MANAGEMENT

CDER PROGRAM DELEGATIONS OF AUTHORITY

CONTENTS

PURPOSE This MAPP outlines the current program delegations of authority (DOAs) for the Center for Drug Evaluation and Research (CDER). A matrix is attached which specifies, by office and management level, the positions to which all of these authorities have been redelegated. In addition, a table is attached which outlines, by management level, the position title(s) and organizational component(s) to which these authorities have been redelegated. Also attached for more detailed information on each specific delegation is a narrative summary of the text extracted from the Code of Federal Regulations (CFR), 21 CFR Chapter 1, Part 5, Subpart B, on redelegations of authority from the Commissioner of Food and Drugs to CDER officials.

BACKGROUND

As a result of the organizational restructuring of the Center for Drug Evaluation and Research (CDER) effective in October 1995, changes have been made in the positions and organizational components to which the CDER program delegations of authority apply. In most cases, the changes involved revising the organizational component name and position titles to reflect the Center's new structure. In other cases, however, additional positions and management levels were added to the delegations in an effort to streamline and decentralize decision making and approval authority in accordance with the National Performance Review initiatives.

REFERENCES

- CDER MAPP 4634.2, *Changes to CDER Program Delegations of Authority*.
- FDA Staff Manual Guide 1401.1, *Policy and Procedures Governing Delegations of Authority*.
- HHS Chapter 8-100 General Administration Manual, HHS Transmittal 93.02, *Delegations of Authority*.
- 21 CFR, Chapter 1, Part 5, Subpart B. "Redelegations of Authority from the Commissioner of Food and Drugs"

DEFINITIONS

The CDER program delegations of authority are formal assignments or commitments of legal power to particular officials in the Center that empower the delegates to take substantive actions and perform certain functions of the Commissioner of Food and Drugs. These functions involve regulatory activities such as approval of new drug applications and their supplements granting or denying citizen petitions or issuing responses, issuance of written reports of minor violations and notices of warning, requiring a manufacturer to conduct postmarket surveillance, and granting extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

POLICY

These authorities must be carried out by persons in an official acting capacity and may not be further redelegated.

RESPONSIBILITIES

The Management Analysis Branch (MAB), Division of Planning, Evaluation and Research (DPERM), Office of Management (OM), has been designated as the central coordination point for issuance of program delegations of authority. The official file of all program delegations of authority will be maintained by that branch.

PROCEDURES

For information on procedures for requesting changes to CDER program delegations of authority, please refer to CDER MAPP 4634.2, *Changes to CDER Program Delegations of Authority*. You may also contact MAB at (301) 827-0510 for further assistance.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Summary of CDER Program Delegations of Authority (DOAs) by Management Level Attachment A

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.22 - Certification of true copies & use of Department seal	(a)(12)(i): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(12)(ii): Director/Deputy Director, OM (a)(12)(iii): Director/Deputy Director, OC (a)(12)(iv): Directors, ODEs I-V/ORM Director/Deputy Director, OEB/ORM (a)(12)(v): Director/Deputy Dir, OGD/OPS Director/Deputy Director, ONDC/OPS Director/Deputy Director, OTR/OPS Director/Deputy Director, OCPB/OPS	(a)(12)(vii): Directors, DLNDC, DMPQ, DPDCS/OC (Note: excludes DSI) (a)(12)(viii): Director/Deputy Director, DB/OGD/OPS	(a)(12)(vi): Chief, FOI Staff/OTCOM
5.23 - Disclosure of official records				(a)(5): Program Officials at all org levels down to and including branch level for all HQ orgs (a)(9): FOI Officers and other employees engaged in FOI activities (b): Chief, PIMB/DDM/OM

