, including transmission of maternal antibodies through the milk, and evaluate new vaccine platforms for the development of improved PEDv vaccines.

Pulse Health Initiative.—The Committee is aware of the need to investigate the ability of pulse crops, such as dry beans, dry peas, lentils, and chickpeas, to provide solutions to critical health issues and to improve the sustainability of crop rotations by improving the nitrogen-fixing abilities of pulse crops. The Committee encourages ARS to continue its work on these important issues.

Safe and Abundant Water Supply.—The Committee supports technological development to address key agricultural water resource issues across the U.S. The Committee recommendation includes an additional $4,000,000 above fiscal year 2016 to conduct further research for Safe and Abundant Water Supplies to Support U.S. Agricultural Production.

Sage Grouse.—The Committee is aware that listing the greater sage grouse as endangered under the Endangered Species Act has the potential to negatively affect rural communities in the 11 states that have sage brush ecosystems. The Committee encourages ARS to work with its partners on sage brush and related rangeland research that will help preserve the greater sage grouse and the other species that rely on the sage brush ecosystem.

Sclerotinia Initiative.—The Committee is aware of the importance of controlling *Sclerotinia* in sunflowers, soybeans, canola, edible beans, peanuts, peas, lentils, and chickpeas and encourages ARS to continue its support of this initiative.

Small Grain Genomics.—The Committee supports research on small grain genomics and recognizes its importance in improving crop traits and developing new cultivars. The Committee provides an increase of $1,000,000 above fiscal year 2016 to support the Small Grains Genomic Initiative.

Sodium Consumption.—The Committee directs the ARS Human Nutrition Research Centers to provide a plan within 90 days of enactment of this Act for conducting a study on the levels of sodium consumption in school-aged children. The plan shall include the methodology and timeframes necessary to conduct such a study, focusing on whether the consumption levels are within or outside the usual range of consumption, both domestically and worldwide.

Sorghum in Agriculture.—The Committee recognizes the growing significance of sorghum in agriculture due to water conservation traits and increased utilization. Funding is included to initiate gene flow research to advance the durability and sustainability of fitness traits in sorghum.

U.S. Sheep Experiment Station (USSES).—The Committee recognizes the unique and valuable contributions the USSES makes to-

ward increasing the production efficiency of sheep and improving sustainable rangeland ecosystems. The Committee also recognizes a unique opportunity to expand other research initiatives. The Committee encourages ARS to work with various stakeholders regarding efforts to propose mission improvements for the USSES.

U.S. Wheat and Barley Scab (USWBS).—The Committee recognizes that *fusarium* head blight is a major threat to agriculture, inflicting substantial yield and quality losses throughout the U.S. The Committee supports research carried out through the USWBS initiative. The Committee recommendation includes an additional $2,000,000 above fiscal year 2016 to conduct further research for the USWBS initiative to enhance food safety and supply by reducing the impact of *fusarium* head blight on wheat and barley.

BUILDINGS AND FACILITIES

2016 appropriation	$212,101,000
2017 budget estimate	94,500,000
Provided in the bill	99,600,000
Comparison:	
2016 appropriation	−112,501,000
2017 budget estimate	+5,100,000

COMMITTEE PROVISIONS

For Agricultural Research Service, Buildings and Facilities, the Committee provides an appropriation of $99,600,000 for priorities identified in the USDA ARS Capital Investment Strategy, April 2012, including not less than $5,100,000 for planning and design purposes for the next highest priorities identified in the USDA ARS Capital Investment Strategy.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

RESEARCH AND EDUCATION ACTIVITIES

2016 appropriation	$819,685,000
2017 budget estimate	836,915,000
Provided in the bill	832,860,000
Comparison:	
2016 appropriation	+13,175,000
2017 budget estimate	−4,055,000

COMMITTEE PROVISIONS

For Research and Education Activities, the Committee provides an appropriation of $832,860,000.

Agriculture and Food Research Initiative (AFRI).—The Committee recognizes the importance of the research conducted through AFRI and provides an increase of $25,000,000 for this competitive grant program. The Committee believes that each of the six AFRI Challenge Areas are of equal importance to the agricultural community and rejects the President's proposal that any increase to the AFRI program be available only to the Sustainable Bioenergy Challenge Area.

Agricultural Research Enhancement Awards.—The Committee continues to direct that not less than 15 percent of the competitive research grant funds be used for USDA's agriculture research enhancement awards program, including USDA–EPSCoR, in accordance with 7 U.S.C. 450i.

Budget Request for Fiscal Year 2018.—The Committee appreciates NIFA's efforts to provide additional information in its budget requests over the past three years. For the fiscal year 2018 budget request, the Committee is particularly interested in the request for the Agriculture and Food Research Initiative and requests that the agency provide greater detail on the levels proposed to be allocated to and the expected publication date, scope, and allocation level for each request for awards to be published under each priority area specified in section 2(b)(2) of the Competitive, Special, and Facilities Research Grant Act (7 U.S.C. 450i(b)(2)).

Childhood Obesity.—Within the funds made available for AFRI, the Committee encourages NIFA to support innovative efforts to address the unique challenges faced in addressing childhood obesity through a combination of family education and clinical studies focused on early life influences on obesity risk; the development of eating behavior during infancy and early childhood; the role of sleep in the development of childhood obesity; and obesity prevention strategies for low-income children in childcare and educational settings.

Citrus Disease Research Program.—The 2014 farm bill established the Emergency Citrus Disease Research and Extension Program, which is intended to discover and develop tools for early detection, control, and eradication of diseases and pests that threaten domestic citrus production and processing, and provided $25,000,000 per year in mandatory funding for the program through the Specialty Crop Research Initiative. The Committee believes research projects funded under this authority should be prioritized based on the critical threat of citrus greening and encourages NIFA, to the maximum extent practicable, to follow the recommendations of the National Agricultural Research, Extension, and Education Advisory Board's citrus disease subcommittee and to collaborate with the HLB MAC group.

Food Manufacturing Efficiencies.—The Committee is aware of many new and promising food manufacturing processes and technologies. The nation's food supply can be made safer, more secure, and more affordable through means such as automation of equipment and modifying processes along the entire supply chain to work more efficiently and use less water, energy and other resources. The Committee urges the Department to promote enhanced technology, processes, and data analysis throughout the food manufacturing industry.

Livestock and Poultry Waste Research.—The Committee recognizes the benefits of improved methods of managing animal waste in livestock and poultry production and encourages NIFA to support research and development of innovative technologies, particularly those that are operationally and economically feasible and have a high probability of widespread implementation.

Organic Agriculture.—The Committee encourages USDA to ensure that the needs of the U.S. organic sector are more fully addressed through AFRI. As USDA's flagship competitive agricultural research grant program, AFRI funding should be reflective of the needs of all aspects of U.S. agriculture, including organic. The Committee directs USDA to develop a plan for meeting this goal, including how the agency will ensure organic research conducted through AFRI is not duplicative of research conducted with manda-

tory funds through the Organic Agriculture Research and Extension Initiative and other research programs, and report back to the Committee within 60 days of enactment of this Act.

Research at Historically Black Colleges and Universities and Hispanic Serving Institutions.—The Committee encourages NIFA to continue to support biotechnology by promoting research at the land-grant colleges and universities, including the Historically Black Colleges and Universities and Hispanic Serving Institutions, and directs NIFA to encourage partnerships among universities and industry.

Unmanned Aircraft Systems.—The rapidly evolving field of Unmanned Aircraft Systems (UAS) provides highly promising opportunities for timely collection of geospatial data that can be used to increase profitability for agricultural producers and improve environmental stewardship in a broad range of areas. The Committee believes that research, development, education, and extension programs are needed to help further develop the technology and educate farmers and natural resource managers on best practices and safe operation of UAS. The Committee encourages NIFA to support the research, development, education and training of techniques, sensor and imaging technology, data analytics tools, best practices, and the safe and efficient deployment of UAS for improved agriculture and environmental stewardship.

Urban Agriculture.—The Committee acknowledges the need for expanded research in support of urban agriculture in American cities. Support from the Department is lacking for urban producers who often have different needs than rural producers. Therefore, the Committee directs USDA to evaluate its policies and programs and deliver a report to the Committee explaining how to further advance urban agriculture.

Zoonotic Disease Research.—The eradication of zoonotic livestock diseases has been a priority of federal and state animal health officials, as was reflected in the 2014 farm bill. The Committee recognizes the need for this research and encourages NIFA to support the development of improved management tools for zoonotic livestock diseases that have significant wildlife reservoirs.

The following table reflects the amount provided by the Committee:

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE—RESEARCH AND EDUCATION ACTIVITIES

[Dollars in Thousands]

Program/Activity	Authorization	2016 enacted	2017 estimate	Committee provision
Hatch Act	7 U.S.C. 361a–i	$243,701	$243,701	$243,701
McIntire-Stennis Cooperative Forestry Act	16 U.S.C. 582a through a–7	33,961	33,961	33,961
Research at 1890 Institutions (Evans-Allen Program).	7 U.S.C. 3222	54,185	58,000	54,185
Payments to the 1994 Institutions	7 U.S.C. 301 note	3,439	3,654	3,439
Education Grants for 1890 Institutions	7 U.S.C. 3152(b)	19,336	20,410	19,336
1890s Capacity Coordination Initiative		– – –	10,000	– – –
Education Grants for Hispanic-Serving Institutions	7 U.S.C. 3241	9,219	9,219	9,219
Education Grants for Alaska Native and Native Hawaiian-Serving Institutions.	7 U.S.C. 3156	3,194	3,194	3,194
Research Grants for 1994 Institutions	7 U.S.C. 301 note	1,801	3,914	1,801
Capacity Building for Non Land-Grant Colleges of Agriculture.	7 U.S.C. 3319i	5,000	– – –	– – –

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE—RESEARCH AND EDUCATION ACTIVITIES—Continued

[Dollars in Thousands]

Program/Activity	Authorization	2016 enacted	2017 estimate	Committee provision
Grants for Insular Areas	7 U.S.C. 3222b–2, 3362 and 3363.	2,000	1,800	1,800
Agriculture and Food Research Initiative	7 U.S.C. 450i(b)	350,000	375,000	375,000
Veterinary Medicine Loan Repayment	7 U.S.C. 3151a	5,000	5,000	6,500
Veterinary Services Grant Program	7 U.S.C. 3151b	2,500	– – –	2,500
Food and Agriculture Resiliency Program for Military Veterans.		– – –	2,500	– – –
Continuing Animal Health and Disease Research Program.	7 U.S.C. 3195	4,000	– – –	4,000
Supplemental and Alternative Crops	7 U.S.C. 3319d	825	– – –	– – –
Multicultural Scholars, Graduate Fellowship and Institution Challenge Grants.	7 U.S.C. 3152(b)	9,000	– – –	9,000
Secondary and 2-year Post-Secondary Education	7 U.S.C. 3152(j)	900	– – –	900
Aquaculture Centers	7 U.S.C. 3322	4,000	– – –	4,000
Sustainable Agriculture Research and Education	7 U.S.C. 5811, 5812, 5831, and 5832.	24,667	29,967	24,667
Farm Business Management	7 U.S.C. 5925f	1,450	– – –	– – –
Sun Grant Program	7 U.S.C. 8114	2,500	– – –	– – –
Alfalfa and Forage Research Program	7 U.S.C. 5925	2,000	– – –	– – –
Minor Crop Pest Management (IR–4)	7 U.S.C. 450i(c)	11,913	11,913	11,913
Special Research Grants:	7 U.S.C. 450i(c)			
Global Change/UV Monitoring		1,405	1,405	1,405
Potato Research	7 U.S.C. 450i(c)	2,000	– – –	2,000
Aquaculture Research	7 U.S.C. 450i(c)	1,350	– – –	– – –
Total, Special Research Grants		4,755	1,405	3,405
Necessary Expenses of Research and Education Activities:				
Grants Management Systems		7,830	9,790	7,830
GSA Rent and DHS Security Expenses		5,960	5,960	5,960
Federal Administration—Other Necessary Expenses.		6,549	7,527	6,549
Total, Necessary Expenses		20,339	23,277	20,339
Total, Research and Education Activities.		$819,685	$836,915	$832,860

NATIVE AMERICAN INSTITUTIONS ENDOWMENT FUND

2016 appropriation	($11,880,000)
2017 budget estimate	(11,880,000)
Provided in the bill	(11,880,000)
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For the Native American Institutions Endowment Fund, the Committee provides $11,880,000.

EXTENSION ACTIVITIES

2016 appropriation	$475,891,000
2017 budget estimate	501,859,000
Provided in the bill	477,391,000
Comparison:	
2016 appropriation	+1,500,000
2017 budget estimate	−24,468,000

COMMITTEE PROVISIONS

For Extension Activities, the Committee provides an appropriation of $477,391,000.

Rural Health and Safety Education Programs.—The opioid abuse epidemic is one of the greatest threats facing rural America today, and the Committee supports all efforts to address this problem through improved health and safety education and outreach. The Committee provides $3,000,000 for Rural Health and Safety Education Programs to combat opioid abuse in rural communities.

The following table reflects the amount provided by the Committee:

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

EXTENSION ACTIVITIES

[Dollars in Thousands]

Program/Activity	Authorization	FY 2016 enacted	FY 2017 estimate	Committee provision
Smith-Lever Act, Section 3(b) and (c) programs and Cooperative Extension.	7 U.S.C. 343(b) and (c) and 208(c) of P.L. 93–471.	$300,000	$300,000	$300,000
Extension Services at 1890 Institutions	7 U.S.C. 3221	45,620	48,350	45,620
Extension Services at 1994 Institutions	7 U.S.C. 343(b)(3)	4,446	6,724	4,446
Facility Improvements at 1890 Institutions	7 U.S.C. 3222b	19,730	21,703	19,730
Renewable Resources Extension Act	16 U.S.C. 1671 et seq.	4,060	4,060	4,060
Rural Health and Safety Education Programs	7 U.S.C. 2662(i)	1,500	– – –	3,000
Food Animal Residue Avoidance Database Program	7 U.S.C. 7642	1,250	– – –	1,250
Women and Minorities in STEM Fields	7 U.S.C. 5925	400	– – –	400
Grants to Youth Organizations		– – –	1,000	– – –
Food Safety Outreach Program	7 U.S.C. 7625	5,000	5,000	5,000
Smith-Lever Act, Section 3(d):	7 U.S.C. 343(d)			
Food and Nutrition Education		67,934	68,034	67,934
Farm Safety and Youth Farm Safety Education Programs.		4,610	4,610	4,610
New Technologies for Agricultural Extension		1,550	– – –	1,550
Children, Youth, and Families at Risk		8,395	8,395	8,395
Federally Recognized Tribes Extension Program		3,039	5,839	3,039
Home Visits for Remote Areas		– – –	20,000	– – –
Total, Section 3(d)		85,528	106,878	85,528
Necessary Expenses of Extension Activities:				
Agriculture in the K–12 Classroom	7 U.S.C. 3152(j)	552	– – –	552
Federal Administration—Other Necessary Expenses for Extension Activities.		7,805	8,144	7,805
Total, Necessary Expenses		8,357	8,144	8,357
Total, Extension Activities		$475,891	$501,859	$477,391

INTEGRATED ACTIVITIES

2016 appropriation	$30,900,000
2017 budget estimate	28,900,000
Provided in the bill	30,900,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+2,000,000

COMMITTEE PROVISIONS

For Integrated Activities, the Committee provides an appropriation of $30,900,000.

Food and Agriculture Defense Initiative (FADI).—The Committee supports the important work being done through the diagnostic laboratory network and encourages NIFA to prioritize funding to strengthen animal health diagnostic laboratories operated and administered by Colleges of Veterinary Medicine at land grant institutions. NIFA should take into consideration the degree to which the capacity for surveillance, monitoring, response, and capacity is enhanced; the concentration of human and animal populations that are directly at risk; trade, tourism, and cultural considerations; geography, ecology, and climate; the strength of biomedical, agricultural, environmental, and public health expertise at the hosting land grant university; evidence of active collaboration with, and support of, the state department of agriculture; and evidence of stakeholder support and engagement.

The following table reflects the amount provided by the Committee.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

INTEGRATED ACTIVITIES

[Dollars in Thousands]

Program/Activity	Authorization	FY 2016 enacted	FY 2017 estimate	Committee provision
Methyl Bromide Transition Program	7 U.S.C. 7626	$2,000	$– – –	$2,000
Organic Transition Program	7 U.S.C. 7626	4,000	4,000	4,000
Regional Rural Development Centers	7 U.S.C. 450i(c)	1,000	1,000	1,000
Food and Agriculture Defense Initiative	7 U.S.C. 3351	6,700	10,000	6,700
Crop Protection/Pest Management Program	7 U.S.C. 7626	17,200	20,200	17,200
Total, Integrated Activities		$30,900	$35,200	$30,900

OFFICE OF THE UNDER SECRETARY FOR MARKETING AND REGULATORY PROGRAMS

2016 appropriation	$893,000
2017 budget estimate	901,000
Provided in the bill	893,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−8,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Marketing and Regulatory Programs, the Committee provides an appropriation of $893,000.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

SALARIES AND EXPENSES

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$894,415,000
2017 budget estimate	901,196,000
Provided in the bill	930,831,000
Comparison:	
2016 appropriation	+36,416,000
2017 budget estimate	+29,635,000

COMMITTEE PROVISIONS

For the Animal and Plant Health Inspection Service, Salaries and Expenses, the Committee provides an appropriation of $930,831,000.

Included in this funding level are increases of $21,000,000 for Emergency Preparedness and Response; $9,916,000 for Zoonotic Disease Management; $9,500,000 for Specialty Crop Pests; $1,750,000 for the National Veterinary Stockpile; $1,500,000 for Equine, Cervid, and Small Ruminant Health; and $1,518,000 for Animal Health Technical Services. The Committee maintains recent increases for such functions as Avian Health; Overseas Technical and Trade Operations in order to help resolve sanitary and phytosanitary trade issues that could result in the opening of new markets and retaining and expanding existing market access for U.S. agricultural products; the National Animal Health Lab Network; the Citrus Health Response Program; and Wildlife Damage Management.

Within the amount included for Specialty Crop Pests, the Committee includes increases of $1,500,000 for fruit fly exclusion and detection; $5,000,000 for the Citrus Health Response Program; $2,000,000 for the glassy-winged sharpshooter; and $1,000,000 for the light brown apple moth. Funding for the European grapevine moth should be no less than the amount provided in fiscal year 2016. The Committee continues to provide an additional $5,500,000 for citrus greening emergency response to the HLB MAC.

The following table reflects the amounts provided by the Committee:

[Dollars in Thousands]

	Committee provision
Animal Health Technical Services	$36,857
Aquatic Animal Health	2,253
Avian Health	55,340
Cattle Health	91,500
Equine, Cervid, and Small Ruminant Health	21,000
National Veterinary Stockpile	5,723
Swine Health	24,800
Veterinary Biologics	16,417
Veterinary Diagnostics	36,540
Zoonotic Disease Management	19,439
Subtotal, Animal Health	*309,869*
Agricultural Quarantine Inspection (Appropriated)	27,900
Cotton Pests	11,520
Field Crop & Rangeland Ecosystem Pests	8,826
Pest Detection	27,446
Plant Protection Methods Development	20,686
Specialty Crop Pests	167,500
Tree & Wood Pests	45,933
Subtotal, Plant Health	*309,811*
Wildlife Damage Management	100,376
Wildlife Services Methods Development	18,856
Subtotal, Wildlife Services	*119,232*
Animal & Plant Health Regulatory Enforcement	16,224
Biotechnology Regulatory Services	18,875
Subtotal, Regulatory Services	*35,099*
Contingency Fund	470

[Dollars in Thousands]

	Committee provision
Emergency Preparedness & Response	37,966
Subtotal, Safeguarding and Emergency Preparedness	*38,436*
Agriculture Import/Export	15,099
Overseas Technical and Trade Operations	22,114
Subtotal, Safe Trade & International Technical Assistance	*37,213*
Animal Welfare	28,510
Horse Protection	697
Subtotal, Animal Welfare	*29,207*
APHIS Information Technology Infrastructure	4,251
Physical/Operational Security	5,146
GSA Rental and DHS Security Payments	42,567
Subtotal, Agency Management	*51,964*
Total, Salaries & Expenses	$930,831

Animal Welfare.—The bill provides $28,510,000 for the Animal Welfare program in order to ensure that minimum standards of care and treatment are provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. The Committee provides $500,000 to support the renewal of a Memorandum of Understanding (MOU) between APHIS and ARS. The MOU is necessary for ARS to utilize the skills and expertise of APHIS' animal care staff and to help ARS address some of their recent failures to maintain high standards of care for animals used in ARS funded research. At a minimum, the MOU should ensure that ARS is adhering to its own standards and guidelines for research practices as required by the Humane Animal Care and Use policy, a policy that is closely aligned with the Animal Welfare Act; ensure that every ARS location engaging in research and testing on vertebrate animals has a fully functioning Institutional Animal Care and Use Committee (IACUC) in place; and, ensure that each IACUC produces a semi-annual report with a description of and the reasons for any major deviations from the requirements outlined in ARS policy.

Antimicrobial Resistance.—There is currently no evidence to support the claim that agriculture is largely to blame for the increase in antibiotic-resistant strains of bacteria, and so the Committee supports funding to collect additional data that will inform policy related to the appropriate antibiotic use in all settings across agriculture and clinical medicine. The Committee provides $9,916,000 for on-farm surveillance and data collection to enhance the understanding of on-farm levels of antibiotic use and the impact on antimicrobial resistance levels. The information collected should clearly delineate between antibiotics used for food-producing and companion animals. Further, to avoid duplication with existing programs like the National Antimicrobial Resistance Monitoring System, the Committee expects surveys regarding on-farm usage to be limited to collecting information about the antibiotics used and should not be utilized for other regulatory purposes. In designing these surveys, the Committee expects the agency to work primarily with end-users of antibiotics and veterinarians providing care to the animals. APHIS will collect this information through its statistical unit under the Confidential Information Protection and Statis-

tical Efficiency Act, which will guarantee that all information collected is protected from distribution in a manner that could identify an individual respondent for the full time the data is in existence. This information is needed for use in the larger National Strategy for Combatting Antibiotic Resistant Bacteria with other federal partners.

Aquatic Animal Health.—Nearly half of the seafood consumed across the world is the product of aquaculture. In addition, the aquaculture industry is a critical and growing part of the U.S. economy. Unfortunately, the monitoring of aquatic animal health issues is not adequate to meet the needs of the growing industry. For example, the shrimp and catfish aquaculture industries are losing revenue due to the lack of tracking and monitoring of aquatic animal pathogens. These losses could have been prevented if the pathogens had been promptly identified and effective treatments or prevention procedures were developed and available. The Committee encourages the agency to support and protect this important industry. Collaborative efforts among the agency, industry, and other federal and state partners are essential to improving preparedness, surveillance, and response capabilities, as well as reducing the likelihood of disease spread. APHIS should collaborate with ARS' Aquatic Animal Health Research Unit as necessary to support its aquatic animal health efforts.

Biotechnology Review Process.—The Committee is aware of an Administration-wide effort to modernize the regulatory system for biotechnology products. As noted by the White House Office of Science and Technology Policy memo on the subject dated July 2, 2015, this regulatory system ". . . must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." In moving forward, it should be noted that, since the establishment of the original coordinated framework over three decades ago, there are no known validated instances of harm to the environment, agriculture, or non-target organisms arising from the use of plants regulated by APHIS. The Committee encourages the agency to continue to maintain some of the benefits of the existing regulatory system, but find greater efficiencies and utilize this opportunity to include advances in biotechnology methodology. The agency should engage in a deliberative, science-based process devoid of political agendas and the baseless scare tactics used to disparage the industry.

Cervid Health.—Data from 2007 indicates that the cervid industry in the United States accounts for 5,600 deer farms and 1,900 elk farms, has an economic value of $894,000,000, and supports nearly 30,000 jobs. This industry continues to participate in the agency's national, voluntary Herd Certification Program (HCP) that supports the domestic and international marketability of U.S. cervid herds. The Committee encourages APHIS to maintain its commitment to the HCP and the cervid industry and directs the agency to spend no less than $3,500,000 for cervid health activities. Within the funds provided, the agency should give consideration to indemnity payments if warranted.

Citrus Health Response Program (CHRP).—CHRP is a national effort to protect the U.S. citrus industry from the ravages of invasive pests and diseases. These funds are designed to partner

with state departments of agriculture and industry groups to address the challenges of citrus pests and diseases. In addition to the funds provided in this account, the Committee encourages APHIS to utilize the funds available in the Plant Pest and Disease Management and Disaster Prevention Programs account to the greatest extent possible in an attempt to sustain the economic viability of the citrus industry.

Cost Sharing with States and Other Cooperators.—The Committee directs APHIS to maximize the use of cost-sharing agreements or matching requirements with states, territories, producers, foreign governments, non-governmental organizations, and any other recipient of services in order to reduce the cost burden on the agency.

Cotton Pests.—The Committee is concerned that every effort be made by APHIS and the cotton industry to ensure the boll weevil does not re-infest areas of the United States where it has been successfully eradicated. The Boll Weevil Eradication Program, an outstanding example of a public-private partnership, has successfully eradicated the boll weevil from all U.S. cotton-producing regions except for the extreme lower parts of Texas in the Lower Rio Grande Valley (LRGV) bordering Tamaulipas, Mexico. Growers in the LRGV, with assistance from APHIS and the support of the entire industry, continue to conduct an active program to eradicate the boll weevil. The LRGV serves as the barrier between boll weevil infested areas of Mexico and boll weevil-free areas of the United States. The Department is directed to work with the U.S. cotton industry to develop a plan of action to protect the United States from re-infestation and to report its findings to the Committee not less than 120 days after enactment of this Act.

Emergency Outbreaks.—The Committee continues to include specific language relating to the availability of funds to address emergencies related to the arrest and eradication of contagious or infectious diseases or pests of animals, poultry or plants. The Committee expects the Secretary to continue to use the authority provided in this bill to transfer funds from the CCC for the arrest and eradication of animal and plant pests and diseases that threaten American agriculture. By providing funds in this account, the Committee is enhancing, not replacing, the use of CCC funding for emergency outbreaks.

Export Certification.—The Committee recognizes personnel constraints on the U.S.-Mexico border, with regard to phytosanitary inspections for exported goods. In the best interest of cross-border trade and agribusiness, the Committee encourages APHIS to ensure adequate levels of staffing to provide timely phytosanitary certification in support of exports.

Feral Swine Management.—Feral swine are found in at least 41 states with a population of more than 5,000,000 and cause more than $1,500,000,000 in damages and control costs in the United States each year, with at least $800,000,000 of this due to direct damage to agriculture. The Committee believes this damage assessment far underestimates the level of damage when considering the impact to the environment, native species, habitat, historic sites, and residential and commercial areas. The Committee supports APHIS' National Feral Swine Damage Management Program but has concerns that the currently budgeted amount does not provide

sufficient funding to allow for the increasing demands in the areas of research, development, education, outreach, and coordination. Therefore, the Committee provides an increase of $3,000,000 above the funds provided in fiscal year 2016 and directs APHIS to use these funds to support its existing cooperative service agreement process, which identifies and develops unmet needs for feral swine control nationwide.

Foreign Market Access Requests.—Increasingly, U.S. agriculture is facing non-tariff trade barriers, which are limiting the ability for U.S. agriculture to open and maintain access to key export markets. The Committee directs APHIS to review and update the list of foreign market access requests submitted by U.S. producers, producer groups, companies and/or non-government agencies. All efforts should be made to assign the appropriate agency resources to opening and maintaining access to foreign markets for U.S. products. By March 2017, the agency should provide an update to the Committee on the number of foreign market access requests that have been successfully granted for U.S. agriculture; export volumes; the number of foreign market access requests that have been granted for imports to the U.S. marketplace; and the number of outstanding requests and the length of time each request has been pending before the agency. The agency should identify the limitations in achieving and maintaining foreign market access for U.S. agriculture.

Foreign Zoonotic Disease Response.—The Committee recognizes and commends APHIS for its efforts to address the challenges associated with eradicating foreign zoonotic diseases such as HPAI and FMD in a timely manner. In order to reduce the spread of disease outbreaks in the future, the Committee directs APHIS to use existing funds to undertake a review of existing protocols for foreign zoonotic disease eradication, including stamping-out policies, and to develop a strategy that improves agency, state and local, and industry responsiveness. This plan should take into consideration existing technology limitations, adverse weather, lack of water, and other issues that may hinder APHIS' eradication efforts in the event of future outbreaks. Furthermore, APHIS should consider funds available to states through the current cooperative agreements for surveillance testing and backyard flock surveillance; grant or cost share opportunities for farmers to give them the ability to enhance biosecurity measures at their operations; the need for veterinarian positions in states for biosecurity activities; and needs to address the unavailability of vaccine for FMD.

