FOOD AND DRUG ADMINISTRATION

Salaries & Expenses (Administrative Costs)

Budget Authority

	FY 2002 Appropriation	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
PERSONNEL COMPENSATION:				
11.1 Full-time permanent	$546,029,000	$581,853,000	$625,551,000	$43,698,000
11.3 Other than full-time perm	34,294,000	34,294,000	35,450,000	1,156,000
11.5 Other personnel comp	19,621,000	19,621,000	20,282,000	661,000
11.8 Special personal svcs pay	144,000	144,000	149,000	5,000
11.9 Total Personnel Comp	***$600,088,000***	***$635,912,000***	***$681,432,000***	***$45,520,000***
12.1 Civilian Personnel Benefits	138,097,000	147,847,000	159,391,000	11,544,000
Personnel Benefits, Accrued Retirement	50,238,000	50,238,000	53,770,000	3,532,000
13.0 Benefits -former personnel	19,000	19,000	19,000	0
Pay Costs, Current Law [1]	**$738,204,000**	**$783,778,000**	**$840,842,000**	**$57,064,000**
Pay Costs, Proposed Law [2]	**$788,442,000**	**$834,016,000**	**$894,612,000**	**$60,596,000**
21.0 Travel & Transportation of persons	21,393,000	25,992,000	27,514,000	1,522,000
22.0 Transportation of things	3,493,000	5,548,000	7,000,000	1,452,000
23.2 Rent payments to others	5,745,000	5,745,000	5,745,000	0
23.3 Communication, Util & Misc Services	26,737,000	30,246,000	28,803,000	(1,443,000)
24.0 Printing & Reproduction	3,337,000	3,337,000	3,337,000	0
Contractual Costs:				
25.1 Advisory and Assistance Services	16,222,000	17,216,000	16,918,000	(298,000)
25.2 Other Services	51,615,000	83,019,000	77,674,000	(5,345,000)
25.3 Purchase of Goods & Svcs from Govt Acts	50,566,000	50,566,000	50,239,000	(327,000)
Purchase of Goods & Svcs from Govt Acts, Accrued Retirement	944,000	944,000	981,000	37,000
25.4 Operation & Maintenance of Facilities	26,523,000	43,452,000	34,451,000	(9,001,000)
25.7 Operation & Maintenance of Equipment	27,585,000	28,638,000	27,978,000	(660,000)
Contractual Costs, Current Law	**$172,468,000**	**$222,891,000**	**$207,260,000**	**($15,631,000)**
Contractual Costs, Proposed Law	**$173,455,000**	**$223,835,000**	**$208,241,000**	**($15,594,000)**
26.0 Supplies & Materials	20,600,000	25,562,000	24,523,000	(1,039,000)
Non-Pay Costs, Current Law	**$253,816,000**	**$319,321,000**	**$304,181,000**	**($15,140,000)**
Non-Pay Costs, Proposed Law	**$254,760,000**	**$320,265,000**	**$305,163,000**	**($15,102,000)**
Total, Accrued Retirement Costs	**$51,182,000**	**$51,182,000**	**$54,751,000**	**$3,569,000**
99.0 CURRENT LAW DIRECT OBLIGATION	**$992,020,000**	**$1,103,099,000**	**$1,145,023,000**	**$41,924,000**
99.0 PROPOSED LAW DIRECT OBLIGATION	**$1,043,202,000**	**$1,154,281,000**	**$1,199,775,000**	**$45,494,000**

Note: This table does not reflect comparable adjustment in FY 2002 as a result of the FY 2003 Legislation and Public Affairs Transfer to DHHS.

[1]Current Law reflects no comparability in FY 2002 for retirement accruals.

[2]Proposed Law reflects comparable adjustments in FY 2002 for retirement accruals as though the proposal had been in effect.