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.24 - Authority relating to technology transfer	(b)(3): Director only			
5.25 - Research, investigation, and testing programs and health information and health promotion programs	(a)(6): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science			
5.26 - Service fellowships	(g): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(g): Director/Deputy Director, OM		
5.30 - Hearings	(a)(2) & (c)(3): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(2) & (c)(3): Directors, ODEs I-V/ORM Director/Deputy Director, OC		
5.31 - Petitions under part 10	(a)(2)(i), (b)(1), (c)(1), (d)(1), (e)(4), (f)(2), (f)(5)(ii): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(2)(ii): Directors, ODEs I-V/ORM (b)(2) & (d)(2): Director, ODE V/ORM	(b)(3) & (d)(3): Director/Deputy Director, DOTCDP/ODE V/ORM (f)(3): Director/Deputy Director, DB/OGD/OPS	

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.33 - Pre-market approval of a product that is or contains a biologic, device, or drug	(c): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(c): Directors, ODEs I-V/ORM		
5.34 - Select temporary voting members for advisory committees and authority to sign conflict of interest waivers	(a) & (b): Director only			
5.35 - Enforcement activities				(a)(1) and (2), (b)(1)(i)-(v), (b)(2), (c), & (d)(1)-(4): Designated officers and employees of FDA who have been issued FDA official credentials relating to enforcement activities, including examinations, investigations, or inspections, and specialized law enforcement support involving criminal investi-gations under the FFDCA
5.37 - Issuance of reports of minor violations	(a)(5)(i): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(5)(ii); Director/Deputy Director, OC	(a)(5)(iv): Director, DDMAC/ODE I/ORM	(a)(5)(iii): Associate Director for Medical Policy, OCD

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.38 - Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs	(a)(1): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(2): Director/Deputy Director, OC	(a)(3)-(6): Directors, DLNDC, DMPQ, DPDCS, and DSI/OC	
5.44 - Export of unapproved drugs	(a)(1)(iii) & (b)(1)(iii): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(1)(iv) & (b)(1)(iv): Director/Deputy Director, OC		
5.45 - Imports and exports	(f)(2): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(f)(2): Director/Deputy Director, OC		
5.54 - Determinations that medical devices present unreasonable risk of substantial harm	(c): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(c): Director/Deputy Director, OC		
5.55 - Orders to repair or replace, or make refunds for, medical devices	(c): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(c): Director/Deputy Director, OC		

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.56 - Recall authority	(c): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(c): Director/Deputy Director, OC		
5.57 - Temporary suspension of a medical device application	(d): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(d): Director/Deputy Director, OC Directors, ODEs I-V/ORM Director/Deputy Director, OGD/OPS		
5.58 - Orphan products	(c)(1)(i): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(c)(1)(ii): Directors, ODEs I-V/ORM	(c)(1)(iii): Directors/Deputy Directors of Divisions in ODEs I-V/ORM	
5.60 - Required and discretionary postmarket surveillance	(a)(7) & (b)(6): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(9), (a)(8), (b)(7) & (b)(8): Directors, ODEs I-V/ORM Director/Deputy Director, OC		
5.70 - Issuance of notice implementing the provisions of the Drug Amendments of 1962	Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science			

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.71 - Termination of exemptions for new drugs for investigational use in human beings and in animals	(a)(2): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b)(1) & (c)(1): Directors, ODEs I-V/ORM	(b)(2) & (c)(2): Directors/Deputy Directors of Divisions in ODEs I-V/ORM	
5.72 - Authority to approve and to withdraw approval of a charge for investigational new drugs	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science			
5.73 - Certification of insulin	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b): Director, ODE II/ORM (d): Director/Deputy Director, OC	(c): Director/Deputy Director, DMEDP, ODE II/ORM (e): Director/Deputy Director, DPDCS/OC	(f): Team Leader and Assistant, Post-marketing Surveillance Team, DPDCS/OC
5.74 - Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b): Director, ODE II/ORM (d): Director/Deputy Director, OC	(c): Director/Deputy Director, DMEDP, ODE II/ORM	
5.75 - Designation of official master and working standards for antibiotic drugs	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b): Director/Deputy Director, OTR/OPS	(c): Director/Deputy Director, DRT/OTR/OPS	