Grapevine Import Regulations.—The Committee urges APHIS to update its import regulations for grapevines. The current regulatory review process and requirements for pathogen screening of imports are expensive, cumbersome and time-consuming. Complying without the use of available technology can take in excess of thirteen years to complete. APHIS should issue new regulations that dramatically shorten the review timeline by using new technology and prioritize the approval of new grape varieties suited for colder, harsher climates.

Horse Protection Act.—The Committee has continually encouraged APHIS to work more closely with stakeholders pursuant to the Horse Protection Act. Specifically, the agency has been directed to provide greater and more consistent transparency, to work more

closely with stakeholders on rules and regulations, and to move away from the subjective nature of current inspection methods in favor of objective measurements. The Committee is disappointed that the agency has not worked in good faith to address the Committee's requests, which are intended to further the dual goals of the Horse Protection Act—to care for animals engaged in the trade and promote the industry in a safe manner. The Committee has become aware that APHIS intends to modify regulations associated with Horse Protection Act through rule-making actions and notes that any substantive changes to the statute or its intent should be made by Congress through the legislative process.

Huanglongbing Emergency Response.—The Committee maintains the increased funding levels for Huanglongbing Emergency Response within the Specialty Crop Pests line item. The Committee encourages APHIS to allocate sufficient resources in order to continue vital management, control, and associated activities to address citrus greening. The disease, for which there is no cure, has caused a reduction in citrus production by over 60 percent since 2007 in Florida alone. All citrus producing counties in Texas are under quarantine, and California has found the Asian Citrus Psyllid, the vector of the disease, in some backyard trees. The spread of this disease has called the future of the domestic citrus industry into question, costing thousands of jobs and millions of dollars in lost revenue. In addition, the agency is encouraged to support priorities and strategies identified by the HLB MAC group to benefit the citrus industry. The agency should appropriately allocate resources based on critical need and maximum effect to the citrus industry.

The Committee maintains the $2,000,000 increase from fiscal year 2016 for citrus health to support priorities and strategies identified by the HLB MAC group. The MAC is focused on short-term solutions to help the citrus industry, and the cooperative nature of federal, state, and industry representatives in this group is expected to result in the development of tools and techniques to address this devastating disease. Helping growers explore new possible solutions, the MAC has been an effective resource. The agency should appropriately allocate resources based on critical need and maximum impact to the citrus industry. These citrus health activities directly protect citrus production on approximately 765,000 acres in the United States worth more than $3,300,000,000 for the 2014–2015 growing season.

Light Brown Apple Moth.—The Committee encourages APHIS to engage state and international regulatory bodies to deregulate the light brown apple moth. The Committee is concerned that if APHIS simply withdraws federal regulation without the necessary work with other regulatory officials, APHIS will shift, not reduce, the regulatory burden. Should APHIS withdraw the federal order for light brown apple moth, it must take steps to reduce the overall burden on growers. The Committee includes an increase for the light brown apple moth to support the second phase of the Joint Forward Plan and urges the Department to develop initiatives for permanent, ongoing departmental regulatory partnerships while continuing to engage stakeholders and trading partners throughout North America.

National Animal Health Laboratory Network (NAHLN).—The laboratories within the NAHLN network are on the frontline for detection of newly identified and reemerging animal diseases. NAHLN laboratories provide a critical contribution to animal and public health. The bill provides funding for NAHLN through both APHIS and NIFA at approximately $12,000,000 and $3,000,000, respectively, resulting in a total investment of $15,000,000 for fiscal year 2017.

NAHLN laboratories were invaluable during the 2015 outbreak of HPAI, which significantly increased testing needs. At the same time, NAHLN laboratories must also continue testing for other animal diseases of concern. The Committee encourages NAHLN to consider partnering with other accredited private laboratories as necessary to assist with increased testing demands in order to prevent backlogs and provide results as quickly as possible.

Orobanche Ramosa.—The Committee recognizes that APHIS-funded efforts to control *orobanche ramosa*, also known as branched broomrape, in Texas were not completely successful and its spread is a threat to agriculture. As such, the Committee encourages APHIS to work with the appropriate Congressional Committees, along with states and local stakeholders to formulate a plan to manage branched broomrape.

Phytopthora ramorum.—The Committee expects APHIS to continue its efforts to manage *P. ramorum* while minimizing disruption to the interstate movement of plant materials and commercial trade. The agency should use an appropriate portion of funds from the Specialty Crop Pests account to expeditiously implement the review of the Federal Order governing shipment of plant materials from quarantined and regulated counties as well as to continue its review of the efficacy of the pre-notification requirements for western nurseries. APHIS also should continue efforts to partner with the regulated states to develop new best management practices regarding *P. ramorum* during the effective period of the Order.

Potato Cyst Nematode Eradication.—The Committee includes funding to maintain resources for the potato cyst nematode eradication program at the fiscal year 2016 level in order to continue with successful efforts to eradicate this pest. If left untreated, this pest could spread, affecting other crops.

Regional Biosecurity Plans.—The Secretary of Agriculture shall submit to the Committees on Appropriations of the House and Senate, at the time the President's budget for fiscal year 2018 is submitted under section 1105(a) of title 31, United States Code, a report describing the steps USDA has taken to implement the Regional Biosecurity Plan for Micronesia and Hawaii, as developed jointly by the Department and other federal and non-federal entities. The report shall include an update on previous and upcoming implementation activities, including estimates of additional funding to be used or needed for planned activities.

Vaccine for Foot-and-Mouth Disease.—FMD is a highly contagious viral disease eradicated from the U.S. in 1929, but it is still a threat since countries around the globe continue grappling with the disease. This disease could cause billions of dollars in damage to the economy if unchecked. APHIS has publicly stated that the FMD vaccine bank is insufficient to deal with a large scale FMD outbreak in the U.S. and that a larger vaccine bank is needed.

APHIS has also noted that expanding the current FMD vaccine supply is an expensive investment. Having sufficient quantities of vaccine readily available and deployable to control an FMD outbreak would appear to be a critical part of the USDA APHIS mission. Rapid control of FMD protects the security of the U.S. food supply, limiting the economic damage from livestock losses due to the disease, and also shortens disruptions to trade and commerce that would occur as long as FMD goes uncontrolled due to a lack of vaccine. The Committee is concerned that this potential vaccine shortage could result in the compromised management of an FMD outbreak in the United States. In order that the Committee can better understand the budget implications required to address this vaccine shortage, APHIS is directed to report to the Committees on Appropriations of the House and Senate within 90 days of enactment of this Act on contingency plans to develop an expanded vaccine bank and the estimated funding necessary for implementation and maintenance.

Wildlife Damage Management.—While receiving support from cooperators to conduct wildlife management operations, special emphasis should be placed on those areas such as oral rabies vaccination, livestock protection, predator damage management for avian predators such as the raven in Western states and cormorants in the south, and other such activities that will reduce or eliminate threats to agricultural industries. The Committee expects APHIS to provide no less than $28,000,000 for the national rabies control and surveillance efforts.

Of particular concern is the continued and repeat depredation by wolves and packs in the Pacific Northwest. In certain states where state management plans require state agencies to utilize lethal control of wolves, it is important these actions are taken to protect livestock. As experts in the field of managing predators to prevent depredation, USDA has valuable knowledge, tools and resources that can assist states in managing the federally reintroduced wolves. The Committee directs USDA to prioritize and complete the documentation and processes needed to allow them to assist states and local livestock producers with managing this situation.

BUILDINGS AND FACILITIES

2016 appropriation	$3,175,000
2017 budget estimate	3,175,000
Provided in the bill	3,175,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For Animal and Plant Health Inspection Service, Buildings and Facilities, the Committee provides an appropriation of $3,175,000.

Facilities for Fruit Fly Eradication.—In Section 743, the Committee provides $30,000,000 for the improvement and repair of facilities and infrastructure related to the research and production of fruit fly eradication initiatives. Recent fruit fly contaminations have cost producers more than $1,100,000,000 in economic loss. The Committee directs APHIS to provide a report and consult with the Committee on plans for construction and location of the new facilities.

AGRICULTURAL MARKETING SERVICE

MARKETING SERVICES

2016 appropriation	$81,223,000
2017 budget estimate	81,933,000
Provided in the bill	82,223,000
Comparison:	
2016 appropriation	+1,000,000
2017 budget estimate	+290,000

COMMITTEE PROVISIONS

For Marketing Services of the Agricultural Marketing Service, the Committee provides an appropriation of $82,223,000. The Committee notes the Department has the authority to include state organic program fees and transitional certification fees when administering the program under 7 U.S.C. 6523.

Organic Integrity.—The Committee is aware that the National Organic Standards Board (NOSB) is conducting its sunset review process for reviewing substances on the National List. It is important that this process includes sound science and robust stakeholder participation. The Committee expects both the NOSB and USDA to fully consider all currently available scientific information during the sunset review and rulemaking procedures.

Organic Rulemaking.—The Committee is aware that USDA released a proposed rule on April 7, 2016, titled "National Organic Program: Organic Livestock and Poultry Practices." The Committee is concerned about the potential disruption to existing organic producers and their supply chains, as well as ensuring that animal health is fully protected. Before finalizing this regulation, the Committee directs USDA to conduct an additional, thorough assessment on the costs of compliance and alternatives for existing organic producers so that producers and supply chains directly impacted by the change in rules will be minimally impacted.

Research and Promotion Programs.—The Committee notes that the commodity Research and Promotion boards that the agency oversees are not agencies of the federal government, nor are Research and Promotion programs funded with federal funds. The funding used to operate and carry out the activities of the various Research and Promotion programs is provided by producers and industry stakeholders, and employees of the boards are not federal employees. Therefore, the Committee urges USDA to recognize that such boards are not subject to the provisions of 5 U.S.C. Section 552.

Rural Infrastructure.—Inadequate market access is a critical barrier to economic growth in rural and agricultural communities. The Committee provides $1,000,000 for the Transportation Services Division to continue working with other federal, state and local agencies, as well as producers and those involved in all sectors of agricultural transportation, to address rural infrastructure needs to ensure producers have domestic and international market access.

LIMITATION ON ADMINISTRATIVE EXPENSES

2016 limitation	($60,982,000)
2017 budget limitation	(61,227,000)
Provided in the bill	(61,227,000)
Comparison:	
2016 limitation	+245,000
2017 budget limitation	– – –

COMMITTEE PROVISIONS

The Committee provides a limitation of $61,227,000 on Administrative Expenses of the Agricultural Marketing Service.

FUNDS FOR STRENGTHENING MARKETS, INCOME, AND SUPPLY
(SECTION 32)

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	($20,489,000)
2017 budget estimate	(20,705,000)
Provided in the bill	(20,489,000)
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−216,000

COMMITTEE PROVISIONS

For the Marketing Agreements and Orders Program, the Committee provides a transfer from Section 32 funds of $20,489,000.

The following table reflects the status of this fund for fiscal years 2016 and 2017:

ESTIMATED TOTAL FUNDS AVAILABLE AND BALANCE CARRIED FORWARD FISCAL YEARS 2016–2017

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate
Appropriation (30% of Customs Receipts)	$10,316,645	$10,929,841
Less Transfers:		
Food & Nutrition Service	−8,969,178	−9,462,665
Commerce Department	−145,811	−145,175
Total, Transfers	−9,114,989	−9,607,840
Prior Year Appropriation Available, Start of Year	223,344	125,000
Unavailable for Obligations (recoveries & offsetting collections)	0	0
Transfer of Prior Year Funds to FNS (F&V)	−122,000	−125,000
Budget Authority:	1,303,000	1,322,000
Rescission of Current Year Funds	−215,636	−231,443
Appropriations Temporarily Reduced—Sequestration	−77,384	−79,557
Unavailable for Obligations (F&V Transfer to FNS)	−125,000	−125,000
Available for Obligation:	884,980	886,000
Less Obligations:		
Child Nutrition Programs (Entitlement Commodities)	465,000	465,000
State Option Contract	5,000	5,000
Removal of Defective Commodities	2,500	2,500
Emergency Surplus Removal	118,500	0
Small Business Support	0	0
Disaster Relief	5,000	5,000
Additional Fruits, Vegetables, and Nuts Purchases	107,500	206,000
Fresh Fruit and Vegetable Program	40,000	44,000
Estimated Future Needs	87,192	102,571
Total, Commodity Procurement	830,692	830,071
Administrative Funds:		
Commodity Purchase Support	33,799	35,440
Marketing Agreements and Orders	20,489	20,489

ESTIMATED TOTAL FUNDS AVAILABLE AND BALANCE CARRIED FORWARD FISCAL YEARS 2016–2017—Continued

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate
Total, Administrative Funds	54,288	55,929
Total Obligations	884,980	886,000
Unobligated Balance, End of Year	0	0
Unavailable for Obligations (F&V Transfer to FNS)	125,000	125,000
Balances, Collections, and Recoveries Not Available	0	0
Total, End of Year Balances	$125,000	$125,000

PAYMENTS TO STATES AND POSSESSIONS

2016 appropriation	$1,235,000
2017 budget estimate	1,235,000
Provided in the bill	1,235,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For Payments to States and Possessions, the Committee provides an appropriation of $1,235,000.

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

SALARIES AND EXPENSES

2016 appropriation	$43,057,000
2017 budget estimate	43,482,000
Provided in the bill	43,057,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−425,000

COMMITTEE PROVISIONS

For the Grain Inspection, Packers and Stockyards Administration, the Committee provides $43,057,000.

LIMITATION ON INSPECTION AND WEIGHING SERVICES EXPENSES

2016 limitation	($55,000,000)
2017 budget limitation	(57,500,000)
Provided in the bill	(55,000,000)
Comparison:	
2016 limitation	– – –
2017 budget limitation	−2,500,000

COMMITTEE PROVISIONS

The Committee includes a limitation on inspection and weighing services expenses of $55,000,000. The Committee does not concur with the agency's proposal to eliminate the limitation on inspection and weighing services expenses. The agency has sufficient carryover balances in this account for these activities. Additionally, the bill includes authority to exceed by 10 percent the limitation on inspection and weighing services with notification to the Committees on Appropriations of the House and Senate.

OFFICE OF THE UNDER SECRETARY FOR FOOD SAFETY

2016 appropriation	$816,000
2017 budget estimate	819,000
Provided in the bill	816,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Food Safety, the Committee provides an appropriation of $816,000.

FOOD SAFETY AND INSPECTION SERVICE

2016 appropriation	$1,014,871,000
2017 budget estimate	1,030,405,000
Provided in the bill	1,030,405,000
Comparison:	
2016 appropriation	+15,534,000
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For the Food Safety and Inspection Service (FSIS), the Committee provides an appropriation of $1,030,405,000.

The following table reflects the Committee's recommendations for fiscal year 2017:

FOOD SAFETY AND INSPECTION SERVICE

[Dollars in Thousands]

	Recommendation
Federal Inspection	$914,098
Public Health Data Communication Infrastructure System	34,580
International Food Safety and Inspection	16,487
State Food Safety and Inspection	61,568
Codex Alimentarius	3,672
Total, Food Safety and Inspection Service	$1,030,405

Humane Methods of Slaughter.—FSIS shall ensure that inspectors hired with funding previously specified for enforcement under the Humane Methods of Slaughter Act focus their attention on overseeing compliance with humane handling rules for live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas, and that all inspectors receive robust national training, including on the Regulatory Essentials, Humane Animal Tracking System, and Public Health Information System.

Siluriformes Inspection Report—Within 120 days of enactment, the Secretary shall report to the Committee the status of the implementation of the mandatory inspection program for siluriformes and catfish products. The report shall contain the dates of domestic public and technical meetings held to explain the new program and their locations; the dates of foreign technical meetings held to explain the new program and their locations; domestic catfish slaughter and processing facilities visited by inspection personnel broken down by state and the types of regulatory actions taken, if any; the names countries that notified the Department by March 1 of their intention to continue to export siluriformes to the U.S. and the

number of establishments that would be eligible to export; the names of countries that notified the Department after March 1 of their intention to continue to export siluriformes to the U.S. and the number of establishments that would be eligible to export; the number of pounds of siluriformes imported beginning on April 15, 2016 broken down by country; the number of pounds that were subject to TOIs broken down by country; the specific TOIs performed broken down by country; the number of chemical and microbiological samples taken by country; the types and numbers of regulatory violations found by country. The Secretary shall also report the number of field inspection personnel assigned to the domestic facilities and the number of field inspection personnel assigned to perform import inspection.

Water Conserving Technologies.—The Committee continues to direct FSIS to utilize water conserving technologies that allow handwashing facilities to be immediately activated and deactivated in a hands-free manner to reduce cross-contamination.

OFFICE OF THE UNDER SECRETARY FOR FARM AND FOREIGN AGRICULTURAL SERVICES

2016 appropriation	$898,000
2017 budget estimate	901,000
Provided in the bill	898,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Farm and Foreign Agricultural Services, the Committee provides an appropriation of $898,000.

FARM SERVICE AGENCY

SALARIES AND EXPENSES

(INCLUDING TRANSFERS OF FUNDS)

	Appropriation	Transfer from Program Accounts	Total, FSA S&E
2016 appropriation	$1,200,180,000	($309,880,000)	($1,510,060,000)
2017 budget estimate	1,209,751,000	(309,610,000)	(1,519,361,000)
Provided in the Bill	1,200,180,000	(309,610,000)	(1,509,790,000)
Comparison:			
2016 appropriation	– – –	−270,000	(−270,000)
2017 budget estimate	−$9,571,000	$– – –	(−$9,571,000)

COMMITTEE PROVISIONS

For Salaries and Expenses of the Farm Service Agency (FSA), the Committee provides an appropriation of $1,200,180,000 and transfers of $309,610,000, for a total program level of $1,509,790,000.

Oriental Fruit Fly.—The Committee strongly urges FSA to make funds available to those farmers who were negatively impacted by an Oriental Fruit Fly quarantine from October 2015 through February 2016. The farmers, who were unable to bring their crop to market, sustained devastating losses, although the quarantine was

necessary and successful in eradicating the Oriental Fruit Fly pest. Because crop insurance and other similar programs do not apply in instances of a state or federally declared quarantine, the impacted farmers are in need of relief. The Committee believes it is within FSA's purview to make funds available to the impacted farmers.

FSA Farm Loan Levels.—The Committee does not agree with FSA's proposal to waive loan fees for certain groups of farmers. However, the Committee does recognize increased demand for overall loan levels and provides this relief in accordance with the President's budget request, including additional funding for Emergency Loans. In general, USDA data demonstrates that farmers are experiencing a significant decline in farm income and the cost of doing business is growing. As such, the need for larger individual loan limitations and flexibility may be increasing. The Department is directed to work with stakeholders to address these issues.

Budgetary Reductions.—FSA has submitted consecutive proposals for significant annual budget savings through "operational efficiencies" with little detail for achieving these goals. FSA proposed nearly $40,000,000 in reductions for fiscal year 2016. An additional $24,000,000 in IT savings is proposed for fiscal year 2017 through contractual savings. The Committee directs FSA to provide a report by the end of fiscal year 2016 detailing the specific contracts and amounts FSA proposes to achieve these savings from.

Proposal to Close County Offices.—The Committee includes statutory language preventing the closure of county offices.

FSA IT.—The agreement includes statutory language that allows FSA to release funds for farm program delivery IT projects only after the submission of a spending plan to the Committees on Appropriations of the House and Senate. The roadmap submitted by FSA in fiscal year 2015 and submission of a spend plan for review to the Government Accountability Office (GAO) in fiscal year 2016 were the first steps toward bringing accountability and guidance to almost a decade of mismanagement of the Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) IT system. MIDAS was over budget by hundreds of millions of dollars, took years longer than expected, and only delivered a fraction of the promised results. While FSA has made some improvements in reforming the program, the Committee further directs the agency to provide a report within 90 days of enactment of this Act on its future plans for MIDAS-specific IT functions.

Loan Deficiency Payments.—The Committee encourages the Secretary to work with producers who have already received a benefit under 7 U.S.C. 7935 with respect to the 2015 crop of a commodity prior to the availability of a benefit under 7 U.S.C. 8286 as provided by amendments made by Public Law 114–113.

Alternative Imaging Capabilities.—The Committee notes that space-based infrared and hyper-spectral satellites are ideally suited to managing and monitoring agricultural lands and waters. These commercially-available capabilities could do much toward more efficient use of agriculture resources. Accordingly, the Committee encourages the Department to examine the utility and cost of new, commercially-derived, space-based imaging data systems that can support the agriculture community, including ways that improve efficiencies within the Farm and Foreign Agricultural Services mission area.

Economic Impact of Livestock and Conservation Reserve Program (CRP).—CRP is a federal program under FSA that pays a yearly rental payment in exchange for farmers and ranchers to remove environmentally sensitive land from agricultural production. Due to increasing enrollment in CRP in certain areas, livestock operations have been reduced. In an effort to focus on the economic impact of CRP in rural communities, specifically livestock production, the Committee directs FSA to submit a report within 60 days of enactment of this Act. Central facets of the report should focus on (1) the opportunities livestock production brings to rural communities; (2) determine the economic impact livestock production has on rural communities (feed sales, construction/fencing costs, management practice investments that increase revenue for local businesses); (3) explore the tax benefits for rural school districts resulting from property taxes and cash receipts due to livestock production; and (4) assess the ability for nutrients to be captured and soil quality maintained by grazing livestock (similar to the CRP program).

STATE MEDIATION GRANTS

2016 appropriation	$3,404,000
2017 budget estimate	3,404,000
Provided in the bill	3,404,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For State Mediation Grants, the Committee provides an appropriation of $3,404,000.

GRASSROOTS SOURCE WATER PROTECTION PROGRAM

2016 appropriation	$6,500,000
2017 budget estimate	– – –
Provided in the bill	6,500,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+6,500,000

COMMITTEE PROVISIONS

For the Grassroots Source Water Protection Program, the Committee provides an appropriation of $6,500,000.

DAIRY INDEMNITY PROGRAM

(INCLUDING TRANSFER OF FUNDS)

2016 appropriation	[1]$500,000
2017 budget estimate	[1]500,000
Provided in the bill	[1]500,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

[1] Current indefinite appropriation.

COMMITTEE PROVISIONS

For the Dairy Indemnity Program, the Committee provides an appropriation of such sums as may be necessary (estimated to be $500,000 in the President's fiscal year 2017 budget request).

AGRICULTURAL CREDIT INSURANCE FUND PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

ESTIMATED LOAN LEVELS

2016 loan level	$6,402,114,000
2017 budget estimate	6,655,053,000
Provided in the bill	6,667,144,000
Comparison:	
2016 loan level	+265,030,000
2017 budget estimate	+12,091,000

COMMITTEE PROVISIONS

For the Agricultural Credit Insurance Fund program account, the Committee provides a loan level of $6,667,144,000.

The following table reflects the loan levels for the Agricultural Credit Insurance Fund program account:

AGRICULTURE CREDIT PROGRAMS—LOAN LEVELS

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Farm Loan Programs:			
Farm Ownership:			
Direct	$1,500,000	$1,500,000	$1,500,000
Unsubsidized Guaranteed	2,000,000	2,000,000	2,000,000
Farm Operating:			
Direct	1,252,004	1,460,047	1,460,047
Unsubsidized Guaranteed	1,393,443	1,432,430	1,432,430
Emergency Loans	34,667	22,576	34,667
Indian Tribe Land Acquisition Loans	2,000	20,000	20,000
Conservation Loans:			
Unsubsidized Guaranteed	150,000	150,000	150,000
Indian Highly Fractionated Land	10,000	10,000	10,000
Boll Weevil Eradication	60,000	60,000	60,000
Total	$6,402,114	$6,655,053	$6,667,144

ESTIMATED LOAN SUBSIDY AND ADMINISTRATIVE EXPENSES LEVELS

[Dollars in Thousands]

	Direct Loan subsidy	Guaranteed loan subsidy	Grants	Administrative expenses
2016 appropriation	$53,961	$14,352	$– – –	$314,918
2017 budget estimate	62,198	15,327	1,500	317,068
Provided in the Bill	62,198	15,327	– – –	314,918
Comparison:				
2016 appropriation	+8,237	+975	– – –	– – –
2017 budget estimate	$ – – –	$ – – –	– $1,500	– $2,150

The following table reflects the costs of loan programs under credit reform:

AGRICULTURE CREDIT PROGRAMS—SUBSIDIES AND GRANTS

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Farm Loan Subsidies:			
Farm Operating:			
Direct	$53,961	$62,198	$62,198

AGRICULTURE CREDIT PROGRAMS—SUBSIDIES AND GRANTS—Continued

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Unsubsidized Guaranteed	14,352	15,327	15,327
Emergency Loans	1,262	1,262	1,938
Indian Highly Fractionated Land	– – –	2,550	2,550
Individual Development Accounts	– – –	1,500	– – –
Total	69,575	82,837	82,013
ACIF Expenses:			
Salaries and Expenses	306,998	306,998	306,998
Administrative Expenses	7,920	10,070	7,920
Total, ACIF Expenses	$314,918	$317,068	$314,918

RISK MANAGEMENT AGENCY

SALARIES AND EXPENSES

2016 appropriation	$74,829,000
2017 budget estimate	[1] 66,615,000
Provided in the bill	74,829,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+8,214,000

[1] Does not include up to $20,000,000 transfer from mandatory crop insurance funding.

COMMITTEE PROVISIONS

For the Risk Management Agency, the Committee provides an appropriation of $74,829,000.

Standard Reinsurance Agreement (SRA) Discrepancies.—The Committee notes that stakeholders, including specialty crop insurance agents, are concerned about commissions received for their products as compared to other crops. In a manner consistent in law, the Committee encourages RMA to address this issue by working with all such stakeholders and involving them in any future negotiations of the SRA. The Committee directs RMA to provide a report to the Committee on the amount of commissions paid to crop insurance agents, broken down by state, year, and crop for fiscal years 2006 through 2015. The report shall also provide such information by insurance products subject to and not subject to the administrative and operating expenses limitation in the SRA and the 80 percent limitation on agent commissions by state.

Crop Insurance in Drought Areas.—The Committee encourages the Secretary to be flexible in administering the Federal Crop Insurance program in areas impacted by natural disasters, including in drought-affected areas.

CORPORATIONS

FEDERAL CROP INSURANCE CORPORATION FUND

2016 appropriaion	[1] $7,857,970,000
2017 budget estimate	[1] 8,839,089,000
Provided in the bill	[1] 8,839,089,000
Comparison:	
2016 appropriation	+981,119,000
2017 budget estimate	– – –

[1] Current indefinite appropriation.

COMMITTEE PROVISIONS

For the Federal Crop Insurance Corporation Fund, the Committee provides an appropriation of such sums as may be necessary (estimated to be $8,839,089,000 in the President's fiscal year 2017 budget request).

COMMODITY CREDIT CORPORATION FUND

REIMBURSEMENT FOR NET REALIZED LOSSES

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	[1] $6,871,132,000
2017 budget estimate	[1] 13,476,854,000
Provided in the bill	[1] 13,476,854,000
Comparison:	
2016 appropriation	+6,605,722,000
2017 budget estimate	– – –

[1] Current indefinite appropriation.

COMMITTEE PROVISIONS

For Reimbursement for Net Realized Losses to the Commodity Credit Corporation, the Committee provides such sums as may be necessary to reimburse for net realized losses sustained but not previously reimbursed (estimated to be $13,476,854,000 in the President's fiscal year 2017 budget request).

HAZARDOUS WASTE MANAGEMENT

(LIMITATION ON EXPENSES)

2016 limitation	($5,000,000)
2017 budget estimate	(5,000,000)
Provided in the bill	(5,000,000)
Comparison:	
2016 limitation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For Hazardous Waste Management, the Committee provides a limitation of $5,000,000.

TITLE II

CONSERVATION PROGRAMS

OFFICE OF THE UNDER SECRETARY FOR NATURAL RESOURCES AND ENVIRONMENT

2016 appropriation	$898,000
2017 budget estimate	901,000
Provided in the bill	898,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Natural Resources and Environment, the Committee provides an appropriation of $898,000.