FOOD AND DRUG ADMINISTRATION

Object Class Distribution - Budget Authority

FY 2001 - FY 2003

	FY 2001 Actual	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
PERSONNEL COMPENSATION:				
11.1 Full-time permanent	$476,612,000	$581,853,000	$625,551,000	$43,698,000
11.3 Other than full-time perm	35,532,000	34,294,000	35,450,000	1,156,000
11.5 Other personnel comp	17,902,000	19,621,000	20,282,000	661,000
11.8 Special personal svcs pay	212,000	144,000	149,000	5,000
11.9 Total Personnel Comp	***$530,258,000***	***$635,912,000***	***$681,432,000***	***$45,520,000***
12.1 Civilian Personnel Benefits	129,233,000	147,847,000	159,391,000	11,544,000
Personnel Benefits, Accrued Retirement	45,890,000	50,238,000	53,770,000	3,532,000
13.0 Benefits -former personnel	74,000	19,000	19,000	0
Pay Costs, Current Law [1]	**$659,565,000**	**$783,778,000**	**$840,842,000**	**$57,064,000**
Pay Costs, Proposed Law [2]	**$705,455,000**	**$834,016,000**	**$894,612,000**	**$60,596,000**
21.0 Travel & Transportation of persons	21,937,000	25,992,000	27,514,000	1,522,000
22.0 Transportation of things	3,210,000	5,548,000	7,000,000	1,452,000
23.1 Rental payments to GSA	87,276,000	98,876,000	98,556,000	(320,000)
23.2 Rent payments to others	4,403,000	5,745,000	5,745,000	0
23.3 Communication, Util & Misc Services	22,452,000	30,246,000	28,803,000	(1,443,000)
24.0 Printing & Reproduction	2,728,000	3,337,000	3,337,000	0
Contractual Costs:				
25.1 Advisory and Assistance Services	14,404,000	17,216,000	16,918,000	(298,000)
25.2 Other Services	40,861,000	83,019,000	77,674,000	(5,345,000)
25.3 Purchase of Goods & Svcs from Govt Acts	48,145,000	50,566,000	50,239,000	(327,000)
Purchase of Goods & Svcs from Govt. Acts, Accrued Retirement	987,000	944,000	981,000	37,000
25.4 Operation & Maintenance of Facilities	27,331,000	43,452,000	34,451,000	(9,001,000)
25.5 Research & Development Contracts	26,394,000	42,851,000	43,388,000	537,000
25.7 Operation & Maintenance of Equipment	25,631,000	28,638,000	27,978,000	(660,000)
Contractual Costs, Current Law	**$182,766,000**	**$265,742,000**	**$250,647,000**	**($15,095,000)**
Contractual Costs, Proposed Law	**$183,753,000**	**$266,686,000**	**$251,629,000**	**($15,057,000)**
26.0 Supplies & Materials	17,435,000	25,562,000	24,523,000	(1,039,000)
31.0 Equipment	39,982,000	69,748,000	61,626,000	(8,122,000)
32.0 Land & Structure	29,020,000	25,686,000	0	(25,686,000)
41.0 Grants, subsidies & contributions	26,672,000	27,022,000	27,022,000	0
42.0 Ins claims & indemnities	1,991,000	1,769,000	1,769,000	0
62.0 Receivables collected	(126,000)	0	0	0
Non-Pay Costs, Current Law	**$439,746,000**	**$585,273,000**	**$536,543,000**	**($48,730,000)**
Non-Pay Costs, Proposed Law	**$440,733,000**	**$586,217,000**	**$537,524,000**	**($48,693,000)**
Total, Accrued Retirement Costs	**$46,877,000**	**$51,182,000**	**$54,751,000**	**$3,569,000**
99.0 CURRENT LAW DIRECT OBLIGATION	**$1,099,311,000**	**$1,369,051,000**	**$1,377,385,000**	**$8,334,000**
99.0 PROPOSED LAW DIRECT OBLIGATION	**$1,146,188,000**	**$1,420,233,000**	**$1,432,136,000**	**$11,903,000**
FTE [3]	**7,805**	**8,779**	**9,116**	**337**

Note: This table does not reflect comparable adjustment in FYs 2001 and 2002 as a result of the FY 2003 Legislation and Public Affairs Transfer to DHHS.

[1]Current Law reflects no comparability in FYs 2001 & 2002 for retirement accruals.

[2]Proposed Law reflects comparable adjustments in FYs 2001 & 2002 for retirement accruals as though the proposal had been in effect.

[3]Does not include Reimbursable FTE of 89 for each year.