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.76 - Certification of antibiotic drugs	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b): Director/Deputy Director, OC	(c): Director/Deputy Director, DPDCS/OC	(d): Team Leader and Assistant, Post-marketing Surveillance Team, DPDCS/OC
5.78 - Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs	(1): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(2): Director, ODE I/ORM (3): Director, ODE IV/ORM (7): Director/Deputy Director, OC	(4): Director/Deputy Director, DODP/ODE I/ORM (5): Director/Deputy Director, DAIDP/ODE IV/ORM (6): Director/Deputy Director, DAVDP/ODE IV/ORM	
5.80 - Approval of new drug applications and their supplements	(a)(1)(i): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(a)(1)(ii) & (c)(1)(ii): Directors, ODEs I-V/ORM (d)(1)(i): Director/Deputy Director, OGD/OPS	(b): Directors/Deputy Directors of Divisions in ODEs I-V/ORM (d)(1) and (2): Directors/Deputy Directors, DC I and II/OGD/OPS (e): Director/Deputy Director, DLPS/OGD/OPS	(d)(3): Associate Director for Chemistry, OPS (f): Supervisory and team leader chemists, DNDC I-III/ ONDC/OPS
5.82 - Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science			

CDER Program DOA	Center Director/Deputy Center Directors	Office Directors/Deputy Directors	Division Directors/Deputy Directors	Other Positions
5.93 - Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science		(b): Director/Deputy Director, DB/OGD/OPS	
5.94 - Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs	(b)(1): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science	(b)(2): Directors, ODEs I-V/ORM	(b)(3): Directors/Deputy Directors of Divisions in ODEs I-V/ORM	
5.99 - Issuance of notices and orders relating to debarment	(a): Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science			

Attachment B

Summary of CDER Program Delegations of Authority (DOAs) by Office and Position

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.22 - Certification of true copies & use of Department seal	● (a)(12)(i)	● (a)(12)(ii)		● (a)(12)(iv)		● (a)(12)(iv)	● (a)(12)(vi) Chief only	● (a)(12)(iii)	● (a)(12)(vii) DLNDC DMPQ DPDCS Dirs only			● (a)(12)(v)	● (a)(12)(viii) DB only	● (a)(12)(v)		● (a)(12)(v)		● (a)(12)(v)	
5.23 - Disclosure of official records			● (b)				● (a)(9)												● (a)(5)
5.24 - Authority relating to technology transfer	● (b)(3) Dir only																		
5.25 - Research, investigation, and testing programs and health information and health promotion programs	● (a)(6)																		
5.26 - Service fellowships	● (g)	● (g)																	
5.30 - Hearings	● (a)(2)(c)(3)			● (a)(2)(c)(3)				● (a)(2)(c)(3)											

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.31 - Petitions under part 10	● (a)(2)(i) (b)(1) (c)(1) (d)(1) (e)(4) (f)(2) (f)(5)(ii)			● (a)(2) (ii) ● (b)(2) (d)(2) ODE V only	● (a)(2) (iii) ● (b)(3) (d)(3) DOTCDP, ODE V only								● (f)(3) DB only						
5.33 - Premarket approval of a product that is or contains a biologic, device, or drug	● (c)			● (c)															
5.34 - Select temporary voting members for advisory committees and authority to sign conflict of interest waivers	● (a) (b) Dir only																		
5.37 - Issuance of reports of minor violations	● (a)(5)(i) ● (a)(5)(iii) Assoc Dir for Med Pol				● (a)(5) (iv) Dir DDMAC, ODE I only			● (a)(5)(ii)											

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.38 - Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs	● (a)(1)							● (a)(2)	● (a)(3)-(6)										
5.44 - Export of unapproved drugs	● (a)(1)(iii) (b)(1)(iii)							● (a)(1) (iv) (b)(1) (iv)											
5.45 - Imports and exports	● (f)(2)							● (f)(2)											
5.54 - Determinations that medical devices present unreasonable risk of substantial harm	● (c)							● (c)											
5.55 - Orders to repair or replace, or make refunds for, medical devices	● (c)							● (c)											
5.56 - Recall authority	● (c)							● (c)											
5.57 - Temporary suspension of a medical device application	● (d)			● (d)				● (d)				● (d)							