NATURAL RESOURCES CONSERVATION SERVICE

CONSERVATION OPERATIONS

2016 appropriation	$850,856,000
2017 budget estimate	860,374,000
Provided in the bill	855,256,000
Comparison:	
2016 appropriation	+4,400,000
2017 budget estimate	−5,118,000

COMMITTEE PROVISIONS

For Conservation Operations, the Committee provides an appropriation of $855,256,000.

The Committee provides $9,300,000 for the Snow Survey and Water Forecasting Program; $9,400,000 for the Plant Materials Centers; and $80,000,000 for the Soil Surveys Program. The Committee provides $756,556,000 for Conservation Technical Assistance and includes a $15,000,000 increase for written conservation plans and conservation program delivery. The Committee is pleased with the progress of the Conservation Effects Assessment Project and the Conservation Delivery Streamlining Initiative and directs NRCS to continue to invest in these programs.

Administrative Reorganization.—The Committee commends NRCS for its organizational realignment of administrative functions and appreciates the savings this will generate. NRCS has worked to become a more efficient, accountable organization, and the Committee encourages NRCS to work with other agencies within USDA to do the same.

Agricultural Conservation Easement Program.—Due to the unique ecological needs of each state, the Committee encourages NRCS to work with state and local partners to address these needs and to ensure the priority needs and projects in each state, such as those that are leveraged by public and private resources, are addressed.

Cheat Grass Eradication.—The Committee encourages NRCS to continue to assist farmers and ranchers to eradicate, control, and reduce the fuel loads associated with cheat grass and to collaborate with ARS, as appropriate, on research related to cheat grass.

Conservation Practice Standards.—The Committee is aware that NRCS has been pressured to modify its conservation practice standards in certain circumstances for purposes not related to the conservation of farm and ranch land. The Committee recognizes that conservation practice standards are science-based, undergo a thorough technical review, are open to the public for notice and comment, and reflect the best available knowledge on how to achieve the identified conservation and environmental objective. The Committee directs NRCS to maintain its long-standing process for developing and updating its conservation practice standards.

Floodplain Buyouts.—The Committee commends the successful efforts of NRCS with voluntary floodplain homeowner buyout projects. The Committee encourages the NRCS to continue collaborative efforts with participating towns and counties to mitigate unintended consequences resulting from buyouts, such as utility cost increases for homeowners in these regions.

Harmful Algal Blooms.—The Committee supports NRCS' ongoing work to prevent soil erosion leading to harmful algal blooms

through the introduction of cover crops and encourages continued targeting of watersheds where harmful algal blooms pose a threat.

Herbicide Resistance.—The Committee reminds NRCS of the challenges many producers are facing due to the spread of herbicide-resistant weeds and encourages it to ensure agency staff, partners, and producers are aware of conservation practice standards, conservation activity plans to address herbicide-resistant weeds, and financial assistance available through conservation programs to assist producers in their efforts to control these weeds.

Irrigation Agriculture.—The Committee recognizes the importance of irrigation agriculture and commends efforts to expand irrigation systems in states and regions that have not previously irrigated. The Committee directs NRCS to study the benefits of waiving irrigation history requirements within the Environmental Quality Inventive Program (EQIP) as it has under the Regional Conservation Partnership Program (RCPP) and to submit a report within 60 days of enactment of this Act on actions it can take to prevent unnecessary barriers to states that would otherwise have access to funds for irrigation systems.

Locally Led Conservation.—The Committee recognizes that locally led conservation is the foundation of the Nation's highly successful legacy of conservation and encourages NRCS to work with state, tribal, local, and other partners on voluntary stewardship projects that preserve working agricultural lands while protecting watersheds and wildlife habitat.

Milkweed.—The Committee is concerned about the rapid decline in milkweed for monarch butterfly habitat. The Committee encourages NRCS consider the increased benefits of restoring milkweed for monarch habitat in fiscal year 2017.

National Marine Sanctuaries.—The Committee urges the agency to continue the collaborative agreement with the Office of National Marine Sanctuaries to address sources of agricultural runoff, such as sediments, nitrates, and pesticides.

Resource Conservation and Development Councils (RC&Ds).—The Committee recognizes RC&Ds have been valuable partners in conservation and encourages NRCS to continue working with local councils, as appropriate, to ensure conservation programs meet local resource needs.

Regional Conservation Partnership Program.—The Committee commends NRCS for the success of RCPP, through which NRCS provides assistance to producers through partnership agreements, program contracts, or easement agreements. These programs allow for diverse and innovative conservation projects which leverage both public and private funding. The Committee encourages NRCS to consider the needs of organic farmers, who implement a wide variety of creative methods to improve water quality and enhance the environment, while implementing RCPP.

Sage Grouse Initiative.—The Committee supports NRCS' sage grouse conservation efforts. Through the initiative, NRCS provides technical and financial assistance to help landowners conserve sage grouse habitat on their land. The initiative is an integral part of efforts by federal agencies, several western states, and private landowners to help preclude the listing of the sage grouse as an endangered species.

Water Use Efficiency.—The Committee is encouraged by the work being undertaken by the Bureau of Reclamation and NRCS under the California Bay-Delta Program Water Use Efficiency Grants Program, which coordinates the water use efficiency assistance authorized under the Secure Water Act. The Committee directs NRCS to work with Reclamation to identify and implement ways within existing authorities to extend the benefits of this collaborative effort.

WATERSHED REHABILITATION PROGRAM

2016 appropriation	$12,000,000
2017 budget estimate	– – –
Provided in the bill	12,000,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+12,000,000

COMMITTEE PROVISIONS

For the Watershed Rehabilitation Program, the Committee provides an appropriation of $12,000,000.

TITLE III

RURAL DEVELOPMENT PROGRAMS

OFFICE OF THE UNDER SECRETARY FOR RURAL DEVELOPMENT

2016 appropriation	$893,000
2017 budget estimate	896,000
Provided in the bill	893,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Rural Development, the Committee provides an appropriation of $893,000.

Resource Conservation and Development Councils.—The Committee recognizes that RC&Ds have been valuable partners in rural economic development and encourages RD to continue working with local councils, as appropriate, to address local economic development needs.

Reporting Requirements.—The Committee reminds RD that any action that relocates an office or employees and reorganizes offices, programs, or activities must be reported to the Committees on Appropriations of the House and Senate as required by law.

StrikeForce Initiative.—The Committee appreciates the Department's efforts to target assistance to at-risk communities through the StrikeForce Initiative for Rural Growth and Opportunity. USDA, in collaboration with public and private partners, helps rural counties experiencing chronic poverty improve economic opportunities and quality of life for local residents. The Committee encourages USDA to place special emphasis on persistent poverty counties and continue to utilize a strategy of partnering public resources with local expertise to grow rural economies and create jobs in these poverty-stricken areas.

Persistent Poverty Areas.—The bill directs certain RD programs, including the Section 502 Single Family Housing Direct Loan Pro-

gram, Mutual and Self-Help Housing Grants, Rural Community Facilities Program, Rural Business Program Account, Rural Cooperative Developments Grants, Rural Water and Waste Disposal Program, Rural Electrification and Telecommunications Loans Program, and the Distance Learning, Telemedicine, and Broadband Program, to provide at least 10 percent of the amounts provided to persistent poverty counties, defined as those areas that have 20 percent of their population living in poverty over the past 30 years.

RURAL DEVELOPMENT SALARIES AND EXPENSES

(INCLUDING TRANSFERS OF FUNDS)

	FY 2016 enacted	FY 2017 estimate	Committee provision
Appropriations	$225,835,000	$230,679,000	$225,835,000
Transfer from:			
Rural Housing Insurance Fund Program Account	417,854,000	426,821,000	410,086,000
Rural Development Loan Fund Program Account	4,468,000	4,564,000	3,495,000
Rural Electrification and Telecommunications Loan Program Account	34,707,000	36,451,000	33,414,000
Total, RD Salaries and Expenses	$682,864,000	$698,515,000	$672,830,000

COMMITTEE PROVISIONS

For Salaries and Expenses of the Rural Development mission area, the Committee provides an appropriation of $225,835,000.

RURAL HOUSING SERVICE

RURAL HOUSING INSURANCE FUND PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

[Dollars in Thousands]

	Loan level	Subsidy level	Administrative expenses
2016 Appropriation	$25,148,531	$79,377	$417,854
2017 Budget Estimate	25,233,208	81,963	426,821
Provided in the Bill	25,305,132	89,302	410,086
Comparison:			
2016 Appropriation	+156,601	+9,925	−7,768
2017 Budget Estimate	+$71,924	+$7,339	−$16,735

COMMITTEE PROVISIONS

For the Rural Housing Insurance Fund program account, the Committee provides a loan level of $25,305,132,000.

Section 502 Intermediary Pilot Program.—The bill directs the Secretary to continue and expand the pilot program for packaging section 502 direct loans. The pilot requires not less than ten nonprofit organizations to prepare and review applications for single family loans, saving federal funds and staff time. The Committee expects the Rural Housing Service to expeditiously implement this program.

Section 514 Loan Program.—The Farm Labor Housing program (Section 514) has been successful in assisting in the development of farm housing. The program presently only permits housing of certain farm workers and has not taken into consideration changes

in the agricultural labor market. As a result, farmers are restricted on who can use the housing built with these funds to house the workers they need to prune and harvest their crops. USDA is directed to report to the Committees on Appropriations of the House and Senate within 90 days of enactment of this Act regarding the feasibility and impacts of amending the program to expand the list of eligible tenants permitted to live in existing housing.

Rural Definition.—Communities need transparency and deserve to understand the criteria that are evaluated when determining eligibility for RHS programs. The Committee directs RHS to submit a report listing the criteria used to define "rural in character" in determining program eligibility.

The following table reflects the loan levels for the Rural Housing Insurance Fund program account:

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Rural Housing Insurance Fund Loans:			
Single Family Housing (sec. 502):			
Direct	$900,000	$900,000	$1,000,000
Unsubsidized Guaranteed	24,000,000	24,000,000	24,000,000
Housing Repair (sec. 504)	26,278	26,277	26,277
Rental Housing (sec. 515)	28,398	33,074	35,000
Multi-family Guaranteed (sec. 538)	150,000	230,000	200,000
Site Development Loans	5,000	5,000	5,000
Credit Sales of Acquired Property	10,000	10,000	10,000
Self-help Housing Land Development Fund	5,000	5,000	5,000
Farm Labor Housing	23,855	23,857	23,855
Total, Loan Authorization	$25,148,531	$25,233,208	$25,305,132

The following table reflects the costs of loan programs under credit reform:

ESTIMATED LOAN SUBSIDY AND ADMINISTRATIVE EXPENSES LEVELS

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Rural Housing Insurance Fund Program Account (Loan Subsidies and Grants):			
Single Family Housing (sec. 502):			
Direct	$60,750	$60,930	$67,700
Housing Repair (sec. 504)	3,424	3,663	3,663
Rental Housing (sec. 515)	8,414	9,790	10,360
Farm Labor Housing	6,789	7,052	7,051
Site Development (sec. 524)	– – –	111	111
Self-Help Land (sec. 523)	– – –	417	417
Total, Loan Subsidies	79,377	81,963	89,302
Farm Labor Housing Grants	8,336	8,336	8,336
RHIF Expenses:			
Administrative Expenses	$417,854	$426,821	$410,086

RENTAL ASSISTANCE PROGRAM

2016 appropriation	$1,389,695,000
2017 budget estimate	1,405,033,000
Provided in the bill	1,405,033,000
Comparison:	
2016 appropriation	+15,338,000
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For the Rental Assistance Program, the Committee provides a program level of $1,405,033,000.

MULTIFAMILY HOUSING REVITALIZATION PROGRAM ACCOUNT

2016 appropriation	$37,000,000
2017 budget estimate	37,362,000
Provided in the bill	40,000,000
Comparison:	
2016 appropriation	+3,000,000
2017 budget estimate	+2,638,000

For the Multifamily Housing Revitalization Program Account, the Committee provides an appropriation of $40,000,000, including $18,000,000 for the rural housing voucher program.

MUTUAL AND SELF-HELP HOUSING GRANTS

2016 appropriation	$27,500,000
2017 budget estimate	18,493,000
Provided in the bill	30,000,000
Comparison:	
2016 appropriation	+2,500,000
2017 budget estimate	+11,507,000

COMMITTEE PROVISIONS

For Mutual and Self-Help Housing Grants, the Committee provides an appropriation of $30,000,000.

RURAL HOUSING ASSISTANCE GRANTS

2016 appropriation	$32,239,000
2017 budget estimate	28,701,000
Provided in the bill	33,701,000
Comparison:	
2016 appropriation	+1,462,000
2017 budget estimate	+5,000,000

COMMITTEE PROVISIONS

For the Rural Housing Assistance Grants program, the Committee provides an appropriation of $33,701,000 including $5,000,000 for rural housing preservation grants.

RURAL COMMUNITY FACILITIES PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$42,278,000
2017 budget estimate	37,000,000
Provided in the bill	47,100,000
Comparison:	
2016 appropriation	+4,822,000
2017 budget estimate	+10,100,000

COMMITTEE PROVISIONS

For the Rural Community Facilities Program Account, the Committee provides an appropriation of $47,100,000.

Power Plus.—In conjunction with the Administration's POWER+ initiative and Partnerships for Opportunity and Workforce and Economic Revitalization, the Committee encourages USDA to give consideration to Community Facility investments in coal commu-

nities that have been negatively impacted by changes in the coal industry and power sector.

The following table provides the Committee's recommendations as compared to the budget request:

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Loan Levels:			
Community Facility Direct Loans	($2,200,000)	($2,200,000)	($2,200,000)
Community Facility Guaranteed Loans	(148,305)	(– – –)	(148,305)
Subsidy and Grants:			
Community Facility Guaranteed Loans	3,500	– – –	3,322
Community Facility Grants	25,000	25,000	30,000
Rural Community Development Initiative	4,000	4,000	4,000
Economic Impact Initiative	5,778	– – –	5,778
Tribal College Grants	4,000	8,000	4,000
Total, Rural Community Facilities Program Subsidy and Grants	$42,278	$37,000	$47,100

The following is included in the bill for the Rural Community Facilities Program: $4,000,000 is for the Rural Community Development Initiative.

RURAL BUSINESS-COOPERATIVE SERVICE

RURAL BUSINESS PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$74,000,000
2017 budget estimate	81,444,000
Provided in the bill	76,883,000
Comparison:	
2016 appropriation	+2,883,000
2017 budget estimate	−4,561,000

COMMITTEE PROVISIONS

For the Rural Business Program Account, the Committee provides an appropriation of $76,883,000.

The following table provides the Committee's recommendations as compared to the budget request:

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimated	Committee provision
Loan Level:			
Business and Industry Guaranteed Loans	($919,768)	($892,244)	($919,768)
Subsidy and Grants:			
Business and Industry Guaranteed Loans	35,687	35,779	36,883
Rural Business Development Grants	24,000	55,000	35,000
Delta Regional Authority/Appalachian Regional Commission	3,000	– – –	5,000
Total, Rural Business Program Subsidy and Grants	$62,687	$90,779	$76,883

The following programs are included in the bill for the Rural Business Program account: $500,000 for rural transportation technical assistance and $4,000,000 for Federally Recognized Native American Tribes, of which $250,000 is for transportation technical assistance. The Committee notes that the 2014 farm bill consoli-

dated the Rural Business Opportunity and Rural Business Enterprise grant programs.

Rural Business Development Grants.—The Committee understands the important role that rural business development grants have in supporting the development or expansion of businesses in rural areas. However, the Committee is concerned that scarce grant monies are not always awarded to best stimulate small business through building upon other investments in technology infrastructure. The bill includes $10,000,000 for grants to businesses with proposals that have identified a community need that can be addressed through technology investment. The Committee encourages the Department to award grants to applicants with sound proposals and significant commercial potential.

INTERMEDIARY RELENDING PROGRAM FUND ACCOUNT

(INCLUDING TRANSFER OF FUNDS)

[Dollars in Thousands]

	Loan level	Subsidy level	Administrative expenses
2016 appropriation	$18,889	$5,217	$4,468
2017 budget estimate	18,889	5,476	4,564
Provided in the bill	18,889	5,476	3,495
Comparison:			
2016 appropriation	– – –	+259	−973
2017 budget estimate	$– – –	$– – –	−$1,069

COMMITTEE PROVISIONS

For the Intermediary Relending Program Fund Account, the Committee provides for a loan level of $18,889,000.

For the loan subsidy, the Committee provides an appropriation of $5,476,000. In addition, the Committee provides $3,495,000 for administrative expenses.

RURAL ECONOMIC DEVELOPMENT LOANS PROGRAM ACCOUNT

(INCLUDING RESCISSION OF FUNDS)

2016 appropriation	$33,077,000
2017 budget estimate	85,000,000
Provided in the bill	50,000,000
Comparison:	
2016 appropriation	+16,923,000
2017 budget estimate	−$35,000,000

COMMITTEE PROVISIONS

For the Rural Economic Development Loans Program Account, the Committee provides for a loan level of $50,000,000.

Review and Selection Process.—The Committee recognizes demand for the Rural Economic Development Loan and Grant Program remains high. The Committee encourages the Rural Business-Cooperative Service to award funds on a first-come first-serve basis, after taking all other eligibility requirements into account, and not the prioritization system utilized in fiscal year 2016. The Committee supports utilizing a first-come first-serve award system as the most expeditious means to award funds to eligible projects.

RURAL COOPERATIVE DEVELOPMENT GRANTS

2016 appropriation	$22,050,000
2017 budget estimate	22,250,000
Provided in the bill	26,550,000
Comparison:	
2016 appropriation	+4,500,000
2017 budget estimate	+4,300,000

COMMITTEE PROVISIONS

For Rural Cooperative Development Grants, the Committee provides an appropriation of $26,550,000.

The total includes $2,750,000 for a cooperative agreement for the Appropriate Technology Transfer for Rural Areas program and $15,000,000 for the value-added agricultural product market development grant program.

The Committee notes that the 2014 farm bill provided mandatory funding for value-added agricultural product market development grants.

RURAL ENERGY FOR AMERICA PROGRAM

2016 appropriation	$500,000
2017 budget estimate	18,515,000
Provided in the bill	464,000
Comparison:	
2016 appropriation	−36,000
2017 budget estimate	−18,051,000

COMMITTEE PROVISIONS

For the Rural Energy for America Program, the Committee provides a loan level of $10,000,000 and an appropriation of $464,000 for the loan subsidy to make loans as authorized by section 9007 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 8107).

The Committee notes that the 2014 farm bill provides mandatory funding for this program in fiscal year 2017.

RURAL UTILITIES SERVICE

RURAL WATER AND WASTE DISPOSAL PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$522,365,000
2017 budget estimate	461,593,000
Provided in the bill	533,210,000
Comparison:	
2016 appropriation	+10,845,000
2017 budget estimate	+71,617,000

COMMITTEE PROVISIONS

For the Rural Water and Waste Disposal Program Account, the Committee provides an appropriation of $533,210,000.

Water Supplies for Very Small Communities.—The Committee is aware of concerns that Rural Utilities Service (RUS) grant programs do not adequately help small, disadvantaged, and severely disadvantaged communities access the funding and expertise necessary to develop sustainable water supplies or otherwise improve their wastewater systems, and it directs the agency to focus its ef-

forts to assist these communities with predevelopment planning to help them address their water supply needs.

Carryover Balances for AK, HI, and Colonias Grants.—The Committee is aware of significant carryover balances of unobligated funds provided in prior year appropriations for Water and Waste Disposal grants for Alaskan villages, Native American Tribes, Hawaiian Homelands, and the Colonias. The Committee urges the Department to work with state, local and tribal organization stakeholders to provide assistance via water and waste disposal grant programs as long as such assistance was requested by the respective groups in the year in which the funds were appropriated. The Department has flexibility to shift these prior year funds among the four areas through a reprogramming of funds. Further, the Committee provides flexibility in fiscal year 2017 to move funds to other water and waste disposal priorities in order to reduce the backlog of related needs nationwide.

Open and Free Competition Policy.—The Committee supports the Department's underlying adherence to free and open competition on water and waste projects as contained in 7 CFR 1780.70(b) and (d). The Committee supports efforts to eliminate arbitrary actions in the procurement process but is concerned that the Department is undermining the ability of local communities and the engineer of record to design water and wastewater projects in the manner that best serves the unique needs and considerations of local communities. In particular, the Committee is concerned about the May 17, 2012 memorandum and the implementation of pipe materials. The Committee believes that the Department must apply its policy uniformly to all building materials but is concerned with the Department requirements that would unnecessarily delay projects by including onerous approval processes. Communities and professional engineers are different and specify the pipe materials that best suit the needs of their community and project. These communities and engineers, therefore make different determinations depending on what is suited for a given community, including the existence of applicable federal, state, or local ordinances or standard specifications. The Committee encourages the Department to defer to the engineer of record in the selection of materials that meet nationally recognized standards, including pipe, absent extraordinary circumstances demonstrating arbitrary action.

Domestic Preference.—The bill includes language specifying that funds made available for RUS' Rural Water and Waste Disposal program account shall use iron and steel products produced in the United States. RUS shall apply the Environmental Protection Agency's definition of public water systems while implementing the domestic preference provision.

The following table provides the Committee's recommendations as compared to the budget request:

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Loan Levels:			
Water and Waste Direct Loans	($1,200,000)	($803,802)	($1,200,000)
Water and Waste Guaranteed Loans	(50,000)	– – –	(50,000)
Subsidy and Grants:			
Direct Subsidy	31,320	34,885	52,080
Guaranteed Subsidy	275	– – –	240

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Water and Waste Revolving Fund	1,000	500	1,000
Water Well System Grants	993	500	993
Grants for the Colonias and AK/HI	64,000	42,544	53,000
Water and Waste Technical Assistance Grants	20,000	13,930	20,000
Circuit Rider Program	16,397	13,000	16,897
Solid Waste Management Grants	4,000	1,000	4,000
High Energy Cost Grants	10,000	– – –	– – –
Water and Waste Disposal Grants	364,380	350,234	375,000
306A(i)(2) Grants	10,000	5,000	10,000
Total, Subsidies and Grants	$522,365	$461,593	$533,210

RURAL ELECTRIFICATION AND TELECOMMUNICATIONS LOANS PROGRAM ACCOUNT

(INCLUDING TRANSFER OF FUNDS)

[Dollars in Thousands]

	Loan level	Subsidy level	Administrative expenses
2016 Appropriation	$6,940,000	$104	$34,707
2017 Budget Estimate	7,190,056	14,071	36,451
Provided in the Bill	6,940,000	3,071	33,414
Comparison:			
2016 Appropriation	– – –	+2,967	−1,293
2017 Budget Estimate	−$250,056	−$11,000	−$3,037

COMMITTEE PROVISIONS

For the Rural Electrification and Telecommunications Loans Program Account, the Committee provides a loan level of $6,940,000,000. In addition, the Committee provides $33,414,000 for administrative expenses.

The following table reflects the loan levels for the Rural Electrification and Telecommunications Loans Program Account:

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Loan Authorizations:			
Electric:			
Direct, FFB	$5,500,000	$6,500,000	$5,500,000
Guaranteed Underwriting	750,000	– – –	750,000
Subtotal	6,250,000	6,500,000	6,250,000
Telecommunications:			
Direct, Treasury Rate	690,000	690,056	690,000
Total, Loan Authorizations	$6,940,000	$7,190,056	$6,940,000

DISTANCE LEARNING, TELEMEDICINE, AND BROADBAND PROGRAM

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Broadband Program:			
Loan Authorization	$20,576	– – –	$20,000
Loan Subsidy	4,500	– – –	4,560
Grants	10,372	39,492	33,000
Distance Learning and Telemedicine:			

[Dollars in Thousands]

	FY 2016 enacted	FY 2017 estimate	Committee provision
Grants	22,000	34,950	25,000
Total, Loan Subsidy and Grants	$36,872	$74,442	$62,560

COMMITTEE PROVISIONS

For the Distance Learning, Telemedicine, and Broadband Program, the Committee provides an appropriation of $62,560,000, which includes $25,000,000 for distance learning and telemedicine grants.

Broadband Loan and Grant Program Priorities.—The Committee recognizes the advantages of extending broadband services, including the economic development opportunities and improved health care services that broadband technology provides. Funding provided for the broadband programs is intended to promote availability in those areas where there is not otherwise a business case for private investment in a broadband network. The Committee directs RUS to focus expenditures on projects that bring broadband service to underserved households and areas.

Tribal Communities.—The Committee notes that tribal communities continue to struggle with gaining access to broadband service. The Committee encourages the Secretary to provide a report that identifies the specific challenges Indian Tribal Organizations (ITOs) have in gaining access to broadband service and provide a plan for addressing these challenges, including how the Community Connect program can assist ITOs.

TITLE IV

DOMESTIC FOOD PROGRAMS

OFFICE OF THE UNDER SECRETARY FOR FOOD, NUTRITION, AND CONSUMER SERVICES

2016 appropriation	$811,000
2017 budget estimate	814,000
Provided in the bill	811,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−3,000

COMMITTEE PROVISIONS

For the Office of the Under Secretary for Food, Nutrition, and Consumer Services, the Committee provides an appropriation of $811,000.

Communication from FNS.—The Committee recognizes the efforts made to increase communication and reduce delays by FNS in completing requested reports. Reports requested by the Committees on Appropriations of the House and Senate, as well as information regarding FNS programs, are an important part of the Committees' oversight responsibilities. The directives and issues that are specified in the House, Senate, or conference report are very important to the Committee and the dates specified are mandatory. FNS is expected to keep the Committee apprised of activi-

ties and issues, especially those mentioned in Committee reports. FNS is reminded that the Committee reserves the right to call before it any agency that does not submit reports on time.

Public Release of Information.—The Committee directs FNS to continue making all policy documents related to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program (including, but not limited to, instructions, memoranda, guidance, and questions and answers) available to the public on the Internet within one week of their release to WIC state administrators.

Program Eligibility.—The Committee directs FNS to work with states to ensure full compliance with the law mandating that every WIC and SNAP participant meet all program eligibility requirements. FNS is also directed to ensure these programs are not being promoted to ineligible individuals, which would increase program costs.

Fruit and Vegetable Consumption.—The Committee continues to urge FNS to recognize in relevant agency publications and regulations related to all federal nutrition programs, including nutrition education programs and child nutrition programs, the nutritional benefits provided by all forms of fruits, vegetables, and beans, whether canned, dried, fresh, or frozen.

FOOD AND NUTRITION SERVICE

CHILD NUTRITION PROGRAMS

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$22,149,746,000
2017 budget estimate	23,230,733,000
Provided in the bill	23,175,679,000
Comparison:	
2016 appropriation	+1,025,933,000
2017 budget estimate	−55,054,000

COMMITTEE PROVISIONS

For the Child Nutrition Programs, the Committee provides $23,175,679,000.

School Meals.—The Committee remains concerned about the challenges and costs that local schools face in implementing the various regulations from the Healthy, Hunger-Free Kids Act of 2010. Some schools are continuing to have difficulty complying with the whole grain requirements that went into effect on July 1, 2014, and schools are increasingly concerned with further reductions in the sodium requirements. In order to provide schools with the certainty and flexibility they need for the 2017–2018 school year, the Committee continues to extend the whole grain waiver provision to those school food authorities demonstrating a hardship in implementing the whole grain standards.

The Committee also continues a provision stating that sodium standards cannot be reduced below Target 1 until the latest scientific research establishes that the reduction is beneficial for children. According to information provided by USDA, the overwhelming majority of research that has been reviewed on this issue was conducted more than 10 years ago, with most research conducted in the 1980s and 1990s. The Committee notes that the re-

quirement that the latest scientific research prove that further sodium reductions are beneficial for children has not been met.

As schools seek to implement the school meal standards, the Committee encourages USDA to consider ways to assist schools with technical assistance and training, including the services of not-for-profit culinary institutions, to provide healthy, cost-effective foods that students will eat.

Improper Payments.—The Committee remains concerned about the staggering error rates for the National School Lunch Program (NSLP) and School Breakfast Program (SBP), which were about 16 percent and 23 percent, respectively, in fiscal year 2015. This amounts to $1,800,000,000 in improper payments for NSLP and $875,000,000 for SBP. While the error rate for SBP had a small decrease, there was a slight increase in the error rate for NSLP. OIG completed an audit report in May of 2015 that evaluated how FNS is attempting to lower the error rates, and the Committee acknowledges FNS is working to address this issue. The fiscal year 2016 explanatory statement directed FNS to provide a report addressing OIG's recommendations. The Committee expects this report by June 1, 2016.