FOOD AND DRUG ADMINISTRATION
Object Class Distribution - User Fees
FY 2001 - FY 2003

	FY 2001 Actual	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
PERSONNEL COMPENSATION:				
11.1 Full-time permanent	$83,629,000	$90,871,000	$105,489,000	$14,618,000
11.3 Other than full-time perm	6,262,000	5,612,000	6,514,000	902,000
11.5 Other personnel comp	3,087,000	3,187,000	3,699,000	512,000
11.8 Special personal svcs pay	131000			
11.9 Total Personnel Comp	***$93,109,000***	***$99,670,000***	***$115,702,000***	***$16,032,000***
12.1 Civilian Personnel Benefits	22,147,000	22,636,000	26,278,000	3,642,000
Personnel Benefits, Accrued Retirement	7,287,000	7,900,000	8,454,000	554,000
13.0 Benefits -former personnel	0	0	0	0
Pay Costs, Current Law [1]	**$115,256,000**	**$122,306,000**	**$141,980,000**	**$19,674,000**
Pay Costs, Proposed Law [2]	**$122,543,000**	**$130,206,000**	**$150,434,000**	**$20,228,000**
21.0 Travel & Transportation of persons	3,562,000	3,424,000	9,790,000	6,366,000
22.0 Transportation of things	322,000	309,000	909,000	600,000
23.1 Rental payments to GSA	6,184,000	6,240,000	7,140,000	900,000
23.2 Rent payments to others	196,000	396,000	1,171,000	775,000
23.3 Communication, Util & Misc Services	782,000	1,551,000	4,394,000	2,843,000
24.0 Printing & Reproduction	87,000	264,000	772,000	508,000
Contractual Costs:				
25.1 Advisory and Assistance Services	1,077,000	325,000	613,000	288,000
25.2 Other Services	27,208,000	26,444,000	57,759,000	31,315,000
25.3 Purchase of Goods & Svcs from Govt Acts	5,627,000	5,384,000	15,821,000	10,437,000
25.4 Operation & Maintenance of Facilities	390,000	323,000	845,000	522,000
25.5 Research & Development Contracts	1,863,000	2,727,000	8,047,000	5,320,000
25.7 Operation & Maintenance of Equipment	3,787,000	2,046,000	5,497,000	3,451,000
Subtotal Contractual Costs:	**$39,952,000**	**$37,249,000**	**$88,582,000**	**$51,333,000**
26.0 Supplies & Materials	4,201,000	3,749,000	10,640,000	6,891,000
31.0 Equipment	8,287,000	7,512,000	20,617,000	13,105,000
32.0 Land & Structure	2,000	364,000	368,000	4,000
41.0 Grants, subsidies & contributions	1,000	118,000	342,000	224,000
42.0 Ins claims & indemnities	4,000	5,000	5,000	0
62.0 Receivables collected	0	0	0	0
SUBTOTAL NON-PAY COSTS:	**$63,580,000**	**$61,181,000**	**$144,730,000**	**$83,549,000**
Total, Accrued Retirement Costs	**$7,287,000**	**$7,900,000**	**$8,454,000**	**$554,000**
99.0 CURRENT LAW DIRECT OBLIGATION	**$178,836,000**	**$183,487,000**	**$286,710,000**	**$103,223,000**
99.0 PROPOSED LAW DIRECT OBLIGATION	**$186,123,000**	**$191,387,000**	**$295,164,000**	**$103,777,000**
FTE	**1,184**	**1,203**	**1,343**	**140**

[1]Current Law reflects no comparability in FYs 2001 & 2002 for retirement accruals.
[2]Proposed Law reflects comparable adjustments in FYs 2001 & 2002 for retirement accruals as though the proposal had been in effect.

FOOD AND DRUG ADMINISTRATION
Object Class Distribution - Program Level
FY 2001 - FY 2003