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.58 - Orphan products	● (c)(1)(i)			● (c)(1) (ii)	● (c)(1) (iii)														
5.60 - Required and discretionary postmarket surveillance	● (a)(7) (b)(6)			● (a)(8) (b)(7)				● (a)(9) (b)(8)											
5.70 - Issuance of notice implementing the provisions of the Drug Amendments of 1962	●																		
5.71 - Termination of exemptions for new drugs for investigational use in human beings and in animals	● (a)(2)			● (b)(1) (c)(1)	● (b)(2) (c)(2)														
5.72 - Authority to approve and to withdraw approval of a charge for investigational new drugs	● (a)																		
5.73 - Certification of insulin	● (a)			● (b) ODE II only	● (c) DMEDP, ODE II only			● (d)	● (e) DPDCS only	● (f) PSB, DPDCS only									
5.74 - Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin	● (a)			● (b) ODE II only	● (c) DMEDP, ODE II only			● (d)											

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.75 - Designation of official master and working standards for antibiotic drugs	● (a)															● (b)	● (c)		
5.76 - Certification of antibiotic drugs	● (a)							● (b)	● (c) DPDCS only	● (d) PSB, DPDCS only									
5.78 - Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs	● (1)			● (2) ODE I only (3) ODE IV only	● (4) DODP, ODE I only (5) DAIDP, ODE IV only (6) DAVDP, ODE IV only			● (7)											
5.80 - Approval of new drug applications and their supplements	● (a)(1)(i)			● (a)(1)(ii) (c)(1)(ii)	● (b)						● (d)(3)	● (c)(1)(i)	● (d)(1) (d)(2) DC I/II ● (e) Dir DLPS only		● (f)				

CDER Program Delegations of Authority	OCD	OM		ORM			OT COM	OC			OPS								Ctr wide
				ODEs I - V		OEB					OPS	OGD		ONDC		OTR		OC PB	
	Dir & Deps	Dir & Dep	Chief PIMB DDM	Dirs	Div Dirs & Deps	Dir & Dep	Chief FOIS & FOI Ofcrs	Dir & Dep	Div Dirs & Deps	TL & Asst	Assoc Dir for Chem	Dir & Dep	Div Dirs & Deps	Dir & Dep	Supv & TL Chems, DNDC I-III	Dir & Dep	DRT Div Dir & Dep	Dir & Dep	Prgm Offi-cials to brnch level
5.82 - Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements	● (a)																		
5.93 - Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications	● (a)												● (b) DB only						
5.94 - Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs	● (b)(1)			● (b)(2)	● (b)(3)														
5.99 - Issuance of notices and orders relating to debarment	● (a)																		
5.35 - Enforcement activities	Designated officers and employees of FDA who have been issued FDA official credentials relating to enforcement activities, including examinations, investigations, or inspections, and specialized law enforcement support involving criminal investigations under the FFDCA.																		

Attachment C

SUMMARY OF PROGRAM DELEGATIONS OF AUTHORITY CENTER FOR DRUG EVALUATION AND RESEARCH

Redelegations of Authority from the Commissioner of Food and Drugs 21 CFR Chapter 1, Part 5, Subpart B

5.22 Certification of true copies and use of Department seal

(a) Authority to certify true copies of or extracts from any books, record, papers, or other documents on file within the Food and Drug Administration (FDA), to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the FDA, and to cause the seal of the Department to be affixed to such certifications:

(12)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).
(ii) The Director and Deputy Director, Office of Management, CDER.
(iii) The Director and Deputy Director, Office of Compliance, CDER.
(iv) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Epidemiology and Biostatistics, Office of Review Management, CDER.
(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.
(vi) The Chief, Freedom of Information Staff, Office of Training and Communication, CDER.
(vii) The Directors of the Divisions of Labeling and Nonprescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.
(viii) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

5.23 Disclosure of official records

(a) Authority to make determinations to disclose official records and information under CFR Ch. 1, Part 20, excluding information under Ch. 1, §§ 20.82, 20.85, and 20.89:

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(9) Freedom of Information Officers and other employees engaged in FOI activities.