Potable Water.—The Committee is aware of the statutory requirement that schools and child care centers make potable water available to children free of charge during meal times in the place where meals are served. The Committee directs USDA to provide a report on the actions that have been taken to ensure that potable water is being provided in schools and child care centers.

Technology Use in School Meal Programs.—The Committee supports increased use of technology as a strategy to combat waste, fraud and abuse in the school meal programs and urges USDA to continue to allow local control in the selection of technology platforms. The Committee directs USDA to clearly communicate to recipients of any funding that can be used for technology infrastructure in or for the support of school meal programs that the funds are intended to establish state systems that are capable of interoperability or interface with the technology platforms selected by school districts.

The following table reflects the Committee recommendations for the child nutrition programs:

[Dollars in Thousands]

Child Nutrition Programs:	
School Lunch Program	$12,756,627
School Breakfast Program	4,486,347
Child and Adult Care Food Program	3,446,278
Summer Food Service Program	628,484
Special Milk Program	9,236
State Administrative Expenses	279,058
Commodity Procurement	1,428,089
Food Safety Education	2,869
Coordinated Review	10,000
Computer Support and Processing	11,876
Training and Technical Assistance	18,137
CNP Studies and Evaluations	21,274
CN Payment Accuracy	10,974
Farm to School Team	3,426
Team Nutrition	15,504
Healthier U.S. Schools Challenge	1,500
School Meals Equipment Grants	25,000

[Dollars in Thousands]

Summer EBT Demonstration	21,000
Total	$23,175,679

SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC)

2016 appropriation	$6,350,000,000
2017 budget estimate	6,350,000,000
Provided in the bill	6,350,000,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For the Special Supplemental Nutrition Program for Women, Infants, and Children, the Committee provides an appropriation of $6,350,000,000. The Committee provides for continuation of the breastfeeding peer counselor program and infrastructure.

USDA data shows that WIC participation rates have decreased steadily since fiscal year 2010. The President's budget request includes a projection of an average monthly participation rate of 8.1 million women, infants, and children for fiscal year 2017. However, the average monthly participation rate was 8.0 million for fiscal year 2015, and the current average for fiscal year 2016 is 7.9 million. Birth rates also remain at an all-time low according to the Centers for Disease Control and Prevention (CDC).

USDA is estimating recovery and carryover funds to be much higher than average at more than $600,000,000. Furthermore, the Secretary has a sufficient WIC contingency reserve fund as a safety net to meet unexpected demand. With lower participation rates, higher carryover funds, and an ample reserve fund, the Committee provides funding that will ensure all eligible participants will be served. The Committee will continue to monitor WIC participation, carryover funds, and food costs and take additional action as necessary to ensure that funding provided in fiscal year 2017 remains sufficient to serve all eligible applicants.

Income Eligibility Standards.—The Committee continues to monitor WIC income eligibility standards to ensure all procedures are followed by the WIC state and local agencies. FNS has been conducting Certification and Eligibility Management Evaluations on all state agencies and ITOs in order to ensure compliance and maintain program integrity in the participant certification process. USDA is directed to provide a report describing the results of these evaluations, detailing discrepancies found in determining participant eligibility and the certification process. The report should include steps FNS will take to ensure state agencies and ITOs adhere to the income verification procedures that the Department has implemented.

Program Integrity and Fraudulent Activities.—The FNS WIC Program Integrity and Monitoring Branch plays a role in helping WIC state agencies address vendor management, cost containment, and fraudulent activities such as the online sale of WIC-provided infant formula. The Committee remains concerned about fraud and abuse in the program and directs FNS to provide a report on this branch's efforts and results in addressing these areas.

WIC Eligibility of Multivitamins.—The Committee encourages FNS to prepare a report assessing the inclusion of vitamins eligible for purchase as part of the supplemental foods under the special supplemental nutrition program for women, infants, and children (WIC). Such report shall include: whether there are dietary deficiencies within the WIC population that could be enhanced through such inclusion; considerations regarding the implementation and possible health impacts of such inclusion; cost considerations related to such inclusion. This report shall be submitted to the Committee not later than 90 days after enactment of this Act.

Zika Outreach and Education.—The Committee is supportive of ensuring pregnant women are educated on the various methods for preventing exposure to the Zika virus during pregnancy. The Committee directs the Department, in consultation with the Centers for Disease Control and Prevention, to continue its education and outreach efforts through the WIC program to provide pregnant women with the information they need to prevent Zika. During fiscal year 2017, the Department is directed to designate $10,000,000 to assist with Zika outreach and education, with priority given to States with the greatest need.

SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM

2016 appropriation	$80,849,383,000
2017 budget estimate	81,689,168,000
Provided in the bill	79,673,277,000
Comparison:	
2016 appropriation	−1,176,106,000
2017 budget estimate	−2,015,891,000

COMMITTEE PROVISIONS

For the Supplemental Nutrition Assistance Program, the Committee provides $79,673,277,000. The total amount includes $3,000,000,000 for a contingency reserve to be used only in the amount necessary. Section 748 provides an additional $19,000,000 for the purchase of TEFAP commodities in order to maintain the fiscal year 2016 funding level.

The Committee provides an increase of $4,000,000 for Nutrition Education and Program Information solely for SNAP Employment and Training technical assistance. The Committee is aware of coordinated attempts to circumvent the directive in the fiscal year 2016 explanatory statement in order to provide funding for existing Centers of Excellence. Therefore, consistent with the Consolidated Appropriations Act of 2016, the Committee does not provide funding for new or existing Centers of Excellence, which have not been authorized by Congress.

Required Reporting for Out-of-State Moves.—The Committee remains committed to eliminating fraud and abuse within SNAP. Bill language is included to require SNAP participants to report to the state agency when they move outside of the state in which they are certified. This provision closes a loophole in order to prevent fraudulent SNAP participation in multiple states.

SNAP Purchase Report.—The Committee is aware that FNS is preparing a report describing purchases made by SNAP recipients as compared to non-SNAP recipients. FNS is directed to complete this report as soon as practicable and make this report publicly available.

SNAP Error Rates.—An OIG report issued in September of 2015 reviewed the FNS quality control process for determining the SNAP error rate associated with benefits provided to recipients. OIG found vulnerabilities and inconsistencies in the methods used to determine the error rate and concluded FNS' quality control process resulted in an understatement of SNAP's error rates. The fiscal year 2016 explanatory statement directed the Department to provide a report on how FNS will address OIG's recommendations. The Committee expects this report no later than June 1, 2016.

Recruitment Activities.—The Committee continues to direct USDA to ensure that Section 4018 of the 2014 farm bill is implemented and enforced in a manner consistent with the statute which prohibits USDA from conducting recruitment activities, advertising the program, or entering into agreements with foreign governments to promote SNAP benefits. The Committee continues to direct USDA to enforce this provision to ensure that state agencies are not reimbursed for such activities consistent with the statute.

Issuance of SNAP Benefits.—The Committee notes that some states issue SNAP benefits to recipients in a compressed time frame, usually at the beginning of the month, which causes challenges for both SNAP participants and retailers. The Committee continues to direct FNS to work with those states with a compressed issuance schedule to provide benefits at least twice per month and to report to the Committees on Appropriations of the House and Senate progress made on this issue.

Electronic Benefit Transfer (EBT) Equipment.—The Committee is aware that some farmers markets and farmers selling directly to consumers are interested in EBT equipment that operates for a variety of federal nutrition programs. FNS is encouraged to assist farmers markets and direct-selling farmers in obtaining EBT equipment that allows participation in other federal nutrition programs.

The following table reflects the Committee recommendations for SNAP:

[Dollars in Thousands]

Supplemental Nutrition Assistance Program Account:	
Benefits	$68,801,122
Contingency Reserve	3,000,000
Administrative Costs:	
State Administrative Costs	4,348,604
Nutrition Education and Obesity Prevention Grant Program	414,000
Employment and Training	465,680
Mandatory Other Program Costs	193,417
Discretionary Other Program Costs	998
Administrative Subtotal	5,422,699
Nutrition Assistance for Puerto Rico (NAP)	1,965,415
American Samoa	7,893
Food Distribution Program on Indian Reservations	151,000
TEFAP Commodities	299,000
Commonwealth of the Northern Mariana Islands	12,148
Community Food Project	9,000
Program Access	5,000
Subtotal	2,449,456
Total	$79,673,277

COMMODITY ASSISTANCE PROGRAM

2016 appropriation	$296,217,000
2017 budget estimate	313,139,000
Provided in the bill	315,139,000
Comparison:	
2016 appropriation	+18,922,000
2017 budget estimate	+2,000,000

COMMITTEE PROVISIONS

The Committee provides an appropriation of $315,139,000 for the Commodity Assistance Program. The recommended funding level for the Commodity Supplemental Food Program is $236,120,000.

The Committee recommendation includes $18,548,000 for the Farmers' Market Nutrition Program.

The Committee has included $59,401,000 for administrative funding for The Emergency Food Assistance Program (TEFAP).

For the Food Donations Programs, the Committee provides an appropriation of $1,070,000 for Pacific Island Assistance.

TEFAP Handling and Distribution Costs.—In addition to grant funds supporting commodity handling and distribution costs, the bill permits states to use up to 10 percent of the funds provided for purchasing TEFAP commodities to help with the costs of storing, transporting, and distributing commodities. The Committee expects state agencies to consult with their emergency feeding organizations on the need for the conversion of such funds.

NUTRITION PROGRAMS ADMINISTRATION

2016 appropriation	$150,824,000
2017 budget estimate	179,447,000
Provided in the bill	168,524,000
Comparison:	
2016 appropriation	+17,700,000
2017 budget estimate	−10,923,000

COMMITTEE PROVISIONS

For Nutrition Programs Administration, the Committee provides $168,524,000. This funding level includes $1,000,000 for FNS to contract for an independent study to identify the best means of efficiently consolidating Child Nutrition Program reporting requirements for school food authorities and state agencies. The Committee expects the study to be completed no later than 18 months from the date of enactment of this Act.

TITLE V

FOREIGN ASSISTANCE AND RELATED PROGRAMS

FOREIGN AGRICULTURAL SERVICE

SALARIES AND EXPENSES

(INCLUDING TRANSFERS OF FUNDS)

	Appropriation	Transfer from export loan account	Total
2016 appropriation	$191,566,000	$6,394,000	$197,960,000
2017 budget estimate	196,571,000	6,074,000	202,645,000
Provided in the Bill	194,566,000	6,074,000	200,640,000
Comparison:			
2016 appropriation	+3,000,000	−320,000	+2,680,000
2017 budget estimate	−$2,005,000	$– – –	−$2,005,000

COMMITTEE PROVISIONS

For the Foreign Agricultural Service, the Committee provides an appropriation of $194,566,000 and transfer of $6,074,000, for a total appropriation of $200,640,000.

This amount includes a $3,000,000 increase above estimated amounts specifically for the Country Strategy Support Fund. This should be specifically targeted to increase U.S. exports and remove existing trade barriers.

Farmer-to-Farmer.—The Farmer-to-Farmer program provides valuable outreach opportunities for U.S. agricultural exports. The program enhances agricultural efforts overseas and strengthens international ties. USDA should take a lead role in promoting and administering the program.

FOOD FOR PEACE TITLE I DIRECT CREDIT AND FOOD FOR PROGRESS PROGRAM ACCOUNT

(INCLUDING TRANSFER OF FUNDS)

2016 appropriation	$2,528,000
2017 budget estimate	149,000
Provided in the bill	149,000
Comparison:	
2016 appropriation	−2,379,000
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For administrative expenses to carry out the credit program of Food for Peace Title I, Food for Peace Act, and the Food for Progress Act, the Committee provides an appropriation of $149,000.

FOOD FOR PEACE TITLE II GRANTS

2016 appropriation	$1,466,000,000
2017 budget estimate	1,350,000,000
Provided in the bill	1,466,000,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+116,000,000

For Food for Peace Title II grants, the Committee provides $1,466,000,000, of which $350,000,000 is for non-emergency assistance. This is $116,000,000 above the President's request and includes statutory language that requires the U.S. Agency for International Development (USAID) to meet the level for non-emergency assistance using the funds appropriated for the Food for Peace Act (FFPA).

Food Aid Funding and Reform.—The Committee provides $116,000,000 in funding above the President's budget request level. The Committee is concerned that U.S. commodity purchases and maritime sealift capabilities have been significantly reduced due to reforms and circumvention of the spirit of the FFPA. This lack of participation by key stakeholder and constituency groups has resulted in decreased demand and support for the Title II program as reflected in the levels proposed in the President's budget request for the past two years, the most recent of which is $116,000,000 below the fiscal year 2016 enacted level.

In fiscal year 2014, approximately 15 percent, or $210,000,000, was spent on local and regional purchases, vouchers, cash and other delivery methods under reforms enacted in the 2014 farm bill and the Community Development Fund (CDF). These reforms have reduced the amount of U.S commodities since fiscal year 2011 from 45 percent to 25 percent of the program, while Internal Transportation, Storage, and Handling (ITSH) costs have increased by a similar amount.

The Committee is concerned that no data has shown that the enactment of these reforms has produced increased feeding of beneficiaries and quicker food aid delivery as promised. These reforms have only resulted in decreased support and proposed funding for the program. USAID's IG audit report 7–962–16–003–P examined $23,000,000 in cash and voucher transfers under the Office of Food for Peace. The report found that "None of the implementers completed distributions on time, the average delay being 3 months." In addition, one implementer predicted being able to feed 20,000 beneficiaries, but 6 months past the target date, had only reached approximately 6,000. This data is disturbing and significantly undermines the claims of benefits that would be achieved through the farm bill reforms and further changes proposed by the President's budget.

Nonemergency Assistance.—In a recent legal opinion, GAO determined that "USAID only obligated $261.6 million of the appropriation for nonemergency food assistance" out of the $350 million required by the FFPA. While the Committee acknowledges that USAID was able to waive this level legally through "notwithstanding" authority in the FFPA for emergency funding purposes, the 2014 farm bill excluded the authority for USAID to waive the level for nonemergency assistance. Therefore, the Committee does not include the new bill language requested by USAID to credit funding from the CDF to the FFPA for nonemergency assistance. Instead, the Committee includes statutory language requiring USAID to meet the nonemergency assistance level for FY 2017 as intended by Congress. The Committee notes that USAID has access to the Bill Emerson Humanitarian Trust (BEHT) for emergency

purposes, for which the Committee provided additional funding in FY 2016. USAID requested use of emergency funds from the BEHT as recently as 2014 when USDA released $50 million from the BEHT to procure an estimated 67,400 metric tons of commodities, and this action was further supported by an additional $130 million from USDA's CCC for associated costs, including transportation and distribution.

CCC Financial Statements.—The Committee directs the Department and USAID to address issues arising from deficiencies identified in USDA's delayed financial statements and the parent-child relationship between USDA and USAID. The Committee further directs both agencies to continue to update and ratify a written agreement that clearly defines roles and responsibilities for carrying out the Food for Peace Title II program.

ITSH Costs.—The Committee directs the Department and USAID to provide a clear definition of these costs, how they are incurred, and how they differ from Inland Freight Costs. The Committee is concerned that these costs have increased significantly in recent years and seeks to understand the causes. The Committee also directs USAID to identify whether local and regional purchases, cash, and vouchers are counted as a part of these costs. USAID is directed to provide this information within 60 days of enactment of this Act.

Central American Food Assistance.—The Administrator of USAID is directed to provide a report within 90 days of enactment of this Act on the amounts and types of food aid to Honduras, Guatemala, and El Salvador.

MCGOVERN-DOLE INTERNATIONAL FOOD FOR EDUCATION AND CHILD NUTRITION PROGRAM GRANTS

2016 appropriation	$201,626,000
2017 budget estimate	182,045,000
Provided in the bill	201,626,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	+19,581,000

COMMITTEE PROVISIONS

For McGovern-Dole International Food for Education and Child Nutrition Program Grants, the Committee provides an appropriation of $201,626,000.

COMMODITY CREDIT CORPORATION EXPORT (LOANS)

CREDIT GUARANTEE PROGRAM ACCOUNT

(INCLUDING TRANSFERS OF FUNDS)

2016 appropriation	$6,748,000
2017 budget estimate	8,537,000
Provided in the bill	8,537,000
Comparison:	
2016 appropriation	+1,789,000
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For administrative expenses of the Commodity Credit Corporation Export Loans Credit Guarantee Program Account, the Committee provides an appropriation of $8,537,000.

TITLE VI

RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

SALARIES AND EXPENSES

[Dollars in Thousands]

	Appropriation	User Fees	Total, FDA S&E
2016 appropriation	$2,720,808	$1,960,584	$4,681,392
2017 budget estimate	2,730,924	2,025,020	4,755,944
Provided in the bill	2,753,855	2,025,020	4,778,875
Comparison:			
2016 appropriation	+33,047	+64,436	+97,483
2017 budget estimate	+$22,931	$– – –	+$22,931

The Committee provides an appropriation of $2,753,855,000 in new budget authority for the FDA. In addition, the Committee recommends the following user fee amounts: $865,653,000—prescription drugs; $144,859,000—medical devices; $324,085,000—human generic drugs; $22,079,000—biosimilar biologicals; $22,977,000—animal drugs; $10,367,000—animal generic drugs; $635,000,000—tobacco products; estimated $21,000,000—mammography quality standards; estimated $1,000,000—food and feed recalls; estimated $6,000,000—food reinspection; and, estimated $5,000,000—voluntary qualified importers. The combination of new budget authority and definite user fees provides the FDA with a total discretionary salaries and expenses level of $4,778,875,000. This total does not include permanent, indefinite user fees for mammography, pharmacy compounding, export, and color certification.

The Committee recommendation does not include proposed user fees for Export and Color Certification, Food Facility Registration and Inspection, Food Import, International Courier, Cosmetics, or Food Contact Notification.

The Committee does not include funding for a civilian pay increase across the agency. Should the President provide a civilian pay increase for fiscal year 2017, it is assumed that the cost of such a pay increase will be absorbed within existing appropriations for fiscal year 2017.

The Committee recommendation maintains fiscal year 2016 funding levels for the medical countermeasures initiative as well as recent funding increases for antimicrobial resistance, counterfeit drugs, food safety, foreign drug inspections, import safety, and pharmacy compounding.

Funding for Food Safety.—The Committee includes increases of $33,152,000 for the implementation of FSMA. These increases include $19,139,000 for the National Integrated Food Safety System (NIFSS) and $14,013,000 for Import Safety. The increases provided

in this bill and the increases provided since fiscal year 2011 should assist the FDA in preparation for the implementation of FSMA prior to the effective dates of the seven foundational proposed rules. While the FDA has not implemented the final rules, the Committee understands that most businesses will not need to comply with the two rules for preventive controls for human food and for animal food until August 2016 and that the other five rules will not be effective until fiscal year 2017 and later. Within the amount provided for NIFSS, the Committee includes $5,000,000 to allow for the development of a data exchange to maximize standardization and access to farm data across FDA and States.

The Committee notes that with these increases, the estimated total funding for food safety since FSMA was signed into law on January 4, 2011, would be nearly $340,000,000. In addition to the increases for FSMA, the FDA utilizes base resources for its comprehensive food safety efforts. The Committee directs the FDA to provide a detailed accounting of its food safety resources in the fiscal year 2018 budget request, including which pre-2011 base resources are now repurposed for activities in support of FSMA and which resources are the result of appropriated increases from fiscal years 2011 to 2017, a detailed explanation of what the FDA has accomplished with increased food safety resources since fiscal year 2011, and how the aggregate total of these base resources for food safety will be utilized in fiscal year 2017.

Medical Product Safety Funding.—The Committee provides an increase of $9,411,000 for medical product safety initiatives. Included in this amount is $2,911,000 for the Animal Drug and Medical Device Review; $2,000,000 for the Precision Medicine initiative, and $2,500,000 for the Pediatric Device Consortia Grant Program. According to the FDA's fiscal year 2017 budget request, the agency is spending approximately $41,700,000 on antimicrobial resistance activities in fiscal year 2016. In addition, the Committee provides an additional $2,000,000 for Orphan Product Grants as a result of administrative savings from the Office of the Commissioner.

Foreign High Risk Inspections.—The bill provides an additional $2,500,000 and a total of $7,500,000 for the FDA's Office of Global Regulatory Operations and Policy to enhance the compliance of foreign manufacturers and exporters of food, medical devices and pharmaceuticals through on-site verification.

Animal Drug Compounding.—The Committee is concerned that the FDA has proposed draft guidance for industry (#230) for animal drug compounding that applies Sections 503A and 503B of the FDCA to animal health even though these provisions were written in regard to compounding of human drugs. The Committee is concerned that this will result in confusion in the industry and may result in a misallocation of the resources Congress makes available to the FDA to oversee compounding activities. The Committee expects that any final guidance on animal drug compounding will reference statutory provisions that specifically relate to veterinary practices.

Antibiotics.—The Committee urges the FDA to work to foster the development of new antibiotics by supporting greater collaboration between industry and the FDA around adaptive clinical trials and labeling changes. The President's Council of Advisors on Science and Technology has recommended this proposal to help support the

type of robust drug development that will be needed to ensure patients are protected from bacterial resistance.

Biological Products.—The Committee commends the FDA for issuing draft guidance to address the mixing, diluting, or repackaging of biological products outside the scope of an approved biologics license application. The Committee urges the FDA to finalize the guidance without delay following the public comment period and continues to emphasize the need for close FDA inspection and supervision of large-scale compounding and repackaging of sterile injectable drugs and biological products, particularly products that are administered into areas of the human body where there is tempered immunity, such as the eye or spinal column, to ensure that they are processed in keeping with current good manufacturing practice for sterile products, in particular 21 CFR 200.50 regarding ophthalmic preparations.

Biosimilars.—The Committee recognizes that biosimilars offer an important opportunity for expanding the market and reducing costs for patients. The Committee urges the FDA to partner with external stakeholders including patient organizations on educating patients and professionals about biosimilars, with a focus on populations for which approved biosimilars are indicated.

Blood Donor Policies.—The Committee commends the FDA on updating their blood donor policy in the December 2015 Guidance to Industry from a lifetime ban to a one year deferral, however it continues to encourage a permanent policy change based on scientifically supported risk factors and not time passed. The Committee remains concerned that certain questions on the FDA blood donor questionnaire are outdated and discriminatory. This questionnaire should not ask about sexual orientation, rather it should assess risk factors that might expose a potential blood donor to blood-borne illness. The Committee encourages FDA to find an adequate replacement question for the blood donor questionnaire that is cognitively appropriate and will maintain a safe donor pool without discrimination.

Centers of Excellence.—The Committee is encouraged by the ongoing research and collaboration underway at the Centers of Excellence in Regulatory Science and Innovation (CERSI) program. The Committee believes that these programs will help the agency improve public health, address scientific challenges presented by revolutions in medical product development, and improve food safety and quality. The Committee commends the agency for launching this program in 2011 and expanding it in 2014. For this reason, the Committee believes that the agency should continue to invest in the existing four locations in the CERSI network at their original funding level to ensure their efficacy and to capitalize on existing studies.

Compassionate Use.—The Committee is aware of GAO's current plans to conduct a review of the FDA's work with patient stakeholder groups as it relates to Expanded Access or Compassionate Use of human drugs. The Committee encourages the FDA to work with GAO in order to provide them with all the necessary information they need to complete their review of the program.

Continued FDA Approval of Drug Safety Labeling.—The Committee is deeply concerned with the FDA's failure to resolve issues with and finalize its proposed rule entitled "Supplemental Applica-

tions Proposing Labeling Changes for Approved Drugs and Biological Products." The proposed rule, as currently drafted, has the potential to threaten public health and create unprecedented patient and provider confusion by allowing multiple versions of safety labeling for the same bioequivalent product. The Committee urges the FDA to establish in the final rule a system where safety information in prescription drug labeling in a multisource environment (i.e., when there is both an innovator and a generic manufacturer or more than one generic manufacturer) is always FDA-approved, grounded in scientific evidence, and presents no opportunity for mismatched safety information between the innovator and generic versions of a drug. The FDA should be the final decision maker regarding whether a manufacturer should change its labeling in a multisource environment. The FDA is the only entity that possesses all of the clinical trial, safety, and post-marketing data submitted by all manufacturers. Only the agency has all of the necessary tools to make an informed decision when it comes to making safety labeling changes, and, as a result, consistent with the FDA's responsibility to approve drug applications and labeling prior to marketing, only the FDA should determine whether a safety labeling change should occur.

Crop Biotechnology & Biotech Ingredients.—Plants, food, and food ingredients developed using genetic engineering were introduced into the U.S. food supply in the 1990s. Public and private sector scientists knowledgeable in genetic engineering, toxicology, chemistry, nutrition, and other scientific areas have carefully evaluated and assessed the safety of these products and have determined that such products are safe for human and animal consumption. The Committee provides a total of $3,000,000 for the FDA to coordinate with USDA to provide education and outreach to the public on the safety and benefits of crop biotechnology and food and animal feed ingredients derived from biotechnology. The Committee expects this educational information to be posted on both agency websites and through other social media and communications platforms within 60 days of enactment of this Act.

Date Labels on Food.—The Committee is concerned by the amount of food waste resulting from consumer confusion around date labels on food. The Committee notes that there is currently no federal uniform system for food date labels, which are currently determined by the food company to indicate quality rather than the safety of the food. The Committee urges FDA to study current and potential date labeling language and formats to determine what language and/or format is most effective in reducing consumer confusion and communicate such voluntary options to food producers.

Drug Compounding.—The Committee believes patient access to the right drug at the right time is of utmost importance. In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death. Since passage of the Drug Quality and Security Act (DQSA) of 2013, the Committee has had concerns that the FDA interpreted provisions of Section 503A of the FDCA in a manner that might jeopardize the availability of compounded medications for "office use". The practice of "office use" occurs when a compounder will compound a batch of drugs in anticipation of receiving patient-specific prescriptions at a later time.

It may also be the case of a doctor in his or her office maintaining compounded drugs on site because it is unsafe or impractical to issue a traditional prescription. This practice is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that on April 15, 2016, FDA released a new Draft Guidance on the issue of "office-use" compounding. The Committee directs the FDA to issue a Final Guidance that provides for "office-use" compounding of drugs, in appropriate circumstances as well as including drugs compounded in anticipation of a prescription for an identified individual patient. Such "anticipatory" compounded drugs must be based on the history of previous valid compound prescription orders, and on an established history between the prescriber and the patient and the compounder.

Drug Compounding Inspections.—The Committee understands that the FDA is interpreting provisions of Section 503A of the FDCA to inspect state-licensed compounding pharmacies under current Good Manufacturing Practices (cGMPs) instead of under the standards contained in the United States Pharmacopeial Convention (USP) for sterile and non-sterile pharmaceutical compounding or other applicable pharmacy inspection standards adopted by state law or regulation. The Committee reminds the FDA that compounding pharmacies are not drug manufacturers, but rather, are state licensed and regulated health care providers that are inspected by state boards of pharmacy pursuant to state laws and regulations that establish sterility and other standards for the pharmacies operating within their states. Compounding pharmacies are more appropriately inspected using USP standards or other pharmacy inspection standards adopted by state law or regulation in the state in which a pharmacy is licensed.

Drug Compounding of Allergen Extracts.—The Committee is concerned that proposed changes to general chapter 797 of the USP contradicts the legislative intent of Section 503A of DQSA regarding the practice of "office-use" compounding of allergen extracts. The FDA recognizes USP general chapter 797 as federal policy on the practice of drug compounding. The Committee is concerned that the proposed changes to USP general chapter 797 would be inconsistent with its legislative intent of Section 503A and with the agency's own previous positions on the practice of office-use compounding of allergen extracts. It is the sense of the committee that the practice of office-use compounding of allergen extracts by physicians is proven to be both safe and effective for the diagnosis and treatment of allergic conditions. The Committee suggests that the USP work with organizations from the physician and patient communities that represent physicians who regularly engage in office-use compounding of allergen extracts or patients who benefit from such compounding of allergen extracts, to ensure that any changes to USP general chapter 797 regarding office-use compounding of allergen extracts are reflective of the clear legislative intent of Section 503A of the DQSA.