	FY 2001 Actual	FY 2002 Current Estimate	FY 2003 Estimate	Increase or Decrease
PERSONNEL COMPENSATION:				
11.1 Full-time permanent	$560,241,000	$672,724,000	$731,040,000	$58,316,000
11.3 Other than full-time perm	41,794,000	39,906,000	41,964,000	2,058,000
11.5 Other personnel comp	20,989,000	22,808,000	23,981,000	1,173,000
11.8 Special personal svcs pay	343,000	144,000	149,000	5,000
11.9 Total Personnel Comp	***$623,367,000***	***$735,582,000***	***$797,134,000***	***$61,552,000***
12.1 Civilian Personnel Benefits	151,380,000	170,483,000	185,669,000	15,186,000
Personnel Benefits, Accrued Retirement	53,177,000	58,138,000	62,224,000	4,086,000
13.0 Benefits -former personnel	74,000	19,000	19,000	0
Pay Costs, Current Law [1]	**$774,821,000**	**$906,084,000**	**$982,822,000**	**$76,738,000**
Pay Costs, Proposed Law [2]	**$827,998,000**	**$964,222,000**	**$1,045,046,000**	**$80,824,000**
21.0 Travel & Transportation of persons	25,499,000	29,416,000	37,304,000	7,888,000
22.0 Transportation of things	3,532,000	5,857,000	7,909,000	2,052,000
23.1 Rental payments to GSA	93,460,000	105,116,000	105,696,000	580,000
23.2 Rent payments to others	4,599,000	6,141,000	6,916,000	775,000
23.3 Communication, Util & Misc Services	23,234,000	31,797,000	33,197,000	1,400,000
24.0 Printing & Reproduction	2,815,000	3,601,000	4,109,000	508,000
Contractual Costs:				
25.1 Advisory and Assistance Services	15,481,000	17,541,000	17,531,000	(10,000)
25.2 Other Services	68,069,000	109,463,000	135,433,000	25,970,000
25.3 Purchase of Goods & Svcs from Govt Acts	53,772,000	55,950,000	66,060,000	10,110,000
Purchase of Goods & Svcs from Govt Acts, Accrued Retirement	987,000	944,000	981,000	37,000
25.4 Operation & Maintenance of Facilities	27,721,000	43,775,000	35,296,000	(8,479,000)
25.5 Research & Development Contracts	28,257,000	45,578,000	51,435,000	5,857,000
25.7 Operation & Maintenance of Equipment	29,418,000	30,684,000	33,475,000	2,791,000
Contractual Costs, Current Law	**$222,718,000**	**$302,991,000**	**$339,229,000**	**$36,238,000**
Contractual Costs, Proposed Law	**$223,705,000**	**$303,935,000**	**$340,211,000**	**$36,276,000**
26.0 Supplies & Materials	21,636,000	29,311,000	35,163,000	5,852,000
31.0 Equipment	48,269,000	77,260,000	82,243,000	4,983,000
32.0 Land & Structure	29,022,000	26,050,000	368,000	(25,682,000)
41.0 Grants, subsidies & contributions	26,673,000	27,140,000	27,364,000	224,000
42.0 Ins claims & indemnities	1,995,000	1,774,000	1,774,000	0
62.0 Receivables-collected	(126,000)	0	0	0
Non-Pay Costs, Current Law	**$503,326,000**	**$646,454,000**	**$681,273,000**	**$34,819,000**
Non-Pay Costs, Proposed Law	**$504,313,000**	**$647,398,000**	**$682,254,000**	**$34,856,000**
Total, Accrued Retirement Costs	**$54,164,000**	**$59,082,000**	**$63,205,000**	**$4,123,000**
99.0 CURRENT LAW DIRECT OBLIGATION	**$1,278,147,000**	**$1,552,538,000**	**$1,664,095,000**	**$111,557,000**
99.0 PROPOSED LAW DIRECT OBLIGATION	**$1,332,311,000**	**$1,611,620,000**	**$1,727,300,000**	**$115,680,000**
FTE [3]	**8,989**	**9,982**	**10,459**	**477**

Note: This table does not reflect comparable adjustment in FYs 2001 and 2002 as a result of the FY 2003 Legislation and Public Affairs Transfer to DHHS.

[1]Current Law reflects no comparability in FYs 2001 & 2002 for retirement accruals.

[2]Proposed Law reflects comparable adjustments in FYs 2001 & 2002 for retirement accruals as though the proposal had been in effect.

[3]Does not include Reimbursable FTE of 89 for each year.

Exhibit S

Food and Drug Administration - FY 2001
ALL PURPOSE TABLE - Proposed Retirement Accruals - Budget Authority
(Dollars in thousands)