(b) Authority to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments:

The Chief, Product Information Management Branch, Division of Database Management, Office of Management, CDER.

5.24 Authority relating to technology transfer

(b) Authority to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.) as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710(c)(5)(A):

(3) The Director, CDER.

5.25 Research, investigation, and testing programs and health information and health promotion programs

(a) Authority under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the act) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

5.26 Service fellowships

Under authority of sections 207(g) and 208(f) of the Public Health Service Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, authority

to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for individual actions within the ranges established under an approved service fellowship plan:

(g) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Management, CDER.

5.30 Hearings

(a) Authority to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA); section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in CFR Ch. 1, part 5:

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(c) Authority to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of part 16 of CFR Ch. 1. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of CFR Ch. 1 with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in CFR Ch. 1:

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.31 Petitions under part 10

(a) Authority to grant or deny citizen petitions submitted under 21 CFR Ch. 1, § 10.30 for a stay of an effective date in Ch. 1, § 201.59 for compliance with certain labeling requirements for human prescription drugs, for drugs assigned to their organizations:

(2)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) Authority to grant or deny citizen petitions submitted under § 10.30 of CFR Ch. 1 requesting in vitro test modifications under § 331.29 of CFR Ch. 1:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.
(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) Authority to grant or deny citizen petitions submitted under § 10.30 of CFR Ch. 1 for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in § 211.132, § 700.25, or § 800.12 of CFR Ch. 1 for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(d) Authority to grant or deny citizen petitions submitted under § 10.30 of CFR Ch. 1 requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under § 201.63 of CFR Ch. 1, requesting exemption from a general overdose warning required under § 330.1(g) of CFR Ch. 1, and requesting exemption from OTC drug administrative procedures under § 330.10 of CFR Ch. 1:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.
(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(4) Authority to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of CFR Ch. 1 that relate to the assigned functions of that Center:

The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(f)(2) Authority to grant or deny citizen petitions submitted under § 10.30 of CFR Ch. 1 on drug product matters in program areas where they have been delegated final approval authority in the following sections of part 5, CFR Ch. 1:

(i) Section 5.70 Issuance of notices implementing the provisions of the Drug Amendments of 1962 (DESI);
(ii) Section 5.71 Termination of exemptions for new drugs for investigational use in human beings or in animals;
(iii) Section 5.73 Certification of insulin;
(iv) Section 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin;
(v) Section 5.75 Designation of official master and working standards for antibiotic drugs;
(vi) Section 5.76 Certification of antibiotic drugs;
(vii) Section 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs;
(viii) Section 5.80 Approval of new drug applications and their supplements; and
(ix) Section 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(f)(3) Authority to issue responses to citizen petitions submitted under § 10.30 of CFR Ch. 1 seeking a determination of the suitability of an abbreviated new drug application for a drug product, except for those drug products listed in § 314.440(b) of CFR Ch. 1:

The Director and Deputy Director, Division of Bioequivalence, Office of

Generic Drugs, Office of Pharmaceutical Science, CDER.

(f)(5) Authority to issue responses to citizen petitions submitted under § 10.30 of CFR Ch. 1 from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with § 2.125(j) of CFR Ch. 1, an investigational new drug for human use containing a chlorofluorocarbon, for drugs assigned to their organization:

(ii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug

For a product that is or contains a biologic, device, or drug, the following CDER officials who currently hold delegated premarket approval authority for biologics, devices, or drugs are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, device, or drug, or any combination of two or more of these products:

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers

(a) Authority to select members of, and consultants to, scientific and technical FDA advisory committees under CDER's management to serve temporarily as voting members on another advisory committee under CDER's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or his designee.

The Director, CDER.

(b) Authority, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consultants to advisory

committees or in any other capacity within CDER except as advisory committee members:

The Director, CDER.