Duchenne Muscular Dystrophy.—The Committee is encouraged that the FDA has the tools, authorities, and latitude necessary to review and approve safe and effective treatments for rare diseases, such as Duchenne Muscular Dystrophy, as efficiently as possible. In particular, the Committee is aware that the use of intermediate

clinical endpoints (ICE) may be an appropriate approach as it has been in similar deadly diseases with dire unmet needs, such as HIV and cancer.

Emerging Public Health Threat Funding.—In order for the FDA to mount as rapid a response as possible to the spread of the Zika virus, the Committee reinforces its position that the agency obligate unobligated Ebola funds for the higher threat of Zika. The legislative text of the fiscal year 2015 emergency supplemental provided the FDA with such flexibility to deal with future public health emergencies such as those threats associated with the Zika viruses. Due to ongoing threats, the bill includes an appropriation of $10,000,000 to support needs related to work on Ebola and Zika, such as support for FDA staff conducting ongoing response activities; support for regulatory science research to develop the tools, standards, and approaches to characterize investigational medical product safety, efficacy, quality, and performance; and support to expedite the development and availability of medical products for Ebola and Zika.

FDA and Centers for Medicare and Medicaid Services (CMS) Parallel Review Pilot.—The Committee directs the FDA to provide a report within 60 days of enactment of this Act on whether it plans to once again extend the pilot and steps the agency will take to encourage more manufacturers to utilize the pilot, including considerations for manufacturers choosing the 510(k) approval pathway and for novel products deemed covered by CMS but that warrant evaluation to ensure the appropriate level of coverage. The Committee also directs the FDA to report on efforts to work with CMS to balance each agency's evidentiary needs with the burden on manufacturers, including the consideration and use of alternative trial designs.

FDA Partnerships under FSMA.—The purpose of FSMA is to reform the nation's food safety laws to ensure a safe public food supply. As the FDA continues implementation of FSMA, the Committee encourages the FDA to work in partnership with existing government food safety programs, including the use of MOUs, to verify compliance with FSMA rules once they are finalized as a way to eliminate duplication of activities under the law. In addition, the Committee continues to provide $5,000,000 for the Food Safety Outreach Program under NIFA and expects that NIFA will serve as the sole agency providing food safety training, education, outreach, and technical assistance at the farm level.

Federal Employee Conduct.—The federal government grants federal employees with tremendous responsibility and trust to carry out their duties. They must do so free from conflicts of interest and without seeking private gain. Employees are public servants charged with implementing federal programs in a legal and ethical manner. Federal employees are reminded that they shall not advance a personal agenda or give preferential treatment to any outside organization or individual within government programs in which they administer. Information that is received by the employee, including information from the employees, offices, or Committees of the Congress of the United States, should be handled in a professional and confidential manner according to the federal government's code of conduct, standards, regulations, and statutes. The Committee is aware of recent conduct in violation of these

principles, and the Committee believes that it is incumbent upon agency officials to take immediate disciplinary action when they confirm such behavior.

Food Contact Notification User Fees.—The funds made available by this Act include sufficient monies to fund the FDA's Food Contact Notification Program and shall be deemed to satisfy the requirements of 21 U.S.C. 348(h)(5)(A). The Committee recommendation does not include proposed user fees.

Genomic Editing.—The Committee understands the potential benefits to society in the genetic modification of living organisms. However, researchers do not yet fully understand all the possible side effects of editing the genes of a human embryo. Editing of the human germ line may involve serious and unquantifiable safety and ethical issues. Federal and non-federal organizations such as the National Academy of Sciences and National Academy of Medicine continue to understand the potential risks of genome editing and a broader public discussion of the societal and ethical implications of this technique is still ongoing. In accordance with the current policy at the National Institutes of Health, the Committee includes bill language that places a prohibition on the FDA's use of funds involving the genetic modification of a human embryo. The Committee continues to support a wide range of innovations in biomedical research, but will do so in a fashion that reflects well-established scientific and ethical principles.

Harm Reduction.—It is the Committee recommendation that the FDA consider the benefits of harm reduction as part of evaluations under the Deeming regulations for tobacco products.

Indoor Tanning Devices.—Last December, the FDA proposed two rules intended to prevent the use of sunlamp products, including tanning beds, by certain age groups, reduce the risks for adults using these devices, and require manufacturers to take additional safety precautions. While the Committee remains deeply concerned with the deadly threat of melanoma, it questions some elements of the proposed rules. In particular, the Committee requests that the FDA hold a meeting with industry officials as it begins to consider the final regulations to discuss such issues as the number of allowable visits by adults and other similar measures that could create an undue economic burden on the industry.

Late Reports.—The Committee reminds the Commissioner that the timelines specified by the Committees on Appropriations of the House and Senate for fiscal year 2016 reports are deadlines that must be met. While the Committee notes that the FDA has made progress in providing more timely information and updates, the FDA still has several outstanding reports that are delayed due to long reviews and clearances. The Committee directs the Commissioner to submit these overdue reports.

Local Port Cooperation.—The Committee directs the FDA to work with local governments at high volume ports of entry to explore activities which reduce the risk of food borne illnesses and enhance the capacity of local officials in dealing with food borne threats.

Mammography Exam Reports.—More than four years ago, in November 2011, the National Mammography Quality Assurance Advisory Committee approved a change to the mammogram patient report and physician report to include information regarding an indi-

vidual's breast density. This process has not been completed. The Committee urges the FDA to implement this change in an expedited manner and must report to Congress on the status of this change no more than 60 days from the enactment of this Act.

Medical Countermeasures.—The Committee directs that not less than $24,552,000 shall be available for the FDA's Medical Countermeasures Initiative. This total is in addition to the unobligated funds remaining to support the FDA's emergency response to Ebola and related disease outbreaks.

Medical Gas Rulemaking.—The Committee is significantly concerned that the FDA has not initiated rulemaking to address numerous longstanding regulatory issues for medical gases despite the statutory requirement in the Food and Drug Administration Safety and Innovation Act (FDASIA) to issue a final rulemaking addressing all necessary changes for medical gases by July 9, 2016. In fact, the FDA rulemaking on medical gases is not even listed in the most recent Unified Agenda as a priority. Designated medical gases are a unique class of drugs that differ significantly from traditional pharmaceuticals and therefore must be addressed in the federal drug regulations to prevent safety and enforcement issues caused by current regulations. The Committee disagrees with the FDA report to Congress sent on June 30, 2015, which stated that, despite decades of issues created by existing regulations, "the current regulatory framework is adequate and sufficiently flexible to appropriately regulate medical gases." The bill includes language requiring the FDA to issue final regulations revising the federal drug regulations with respect to medical gases not later than July 9, 2016. If the Commissioner fails to issue final regulations with respect to medical gases by the statutory deadline, the Commissioner shall incorporate by reference voluntary consensus safety and labeling standards developed by an ANSI-accredited standard development organization until such time as the Commissioner issues final regulations consistent with Section 1112 of Public Law 112–144.

Laboratories Near High Volume Ports.—The Committee directs the FDA to submit a report within 90 days of enactment of this Act on the potential for implementing pilot programs which will allow for public-private partnerships at high volume ports of entry in an effort to increase the number of FDA-certified public or private labs located near major ports of entry to provide services on weekends and holidays, reduce the risk of food borne illnesses, and enhance the capacity of local officials in dealing with foodborne threats.

Laboratory Developed Tests.—The FDA's draft guidance issued on October 3, 2014, titled "Framework for Regulatory Oversight of Laboratory Developed Tests" (LDTs), puts forth a proposed regulatory framework that is a significant shift in the way LDTs are regulated. Such a shift deserves input from the public, and Congress has been working with stakeholders, constituencies, and the FDA to find common ground on regulating LDTs. The FDA's guidance circumvents the normal rulemaking process and changes expectations for patients, doctors, and laboratories for the first time since the Clinical Laboratory Improvement Amendments Act was passed in 1988. The Committee directs the FDA to suspend further efforts to finalize the LDT guidance and continue working with

Congress to pass legislation that addresses a new pathway for regulation of LDTs in a transparent manner.

Medical Device Facility Inspections.—The Committee is concerned about the lack of transparency and consistency with the medical device facility inspection process. This often leads to inefficiencies and inconsistencies in the inspection process. The Committee urges the agency to work with stakeholders and Congress to improve the facility inspection process. Potential process improvements may include, but are not necessarily limited to, more timely and frequent communications related to inspection observations and remediation plans, as well as changes to the way medical device Export Certificates (e.g., Certificate to Foreign Government, etc.) are affected by FDA Observational Findings following a facility inspection. In addition, the agency shall produce a report to the Committee by September 30, 2016, which provides information on the rates of inspection for facilities across districts and internationally and any FDA efforts to standardize rates of inspections across districts and internationally. The Committee understands that five days is typically sufficient for the FDA to complete an overseas inspection and determine the suitability of the location to provide product into the U.S. market while inspections inside the U.S. can take several weeks or months to complete the same assessment. These discrepancies lead to variations in inspection standards and potentially competitive advantages for those who choose to manufacture outside the U.S.

Menu Labeling.—The Committee is concerned about the recent FDA final determination that increased the size and scope of those affected under restaurant menu labeling regulations. Specifically, the final rule attempts to regulate local grocery chains that typically do not qualify as restaurants. The Committee includes bill language which directs the FDA to implement the final rule no earlier than December 1, 2016, at least one-year following agency publication of related guidance to newly regulated stakeholders.

Nanotechnology.—The Committee recognizes the increased capabilities that the FDA has developed to study environment, health, and safety of nanomaterials within the FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research, and its consolidated headquarters at White Oak, Maryland. The Committee recommends continued collaborative research with universities and industry on the toxicology of nanotechnology products and processes, in accordance with the National Nanotechnology Initiative Environment, Health, and Safety Research Strategy as updated in October 2011.

Nutrient Content Claims.—The Committee expects the FDA to amend its "healthy" nutrient content claim regulation to be based upon significant scientific agreement. In addition, to ensure that food producers can make truthful and non-misleading statements about the healthfulness of products, the Committee directs the FDA to make such regulatory changes during the rulemaking process and issue guidance to industry no more than six months after the enactment of this Act providing for the use of the word "healthy" in food labeling statements.

Nutrition Facts Label.—The Committee is concerned that proposed rules that have been issued to revise the Nutrition and Supplemental Facts labels may create confusion and misinformation

among consumers. The FDA is encouraged to determine how the proposed new label disclosure statements regarding added sugars would be understood and interpreted by consumers before proceeding with a final rule. Additionally, the FDA should evaluate the consumer perception and impact on healthful nutrient dense foods that use added sugar to make the food more palatable.

Office of Cosmetics and Colors.—The Committee recommendation includes not less than $11,700,000 for cosmetics activities, including not less than $7,200,000 for the Office of Cosmetics and Colors (OCAC) and other supporting offices within the Center for Food Safety and Applied Nutrition (CFSAN). Funding provided for CFSAN is for direct support of operation, staffing, compliance, research and international activities. The Committee notes that every year since fiscal year 2012 it has requested that OCAC respond to a citizen petition setting safety levels for trace amounts of lead in cosmetics. The Committee is disappointed that OCAC has not responded to these requests and urges OCAC to make this a priority. Therefore, the Committee directs OCAC to respond to the petition by September 15, 2016.

The Committee appreciates OCAC's willingness to engage with China in 2016 for a cosmetics regulatory dialogue. In light of China's importance to U.S.-based manufacturers and consumers, the Committee directs the FDA to seek ways to continually enhance engagement with Chinese regulators on cosmetic technical and regulatory issues. The Committee directs the FDA to promote international regulatory harmonization and trade in cosmetic products by supporting international trade negotiations on cosmetics in the Transatlantic Trade and Investment Partnership, the International Cooperation on Cosmetics Regulation (ICCR), and other bilateral and multilateral trade agreements.

Olive Oil.—The Committee is concerned with reports that consistently describe the prevalence of adulterated and fraudulently labeled olive oil imported into the United States and sold to American consumers. In addition, some products labeled as olive oil may contain seed oil, which poses a serious health risk to consumers who are allergic to seed oil. The Committee directs the FDA to take a sampling of imported olive oil to determine if it is adulterated or misbranded, pursuant to Section 342 or Section 343 of the FDCA, respectively, and report to Congress within 270 days on its findings and what actions the FDA will take to ensure consumer safety and proper labeling of imported olive oil.

Opioid Abuse.—The abuse, misuse and diversion of opioid painkillers has precipitated an epidemic in the United States. The CDC indicates that one American loses his or her battle with addiction every twenty minutes. For years, the Committee has encouraged the FDA to utilize the full breadth of its regulatory authority to address this challenge. The Committee is pleased that, with the Opioids Action Plan, the FDA has acknowledged that the agency shoulders some responsibility for turning the tide of abuse. The FDA's recent regulatory changes related to scheduling and labeling of opioids are positive developments, as are efforts to encourage the development of abuse-deterrent formulations (ADF) and new evidence-based medication-assisted therapies (MAT).

The use of opioids as first-line therapies for any form of pain has led to over-prescribing, and the CDC has made clear that clinicians

should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh the risks to the patient. With respect to prescribing patterns, the Committee supports efforts to incentivize ADF use by clinicians and to increase the number of prescribers who receive training on pain management and safe prescribing of opioid drugs in order to decrease inappropriate opioid prescribing. The Committee notes that 38,370 Extended Release/Long-Acting (ER/LA) opioid analgesic prescribers have been trained through the FDA's Risk Evaluation and Mitigation Strategy (REMS), but is disappointed that this constitutes less than half of the 80,000 prescriber training goal that was established in 2012. Even if the FDA was on track to meet its lofty goal of having 60 percent of ER/LA prescribed take a REMS class by 2017, there will still be some 128,000 prescribers without additional, opioid-specific training. The Committee understands that FDA intends to share these lackluster results with an advisory committee to assess its impact on preventing the misuse and abuse of opioids, and to determine what changes, if any, need to be made to the program.

The Committee notes that treatment is not a "one size, fits all" enterprise and that every patient's treatment regimen should be tailored by his or her doctor to his or her unique needs. The federal government, therefore, ought to be promoting the full suite of available treatment options—including abstinence-based models and non-opioid medications—rather than picking winners and losers. The Committee supports efforts at the FDA and elsewhere to develop MATs that improve efficacy of daily administration, are resistant to diversion and misuse, and/or help patients on a path to abstinence. Finally, the Committee has been supportive of naloxone distribution and training licensed healthcare professionals and emergency responders on its use. When considering the appropriateness of providing naloxone over the counter, the Committee asks the FDA to ensure that the administration of naloxone serves as a point of intervention to spur an honest conversation between the patient and his doctor about addiction and treatment.

Over-the-Counter (OTC) Monograph Resources.—The Committee understands that, over the past few years, funding allocated to OTC monograph issues has declined, in part due to stagnation in rulemaking and timely responses to Citizen Petitions related to OTC Monograph ingredients. The FDA is directed to provide an exhibit within the fiscal year 2018 budget justification with the total obligations and staffing levels associated with OTC Monograph issues for the past 11 years (fiscal years 2006–2016). In addition, the FDA is directed to develop detailed justifications and supporting documentation if the agency proposes to increase funding or staffing levels with regard to reforms of the OTC process in future budget submissions.

Packaged Ice.—The Committee recognizes that packaged ice is produced in the U.S., traded internationally, and consumed as both a packaged food and a food ingredient. The FDA has had a citizen petition regarding a proposed standard of identity for packaged ice for a significant and unacceptable length of time and is directed to provide quarterly status reports to the Committee on this effort until a response has been provided. Further, the Conference for Food Protection recently reviewed issues related to commercial ice

machines in the retail environment and found that research is needed to identify the type of microbial growth and locations of concern within these machines. Therefore, the FDA is directed to research the issue more carefully and establish a cleaning and sanitizing frequency standard for commercial ice machines.

Pediatric Devices.—The Committee applauds the FDA's support of development of pediatric medical devices through the Pediatric Device Consortia and notes the significant investment of more than $65,000,000 in non-FDA funding that consortia members have raised to advance pediatric device projects. The program funds consortia to assist innovators in developing medical and surgical devices designed for the unique needs of children that often go unmet by devices currently available on the market. The Committee provides an increase of $2,500,000 in fiscal year 2017 for the consortium to better leverage federal investments and move more devices to the market. The Committee directs that the agency spend no less than $6,000,000 in order to attract additional funds for these vital projects.

Pet Food Imports.—As of September 2014, the FDA has received more than 5,800 complaints of illness related to consumption of chicken, duck, or sweet potato jerky treats, nearly all of which are imported from China. The reports involve more than 5,800 dogs, 25 cats, three humans and include more than 1,000 pet deaths. These incidents date back to 2007. The Committee requests that the FDA provide it with a timeline of all activities associated with the investigation into the pet illnesses associated these products, including any import alerts and import refusals, within 60 days of the enactment of this Act. In addition, the Committee requests that the agency provide it with semi-annual reports on the status of the investigation into these illnesses beginning in April 2016 and continuing until the issue has been resolved.

Pharmacy Compounding.—The Committee remains concerned with the draft MOU that the FDA proposed under Section 503A of the FDCA. Section 503A distinguishes between "distribution" and "dispensing" for the purposes of the MOU. In the DQSA, Congress only allowed the FDA to regulate "distribution". The MOU appears to exceed the authority granted in the statute by redefining "distribution" in a manner that includes dispensing. Congress did not intend to include dispensing of compounded drugs over state lines within the scope of the MOU. The MOU should not address dispensing of compounded drugs to a patient over state lines if all other requirements of 503A are met.

Premium Cigars.—The Committee includes statutory language exempting premium and traditional large cigars, in keeping with FDA's intent under Option 2 of its proposed rule "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act (TCA); Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Docket No. FDA–2014–N–0189). The Committee notes that premium cigars are shown to be distinct from other tobacco products in their effects on youth initiation, the frequency of their use by youth and young adults, and other such behavioral and economic factors. Lastly, a large number of participants in this unique business are small and very small operations that might not be

able to maintain jobs and a physical presence in the United States due to the financial impact of this pending regulatory burden. Given that there is very little mention of cigars throughout the TCA, it is clear Congress did not intend to focus on the unique subset of premium cigars.

Prescription Drug Labeling Inserts.—The Committee is aware of FDA proposals that would subvert repeatedly expressed Congressional intent by permitting the distribution of prescription drugs without printed prescribing information on or within the packages from which such drugs are to be dispensed. The FDA intends to replace such printed labeling with an electronic labeling system for the majority of prescription drugs. On several occasions Congress has directly declined to provide the FDA the necessary statutory authority to implement this change. As recently as 2012, Congress commissioned a GAO report (GAO–13–592) discussing this issue. The GAO report concluded that such a change could adversely impact public health. Thus, the Committee is very concerned that the FDA is moving to promulgate a regulation that would generally eliminate printed prescribing information inserts for prescription drugs. Therefore, the Committee has included a provision prohibiting the FDA from utilizing any funds to propose or otherwise promulgate any rule that requires or permits any prescription drug or biologic products to be distributed without printed prescribing information on or within the packaging from which such products are to be dispensed, unless such actions are expressly provided by an amendment to the FDCA.

President's Budget Submission to Congress.—The Administration has submitted the President's budget request the past two years with a false level of base funding for the agency. Congress provided funds for the Department of Health and Human Services OIG in the FDA's Salaries and Expenses Appropriation in fiscal years 2015 and 2016. While those funds were transferred to the OIG following an apportionment by the Office of Management and Budget, such a transfer did not alter the Congressional appropriation level for the FDA. The Subcommittee directs the FDA to incorporate the actual funding level approved by Congress when displaying the previous year funding level in the fiscal year 2018 President's budget.

Private Accredited Laboratories.—As the FDA begins to implement the regulations associated with FSMA and increase sampling of food products, the agency is encouraged to use and contract with, when appropriate, ISO/IEC 17025 certified, and other certified laboratories to advance the goals of FSMA and for other data collection purposes.

Protecting Proprietary Information.—The Committee is concerned about the FDA's ability to protect trade secrets and confidential information the agency obtains from its regulated industries. FDA's access to such information has been expanded under FSMA and other regulatory actions. Recent cybersecurity breaches at the FDA underscore the importance of the FDA's ability to safeguard sensitive information. The agency has a legal obligation under the FDCA to protect confidential information. The Committee directs the FDA to provide a detailed plan on how this information will be protected no later than 60 days after enactment.

Public Disclosure.—The FDA's current rules and policies governing what drug and device developers may say about their own

products were designed decades ago. Since then, the way that medicine is practiced and delivered and the way that information is communicated have fundamentally changed. The Committee urges the FDA to convene a working group with stakeholders, including representatives from government, industry, health professionals, and patient advocacy groups, in order to solicit information to inform the FDA's evaluation of its rules and policies regarding the appropriate scope of scientific and medical information that can be shared with physicians, insurers, and researchers, with appropriate safeguards, in order to optimize patient care.

Ready-to-Eat Foods.—The Committee is aware that the FDA is in the process of finalizing guidance documents regarding *Listeria monocytogenes* in ready-to-eat (RTE) foods, which may include frozen vegetables that are not currently considered as RTE foods. Reducing incidents of *listeriosis* is an important health goal, and the Committee supports the issuance of scientifically based guidance. However, including foods that are not considered RTE should be justified based upon a quantitative risk assessment. The Committee urges the FDA to conduct such an assessment prior to taking any action that would formally consider frozen vegetables or other foods currently not considered RTE as RTE foods.

Scientific Integrity.—Pursuant to the President's 2009 memorandum and as directed by the Office of Science and Technology Policy, the FDA adopted a scientific integrity policy in 2012. It appears to conform to the President's directive by maintaining a firm commitment to science-based, data-driven decision making, facilitating the free flow of scientific and technical information, and requiring a fair and transparent approach to resolving scientific disputes. The Committee directs the Commissioner to ensure all FDA centers agencies are complying with the policy and using it to guide their policy and regulatory decisions.

Sodium Guidance.—The Committee is aware that the FDA is considering issuing guidance to food manufacturers in order to reduce sodium in various food categories. It is imperative that any guidance be issued using the latest sound science. The Centers for Disease Control and Prevention and the IOM are working together to update the Dietary Reference Intake (DRI) report on sodium. The FDA is encouraged to issue any voluntary or mandatory guidance based upon an updated DRI report.

Spent Grains.—The Committee recognizes that the FDA took into consideration public comments and revised some of its proposed regulations on spent grains used for animal food. Processors already complying with FDA human food safety requirements would not need to implement additional preventive controls when supplying a by-product like wet spent grains for animal food. However, further processing a by-product for use as animal food such as drying spent grains, would require additional compliance under the proposed rule. The FDA has said that potential hazards associated with spent grains are minimal and steps to prevent contamination are likely already in place. The Committee includes bill language to ensure dry and wet spent grains used for animal food are regulated equally.

State Inspections.—The Committee is aware of the December 2011 OIG report that outlined vulnerabilities in the agency's oversight of non-FDA food inspections and the agency's intention to fur-

ther rely on state inspections. The Committee understands that both the federal government and states share authority and responsibility for domestic food facilities and that the FDA will continue to contract with the states to conduct inspections on its behalf, which is critical to performing its mission in an efficient and effective manner. The agency must assure it has strong federal inspection standards that are met by both federal investigators and state inspectors. The FDA must continue its progress in improving federal oversight and monitoring of state inspection programs, reviewing and strengthening internal directives and processes, and identifying new methods to improve oversight capabilities.

The FDA should continue working with states to: (1) build the capacity and effectiveness of their inspection programs through implementation of national program standards, such as the Manufactured Food Regulatory Program Standards and the Animal Feed Regulatory Program Standards; (2) utilize state or private laboratory services with ISO/IEC 17025 laboratory accreditation; and (3) improve federal-state collaboration during investigations and responses to food borne illness outbreaks by supporting the implementation of Rapid Response Teams.

The Committee is aware of the FDA's continuing progress to modernize existing IT systems and infrastructure, allowing for the secure and efficient exchange of data between the FDA and the states, in addition to efforts to add capabilities supporting mobile inspection applications. The FDA should continue work with state partners toward promoting data standards and developing shared database schemas to facilitate secure electronic information sharing.

Staffing at Land Ports of Entry.—The Committee is concerned that USDA, FDA, and Customs and Border Protection are relying on historical data in determining their staffing models at Land Ports of Entry. Recent reports on agriculture imports show steep increases in the future, especially along the Southwest border and South Texas in particular. It is the sense of the Committee that these agencies should be utilizing forward looking data for their staffing models to ensure we have an appropriate workforce available in the future to inspect and certify this growth in agriculture imports as efficiently, safely and expeditiously as possible.

Sunscreen Ingredients.—The Committee is significantly concerned that despite the increase in incidence of skin cancer in the United States, the Surgeon General's 2014 Call to Action to Prevent Skin Cancer, unanimous passage of the Sunscreen Innovation Act (SIA) in Congress and President Obama's January 2016 Presidential Memorandum creating the White House Cancer Moonshot Task Force to prevent and cure cancer, the FDA has still not approved a new OTC sunscreen ingredient through the process created by the SIA. For several years, the House and Senate Appropriations Committees have directed the FDA to clear the sunscreen backlog and ensure that Americans have access to the latest skin cancer prevention technology (H. Rept. 113–116, H. Rept. 113–468, H. Rept. 114–205, S. Rept. 114–82). The agency has failed to do so. The Committee directs the FDA to work with stakeholders to develop a benefit-risk testing regimen that appropriately balances the benefit of additional skin cancer prevention tools versus the risk of skin cancer to the 5 million Americans that will be diagnosed with

the condition this year. The agency is directed to reach agreement with stakeholders on this testing regimen by June 20, 2016 and publish the summary of the meetings and results of the specific testing requirements on its website. The Committee reminds the FDA that section 4(c) of the SIA requires the FDA to report to the Senate Health, Education, Labor and Pensions Committee and House Energy & Commerce Committee on the implementation of the Act on or before May 26, 2016. The FDA shall include in this report a detailed analysis of how the FDA is balancing the Surgeon General's Call to Action, the President's Moonshot effort to remove administrative hurdles to cancer prevention, the known public health benefits that regular sunscreen use provides to prevent skin cancer and melanoma, and the long history of safe and effective use of sunscreens currently backlogged at the FDA in comparable countries versus the hypothetical risk sunscreens theoretically may pose to human health in FDA's GRAS standard. The funding level for the FDA maintains the $700,000 increase in fiscal year 2016 to help address the critical public health threat resulting from no new sunscreen ingredients being available to the public.

Surrogate Endpoints.—The Committee urges the FDA to issue guidance on the use of surrogate and intermediate endpoints for accelerated approval of regenerative medicine products under section 506(c) of the FDCA (21 U.S.C. 356(c)). In the process of issuing guidance, the FDA shall consult with appropriate stakeholders in the development of this guidance.

User Fee Collections/Obligations.—The Committee continues to be concerned about the financial management of the FDA's user fee programs. The Committee directs that not later than 30 days after enactment of this Act, and each month thereafter through the months covered by this Act, the Commissioner to submit to the Committees on Appropriations of the House and Senate a report on user fees collected for each user fee program included in the Act. The report shall also include monthly obligations incurred against such fee collections. The report shall include a distinct categorization of the user fee balances that are being carried forward into fiscal year 2018 for each user fee account as well as a detailed explanation of what accounts for the balance and what the balance will be used for.

BUILDINGS AND FACILITIES

2016 appropriation	$8,788,000
2017 budget estimate	11,788,000
Provided in the bill	11,788,000
Comparison:	
2016 appropriation	+3,000,000
2017 budget estimate	– – –

COMMITTEE PROVISIONS

For Buildings and Facilities of the Food and Drug Administration, the Committee provides $11,788,000.

INDEPENDENT AGENCIES

COMMODITY FUTURES TRADING COMMISSION

2016 appropriation	$250,000,000
2017 budget estimate	330,000,000
Provided in the bill	250,000,000
Comparison:	
2016 appropriation	– – –
2017 budget estimate	−80,000,000

COMMITTEE PROVISIONS

For the Commodity Futures Trading Commission, the Committee provides an appropriation of $250,000,000, of which $50,000,000 is for the purchase of IT and $3,000,000 is for the Inspector General. The bill includes language to permit the Commission to sublease its excess space for cost savings and allow the Commission to correct leasing payments and potential violations of the Anti-Deficiency Act.