PROGRAM	FY 2001 Current Estimate		FY 2001 Accrued Retirement	FY 2001 Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Foods	**2,389**	**$287,530**	**$14,078**	**2,389**	**$301,608**
Center	*865*	*125,729*	*5,097*	*865*	*130,826*
Field	*1,524*	*161,801*	*8,981*	*1,524*	*170,782*
Human Drugs	**1,921**	**218,527**	**11,466**	**1,921**	**229,993**
Center	*1,197*	*151,089*	*7,145*	*1,197*	*158,234*
Field	*724*	*67,438*	*4,321*	*724*	*71,759*
Biologics	**826**	**108,310**	**4,930**	**826**	**113,240**
Center	*604*	*86,242*	*3,605*	*604*	*89,847*
Field	*222*	*22,068*	*1,325*	*222*	*23,393*
Animal Drugs and Feeds	**454**	**64,075**	**2,710**	**454**	**66,785**
Center	*302*	*48,861*	*1,803*	*302*	*50,664*
Field	*152*	*15,214*	*907*	*152*	*16,121*
Devices and Radiological Health	**1,423**	**165,316**	**8,045**	**1,423**	**173,361**
Center	*966*	*122,077*	*5,461*	*966*	*127,538*
Field	*457*	*43,239*	*2,584*	*457*	*45,823*
National Center for Toxicological Research	**227**	**36,249**	**2,011**	**227**	**38,260**
Other Activities	**638**	**67,992**	**3,637**	**638**	**71,629**
Office of the Commissioner	*87*	*10,009*	*563*	*87*	*10,572*
Office of Management & Systems	*339*	*29,551*	*2,132*	*339*	*31,683*
Office of Senior Associate Commissioner	*76*	*7,772*	*295*	*76*	*8,067*
Office of International & Constituent Relations	*56*	*6,370*	*322*	*56*	*6,692*
Office of Policy, Planning, & Legislation	*80*	*7,453*	*325*	*80*	*7,778*
Central Services	*0*	*6,837*	*0*	*0*	*6,837*
Other Rent and Rent Related Activities	**0**	**30,898**	**0**	**0**	**30,898**
GSA Rental Payments	**0**	**87,276**	**0**	**0**	**87,276**
SUBTOTAL, Salaries & Expenses	**7,878**	**$ 1,066,173**	**$ 46,877**	**7,878**	**$ 1,113,050**
Center Activities	*4,799*	*638,239*	*28,760*	*4,799*	*666,999*
Field Activities	*3,079*	*309,760*	*18,117*	*3,079*	*327,877*
Rent Activities	*0*	*118,174*	*0*	*0*	*118,174*
Buildings and Facilities		**$31,281**			**$31,281**
TOTAL Budget Authority	**7,878**	**$1,097,454**	**$46,877**	**7,878**	**$1,144,331**

Exhibit S

Food and Drug Administration - FY 2002
ALL PURPOSE TABLE - Proposed Retirement Accruals - Budget Authority

(Dollars in thousands)

PROGRAM	FY 2002 Current Estimate		FY 2002 Accrued Retirement	FY 2002 Actual Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Foods	**2,851**	**$404,599**	**$16,856**	**2,851**	**$421,455**
Center	*909*	*145,293*	*5,374*	*909*	*150,667*
Field	*1,942*	*259,306*	*11,482*	*1,942*	*270,788*
Human Drugs	**2,019**	**260,709**	**11,841**	**2,019**	**272,550**
Center	*1,251*	*183,531*	*7,337*	*1,251*	*190,868*
Field	*768*	*77,178*	*4,504*	*768*	*81,682*
Biologics	**937**	**140,331**	**5,496**	**937**	**145,827**
Center	*689*	*112,456*	*4,041*	*689*	*116,497*
Field	*248*	*27,875*	*1,455*	*248*	*29,330*
Animal Drugs and Feeds	**594**	**86,467**	**3,484**	**594**	**89,951**
Center	*320*	*56,041*	*1,877*	*320*	*57,918*
Field	*274*	*30,426*	*1,607*	*274*	*32,033*
Devices and Radiological Health	**1,477**	**181,021**	**7,932**	**1,477**	**188,953**
Center	*996*	*132,210*	*5,349*	*996*	*137,559*
Field	*481*	*48,811*	*2,583*	*481*	*51,394*
National Center for Toxicological Research	**237**	**42,882**	**1,983**	**237**	**44,865**
Other Activities	**664**	**77,137**	**3,590**	**664**	**80,727**
Office of the Commissioner	*101*	*12,429*	*595*	*101*	*13,024*
Office of Management & Systems	*350*	*34,670*	*2,102*	*350*	*36,772*
Office of Senior Associate Commissioner	*75*	*8,088*	*255*	*75*	*8,343*
Office of International & Constituent Relations	*57*	*7,207*	*357*	*57*	*7,564*
Office of Policy, Planning, & Legislation	*81*	*7,906*	*281*	*81*	*8,187*
Central Services	*0*	*6,837*	*0*	*0*	*6,837*
Other Rent and Rent Related Activities	**0**	**42,748**	**0**	**0**	**42,748**
GSA Rental Payments	**0**	**98,876**	**0**	**0**	**98,876**
SUBTOTAL, Salaries & Expenses	**8,779**	**$ 1,334,770**	**$ 51,182**	**8,779**	**$ 1,385,952**
Center Activities	*5,066*	*749,550*	*29,551*	*5,066*	*779,101*
Field Activities	*3,713*	*443,596*	*21,631*	*3,713*	*465,227*
Rent Activities	*0*	*141,624*	*0*	*0*	*141,624*
Buildings and Facilities		**$34,281**			**$34,281**
TOTAL Budget Authority	**8,779**	**$1,369,051**	**$51,182**	**8,779**	**$1,420,233**