5.35 Enforcement activities

(a) Designated officers and employees of the Food and Drug Administration who have been issued the FDA official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the FFDCA; and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, and Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the FDA who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the FDA Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

(i) Carry firearms;
(ii) Serve and execute search warrants and arrest warrants;
(iii) Execute seizure by process issued pursuant to libel under section 304 of the act;
(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(c) Any officer or employee of the FDA who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the FFDCA, and other duties as assigned by the Commissioner, and issued the FDA Official Credential consisting of Form FDA-200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations promulgated under the act.

(d) The FDA's official credentials referred to in paragraphs (a), (b), and (c) of this section are described as follows:

(1) Form FDA-200A entitled "Identification Record" bears a color photograph, a description, and the signature of the holder, an identification number, an expiration date, the Department of Health and Human Services' seal with blue imprint, on the left of the photograph, and the FDA's symbol, on the right of the photograph.

(2) Form FDA-200B entitled "Specification of General Authority" bears the holder's name, his or her general authority, an identification number, an expiration date, the Commissioner's signature, the names of the Department of Health and Human Services , the Public Health Service, and the Food and Drug Administration. The form is superimposed with the Department's seal with blue imprint.

(3) Form FDA-200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372, and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

(4) Form FDA-200E, entitled "Special Authority for Criminal Investigative Specialists," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under the act, and other duties under the law, as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature,the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the FDA symbol with blue imprint, and part 2 is superimposed with the FDA criminal investigative specialist's badge with blue imprint.

5.37 Issuance of reports of minor violations

(a) Authority to perform all the functions of the Commissioner of Food and Drugs under section 306 of the FFDCA regarding the issuance of written notices or warnings:

(5)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(ii) The Director and Deputy Director, Office of Compliance, CDER.
(iii) The Associate Director for Medical Policy, CDER.
(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Drug Evaluation I, Office of Review Management, CDER.

5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs

(a) Authority to perform all the functions of the Commissioner of Food and Drugs under section 505(e) of the FFDCA regarding the issuance of written notices:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(2) The Director and Deputy Director, Office of Compliance, CDER.
(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.
(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.
(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.
(6) The Director and Deputy Director, Division of Scientific Investigations,

Office of Compliance, CDER.

5.44 Export of unapproved drugs

(a) Authority, under section 802(b) of the FFDCA, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(iv) The Director and Deputy Director, Office of Compliance, CDER.

(b) Authority, under section 802(f) of the FFDCA, to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease:

(1) For human drugs assigned to their respective organizations:

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(iv) The Director and Deputy Director, Office of Compliance, CDER.

5.45 Imports and exports

(f) Authority to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FFDCA for emergency medical care:

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.54 Determinations that medical devices present unreasonable risk of substantial harm

For medical devices assigned to their respective organizations, authority to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the FFDCA:

(c) The Director, Deputy Center Director for Review Management, and Deputy Center

Director for Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.55 Orders to repair or replace, or make refunds for, medical devices

For medical devices assigned to their respective organizations, authority to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the FFDCA:

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.56 Recall authority

For medical devices assigned to their respective organizations, authority to perform all of the recall functions under section 518(e) of the FFDCA which have been delegated to the Commissioner of Food and Drugs:

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.57 Temporary suspension of a medical device application

For medical devices assigned to their respective organizations, authority under section 515(e) of the FFDCA to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, authority to issue an order to temporarily suspend the approval of an application:

(d) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

5.58 Orphan products

(c) Authority to provide sponsors, under section 525(a) of the FFDCA, with recommendations for nonclinical or clinical investigations believed to be necessary

for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

5.60 Required and discretionary postmarket surveillance

(a) For any device (including any device that is or contains a drug or biologic) that was first introduced or delivered for introduction into interstate commerce after January 1, 1991, and that is either a permanent implant, the failure of which may cause serious adverse health consequences or death, a life-sustaining or life-supporting device, or a device that potentially presents a serious risk to human health, authority to require a manufacturer of such device to conduct postmarket surveillance:

(7) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(8) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(9) The Director and Deputy Director, Office of Compliance, CDER.