GAO Review of Leasing Costs.—The Committee requested a review of GAO's leasing costs following the CFTC's IG review, which found approximately $74,000,000 in savings over the life of the Commission's leases. GAO's review found that: (1) if CFTC had received its full budget request in recent years, it could have staffed 1,015 Full Time Equivalents (FTEs) versus a capacity of 1,289 FTEs; (2) CFTC's actual occupancy rate of FTE ranges from 38 percent to 78 percent; and (3) 26 percent of CFTC's claimed occupancy rate is fulfilled by on-site contractors that have increased by 324 percent from fiscal year 2008 to fiscal year 2015. The Committee's inclusion of authority to sublease space will allow the agency to find cost-savings through increasing occupancy rates of leased space. The Committee also encourages the Commission to have its on-site contractors bear the cost of office space through renegotiation of current contracts.

Collective Bargaining Agreement Reductions.—The Committee notes that the Commission's level of FTEs has been reduced from a projection of 746 in fiscal year 2015 to an actual level of 690. These reductions are the result of a self-imposed collective bargaining agreement that has limited the Commission's ability to increase staffing levels.

FARM CREDIT ADMINISTRATION

LIMITATION ON ADMINISTRATIVE EXPENSES

2016 limitation	($65,600,000)
2017 budget estimate	(69,800,000)
Provided in the bill	(65,600,000)
Comparison:	
2016 limitation	– – –
2017 budget estimate	−4,200,000

COMMITTEE PROVISIONS

For a limitation on the expenses of the Farm Credit Administration (FCA), the Committee provides $65,600,000.

TITLE VII

GENERAL PROVISIONS

(INCLUDING RESCISSIONS AND TRANSFERS OF FUNDS)

The General Provisions contained in the accompanying bill for fiscal year 2017 are fundamentally the same as those included in last year's appropriations bill.

The following general provisions are included in the bill:

Section 701: Limitation on the purchase of passenger motor vehicles.

Section 702: Transfer authority regarding the Working Capital Fund.

Section 703: Limitation on certain obligations.

Section 704: Indirect cost rates for cooperative agreements with nonprofit institutions.

Section 705: Disbursement of rural development loans.

Section 706: Authority of the Chief Information Officer relating to new IT systems.

Section 707: Availability of mandatory conservation program funding.

Section 708: Rural Utility Service borrower eligibility.

Section 709: Rescission of certain unobligated balances.

Section 710: Prohibition on first-class airline travel.

Section 711: Use of funds authorized by the Commodity Credit Corporation Charter Act.

Section 712: Funding for advisory committees.

Section 713: Indirect costs for competitive agricultural research grants.

Section 714: Limitation on certain funds.

Section 715: Limitation on certain funds.

Section 716: Language on user fee proposals without offsets.

Section 717: Language on reprogramming.

Section 718: Language on fees for the business and industry guaranteed loan program.

Section 719: Language on questions for the record.

Section 720: Language regarding prepackaged news stories.

Section 721: Language on prohibition on paid details in excess of 60 days.

Section 722: Language regarding rulemaking.

Section 723: Language regarding spending plans.

Section 724: Language on controls over humanitarian food assistance.

Section 725: Language regarding Single Family Housing Direct Loan Program.

Section 726: Language regarding USDA loan programs.

Section 727: Transfer authority regarding the Working Capital Fund.

Section 728: Language regarding purchases made through Child Nutrition Programs.

Section 729: Language regarding potable water supplies.

Section 730: Language regarding research programs.

Section 731: Language regarding child nutrition programs.

Section 732: Language regarding nutrition research.

Section 733: Language regarding housing loan programs.

Section 734: Language regarding consumer information.
Section 735: Language regarding menu labeling.
Section 736: Language regarding tissue regulation.
Section 737: Language regarding animal feed.
Section 738: Language regarding APHIS regulation.
Section 739: Language regarding animal research.
Section 740: Language regarding FDA regulation.
Section 741: Language regarding rural housing lender fees.
Section 742: Language regarding IT systems.
Section 743: Language regarding APHIS Buildings & Facilities.
Section 744: Language regarding nutrition programs.
Section 745: Language regarding certain unobligated balances.
Section 746: Language regarding domestic preference.
Section 747: Language regarding FDA regulations.
Section 748: Language regarding emergency food assistance.
Section 749: Language regarding FDA regulation.
Section 750: Language regarding persistent poverty.
Section 751: Language regarding community eligibility.
Section 752: Language regarding Ebola virus funding.
Section 753: Language regarding watershed programs.
Section 754: Language regarding lobbying.
Section 755: Language regarding 21st Century Cures.
Section 756: Language regarding FDA regulation.
Section 757: Language regarding citrus greening.
Section 758: Language regarding certain unobligated balances.
Section 759: Language regarding certain unobligated balances.
Section 760: Language regarding APHIS regulation.
Section 761: Language regarding FDA regulation.
Section 762: Language regarding the use of funds for certain horse inspection activities.
Section 763: Language regarding the SNAP program.
Section 764: Language regarding FDA guidance.
Section 765: Language regarding CFTC regulation.
Section 766: Language regarding food retailer financing.
Section 767: Language regarding livestock marketing arrangements.

TITLE VIII

GENERAL PROVISIONS

(INCLUDING TRANSFERS OF FUNDS)

The following general provisions are included in the bill:
Section 801: Language regarding the use of certain unobligated balances.
Section 802: Language regarding the Spending Reduction Account.

HOUSE OF REPRESENTATIVES REPORT REQUIREMENTS

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those against, are printed below:

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 1

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mrs. Lowey
Description of Motion: To decrease funds and strike language supporting consumer outreach for crop biotechnology and increase funds for pediatric medical product needs.
Results: Defeated 20 yeas to 29 nays

Members Voting Yea
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Farr
Ms. Herrera Beutler
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 2

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mr. Cole
Description of Motion: To establish a new predicate date for tobacco products as well as restrictions on the sale of such products.
Results: Adopted 31 yeas to 19 nays

Members Voting Yea
Mr. Aderholt
Mr. Amodei
Mr. Bishop
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Cuellar
Mr. Culberson
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

Members Voting Nay
Ms. DeLauro
Mr. Dent
Mr. Farr
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 3

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mr. Farr
Description of Motion: To prohibit the use of funds for certain horse inspection activities.
Results: Adopted 25 yeas to 23 nays

Members Voting Yea
Mr. Bishop
Mr. Crenshaw
Ms. DeLauro
Mr. Dent
Mr. Farr
Mr. Honda
Mr. Israel
Mr. Jolly
Mr. Joyce
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Mr. Rooney
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz
Mr. Yoder

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Young

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 4

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Ms. Lee
Description of Motion: To require a study on the impact of restoring access to the Supplemental Nutrition Assistance Program for certain persons.
Results: Defeated 19 yeas to 30 nays

Members Voting Yea
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Farr
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 5

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mr. Valadao
Description of Motion: To limit the use of funds provided to the Commodity Futures Trading Commission to implement certain regulations.
Results: Adopted 30 yeas to 19 nays

Members Voting Yea
Mr. Aderholt
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Cuellar
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

Members Voting Nay
Mr. Bishop
Ms. DeLauro
Mr. Farr
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 6

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Ms. Lee
Description of Motion: To provide funding for the Healthy Food Financing Initiative.
Results: Adopted 28 yeas to 22 nays

Members Voting Yea
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Dent
Mr. Farr
Mr. Fortenberry
Dr. Harris
Mr. Honda
Mr. Israel
Mr. Jolly
Mr. Joyce
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Mr. Rigell
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Valadao
Mr. Visclosky
Ms. Wasserman Schultz
Mr. Young

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Ms. Herrera Beutler
Mr. Jenkins
Mr. Palazzo
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Womack
Mr. Yoder

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 7

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Dr. Harris
Description of Motion: To prevent the implementation of a regulation that would impact poultry, beef and pork marketing arrangements.
Results: Adopted 26 yeas to 24 nays

Members Voting Yea
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Cuellar
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Mr. Jenkins
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Simpson
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

Members Voting Nay
Mr. Bishop
Ms. DeLauro
Mr. Farr
Mr. Fortenberry
Ms. Herrera Beutler
Mr. Honda
Mr. Israel
Mr. Jolly
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Mr. Rooney
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Stewart
Mr. Visclosky
Ms. Wasserman Schultz

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 8

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Ms. DeLauro
Description of Motion: To strike a provision exempting certain tobacco products from regulation.
Results: Defeated 14 yeas to 34 nays

Members Voting Yea
Ms. DeLauro
Mr. Honda
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ryan
Mr. Visclosky
Ms. Wasserman Schultz

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Bishop
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Cuellar
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Farr
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Ruppersberger
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 9

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mr. Rogers
Description of Motion: To allow unobligated balances of amounts appropriated for the Ebola outbreak to be available to prevent, prepare for, and respond to the Zika virus.
Results: Adopted 30 yeas to 20 nays

Members Voting Yea
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

Members Voting Nay
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Farr
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 10

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Ms. DeLauro
Description of Motion: To provide additional funds for the prevention, preparation, and response to the Zika outbreak.
Results: Defeated 20 yeas to 29 nays

Members Voting Yea
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Farr
Ms. Herrera Beutler
Mr. Honda
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

Members Voting Nay
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

FULL COMMITTEE VOTES

Pursuant to the provisions of clause 3(b) of rule XIII of the House of Representatives, the results of each roll call vote on an amendment or on the motion to report, together with the names of those voting for and those voting against, are printed below:

ROLL CALL NO. 11

Date: April 19, 2016
Measure: Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2017
Motion by: Mrs. Lowey
Description of Motion: To adopt the amendment, as amended, to allow unobligated balances of amounts appropriated for the Ebola outbreak to be available for certain agencies for the prevention, preparation, and response to the Zika outbreak.
Results: Adopted 30 yeas to 20 nays

Members Voting Yea
Mr. Aderholt
Mr. Amodei
Mr. Calvert
Mr. Carter
Mr. Cole
Mr. Crenshaw
Mr. Culberson
Mr. Dent
Mr. Diaz-Balart
Mr. Fleischmann
Mr. Fortenberry
Mr. Frelinghuysen
Ms. Granger
Mr. Graves
Dr. Harris
Ms. Herrera Beutler
Mr. Jenkins
Mr. Jolly
Mr. Joyce
Mr. Palazzo
Mr. Rigell
Mrs. Roby
Mr. Rogers
Mr. Rooney
Mr. Simpson
Mr. Stewart
Mr. Valadao
Mr. Womack
Mr. Yoder
Mr. Young

Members Voting Nay
Mr. Bishop
Mr. Cuellar
Ms. DeLauro
Mr. Farr
Mr. Honda
Mr. Israel
Ms. Kaptur
Mr. Kilmer
Ms. Lee
Mrs. Lowey
Ms. McCollum
Ms. Pingree
Mr. Price
Mr. Quigley
Ms. Roybal-Allard
Mr. Ruppersberger
Mr. Ryan
Mr. Serrano
Mr. Visclosky
Ms. Wasserman Schultz

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the following is a statement of general performance goals and objectives for which this measure authorizes funding:

The Committee on Appropriations considers program performance, including a program's success in developing and attaining outcome-related goals and objectives, in developing funding recommendations.

RESCISSIONS

Pursuant to clause 3(f)(2) of rule XIII of the Rules of the House of Representatives, the following lists the rescissions of unexpended balances included in the accompanying bill:

Program or Activity	Amount
USDA Cushion of Credit	$151,487,000
USDA NRCS	$98,000,000
USDA AMS (prior year balances)	$231,000,000
USDA RD (prior year balances)	$4,221,000
USDA FNS (prior year balances)	$100,000,000

TRANSFERS OF FUNDS

Pursuant to clause 3(f)(2) of rule XIII of the Rules of the House of Representatives, the following list includes the transfers of unexpended balances included in the accompanying bill:

1. *Departmental Administration*.—The bill requires reimbursement for expenses related to certain hearings.

2. *Office of the Assistant Secretary for Congressional Relations*.—The bill allows a portion of the funds appropriated to the Office of the Assistant Secretary to be transferred to agencies.

3. *Agriculture Buildings and Facilities*.—The bill allows funds appropriated in prior years for rental payments to be transferred to meet shortfalls in prior or current year rent.

4. *Hazardous Materials Management*.—The bill allows the funds appropriated to the Department for hazardous materials management to be transferred to agencies of the Department as required.

5. *Animal and Plant Health Inspection Service*.—Authority is included to enable the Secretary of Agriculture to transfer from other appropriations or funds of the Department such sums as may be necessary to combat emergency outbreaks of certain diseases of animals, plants, and poultry.

6. *Funds for Strengthening Markets, Income, and Supply*.—The bill limits the transfer of section 32 funds to purposes specified in the bill.

7. *Farm Service Agency Salaries and Expenses*.—The bill provides that funds provided to other accounts in the agency may be merged with the salaries and expenses account of the Farm Service Agency.

8. *Dairy Indemnity Program*.—The bill authorizes the transfer of funds to the Commodity Credit Corporation, by reference.

9. *Agricultural Credit Insurance Fund Program Account*.—The bill provides funds to be transferred to the Farm Service Agency.

10. *Commodity Credit Corporation*.—The bill includes language allowing certain funds to be transferred to the Foreign Agricultural Service for information resource management activities.

11. *Rural Development Salaries and Expenses*.—The bill provides that prior year balances from certain accounts shall be transferred to and merged with this account.

12. *Rural Housing Insurance Fund Program Account, Intermediary Relending Program Fund Account, and Rural Electrification and Telecommunications Program Account*.—The bill provides that funds in this account shall be transferred to the salaries and expenses of Rural Development.

13. *Rural Community Facilities Program Account, Rural Business Program Account, and Rural Water and Waste Disposal Program Account*.—The bill provides that balances from these accounts may be transferred to and merged with other accounts.

14. *Child Nutrition Programs*.—The bill includes authority to transfer section 32 funds to these programs.

15. *Foreign Agricultural Service, Salaries and Expenses*.—The bill allows for the transfer of funds from the Commodity Credit Corporation Export Loan Program Account.

16. *Food for Peace Title I Direct Credit and Food for Progress Program Account*.—The bill allows funds to be transferred to the Farm Service Agency, Salaries and Expenses account. The bill also provides that funds made available for the cost of title I agreements and for title I ocean freight differential may be used interchangeably.

17. *Commodity Credit Corporation Export Loans Program*.—The bill provides for transfer of funds to the Foreign Agricultural Service and to the Farm Service Agency for overhead expenses associated with credit reform.

18. *Food and Drug Administration, Salaries and Expenses*.—The bill allows funds to be transferred among activities.

19. *General Provisions*.—The bill allows unobligated balances of discretionary funds to be transferred to the Working Capital Fund.

DISCLOSURE OF EARMARKS AND CONGRESSIONALLY DIRECTED SPENDING ITEMS

Neither the bill nor this report contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

COMPLIANCE WITH RULE XIII, CL. 3(e) (RAMSEYER RULE)

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman:

COMPLIANCE WITH RULE XIII, CL. 3(e) (RAMSEYER RULE)

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

RICHARD B. RUSSELL NATIONAL SCHOOL LUNCH ACT

* * * * * * *

SEC. 26. INFORMATION CLEARINGHOUSE.

(a) IN GENERAL.—The Secretary shall enter into a contract with a nongovernmental organization described in subsection (b) to establish and maintain a clearinghouse to provide information to nongovernmental groups located throughout the United States that assist low-income individuals or communities regarding food assistance, self-help activities to aid individuals in becoming self-reliant, and other activities that empower low-income individuals or communities to improve the lives of low-income individuals and reduce reliance on Federal, State, or local governmental agencies for food or other assistance.

(b) NONGOVERNMENTAL ORGANIZATION.—The nongovernmental organization referred to in subsection (a) shall be selected on a competitive basis and shall—

(1) be experienced in the gathering of first-hand information in all the States through onsite visits to grassroots organizations in each State that fight hunger and poverty or that assist individuals in becoming self-reliant;

(2) be experienced in the establishment of a clearinghouse similar to the clearinghouse described in subsection (a);

(3) agree to contribute in-kind resources towards the establishment and maintenance of the clearinghouse and agree to provide clearinghouse information, free of charge, to the Secretary, States, counties, cities, antihunger groups, and grassroots organizations that assist individuals in becoming self-sufficient and self-reliant;

(4) be sponsored by an organization, or be an organization, that—

(A) has helped combat hunger for at least 10 years;

(B) is committed to reinvesting in the United States; and

(C) is knowledgeable regarding Federal nutrition programs;

(5) be experienced in communicating the purpose of the clearinghouse through the media, including the radio and print media, and be able to provide access to the clearinghouse information through computer or telecommunications technology, as well as through the mails; and

(6) be able to provide examples, advice, and guidance to States, counties, cities, communities, antihunger groups, and local organizations regarding means of assisting individuals and communities to reduce reliance on government programs, reduce hunger, improve nutrition, and otherwise assist low-income individuals and communities become more self-sufficient.

(c) AUDITS.—The Secretary shall establish fair and reasonable auditing procedures regarding the expenditures of funds to carry out this section.

(d) FUNDING.—Out of any moneys in the Treasury not otherwise appropriated, the Secretary of the Treasury shall pay to the Secretary to provide to the organization selected under this section, to establish and maintain the information clearinghouse, $200,000 for each of fiscal years 1995 and 1996, $150,000 for fiscal year 1997, $100,000 for fiscal year 1998, $166,000 for each of fiscal years 1999

through 2004, and $250,000 for each of fiscal years [2010 through 2016] *2010 through 2017*. The Secretary shall be entitled to receive the funds and shall accept the funds, without further appropriation.

* * * * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Section 755 of H.R. (insert #) provides as follows: "The provisions of subtitles A, D, and L of title II of H.R. 6, One Hundred Fourteenth Congress (the '21st Century Cures Act'), as passed by the House of Representatives on July 10, 2015, are hereby enacted into law ". The following reflects the provisions of the Federal Food, Drug, and Cosmetic Act, as proposed to be amended by such subtitles of title II of H.R. 6 (as passed by the House of Representatives on July 10, 2015).]

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Sec-

retary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by

the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an ap-

proved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringe-

ment, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in

accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailabilty studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was

submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. [The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and

the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.]

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reason-

able time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection

shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), infor-

mation to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information

submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph

(2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such

patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an ap-

plicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms

of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day ex-

clusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C.

45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year pe-

riod beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under simi-

lar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the

safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the de-

velopment of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not

later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through—

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including—

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the

Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with

the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular, bi-weekly screening of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter;

(B) report to Congress not later than 2 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 on procedures and processes of the Food and Drug Administration for addressing ongoing post market safety issues identified by the Office of Surveillance and Epidemiology and how recommendations of the Office of Surveillance and Epidemiology are handled within the agency; and

(C) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments.

(l)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) ACTION PACKAGE FOR APPROVAL.—

(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at

rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term "responsible person" means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term "covered application" means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 505–1(b).

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on

the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY INFORMATION.—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue

an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under

this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not inten-

tionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of the Act or 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under

part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing, by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of informa-

tion available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2017.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term "date of approval" shall mean the later of—

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(x) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process—

(A) to facilitate the balanced consideration of benefits and risks; and

(B) to develop and implement a consistent and systematic approach to the discussion of, regulatory decisionmaking with respect to, and the communication of, the benefits and risks of new drugs.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall alter the criteria for evaluating an application for premarket approval of a drug.

(y) DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this subsection, the Secretary shall establish and implement processes under which—

(A) an entity seeking to develop patient experience data may submit to the Secretary—

(i) initial research concepts for feedback from the Secretary; and

(ii) with respect to patient experience data collected by the entity, draft guidance documents, completed data, and summaries and analyses of such data;

(B) the Secretary may request such an entity to submit such documents, data, and summaries and analyses; and

(C) patient experience data may be developed and used to enhance the structured risk-benefit assessment framework under subsection (x).

(2) PATIENT EXPERIENCE DATA.—In this subsection, the term "patient experience data" means data collected by patients, parents, caregivers, patient advocacy organizations, disease research foundations, medical researchers, research sponsors, or other parties determined appropriate by the Secretary that is intended to facilitate or enhance the Secretary's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.

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SEC. 505F. UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE.

(a) IN GENERAL.—The Secretary shall establish a program to evaluate the potential use of evidence from clinical experience—

(1) to help to support the approval of a new indication for a drug approved under section 505(b); and

(2) to help to support or satisfy postapproval study requirements.

(b) EVIDENCE FROM CLINICAL EXPERIENCE DEFINED.—In this section, the term "evidence from clinical experience" means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials, including from observational studies, registries, and therapeutic use.

(c) PROGRAM FRAMEWORK.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

(A) the current sources of data developed through clinical experience, including ongoing safety surveillance, registry, claims, and patient-centered outcomes research activities;

(B) the gaps in current data collection activities;

(C) the current standards and methodologies for collection and analysis of data generated through clinical experience; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) CONSULTATION.—

(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties.

(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate; or

(ii) a contract, grant, or other arrangement, as determined appropriate by the Secretary with such a partnership or an independent research organization.

(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 24 months after the date of enactment of this section and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of evidence from clinical experience.

(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on evidence from clinical experience for the purposes described in subsection (a)(1) or (a)(2); and

(B) the appropriate standards and methodologies for collection and analysis of evidence from clinical experience submitted for such purposes;

(2) not later than 36 months after the date of enactment of this section, issue draft guidance for industry as described in paragraph (1); and

(3) not later than 48 months after the date of enactment of this section, after providing an opportunity for public comment on the draft guidance, issue final guidance.

(f) RULE OF CONSTRUCTION.—

(1) Subject to paragraph (2), nothing in this section prohibits the Secretary from using evidence from clinical experience for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

(2) This section shall not be construed to alter—

(A) the standards of evidence under—

(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

(ii) section 351(a) of the Public Health Service Act; or

(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

SEC. 505G. COLLECTING EVIDENCE FROM CLINICAL EXPERIENCE THROUGH TARGETED EXTENSIONS OF THE SENTINEL SYSTEM.

(a) IN GENERAL.—The Secretary shall, in parallel to implementing the program established under section 505F and in order to build capacity for utilizing the evidence from clinical experience described in that section, identify and execute pilot demonstrations to extend existing use of the Sentinel System surveillance infrastructure authorized under section 505(k).

(b) PILOT DEMONSTRATIONS.—

(1) IN GENERAL.—The Secretary—

(A) shall design and implement pilot demonstrations to utilize data captured through the Sentinel System surveillance infrastructure authorized under section 505(k) for purposes of, as appropriate—

(i) generating evidence from clinical experience to improve characterization or assessment of risks or benefits of a drug approved under section 505(c);

(ii) protecting the public health; or

(iii) advancing patient-centered care; and

(B) may make strategic linkages with sources of complementary public health data and infrastructure the Secretary determines appropriate and necessary.

(2) CONSULTATION.—In developing the pilot demonstrations under this subsection, the Secretary shall—

(A) consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, disease research foundations, and other interested parties through a public process; and

(B) develop a framework to promote appropriate transparency and dialogue about research conducted under these pilot demonstrations, including by—

(i) providing adequate notice to a sponsor of a drug approved under section 505 or section 351 of the Public Health Service Act of the Secretary's intent to conduct analyses of such sponsor's drug or drugs under these pilot demonstrations;

(ii) providing adequate notice of the findings related to analyses described in clause (i) and an opportunity for the sponsor of such drug or drugs to comment on such findings; and

(iii) ensuring the protection from public disclosure of any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(3) HIPAA PRIVACY RULE; HUMAN SUBJECT RESEARCH REGULATION.—The Secretary may deem such pilot demonstrations—

(A) public health activities, for purposes of which a use or disclosure of protected health information would be permitted as described in section 164.512(b)(1) of title 45, Code of Federal Regulations (or any successor regulation); and

(B) outside the scope of "research" as defined in section 46.102(d) of title 45, Code of Federal Regulations (or any successor regulation).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2016 through 2020.

SEC. 505H. STREAMLINED DATA REVIEW PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a streamlined data review program under which a holder of an approved application submitted under section 505(b)(1) or under section 351(a) of the Public Health Service Act may, to support the approval or licensure (as applicable) of the use of the drug that is the subject of such approved application for a new qualified indication, submit qualified data summaries.

(b) ELIGIBILITY.—In carrying out the streamlined data review program under subsection (a), the Secretary may authorize the holder of the approved application to include one or more qualified data summaries described in subsection (a) in a supplemental application if—

(1) the drug has been approved under section 505(c) of this Act or licensed under section 351(a) of the Public Health Service Act for one or more indications, and such approval or licensure remains in effect;

(2) the supplemental application is for approval or licensure (as applicable) under such section 505(c) or 351(a) of the use of the drug for a new qualified indication under such section 505(c) or 351(a);

(3) there is an existing database acceptable to the Secretary regarding the safety of the drug developed for one or more indications of the drug approved under such section 505(c) or licensed under such section 351(a);

(4) the supplemental application incorporates or supplements the data submitted in the application for approval or licensure referred to in paragraph (1); and

(5) the full data sets used to develop the qualified data summaries are submitted, unless the Secretary determines that the full data sets are not required.

(c) PUBLIC AVAILABILITY OF INFORMATION ON PROGRAM.—The Secretary shall post on the public website of the Food and Drug Administration and update annually—

(1) the number of applications reviewed under the streamlined data review program;

(2) the average time for completion of review under the streamlined data review program versus other review of applications for new indications; and

(3) the number of applications reviewed under the streamlined data review program for which the Food and Drug Administration made use of full data sets in addition to the qualified data summary.

(d) DEFINITIONS.—In this section:

(1) The term "qualified indication" means—

(A) an indication for the treatment of cancer, as determined appropriate by the Secretary; or

(B) such other types of indications as the Secretary determines to be subject to the streamlined data review program under this section.

(2) The term "qualified data summary" means a summary of clinical data intended to demonstrate safety and effectiveness with respect to a qualified indication for use of a drug.

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PREMARKET APPROVAL

General Requirement

SEC. 515. (a) A class III device—

(1) which is subject to a an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act); or

(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

Order To Require Premarket Approval

(b)(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type;

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, require that such device have an approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain—

(A) the proposed order;

(B) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on such proposed order and findings, and a meeting of a device classification panel described in section 513(b), the Secretary shall (A) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B), or (B) publish a notice terminating the proceeding for the issuance of the administrative order together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

Application for Premarket Approval

(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

(2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. Such a report shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 514.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

(xii) Validation data described in section 510(o)(1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report.

(B) In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device:

(i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1).

(ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

(iii) Each reference in other sections of this Act to an application under this section, other than such a reference in section 737 or 738, shall be considered to be a reference to a report under subparagraph (A).

(iv) Each reference in other sections of this Act to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 737 or 738, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept and review such portion, during any period in which, under section 738(h), the Secretary does not have the authority to collect fees under section 738(a).

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.

Action on an Application for Premarket Approval

(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary

shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f);

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, or

(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

[(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

[(A) representing breakthrough technologies,

[(B) for which no approved alternatives exist,

[(C) which offer significant advantages over existing approved alternatives, or

[(D) the availability of which is in the best interest of the patients.**]**

[(6)**]** *(5)*(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review

period if the notice meets appropriate content requirements for premarket approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

Withdrawal and Temporary Suspension of Approval of Application

(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

Product Development Protocol

(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary—

(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

Review

(g)(1) Upon petition for review of—

(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advi-

sory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

Service of Orders

(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

Revision

(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act),

revising the classification of the device so that the device is classified into class I or class II, unless the administrative order issued under this paragraph requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a).

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the order requiring a device to remain in class III, establish a schedule for the issuance of an administrative order under subsection (b) for each device which is subject to the order requiring the device to remain in class III.

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SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

(1) representing breakthrough technologies;

(2) for which no approved alternatives exist;

(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(4) the availability of which is in the best interest of patients.

(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

(c) DESIGNATION PROCESS.—

(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the Food and Drug Administration and is chaired by a senior manager.

(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

(4) RECONSIDERATION.—

(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

(i) based upon the submission of documents by such person; or

(ii) based upon such documents and a meeting or teleconference.

(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the designation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

(A) this section; or

(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

(d) PRIORITY REVIEW.—

(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (b);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive communication with the sponsor of the device during the review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor); and

(H) assign staff to be available within a reasonable time to address questions posed by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient as practicable, such as through adoption of shorter or smaller clinical trials, application of surrogate

endpoints, and use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

(C) facilitate, to the extent scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes agreed to by the sponsor and the Secretary;

(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

(e) PRIORITY REVIEW GUIDANCE.—

(1) CONTENT.—The Secretary shall issue guidance on the implementation of this section. Such guidance shall include the following:

(A) The process for a person to seek a priority review designation.

(B) A template for requests under subsection (b).

(C) The criteria the Secretary will use in evaluating a request for priority review.