Exhibit S

Food and Drug Administration - FY 2003
ALL PURPOSE TABLE - Proposed Retirement Accruals - Budget Authority
(Dollars in thousands)

PROGRAM	FY 2003 Current Estimate		FY 2003 Accrued Retirement	FY 2003 Actual Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Foods	**3,098**	**$412,097**	**$17,919**	**3,098**	**$430,016**
Center	*922*	*148,112*	*5,333*	*922*	*153,445*
Field	*2,176*	*263,985*	*12,586*	*2,176*	*276,571*
Human Drugs	**2,108**	**277,317**	**13,056**	**2,108**	**290,373**
Center	*1,292*	*190,528*	*8,002*	*1,292*	*198,530*
Field	*816*	*86,789*	*5,054*	*816*	*91,843*
Biologics	**977**	**146,849**	**6,051**	**977**	**152,900**
Center	*727*	*118,414*	*4,503*	*727*	*122,917*
Field	*250*	*28,435*	*1,548*	*250*	*29,983*
Animal Drugs and Feeds	**612**	**88,972**	**3,790**	**612**	**92,762**
Center	*325*	*57,875*	*2,013*	*325*	*59,888*
Field	*287*	*31,097*	*1,777*	*287*	*32,874*
Devices and Radiological Health	**1,501**	**190,720**	**7,964**	**1,501**	**198,684**
Center	*1,000*	*137,420*	*5,306*	*1,000*	*142,726*
Field	*501*	*53,300*	*2,658*	*501*	*55,958*
National Center for Toxicological Research	**238**	**40,688**	**1,989**	**238**	**42,677**
Other Activities	**582**	**77,688**	**3,982**	**582**	**81,670**
Office of the Commissioner	*105*	*13,416*	*717*	*105*	*14,133*
Office of Management & Systems	*346*	*40,671*	*2,349*	*346*	*43,020*
Office of Senior Associate Commissioner	*27*	*4,040*	*199*	*27*	*4,239*
Office of International & Constituent Relations	*57*	*7,410*	*398*	*57*	*7,808*
Office of Policy, Planning, & Legislation	*47*	*5,659*	*319*	*47*	*5,978*
Central Services	*0*	*6,492*	*0*	*0*	*6,492*
Other Rent and Rent Related Activities	**0**	**36,498**	**0**	**0**	**36,498**
GSA Rental Payments	**0**	**98,556**	**0**	**0**	**98,556**
SUBTOTAL, Salaries & Expenses	**9,116**	**$ 1,369,385**	**$ 54,751**	**9,116**	**$ 1,424,136**
Center Activities	*5,086*	*770,725*	*31,127*	*5,086*	*801,852*
Field Activities	*4,030*	*463,606*	*23,623*	*4,030*	*487,229*
Rent Activities	*0*	*135,054*	*0*	*0*	*135,054*
Buildings and Facilities		**$8,000**			**$8,000**
TOTAL Budget Authority	**9,116**	**$1,377,385**	**$54,751**	**9,116**	**$1,432,136**

Exhibit S

Food and Drug Administration - FY 2001
ALL PURPOSE TABLE - Proposed Retirement Accruals - User Fees
(Dollars in thousands)