(b) For any device (including any device that is or contains a drug or biologic), authority to require a manufacturer of a device to conduct postmarket surveillance if the official determines that postmarket surveillance of the device is necessary to protect the public health or provide safety or effectiveness data for the device:

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(8) The Director and Deputy Director, Office of Compliance, CDER.

5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962

Authority to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy

findings on human drugs that are or were subject to the provisions of sections 505 and 507 of the FFDCA:

The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals

(a) For drugs under their jurisdiction, authority to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of 21 CFR Ch. 1 and in animals under § 312.160 of 21 CFR Ch. 1:

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(b) For drugs under their jurisdiction, authority to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1) (viii) of 21 CFR Ch. 1:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(c) For drugs under their jurisdiction, authority to make the findings set forth in § 312.44(b) of 21 CFR Ch. 1 and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs

For drugs under their jurisdiction, authority to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application

under § 312.7(d)(1) of 21 CFR Ch. 1:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

5.73 Certification of insulin

Authority to certify or reject batches of drugs containing insulin pursuant to section 506(a) of the FFDCA:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.
(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.
(d) The Director and Deputy Director, Office of Compliance, CDER.
(e) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.
(f) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin

Authority to perform all the functions of the Commissioner of Food and Drugs under section 506 of the FFDCA regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.
(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.
(d) The Director and Deputy Director, Office of Compliance, CDER.

5.75 Designation of official master and working standards for antibiotic drugs

Authority to designate official FDA master and working standards for antibiotic drugs under § 430.5 of 21 CFR Ch. 1:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(b) The Director and Deputy Director, Office of Testing and Research, Office of

Pharmaceutical Science, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

5.76 Certification of antibiotic drugs

Authority to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the FFDCA:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(b) The Director and Deputy Director, Office of Compliance, CDER.
(c) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.
(d) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs

Authority to perform all the functions of the Commissioner of Food and Drugs under section 507 of the FFDCA regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(2) The Director, Office of Drug Evaluation I, Office of Review Management, CDER.
(3) The Director, Office of Drug Evaluation IV, Office of Review Management, CDER.
(4) The Director and Deputy Director, Division of Oncologic Drug Products, Office of Drug Evaluation I, Office of Review Management, CDER.
(5) The Director and Deputy Director, Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.
(6) The Director and Deputy Director, Division of Anti-Viral Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.
(7) The Director and Deputy Director, Office of Compliance, CDER.

5.80 Approval of new drug applications and their supplements

(a)(1) Authority to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of 21 CFR Ch. 1, that have been submitted under section 505 of the FFDCA:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(b) For drugs under their jurisdiction, authority to perform all the functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of 21 CFR Ch. 1, and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(c) Authority to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or 505(b)(2) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in §§ 5.10(a) and 5.80(a).

(1) For drugs submitted under 21 CFR Ch. 1, §§ 314.50, 314.70, and 314.94, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(d) Authority to perform all the functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in § 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of 21 CFR Ch. 1. (Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.)

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) The Associate Director for Chemistry, Office of Pharmaceutical Science, CDER.

(e) Authority to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in § 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of 21 CFR Ch. 1. (Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests are not included in this paragraph.)

The Director, Division of Labeling and Program Support, Office of Generic Drugs, Offices of Pharmaceutical Science, CDER.

(f) Authority to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drug for human use that are described in 21 CFR Ch. 1, § 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3). Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in 21 CFR Ch. 1, §§ 5.10(a), 5.80(a) and 5.80(b):

The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER.

5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements

(a) Authority to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of 21 CFR Ch. 1, that have been submitted under section 505 of the FFDCA and subpart B of part 314 of 21 CFR Ch. 1 and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived:

The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications

Authority to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505(c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the FFDCA (the act) concerning the date of submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(b) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs

Authority to extend or stay an effective date in § 201.59 of 21 CFR Ch. 1 for compliance with certain labeling requirements for human prescription drugs:

(b) For drugs assigned to their organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.
(2) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
(3) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

5.99 Issuance of notices and orders relating to debarment

(a) Authority to issue notices and orders for debarment and denial of an application to terminate debarment as provided in 21 CFR 5:

The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.