(D) The standards the Secretary will use in assigning a team of staff, including team leaders, to review devices designated for priority review, including any training required for such personnel on effective and efficient review.

(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

(f) CONSTRUCTION.—

(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.

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SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.

(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 510(k), an application under section 515, *a request for designation under section 515B,* or an application for an exemption under section 520(g), including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish such substantive summary to the person who is seeking to submit, or who has submitted, such report or application.

(b) REVIEW OF SIGNIFICANT DECISIONS.—

(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

(3) TIMEFRAME.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.

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CHANGES IN THE APPLICATION OF EXISTING LAW

Pursuant to clause 3(f)(1)(A) of rule XIII of the Rules of the House of Representatives, the following statements are submitted describing the effect of provisions in the accompanying bill that directly or indirectly change the application of existing law.

The bill includes a number of provisions which place limitations on the use of funds in the bill or change existing limitations and which might, under some circumstances, be construed as changing the application of existing law:

1. *Office of the Secretary*.—Language is included to limit the amount of funds for official reception and representation expenses, as determined by the Secretary.

2. *Departmental Administration*.—Language is included to reimburse the agency for travel expenses incident to the holding of hearings.

3. *Agricultural Research Service*.—Language is included that allows the Agricultural Research Service to grant easements at the Beltsville, MD, agricultural research center and to grant easements at any facility for the construction of a research facility for use by the agency.

4. *Animal and Plant Health Inspection Service*.—A provision carried in the bill since fiscal year 1973 regarding state matching funds has been continued to assure more effective operation of the brucellosis control program through state cost sharing, with resulting savings to the Federal budget.

Language is included to allow APHIS to recoup expenses incurred from providing technical assistance goods, or services to non-APHIS personnel, and to allow transfers of funds for agricultural emergencies.

Language is included to limit the amount of funds for representational allowances.

5. *Agricultural Marketing Service, Limitation on Administrative Expenses*.—The bill includes language to allow AMS to exceed the limitation on administrative expenses by 10 percent with notification to the Appropriations Committees. This allows flexibility in case crop size is understated and/or other uncontrollable events occur.

6. *Grain Inspection, Packers and Stockyards Administration, Inspection and Weighing Services*.—The bill includes authority to exceed the limitation on inspection and weighing services by 10 percent with notification to the Appropriations Committees. This allows for flexibility if export activities require additional supervision and oversight, or other uncontrollable factors occur.

7. *Dairy Indemnity Program*.—Language is included by reference that allows the Secretary to utilize the services of the Commodity Credit Corporation for the purpose of making dairy indemnity payments.

8. *Agricultural Credit Insurance Fund Program Account*.—Language is included that deems the pink bollworm a boll weevil for the purposes of administering the boll weevil loan program.

9. *Risk Management Agency*.—Language is included to limit the amount of funds for official reception and representation expenses.

10. *Commodity Credit Corporation Fund*.—Language is included to provide for the reimbursement appropriation. Language is also included to allow certain funds transferred from the Commodity Credit Corporation to be used for information resource management. In addition, language is included which limits the amount of funds that can be spent on operation and maintenance costs of CCC hazardous waste sites.

11. *Natural Resources Conservation Service.—Conservation Operations*.—Language which has been included in the bill since 1938 prohibits construction of buildings on land not owned by the government, although construction on land owned by states and counties is permitted as authorized by law.

12. *Rural Development Salaries and Expenses*.—Language is included to allow funds to be used for advertising and promotional

activities and to limit the amount of funds to provide modest non-monetary awards to non-USDA employees.

13. *Rental Assistance Program*.—Language is included which provides that agreements entered into during the current fiscal year be funded for a one-year period. Language also is included to renew contracts once during any 12-month period.

14. *Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)*.—Language is included to purchase infant formula except in accordance with law and pay for activities that are not fully reimbursed by other departments or agencies unless authorized by law.

15. *Supplemental Nutrition Assistance Program*.—Language is included to enter into contracts and employ staff to conduct studies, evaluations, or to conduct activities related to program integrity.

16. *Foreign Agricultural Service*.—Language carried since 1979 enables this agency to use funds received by an advance or by reimbursement to carry out its activities involving international development and technical cooperation. Language is included to limit the amount of funds for official reception and representation expenses.

17. *Commodity Futures Trading Commission*.—Language is included to limit the amount of funds for official reception and representation expenses.

18. *Farm Credit Administration*.—The bill includes authority to exceed the limitation on assessments by 10 percent with notification to the Appropriations Committees.

19. *General Provisions*.—

Section 704: This provision provides that none of the funds in this Act may be made available to pay indirect costs charged against competitive agricultural research, education, or extension grants awarded by the National Institute of Food and Agriculture in excess of 10 percent of total direct costs.

Section 705: This provision allows funds made available in the current fiscal year for the Rural Development Loan Fund program account; the Rural Electrification and Telecommunications Loans program account; and the Rural Housing Insurance Fund program account to remain available until expended to disburse obligations.

Section 706: Language is included that requires approval of the Chief Information Officer and the concurrence of the Executive Information Technology Investment Review Board for acquisition of new information technology systems or significant upgrades, and that prohibits the transfer of funds to the Office of the Chief Information Officer without the notification of the Committees on Appropriations of both Houses of Congress.

Section 707: Language is included regarding the availability of funds for certain conservation programs.

Section 708: Language is included regarding certain Rural Utilities Service Programs.

Section 709: Language is included that allows unobligated balances of the Farm Service Agency and Rural Development mission areas to be used for information technology purposes.

Section 710: Language is included regarding the prohibition of first-class travel by the employees of agencies funded in this Act.

Section 711: Language is included regarding the funds of the Commodity Credit Corporation.

Section 712 Language is included that limits the amount of spending for USDA Advisory Committees.

Section 713: Language is included regarding indirect costs for grants.

Section 714: Language regarding certain limitations of mandatory programs.

Section 715: Language regarding certain limitations of mandatory programs.

Section 716: Language is included that prohibits funds from being used to prepare a budget submission to Congress that assumes reductions from the previous year's budget due to user fee proposals unless the submission also identifies spending reductions which should occur if the user fees are not enacted.

Section 717: Language is included that requires certain reprogramming procedures of funds provided in Appropriations Acts.

Section 718: Language is included regarding fees for the business and industry guaranteed loan program.

Section 719: This provision prohibits the Department of Agriculture or the Food and Drug Administration from transmitting or making available to any non-Department of Agriculture or non-Department of Health and Human Services employee questions or responses to questions that are a result of information requested for the appropriations hearing process.

Section 720: Language regarding prepackaged news stories.

Section 721: This provision prohibits any employee of the Department of Agriculture from being detailed or assigned to any other agency or office of the Department for more than 60 days unless the individual's employing agency or office is fully reimbursed by the receiving agency or office for the salary and expenses of the employee for the period of assignment.

Section 722: Language is included regarding rulemaking.

Section 723: Language is included requiring spending plans for each agency funded by the Act.

Section 724: Language is included regarding the use funds for humanitarian food assistance programs.

Section 725: Language is included regarding the Single Family Housing Direct Loan Program.

Section 726: Language is included on certain USDA loan programs.

Section 727: Language is included regarding the Working Capital Fund.

Section 728: Language is included regarding purchases made through child nutrition programs.

Section 729: Language is included regarding farm disaster programs.

Section 730: Language is included regarding the Agriculture and Food Research Institute.

Section 731: Language is included regarding school meal programs.

Section 732: Language is included regarding interagency coordination of nutrition research.

Section 733: Language is included regarding rural loan programs.

Section 734: Language is included regarding disclosure of information for pharmaceuticals.
Section 735: Language is included regarding menu labeling.
Section 736: Language is included regarding research exemptions.
Section 737: Language is included regarding spent grains for animal feed.
Section 738: Language is included regarding APHIS.
Section 739: Language is included regarding the Animal Welfare Act.
Section 740: Language is included regarding partially hydrogenated oils.
Section 741: Language is included regarding the Rural Housing Service.
Section 742: Language is included regarding federal IT regulations.
Section 743: Language is included regarding funding for APHIS Buildings and Facilities.
Section 744: Language is included regarding SNAP household reporting requirements.
Section 745: Language is included regarding a rescission of unobligated balances.
Section 746: Language is included regarding RUS programs.
Section 747: Language is included regarding FDA labeling.
Section 748: Language is included regarding the emergency food assistance program.
Section 749: Language is included regarding FDA.
Section 750: Language is included regarding rural poverty programs.
Section 751: Language is included regarding Rural Development programs.
Section 752: Language is included regarding Ebola funding.
Section 753: Language is included regarding the Emergency Watershed Program.
Section 754: Language is included regarding lobbying by federal employees.
Section 755: Language is included regarding 21st Century Cures.
Section 756: Language is included regarding FDA regulation.
Section 757: Language is included regarding citrus greening disease.
Section 758: Language is included regarding a rescission of certain unobligated balances.
Section 759: Language is included regarding a rescission of certain unobligated balances.
Section 760: Language is included regarding APHIS regulation.
Section 761: Language is included regarding FDA regulation.
Section 762: Language is included regarding the use of funds for certain horse inspection activities.
Section 763: Language is included regarding the SNAP program.
Section 764: Language is included regarding FDA guidance.
Section 765: Language is included regarding CFTC regulation.
Section 766: Language is included regarding food retailer financing.
Section 767: Language is included regarding livestock marketing arrangements.

Section 801: Language is included regarding the use of certain unobligated balances.

Section 802: Language is included regarding the Spending Reduction Account.

APPROPRIATIONS NOT AUTHORIZED BY LAW

Pursuant to clause 3(f)(1)(B) of rule XIII of the Rules of the House of Representatives, the following table lists the appropriations in the accompanying bill which are not authorized by law for the period concerned:

Agency/Program	Last year of authorization	Authorization level	Appropriation in last year of authorization	Appropriations in this bill
CFTC	2013	Such sums	205,000,000	250,000,000
Food and Nutrition Service:				
Farmers' Market Nutrition Program:	2015	Such sums	16,548,000	18,548,000
State Administrative Expenses	2015	Such sums	263,686,000	279,058,000
Summer Food Service Program	2015	Such sums	495,521,000	628,484,000
WIC	2015	Such sums	6,623,000,000	6,350,000,000

COMPARISON WITH THE BUDGET RESOLUTION

Pursuant to clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a)(1)(A) of the Congressional Budget Act of 1974, the following table compares the levels of new budget authority provided in the bill with the appropriate allocation under section 302(b) of the Budget Act:

[In millions of dollars]

	302(b) Allocation		This Bill	
	Budget Authority	Outlays	Budget Authority	Outlays
Comparison of amounts in the bill with Committee allocations to its subcommittees: Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:				
Mandatory	115,512	104,156	115,512	[1] 104,156
Discretionary	21,229	22,192	21,299	22,191

[1] Includes outlays from prior-year budget authority.

FIVE-YEAR OUTLAY PROJECTIONS

Pursuant to clause 3(c)(2) of rule XIII and section 308(a)(1)(B) of the Congressional Budget Act of 1974, the following table contains five-year projections associated with the budget authority provided in the accompanying bill as provided to the Committee by the Congressional Budget Office:

[In millions of dollars]

	302(b) Allocation		This Bill	
	Budget Authority	Outlays	Budget Authority	Outlays
Projection of outlays associated with the recommendation:				
2017	n.a	n.a	n.a	[1] 111,433
2018	n.a	n.a	n.a	5,017
2019	n.a	n.a	n.a	1,024
2020	n.a	n.a	n.a	375

[In millions of dollars]

	302(b) Allocation		This Bill	
	Budget Authority	Outlays	Budget Authority	Outlays
2021 and future years	n.a	n.a	n.a	77

[1] Excludes outlays from prior-year budget authority.

ASSISTANCE TO STATE AND LOCAL GOVERNMENTS

Pursuant to clause 3(c)(2) of rule XIII and section 308(a)(1)(C) of the Congressional Budget Act of 1974, the Congressional Budget Office has provided the following estimates of the amounts of financial assistance to State and local governments is as follows:

[In millions of dollars]

	302(b) Allocation		This Bill	
	Budget Authority	Outlays	Budget Authority	Outlays
Financial assistance to State and local governments for 2017 ..	n.a	n.a	40,690	[1] 32,915

[1] Excludes outlays from prior-year budget authority.

PROGRAM DUPLICATION

No provision of this bill establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the GAO to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DIRECTED RULE MAKING

Pursuant to secton 3(i)(1) of H. Res. 5 (114th Congress), the Committee estimates that the bill directs one rulemaking in section 756 and two rulemakings in section 761.

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE I - AGRICULTURAL PROGRAMS					
Production, Processing, and Marketing					
Office of the Secretary					
Office of the Secretary	5,051	10,178	5,051	---	-5,127
Office of Tribal Relations	502	755	502	---	-253
Office of Homeland Security and Emergency Coordination	1,496	1,592	1,496	---	-96
Office of Advocacy and Outreach	1,209	11,220	1,209	---	-10,011
Office of the Assistant Secretary for Administration	804	807	804	---	-3
Departmental Administration	25,124	27,420	24,124	-1,000	-3,296
Subtotal, Departmental Administration	25,928	28,227	24,928	-1,000	-3,299
Office of the Assistant Secretary for Congressional Relations	3,869	3,919	3,869	---	-50
Office of Communications	7,500	8,512	7,500	---	-1,012
Total, Office of the Secretary	45,555	64,403	44,555	-1,000	-19,848

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Executive Operations:					
Office of the Chief Economist	17,777	17,592	16,777	-1,000	-815
National Appeals Division	13,317	13,481	13,317	---	-164
Office of Budget and Program Analysis	9,392	9,525	9,392	---	-133
Subtotal, Executive Operations	40,486	40,598	39,486	-1,000	-1,112
Office of the Chief Information Officer	44,538	65,716	44,538	---	-21,178
Office of the Chief Financial Officer	6,028	9,119	6,028	---	-3,091
Office of the Assistant Secretary for Civil Rights	898	901	898	---	-3
Office of Civil Rights	24,070	24,750	24,070	---	-680
Building and Facilities					
Agriculture Buildings and Facilities	64,189	84,365	84,189	+20,000	-176
Hazardous materials management	3,618	3,633	3,618	---	-15
Office of Inspector General	95,738	100,998	96,040	+302	-4,958
Office of the General Counsel	44,383	49,599	44,383	---	-5,216
Office of Ethics	3,654	4,617	4,556	+902	-61
Total, Departmental Administration	373,157	448,699	392,361	+19,204	-56,338
Office of the Under Secretary for Research, Education, and Economics	893	901	893	---	-8
Economic Research Service	85,373	91,278	86,000	+627	-5,278
National Agricultural Statistics Service	168,443	176,639	168,443	---	-8,196
Census of Agriculture	(42,177)	(42,177)	(41,871)	(-306)	(-306)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Agricultural Research Service:					
Salaries and expenses	1,143,825	1,161,340	1,151,825	+8,000	-9,515
Buildings and facilities	212,101	94,500	99,600	-112,501	+5,100
Total, Agricultural Research Service	1,355,926	1,255,840	1,251,425	-104,501	-4,415
National Institute of Food and Agriculture:					
National Institute of Food and Agriculture (leg. proposal)	---	1,373,974	---	---	-1,373,974
Research and education activities	819,685	---	832,860	+13,175	+832,860
Native American Institutions Endowment Fund	(11,880)	(11,880)	(11,880)	---	---
Hispanic-Serving Agricultural Colleges and Universities Endowment Fund	---	(10,000)	---	---	(-10,000)
Extension activities	475,891	---	477,391	+1,500	+477,391
Integrated activities	30,900	---	30,900	---	+30,900
Total, National Institute of Food and Agriculture	1,326,476	1,373,974	1,341,151	+14,675	-32,823
Office of the Under Secretary for Marketing and Regulatory Programs	893	901	893	---	-8
Animal and Plant Health Inspection Service:					
Salaries and expenses	894,415	901,196	930,831	+36,416	+29,635
Buildings and facilities	3,175	3,175	3,175	---	---
Total, Animal and Plant Health Inspection Service	897,590	904,371	934,006	+36,416	+29,635

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Agricultural Marketing Service:					
Marketing Services	81,223	81,933	82,223	+1,000	+290
Standardization activities (user fees)	(65,000)	(65,000)	(65,000)	---	---
(Limitation on administrative expenses, from fees collected)	(60,982)	(61,227)	(61,227)	(+245)	---
Funds for strengthening markets, income, and supply (Section 32):					
Permanent, Section 32	1,303,000	1,322,000	1,322,000	+19,000	---
Marketing agreements and orders (transfer from section 32)	(20,489)	(20,705)	(20,489)	---	(-216)
Payments to States and Possessions	1,235	1,235	1,235	---	---
Total, Agricultural Marketing Service program	1,446,440	1,466,395	1,466,685	+20,245	+290
Grain Inspection, Packers and Stockyards Administration:					
Salaries and expenses	43,057	43,482	43,057	---	-425
Limitation on inspection and weighing services	(55,000)	(57,500)	(55,000)	---	(-2,500)
Office of the Under Secretary for Food Safety	816	819	816	---	-3
Food Safety and Inspection Service	1,014,871	1,030,405	1,030,405	+15,534	---
Lab accreditation fees	(1,000)	(1,000)	(1,000)	---	---
Total, Production, Processing, and Marketing	6,652,953	6,732,477	6,654,908	+1,955	-77,569

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Farm Assistance Programs					
Office of the Under Secretary for Farm and Foreign Agricultural Services	898	901	898	---	-3
Farm Service Agency:					
Salaries and expenses	1,200,180	1,209,751	1,200,180	---	-9,571
(Transfer from Food for Peace (P.L. 480))	(2,528)	(149)	(149)	(-2,379)	---
(Transfer from export loans)	(354)	(2,463)	(2,463)	(+2,109)	---
(Transfer from ACIF)	(306,998)	(306,998)	(306,998)	---	---
Subtotal, transfers from program accounts	(309,880)	(309,610)	(309,610)	(-270)	---
Total, Salaries and expenses	(1,510,060)	(1,519,361)	(1,509,790)	(-270)	(-9,571)
State mediation grants	3,404	3,404	3,404	---	---
Grassroots source water protection program	6,500	---	6,500	---	+6,500
Dairy indemnity program	500	500	500	---	---
Subtotal, Farm Service Agency	1,210,584	1,213,655	1,210,584	---	-3,071

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Agricultural Credit Insurance Fund (ACIF) Program Account:					
Loan authorizations:					
Farm ownership loans:					
Direct	(1,500,000)	(1,500,000)	(1,500,000)	---	---
Guaranteed	(2,000,000)	(2,000,000)	(2,000,000)	---	---
Subtotal	(3,500,000)	(3,500,000)	(3,500,000)	---	---
Farm operating loans:					
Direct	(1,252,004)	(1,460,047)	(1,460,047)	(+208,043)	---
Unsubsidized guaranteed	(1,393,443)	(1,432,430)	(1,432,430)	(+38,987)	---
Subtotal	(2,645,447)	(2,892,477)	(2,892,477)	(+247,030)	---
Emergency loans	(34,667)	(22,576)	(34,667)	---	(+12,091)
Indian tribe land acquisition loans	(2,000)	(20,000)	(20,000)	(+18,000)	---
Conservation loans:					
Guaranteed	(150,000)	(150,000)	(150,000)	---	---
Indian Highly Fractionated Land Loans	(10,000)	(10,000)	(10,000)	---	---
Boll weevil eradication loans	(60,000)	(60,000)	(60,000)	---	---
Total, Loan authorizations	(6,402,114)	(6,655,053)	(6,667,144)	(+265,030)	(+12,091)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Loan subsidies:					
Farm ownership loans:					
Direct	---	---	---	---	---
Farm operating loans:					
Direct	53,961	62,198	62,198	+8,237	---
Unsubsidized guaranteed	14,352	15,327	15,327	+975	---
Subtotal	68,313	77,525	77,525	+9,212	---
Emergency Loans	1,262	1,262	1,938	+676	+676
Individual Development Account Grants	---	1,500	---	---	-1,500
Indian Highly Fractionated Land Loans	---	2,550	2,550	+2,550	---
Total, Loan subsidies and grants	69,575	82,837	82,013	+12,438	-824
ACIF administrative expenses:					
Salaries and Expenses (transfer to FSA)	306,998	306,998	306,998	---	---
Administrative expenses	7,920	10,070	7,920	---	-2,150
Total, ACIF expenses	314,918	317,068	314,918	---	-2,150
Total, Agricultural Credit Insurance Fund	384,493	399,905	396,931	+12,438	-2,974
(Loan authorization)	(6,402,114)	(6,655,053)	(6,667,144)	(+265,030)	(+12,091)
Total, Farm Service Agency	1,595,077	1,613,560	1,607,515	+12,438	-6,045

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Risk Management Agency:					
RMA Salaries and Expenses	74,829	66,615	74,829	---	+8,214
FCIC User Fee (transfer) (leg. proposal)	---	(20,000)	---	---	(-20,000)
Subtotal, Risk Management Agency	74,829	86,615	74,829	---	-11,786
Total, Farm Assistance Programs	1,670,804	1,681,076	1,683,242	+12,438	+2,166
Corporations					
Federal Crop Insurance Corporation:					
Federal crop insurance corporation fund	7,857,970	8,839,089	8,839,089	+981,119	---
Commodity Credit Corporation Fund:					
Reimbursement for net realized losses	6,871,132	13,476,854	13,476,854	+6,605,722	---
Hazardous waste management (limitation on expenses)	(5,000)	(5,000)	(5,000)	---	---
Total, Corporations	14,729,102	22,315,943	22,315,943	+7,586,841	---
Total, Title I, Agricultural Programs	23,052,859	30,729,496	30,654,093	+7,601,234	-75,403
(By transfer)	(330,369)	(330,315)	(330,099)	(-270)	(-216)
(Loan authorization)	(6,402,114)	(6,655,053)	(6,667,144)	(+265,030)	(+12,091)
(Limitation on administrative expenses)	(120,982)	(123,727)	(121,227)	(+245)	(-2,500)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE II - CONSERVATION PROGRAMS					
Office of the Under Secretary for Natural Resources and Environment	898	901	898	---	-3
Natural Resources Conservation Service:					
Conservation Operations	850,856	860,374	855,256	+4,400	-5,118
Farm Security and Rural Investment program (transfer authority)	---	(1,033,983)	---	---	(-1,033,983)
Total, Conservation operations	850,856	1,894,357	855,256	+4,400	-1,039,101
Watershed rehabilitation program	12,000	---	12,000	---	+12,000
Total, Natural Resources Conservation Service	862,856	860,374	867,256	+4,400	+6,882
Total, Title II, Conservation Programs	863,754	861,275	868,154	+4,400	+6,879

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE III - RURAL DEVELOPMENT					
Office of the Under Secretary for Rural Development...	893	896	893	---	-3
Rural Development:					
Rural development expenses:					
Salaries and expenses.....	225,835	230,679	225,835	---	-4,844
(Transfer from RHIF).....	(417,854)	(426,821)	(410,086)	(-7,768)	(-16,735)
(Transfer from RDLFP).....	(4,468)	(4,564)	(3,495)	(-973)	(-1,069)
(Transfer from RETLP).....	(34,707)	(36,451)	(33,414)	(-1,293)	(-3,037)
Subtotal, Transfers from program accounts.	(457,029)	(467,836)	(446,995)	(-10,034)	(-20,841)
Total, Rural development expenses.....	(682,864)	(698,515)	(672,830)	(-10,034)	(-25,685)
Rural Housing Service:					
Rural Housing Insurance Fund Program Account:					
Loan authorizations:					
Single family direct (Sec. 502).....	(900,000)	(900,000)	(1,000,000)	(+100,000)	(+100,000)
Unsubsidized guaranteed.....	(24,000,000)	(24,000,000)	(24,000,000)	---	---
Subtotal, Single family.....	(24,900,000)	(24,900,000)	(25,000,000)	(+100,000)	(+100,000)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Housing repair (Sec. 504)	(26,278)	(26,277)	(26,277)	(-1)	---
Rental housing (Sec. 515)	(28,398)	(33,074)	(35,000)	(+6,602)	(+1,926)
Multi-family housing guarantees (Sec. 538)	(150,000)	(230,000)	(200,000)	(+50,000)	(-30,000)
Site development loans (Sec. 524)	(5,000)	(5,000)	(5,000)	---	---
Single family housing credit sales	(10,000)	(10,000)	(10,000)	---	---
Self-help housing land develop. (Sec. 523)	(5,000)	(5,000)	(5,000)	---	---
Farm Labor Housing (Sec.514)	(23,855)	(23,857)	(23,855)	---	(-2)
Total, Loan authorizations	(25,148,531)	(25,233,208)	(25,305,132)	(+156,601)	(+71,924)
Loan subsidies:					
Single family direct (Sec. 502)	60,750	60,930	67,700	+6,950	+6,770
Housing repair (Sec. 504)	3,424	3,663	3,663	+239	---
Rental housing (Sec. 515)	8,414	9,790	10,360	+1,946	+570
Site development loans (Sec. 524) (leg. proposal)	---	111	111	+111	---
Farm labor housing (Sec.514)	6,789	7,052	7,051	+262	-1
Self-help land dev. housing loans (Sec. 523) (leg. proposal)	---	417	417	+417	---
Total, Loan subsidies	79,377	81,963	89,302	+9,925	+7,339
Farm labor housing grants	8,336	8,336	8,336	---	---
RHIF administrative expenses (transfer to RD)	417,854	426,821	410,086	-7,768	-16,735
Total, Rural Housing Insurance Fund program	505,567	517,120	507,724	+2,157	-9,396
(Loan authorization)	(25,148,531)	(25,233,208)	(25,305,132)	(+156,601)	(+71,924)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Rental assistance program:					
Rental assistance (Sec. 521)	1,389,695	1,405,033	1,405,033	+15,338	---
Multi-Family Housing Revitalization Program Account:					
Rural housing voucher program	15,000	18,000	18,000	+3,000	---
Multi-family housing revitalization program	22,000	19,362	22,000	---	+2,638
Total, Multi-family housing revitalization	37,000	37,362	40,000	+3,000	+2,638
Mutual and self-help housing grants	27,500	18,493	30,000	+2,500	+11,507
Rural housing assistance grants	32,239	28,701	33,701	+1,462	+5,000
Rural community facilities program account:					
Loan authorizations:					
Community facility:					
Direct	(2,200,000)	(2,200,000)	(2,200,000)	---	---
Guaranteed	(148,305)	---	(148,305)	---	(+148,305)
Total, Loan authorizations	(2,348,305)	(2,200,000)	(2,348,305)	---	(+148,305)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Loan subsidies and grants:					
Community facility:					
Guaranteed	3,500	---	3,322	-178	+3,322
Grants	25,000	25,000	30,000	+5,000	+5,000
Rural community development initiative	4,000	4,000	4,000	---	---
Economic impact initiative grants	5,778	---	5,778	---	+5,778
Tribal college grants	4,000	8,000	4,000	---	-4,000
Total, RCFP Loan subsidies and grants	42,278	37,000	47,100	+4,822	+10,100
Subtotal, grants and payments	102,017	84,194	110,801	+8,784	+26,607
Total, Rural Housing Service	2,034,279	2,043,709	2,063,558	+29,279	+19,849
(Loan authorization)	(27,496,836)	(27,433,208)	(27,653,437)	(+156,601)	(+220,229)
Rural Business--Cooperative Service:					
Rural Business Program Account:					
(Guaranteed business and industry loans)	(919,765)	(892,244)	(919,765)	---	(+27,521)
Loan subsidies and grants:					
Guaranteed business and industry subsidy	35,687	35,779	36,883	+1,196	+1,104
Rural business development grants	24,000	30,000	35,000	+11,000	+5,000
Demonstration Projects (rural child poverty) (leg. proposal)	---	20,000	---	---	-20,000
Data Alignment (rural child poverty) (leg. proposal)	---	5,000	---	---	-5,000
Delta regional authority	3,000	---	5,000	+2,000	+5,000
Total, RBP loan subsidies and grants	62,687	90,779	76,883	+14,196	-13,896