PROGRAM	FY 2001 Current Estimate		FY 2001 Accrued Retirement	FY 2001 Actual Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Human Drugs (PDUFA)	**702**	**$99,298**	**$4,324**	**702**	**$103,622**
Center	*635*	*92,615*	*3,911*	*635*	*96,526*
Field	*67*	*6,683*	*413*	*67*	*7,096*
Biologics (PDUFA)	**253**	**$32,154**	**1,559**	**253**	**33,713**
Center	*246*	*31,484*	*1,516*	*246*	*33,000*
Field	*7*	*670*	*43*	*7*	*713*
Other Activities (PDUFA)	**127**	**11,961**	**782**	**127**	**12,743**
Office of the Commissioner	*17*	*1,793*	*105*	*17*	*1,898*
Office of Management & Systems	*64*	*5,702*	*394*	*64*	*6,096*
Office of Senior Associate Commissioner	*21*	*1,932*	*129*	*21*	*2,061*
Office of International & Constituent Relations	*9*	*925*	*55*	*9*	*980*
Office of Policy, Planning, & Legislation	*16*	*1,609*	*99*	*16*	*1,708*
GSA Rental Payments (PDUFA)	**0**	**5,860**		**0**	**5,860**
SUBTOTAL, Definite Appropriations	**1,082**	**$149,273**	**$6,665**	**1,082**	**$155,938**
Indefinite Appropriations:					
MQSA	**50**	**$15,128**	**$308**	**50**	**$15,436**
Devices & Radiological Health	48	14,947	296	*48*	15,243
Center	*32*	*4,627*	*197*	*32*	*4,824*
Field	*16*	*10,320*	*99*	*16*	*10,419*
Other Activities	*2*	*181*	*12*	*2*	*193*
Export Certification	**13**	**1,500**	**80**	**13**	**1,580**
Color Certification Fund	**38**	**4,492**	**234**	**38**	**4,726**
Subtotal, Indefinite Appropriations	**101**	**$21,120**	**$622**	**101**	**$21,742**
Total, Current Law User Fees	**1,183**	**$170,393**	**$7,287**	**1,183**	**$177,680**
Center Activities	1,093	146,860	6,732	1,093	153,592
Field Activities	90	17,673	555	90	18,228
Rent Activities	0	5,860	0	0	5,860

Exhibit S

Food and Drug Administration - FY 2002
ALL PURPOSE TABLE - Proposed Retirement Accruals - User Fees
(Dollars in thousands)

PROGRAM	FY 2002 Current Estimate		FY 2002 Accrued Retirement	FY 2002 Actual Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Human Drugs (PDUFA)	**722**	**$106,188**	**$4,741**	**722**	**$110,929**
Center	*655*	*98,338*	*4,301*	*655*	*102,639*
Field	*67*	*7,850*	*440*	*67*	*8,290*
Biologics (PDUFA)	**253**	**35,344**	**1,662**	**253**	**37,006**
Center	*246*	*34,466*	*1,616*	*246*	*36,082*
Field	*7*	*878*	*46*	*7*	*924*
Other Activities (PDUFA)	**127**	**13,944**	**834**	**127**	**14,778**
Office of the Commissioner	*17*	*2,090*	*112*	*17*	*2,202*
Office of Management & Systems	*64*	*6,648*	*420*	*64*	*7,068*
Office of Senior Associate Commissioner	*21*	*2,252*	*138*	*21*	*2,390*
Office of International & Constituent Relation	*9*	*1,078*	*59*	*9*	*1,137*
Office of Policy, Planning, & Legislation	*16*	*1,876*	*105*	*16*	*1,981*
GSA Rental Payments (PDUFA)	**0**	**6,240**		**0**	**6,240**
SUBTOTAL, Definite Appropriations	**1,102**	**$161,716**	**$7,237**	**1,102**	**$168,953**
Indefinite Appropriations:					
MQSA	**50**	**$15,590**	**$328**	**50**	**$15,918**
Devices & Radiological Health	48	15,404	315	*48*	15,719
Center	*32*	*4,768*	*210*	*32*	*4,978*
Field	*16*	*10,636*	*105*	*16*	*10,741*
Other Activities	*2*	*186*	*13*	*2*	*199*
Export Certification	**13**	**1,500**	**85**	**13**	**1,585**
Color Certification Fund	**38**	**4,681**	**250**	**38**	**4,931**
Subtotal, Indefinite Appropriations	**101**	**$21,771**	**$663**	**101**	**$22,434**
Total, Current Law User Fees	**1,203**	**$183,487**	**$7,900**	**1,203**	**$191,387**
Center Activities	1,113	157,883	7,309	1,113	165,192
Field Activities	90	19,364	591	90	19,955
Rent Activities	0	6,240	0	0	6,240

Food and Drug Administration - FY 2003

Exhibit S

ALL PURPOSE TABLE - Proposed Retirement Accruals - User Fees

(Dollars in thousands)