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
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(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Intermediary Relending Program Fund Account:					
(Loan authorization)	(18,889)	(18,889)	(18,889)	---	---
Loan subsidy	5,217	5,476	5,476	+259	---
Administrative expenses (transfer to RD)	4,468	4,564	3,495	-973	-1,069
Total, IRP Fund	9,685	10,040	8,971	-714	-1,069
Rural Economic Development Loans Program Account:					
(Loan authorization)	(33,077)	(85,000)	(50,000)	(+16,923)	(-35,000)
Limit cushion of credit interest spending	(179,000)	(151,487)	(151,487)	(-27,513)	---
(Rescission)	-179,000	-151,487	-151,487	+27,513	---
Rural Cooperative Development Grants:					
Cooperative development	5,800	6,000	5,800	---	-200
Appropriate Technology Transfer for Rural Areas	2,500	2,500	2,750	+250	+250
Grants to assist minority producers	3,000	3,000	3,000	---	---
Value-added agricultural product market development	10,750	10,750	15,000	+4,250	+4,250
Total, Rural Cooperative development grants	22,050	22,250	26,550	+4,500	+4,300
Rural Microenterprise Investment Program Account (leg. proposal):					
(Loan authorization)	---	(23,419)	---	---	(-23,419)
Loan subsidies and grants	---	4,904	---	---	-4,904
Total, Rural Microenterprise Investment	---	4,904	---	---	-4,904

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AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Rural Energy for America Program					
(Loan authorization)	(7,576)	(75,754)	(10,000)	(+2,424)	(-65,754)
Loan subsidy and grants	500	3,515	464	-36	-3,051
Grants	---	15,000	---	---	-15,000
Total, Rural Energy for America Program	500	18,515	464	-36	-18,051
Rural Business Investment Program Account (leg. proposal):					
(Loan authorization)	---	(20,600)	---	---	(-20,600)
Loan subsidy	---	2,577	---	---	-2,577
Grants	---	4,000	---	---	-4,000
Total, Rural Business Investment Program	---	6,577	---	---	-6,577
Healthy Foods Financing Initiative (leg. proposal):					
Grants	---	1,000	---	---	-1,000
Total, Healthy Foods, Healthy Neighborhoods	---	1,000	---	---	-1,000
Total, Rural Business-Cooperative Service	-84,078	2,578	-38,619	+45,459	-41,197
(Loan authorization)	(979,307)	(1,115,906)	(998,654)	(+19,347)	(-117,252)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
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(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Rural Utilities Service:					
Rural water and waste disposal program account:					
Loan authorizations:					
Direct	(1,200,000)	(803,802)	(1,200,000)	---	(+396,198)
Guaranteed	(50,000)	---	(50,000)	---	(+50,000)
Total, Loan authorization	1,250,000	803,802	1,250,000	---	+446,198
Loan subsidies and grants:					
Direct subsidy	31,320	34,885	52,080	+20,760	+17,195
Guaranteed subsidy	275	---	240	-35	+240
Water and waste revolving fund	1,000	500	1,000	---	+500
Water well system grants	993	500	993	---	+493
Colonias and AK/HI grants	64,000	42,544	53,000	-11,000	+10,456
Water and waste technical assistance	20,000	13,930	20,000	---	+6,070
Circuit rider program	16,397	13,000	16,897	+500	+3,897
Solid waste management grants	4,000	1,000	4,000	---	+3,000
High energy cost grants	10,000	---	---	-10,000	---
Water and waste disposal grants	364,380	350,234	375,000	+10,620	+24,766
306A(i)(2) grants	10,000	5,000	10,000	---	+5,000
Total, Loan subsidies and grants	522,365	461,593	533,210	+10,845	+71,617
Rural Electrification and Telecommunications Loans Program Account:					
Loan authorizations:					
Electric:					
Direct, FFB	(5,500,000)	(6,500,000)	(5,500,000)	---	(-1,000,000)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Guaranteed underwriting	(750,000)	---	(750,000)	---	(+750,000)
Subtotal, Electric	(6,250,000)	(6,500,000)	(6,250,000)	---	(-250,000)
Telecommunications:					
Direct, Treasury rate	(690,000)	(345,000)	(345,000)	(-345,000)	---
Direct, FFB	---	(345,056)	(345,000)	(+345,000)	(-56)
Subtotal, Telecommunications	(690,000)	(690,056)	(690,000)	---	(-56)
Total, Loan authorizations	(6,940,000)	(7,190,056)	(6,940,000)	---	(-250,056)
Loan Subsidy:					
Telecommunications Direct, Treasury Rate	104	3,071	3,071	+2,967	---
Loan Modifcations (leg. proposal)	---	11,000	---	---	-11,000
Total, Loan subsidies	104	14,071	3,071	+2,967	-11,000
RETLP administrative expenses (transfer to RD)	34,707	36,451	33,414	-1,293	-3,037
Total, Rural Electrification and Telecommunications Loans Program Account	34,811	50,522	36,485	+1,674	-14,037
(Loan authorization)	(6,940,000)	(7,190,056)	(6,940,000)	---	(-250,056)

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AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Distance learning, telemedicine, and broadband program:					
Loan authorizations:					
Broadband telecommunications	(20,576)	---	(20,000)	(-576)	(+20,000)
Total, Loan authorizations	(20,576)	---	(20,000)	(-576)	(+20,000)
Loan subsidies and grants:					
Distance learning and telemedicine:					
Grants	22,000	34,950	25,000	+3,000	-9,950
Broadband telecommunications:					
Direct	4,500	---	4,560	+60	+4,560
Grants	10,372	39,492	33,000	+22,628	-6,492
Total, Loan subsidies and grants	36,872	74,442	62,560	+25,688	-11,882
Total, Rural Utilities Service	594,048	586,557	632,255	+38,207	+45,698
(Loan authorization)	(8,210,576)	(7,993,858)	(8,210,000)	(-576)	(+216,142)
Total, Title III, Rural Development Programs	2,770,977	2,864,419	2,883,922	+112,945	+19,503
(By transfer)	(457,029)	(467,836)	(446,995)	(-10,034)	(-20,841)
(Loan authorization)	(36,686,719)	(36,542,972)	(36,862,091)	(+175,372)	(+319,119)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE IV - DOMESTIC FOOD PROGRAMS					
Office of the Under Secretary for Food, Nutrition and Consumer Services	811	814	811	---	-3
Food and Nutrition Service:					
Child nutrition programs	22,108,746	23,148,733	23,129,679	+1,020,933	-19,054
School breakfast program equipment grants	25,000	35,000	25,000	---	-10,000
Demonstration projects (Summer EBT)	16,000	26,000	21,000	+5,000	-5,000
Summer Food Service Program (leg. proposal)	---	10,000	---	---	-10,000
Direct Certification (leg. proposal)	---	10,000	---	---	-10,000
Child Nutrition State Exchange Activities (leg. proposal)	---	1,000	---	---	-1,000
Total, Child nutrition programs	22,149,746	23,230,733	23,175,679	+1,025,933	-55,054
Special supplemental nutrition program for women, infants, and children (WIC)	6,350,000	6,350,000	6,350,000	---	---
Supplemental nutrition assistance program: (Food stamp program)	77,848,385	76,681,170	76,672,279	-1,176,106	-8,891
Reserve	3,000,000	5,000,000	3,000,000	---	-2,000,000
FDPIR nutrition education services	998	998	998	---	---
National food consumption survey (leg. proposal)	---	5,000	---	---	-5,000

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Traditional and Local Foods Demonstration Project (leg. proposal)	---	2,000	---	---	-2,000
FY 2018 (first quarter) (leg. proposal)	---	19,647,500	---	---	-19,647,500
Total, Food stamp program	80,849,383	101,336,668	79,673,277	-1,176,106	-21,663,391
Fiscal year 2017	(80,849,383)	(81,689,168)	(79,673,277)	(-1,176,106)	(-2,015,891)
Commodity assistance program:					
Commodity supplemental food program	222,198	236,120	236,120	+13,922	---
Farmers market nutrition program	18,548	16,548	18,548	---	+2,000
Emergency food assistance program	54,401	59,401	59,401	+5,000	---
Pacific island and disaster assistance	1,070	1,070	1,070	---	---
Total, Commodity assistance program	296,217	313,139	315,139	+18,922	+2,000
Nutrition programs administration	150,824	179,447	168,524	+17,700	-10,923
Total, Food and Nutrition Service	109,796,170	131,409,987	109,682,619	-113,551	-21,727,368
FY 2017	(109,796,170)	(111,762,487)	(109,682,619)	(-113,551)	(-2,079,868)
Total, Title IV, Domestic Food Programs	109,796,981	131,410,801	109,683,430	-113,551	-21,727,371
FY 2017	(109,796,170)	(111,762,487)	(109,682,619)	(-113,551)	(-2,079,868)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE V - FOREIGN ASSISTANCE AND RELATED PROGRAMS					
Foreign Agricultural Service					
Salaries and expenses	191,566	196,571	194,566	+3,000	-2,005
(Transfer from export loans)	(6,394)	(6,074)	(6,074)	(-320)	---
Total, Salaries and expenses	197,960	202,645	200,640	+2,680	-2,005
Food for Peace Title I Direct Credit and Food for Progress Program Account, Administrative Expenses Farm Service Agency, Salaries and expenses (transfer to FSA)	2,528	149	149	-2,379	---
Food for Peace Title II Grants: Expenses	1,466,000	1,350,000	1,466,000	---	+116,000

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Commodity Credit Corporation Export Loans Program Account (administrative expenses):					
Salaries and expenses (Export Loans):					
Foreign Agriculture Service, S&E (transfer to FAS)	6,394	6,074	6,074	-320	---
Farm Service Agency S&E (transfer to FSA)	354	2,463	2,463	+2,109	---
Total, CCC Export Loans Program Account	6,748	8,537	8,537	+1,789	---
McGovern-Dole International Food for Education and Child Nutrition program grants	201,626	182,045	201,626	---	+19,581
Local and Regional Food Aid Procurement Program (leg. proposal)	---	15,000	---	---	-15,000
Total, Title V, Foreign Assistance and Related Programs	1,868,468	1,752,302	1,870,878	+2,410	+118,576
(By transfer)	(6,394)	(6,074)	(6,074)	(-320)	---

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
TITLE VI - RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION					
DEPARTMENT OF HEALTH AND HUMAN SERVICES					
Food and Drug Administration					
Salaries and expenses, direct appropriation	2,720,808	2,730,924	2,753,855	+33,047	+22,931
Prescription drug user fees	(851,481)	(865,653)	(865,653)	(+14,172)	---
Medical device user fees	(137,677)	(144,859)	(144,859)	(+7,182)	---
Human generic drug user fees	(318,363)	(324,085)	(324,085)	(+5,722)	---
Biosimilar biological products user fees	(21,540)	(22,079)	(22,079)	(+539)	---
Animal drug user fees	(22,818)	(22,977)	(22,977)	(+159)	---
Animal generic drug user fees	(9,705)	(10,367)	(10,367)	(+662)	---
Tobacco product user fees	(599,000)	(635,000)	(635,000)	(+36,000)	---
Subtotal, user fees, enacted and definite	(1,960,584)	(2,025,020)	(2,025,020)	(+64,436)	---
Subtotal (including user fees)	(4,681,392)	(4,755,944)	(4,778,875)	(+97,483)	(+22,931)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Mammography user fees	(20,109)	(21,000)	(21,000)	(+891)	---
Export and color certification user fees	(13,835)	---	---	(-13,835)	---
Food and Feed Recall user fees	(1,434)	(1,000)	(1,000)	(-434)	---
Food Reinspection fees	(6,414)	(6,000)	(6,000)	(-414)	---
Voluntary qualified importer program fees	(5,300)	(5,000)	(5,000)	(-300)	---
Pharmacy compounding fees (CBO estimate)	(1,000)	---	---	(-1,000)	---
Subtotal, FDA user fees	(2,008,676)	(2,058,020)	(2,058,020)	(+49,344)	---
Subtotal, FDA (including user fees)	(4,729,484)	(4,788,944)	(4,811,875)	(+82,391)	(+22,931)
FDA New User Fees (Leg. proposals):					
Export and color certification user fees cap increase (leg. proposal)	---	(4,280)	---	---	(-4,280)
Food Inspection and Facility Registration user fees	---	(61,252)	---	---	(-61,252)
Food import user fees	---	(105,289)	---	---	(-105,289)
International courier user fees	---	(6,038)	---	---	(-6,038)
Cosmetic user fees	---	(20,230)	---	---	(-20,230)
Food contact substance notification user fees	---	(5,193)	---	---	(-5,193)
Subtotal, FDA new user fees (Leg Proposals)	---	(202,282)	---	---	(-202,282)
Buildings and facilities	8,788	11,788	11,788	+3,000	---
Total, FDA (w/user fees, including proposals)	(4,738,272)	(5,003,014)	(4,823,663)	(+85,391)	(-179,351)
Total, FDA (w/enacted user fees only)	(4,738,272)	(4,805,012)	(4,823,663)	(+85,391)	(+18,651)
Total, FDA (excluding user fees)	2,729,596	2,742,712	2,765,643	+36,047	+22,931

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
INDEPENDENT AGENCIES					
Commodity Futures Trading Commission 1/	250,000	330,000	250,000	---	-80,000
Farm Credit Administration (limitation on administrative expenses)	(65,600)	(69,800)	(65,600)	---	(-4,200)
Total, Title VI, Related Agencies and Food and Drug Administration	2,979,596	3,072,712	3,015,643	+36,047	-57,069
TITLE VII - GENERAL PROVISIONS					
Limit Dam Rehab (Sec.714(1))	-68,000	---	-54,000	+14,000	-54,000
(rescission)	---	-54,000	---	---	+54,000
Limit Environmental Quality Incentives Program (Sec.714(2))	-209,000	---	-111,000	+98,000	-111,000
Limit Environmental Quality Incentives Program FY16 (Sec. 714 (2)) (rescission)	---	---	-98,000	-98,000	-98,000
Limit Biomass Crop Assistance Program (Sec.714(3))	-20,000	---	-20,000	---	-20,000
Limit Biorefinery Assistance (Sec.714(4))	-19,000	---	-30,000	-11,000	-30,000
Limit Conservation Stewardship Program (Sec. 714 (5))	---	---	-5,000	-5,000	-5,000
Limit Ag Management Assistance (Sec. 714 (6))	---	---	-4,000	-4,000	-4,000
Limit fruit and vegetable program (Sec.715)	-125,000	-125,000	-125,000	---	---
Section 32 (Sec.715) (rescission)	-216,000	-311,000	-231,000	-15,000	+80,000
APHIS B&F - Fruit Fly Rearing (Sec. 743)	---	---	30,000	+30,000	+30,000
WIC (rescission) (Sec. 745)	---	---	-100,000	-100,000	-100,000
TEFAP (Sec. 748)	---	---	19,000	+19,000	+19,000

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Ebola/Zika Funding (Sec. 752)	---	---	10,000	+10,000	+10,000
Emergency Watershed Protection Program (Sec. 753)	120,000	---	5,000	-115,000	+5,000
Citrus Greening (Sec. 757)	5,500	---	5,500	---	+5,500
RD balances (Sec. 758) (rescission)	---	-4,221	-4,221	-4,221	---
Healthy Food Financing Initiative	---	---	1,000	+1,000	+1,000
FSA, CCE (rescission)	-1,000	---	---	+1,000	---
RD unobligated balances (rescission)	-13,000	---	---	+13,000	---
Marketing Certificate CHIMP	5,000	---	---	-5,000	---
Watershed Flood and Prevention Program (rescission)	-20,000	---	---	+20,000	---
Emergency Watershed	2,000	---	---	-2,000	---
Hardwood Trees (Reforestation Pilot Program)	600	---	---	-600	---
Water Bank program	4,000	---	---	-4,000	---
Geographic Disadvantaged farmers	1,996	---	---	-1,996	---

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
Emergency Forest Restoration Program	4,000	---	---	-4,000	---
Emergency Conservation Program	17,000	---	---	-17,000	---
Emergency Watershed Protection (disaster relief category)	37,000	---	---	-37,000	---
Emergency Forestry Restoration Program (disaster relief category)	2,000	---	---	-2,000	---
Emergency Conservation Program (disaster relief category)	91,000	---	---	-91,000	---
NAM Study	1,000	---	---	-1,000	---
Summer EBT	7,000	---	---	-7,000	---
School Equipment Grants	5,000	---	---	-5,000	---
Food for Peace	250,000	---	---	-250,000	---
Rural Energy Savings Program	8,000	---	---	-8,000	---
Total, Title VII, General Provisions	-129,904	-494,221	-711,721	-581,817	-217,500
Grand total	141,202,731	170,196,784	148,264,399	+7,061,668	-21,932,385
Appropriations fiscal year 2017	(141,501,731)	(151,069,992)	(148,849,107)	(+7,347,376)	(-2,220,885)
Emergency appropriations	---	---	---	---	---
Disaster relief	(130,000)	---	---	(-130,000)	---
Rescissions	(-429,000)	(-520,708)	(-584,708)	(-155,708)	(-64,000)
Advance appropriations, FY 2017	---	(19,647,500)	---	---	(-19,647,500)
(By transfer)	(793,792)	(804,225)	(783,168)	(-10,624)	(-21,057)
(Loan authorization)	(43,088,833)	(43,198,025)	(43,529,235)	(+440,402)	(+331,210)
(Limitation on administrative expenses)	(186,582)	(193,527)	(186,827)	(+245)	(-6,700)

COMPARATIVE STATEMENT OF NEW BUDGET (OBLIGATIONAL) AUTHORITY FOR 2016
AND BUDGET REQUESTS AND AMOUNTS RECOMMENDED IN THE BILL FOR 2017
(Amounts in thousands)

	FY 2016 Enacted	FY 2017 Request	Bill	Bill vs. Enacted	Bill vs. Request
RECAPITULATION					
Title I - Agricultural programs	23,052,859	30,729,496	30,654,093	+7,601,234	-75,403
Mandatory	(16,032,602)	(23,638,443)	(23,638,443)	(+7,605,841)	---
Discretionary	(7,020,257)	(7,091,053)	(7,015,650)	(-4,607)	(-75,403)
Title II - Conservation programs (discretionary)	863,754	861,275	868,154	+4,400	+6,879
Title III - Rural development (discretionary)	2,770,977	2,864,419	2,883,922	+112,945	+19,503
Title IV - Domestic food programs	109,796,981	131,410,801	109,683,430	-113,551	-21,727,371
Mandatory	(102,958,129)	(124,478,401)	(102,802,956)	(-155,173)	(-21,675,445)
Discretionary	(6,838,852)	(6,932,400)	(6,880,474)	(+41,622)	(-51,926)
Title V - Foreign assistance and related programs (discretionary)	1,868,468	1,752,302	1,870,878	+2,410	+118,576
Title VI - Related agencies and Food and Drug Administration (discretionary) 1/	2,979,596	3,072,712	3,015,643	+36,047	-57,069
Title VII - General provisions (discretionary)	-129,904	-494,221	-711,721	-581,817	-217,500
Total	141,202,731	170,196,784	148,264,399	+7,061,668	-21,932,385

1/ FY2016 CFTC funds were provided in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2016

DISSENTING VIEWS OF THE HON. NITA LOWEY AND THE HON. SAM FARR

The FY2017 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act provides acceptable, though not ideal, funding levels for many important investments. We are grateful that the Committee made some improvements to the bill by voting to restore the ban on inspection of horses for slaughter for human food and, for the first time in this bill, to provide funding for the Healthy Foods Financing Initiative.

However, given our deep concerns about a number of aspects of the bill and the remaining amendments adopted in full Committee, we do not support this bill in its current form.

The bill is $451 million below last year's enacted level and $281 million below the President's request. Yet despite a host of increases for a variety of programs and activities in the bill, the majority has once again funded CFTC at $250 million, equal to the enacted level in 2015 and 2016 and $80 million below the President's request. There is no question that the agency needs more funding than Congress has provided in order to implement the laws that Congress enacted. Unlike previous years, we hope this year the subcommittee will resolve CFTC's funding at a level that allows the agency to fulfill its obligations.

We are disappointed that the Committee adopted bill language locking in the swap dealer *de minimis* level at $8 billion. This is the fourth consecutive year in which the Committee has interjected itself into this matter. We believe CFTC has approached this issue responsibly and that an appropriations bill is not the appropriate place to deal with this issue.

We strongly oppose the Committee's adoption of an amendment that would allow unregulated tobacco products, including e-cigarettes, to stay on the market without pre-market review by the Food and Drug Administration (FDA). There are hundreds of brands of e-cigarettes and more than 7,000 e-cigarette flavors, including Kool-Aid, gummy bears and cotton candy, intended to appeal to young people. And that appeal has worked. CDC found that in 2014, e-cigarettes were the most commonly used tobacco product among both middle school (3.9%) and high school (13.4%) students. CDC also found that the rate of use by high school students of e-cigarettes skyrocketed from 1.5% in 2011 to 13.4% in 2014. Between just 2013 and 2014, the number of high school students using e-cigarette use tripled from 660,000 to 2,000,000.

There is no scientific consensus as to whether e-cigarettes may be less harmful than regular cigarettes. The American people trust FDA to evaluate the data and make unbiased decisions about product safety. Congress certainly lacks the expertise to make such an assessment.

We also regret the adoption of bill language that hinders USDA's efforts to protect the rights of small livestock producers and is strongly opposed by both the American Farm Bureau Federation and the National Farmers Union. By preventing retaliation against small producers for their "lawful expression, spoken or written or association," the proposed rule is intended to protect one of our nation's most important values—freedom of speech. If a small livestock producer writes a letter to a newspaper or participates in a meeting to express his or her views, this bill places the producer at risk of retaliation by packers, contractors or live poultry dealers.

In international food programs, we appreciate the increase over the budget request for both Food for Peace (FFP) and the McGovern-Dole programs. However, we strongly oppose the inclusion of bill language that would block use of certain other USAID funds for non-emergency food aid in FFP, a practice that GAO found to be lawful.

We are again deeply disappointed that the bill does not include the President's requests for flexibility in the FFP and McGovern-Dole programs, while it does include inaccurate report language about the use of cash and local purchase in food aid. We also regret that the bill does not fund the Local and Regional Food Aid Procurement Program.

Moving forward, we will work to increase funding for the Summer EBT Demonstration program, which is funded at $5 million below the request, and to increase funding for USDA's animal welfare activities. Both the Ranking Member of the full committee and subcommittee requested these increases.

ADDRESSING THE ZIKA CRISIS

On February 22, 2016, the Administration requested nearly $1.9 billion to combat the spread of the Zika virus. Two months later, the Republican majority has not taken up the Administration's request, even as the summer months approach and the threat of Zika-infected mosquitoes continues to grow in the United States.

Committee Democrats attempted to address the threat of the Zika virus by offering an amendment to fund the Administration's request of nearly $1.9 billion. The amendment offered by full Committee Ranking Member Nita Lowey would have funded prevention, detection, and response to the Zika virus as well as additional research, development, and procurement of vaccines, therapeutics, and diagnostics. The Republican majority, rather than allow a vote on Ranking Member Lowey's amendment, introduced a perfecting amendment that denied additional emergency funds for a Zika response and reneged on America's commitment to continue to fight Ebola, even as new cases have surfaced in Africa.

After the Committee adopted the Republican majority's amendment, Labor–HHS–Education subcommittee Ranking Member Rosa DeLauro offered an amendment to fund a modified version of the emergency request for Zika, as revised by the Administration. Ranking Member DeLauro's amendment proposed to allocate additional funds for research and advanced development of vaccines and diagnostics through the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), while removing funds requested for CDC facilities and a

contingency fund. The majority blocked the amendment on a largely party-line vote of 20–29.

The result of the Republican majority's amendment is to promote an inadequate response to both Zika and Ebola by syphoning resources from the Ebola response to partially fund a Zika response. We must confront Zika immediately with dedicated resources for CDC, NIH, BARDA, and the U.S. Agency for International Development. U.S. efforts to keep Ebola at bay in Africa must not be weakened as we increase response to the Zika virus in the Americas. We must be prepared to respond to both public health crises.

Moreover, Democrats will find it difficult to support individual FY 2017 appropriations bills until it is clear that Congress will provide needed resources in FY 2016 to respond to the Zika virus.

As the legislative process continues, we will do our best to address the problems we have described here; however, we do not support the bill in its current form.

NITA M. LOWEY.
SAM FARR.

ADDITIONAL VIEWS OF THE HONORABLE ROSA L. DELAURO

The Agricultural Appropriations bill contains some of the nation's most important investments in food and medical product safety, animal and plant health programs, and vital nutrition programs. Unfortunately, the 2017 bill contains a number of partisan ideological provisions that completely undermine our regulatory agencies' abilities to do their jobs, and puts the lives of children, seniors, and families at risk.

The Food and Drug Administration is one of our most critical lines of defense in ensuring the health and wellbeing of Americans. This bill includes language that restricts the FDA's ability to finalize guidance on laboratory developed tests, which are currently unregulated. These tests are the precipice for people receiving treatment from life-threatening diseases, and having FDA oversight of LDTs is crucial to ensuring they have been properly validated and is essential to patient safety. This viewpoint has the support of 36 patient groups who wrote to the Committee in support of FDA's oversight of Laboratory Developed Tests.

Additionally, I am concerned that this bill includes report language to prevent the FDA from finalizing their rule on generic drug labeling. Generic drugs should be able update their labels with new safety information, just like name brand drugs have been able to for almost 30 years.

This bill also delays the FDA from finalizing menu labeling requirements. Americans eat nearly half their meals and snacks outside of their homes, and research shows that many of these foods have more calories and poorer nutritional quality than those prepared at home. Calorie and nutrition transparency is crucial for empowering consumers to make healthy choices and is a key to address our public health crises of obesity and diabetes. A recent Harvard study found restaurant menu calorie labeling could save over $4.6 billion in healthcare costs over ten years. Consumers have the right to know the nutritional content of their food and we should not continue to kick the can down the road when it comes to menu labeling.

Further, the bill includes provisions of the 21st Century Cures Act that would expedite the approval process of medical devices and weaken the statistical standards for clinical trials—such substantial authorizing language has no place in an appropriations bill. This is not how Congress is meant to work.

In 2012, after 753 people were sickened, and 63 died, from contaminated compounded drugs, Congress passed the Drug Quality and Security Act. I was concerned that this law was weak to begin with—in that it set up a voluntary regulatory regime for compounding pharmacies and failed to require a prescription for all compounded drugs. However, this bill contains numerous provi-

sions that further weaken the law by lowering the standards for compounding facility inspections and "office use" compounding. Given that the meningitis outbreak caused by poorly compounded medicines was less than 4 years ago, now is not the time to lower the standards we hold compounding pharmacies to.

In addition, the committee adopted an amendment that will exempt already marketed e-cigarettes, nicotine vapor, and other tobacco products from FDA's tobacco deeming rule. We must protect the nation's youth from the dangers of tobacco use. It is now almost seven years since Congress passed the Family Smoking Prevention and Tobacco Control Act. Yet there are still many kinds of tobacco products that remain unregulated, and youth are using those products at disturbing rates. The Centers for Disease Control and Prevention recently released data showing an alarming increase in use of electronic cigarettes among youth continues—almost a tenfold increase in use over the past 4 years. The report also found that approximately 4.7 million children and teenagers who use tobacco, and that tobacco use and addiction mostly began during youth and young adulthood. More must be done to drive these rates down, and sadly this new rider will do just the opposite.

The issues with the bill are not just limited to provisions regarding the FDA. The bill includes a study to explore allowing the purchase of vitamins by WIC recipients. Vitamins are an unregulated industry with no guarantee of safety or effectiveness. Additionally, this committee adopted an amendment to block USDA rules to protect farmers from unfair and abusive practices that are all too common.

The Committee adopted the Rogers amendment that redirected the funding Congress provided to respond to Ebola public health emergency to the emerging threat posed by the Zika virus. This is shortsighted, and irresponsible for us to shift these funds to another crisis. Instead Congress should immediately pass an emergency supplemental appropriations bill to support our response to the Zika virus. The Administration requested an emergency appropriation of $1.9 billion to face the Zika threat. Unfortunately, the Administration has already been forced to rob nearly $600 million from Ebola to respond to Zika. This is dumbfounding. The Ebola crisis is not over. These funds are being directed away from other critical and threatening global health risks and are being repurposed only as a last resort—not because it is the right thing to do from a policy perspective.

During markup in the full committee, I offered a series of amendments would have stripped harmful provisions that exempt cigars from the tobacco deeming regulation and weaken compounding pharmacy regulations. I am disappointed that special interests prevailed and my amendments were rejected on voice vote.

The bill has too many provisions that would harm the health and safety of Americans by underfunding our food safety regulators and

failing to adequately address nutrition and farm worker protections. I urge all my colleagues to oppose this bill.

ROSA DELAURO.

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