PROGRAM	FY 2003 Current Estimate		FY 2003 Accrued Retirement	FY 2003 Actual Proposed Law	
	FTE	$	$	FTE	$
Salaries and Expenses:					
Proposed User Fees					
Human Drugs (PDUFA)	**821**	**$180,662**	**$5,168**	**821**	**$185,830**
Center	*742*	*165,412*	*4,671*	*742*	*170,083*
Field	*79*	*15,250*	*497*	*79*	*15,747*
Biologics (PDUFA)	**294**	**62,474**	**1,850**	**294**	**64,324**
Center	*283*	*60,496*	*1,781*	*283*	*62,277*
Field	*11*	*1,978*	*69*	*11*	*2,047*
Other Activities (PDUFA)	**127**	**13,944**	**800**	**127**	**14,744**
Office of the Commissioner	*17*	*2,090*	*107*	*17*	*2,197*
Office of Management & Systems	*64*	*6,648*	*403*	*64*	*7,051*
Office of Senior Associate Commissioner	*21*	*2,252*	*132*	*21*	*2,384*
Office of International & Constituent Relation	*9*	*1,078*	*57*	*9*	*1,135*
Office of Policy, Planning, & Legislation	*16*	*1,876*	*101*	*16*	*1,977*
GSA Rental Payments (PDUFA)	**0**	**7,140**		**0**	**7,140**
Subtotal, Proposed User Fees	**1,242**	**$264,220**	**$7,818**	**1,242**	**$272,038**
Center Activities	1,152	239,852	7,252	1,152	247,104
Field Activities	90	17,228	566	90	17,794
Rent Activities	0	7,140	0	0	7,140
Current Law User Fees					
MQSA	**50**	**$16,112**	**$315**	**50**	**$16,427**
Devices & Radiological Health	48	15,920	302	*48*	16,222
Center	*32*	*4,927*	*201*	*32*	*5,128*
Field	*16*	*10,993*	*101*	*16*	*11,094*
Other Activities	*2*	*192*	*13*	*2*	*205*
Export Certification	**13**	**1,500**	**82**	**13**	**1,582**
Color Certification Fund	**38**	**4,878**	**239**	**38**	**5,117**
Subtotal, Current Law User Fees	**101**	**$22,490**	**$636**	**101**	**$23,126**
Center Activities	85	11,497	535	85	12,032
Field Activities	16	10,993	101	16	11,094
Total, User Fees	**1,343**	**$286,710**	**$8,454**	**1,343**	**$295,164**
Center Activities	1,237	251,349	7,787	1,237	259,136
Field Activities	106	28,221	667	106	28,888
Rent Activities	0	7,140	0	0	7,140

EXTRAMURAL RESEARCH FUNDING -- FY 2001

STATE	RECIPIENT	PROJECT TITLE	AMOUNT
AZ	University of Arizona	Role of Irrigation Methods on Microbial Food Safety	$178,717
CA	University of California	DCA Treatment of Congenital Lactic Acidemia	$148,929
CA	University of Southern California	Novel Adjuvants for Peptide-Based Melanoma Vaccines	$376,891
CA	Children's Hospital Oakland	Arginine Therapy for Acute Chest Syndrome in Sickle Cell	$294,613
CA	Harbor-UCLA Research & Education Inst.	L-glutamine therapy for Sickle Cell Anemia	$347,409
CA	University of California, Davis	Effects of Previously S. enteritidis Contaminated Poultry Environ.	$59,294
CN	Neurochem Inc.	Safety & Efficacy of NC-503 in Secondary Amyloidosis	$298,394
CO	Cochlear Corporation	Penetrating Auditory Brainstem Implant for Neurofibromatosis 2	$150,000
CO	Colorado State University	Antimicrobial Use and Resistance in Enteric Bacteria	$196,518
DC	National Academy of Sciences	Nutrient Requirements of Domestic Animals & Critical Roles	$100,000
FL	University of Florida	Dichloroacetate Treatment of Congenital Lactic Acidosis	$25,000
FL	University of Florida	Prevention of Dichloroacetate Toxicity	$414,625
FL	Florida Department of Health	Development of Methods for Virus Extraction from Food	$201,770
GA	University of Georgia Research Found.	Dose Response Model for Food Borne Listeria	$151,950
GA	University of Georgia Research Found.	Inactivation of Pathogens on Produce by GRAS Chemicals	$57,807
GA	University of Georgia Research Found.	Non Thermal Method of Enhance Safety of Fresh Produce	$68,097
GA	University of Georgia Research Found.	Does Antibiotic Usage Create Drug-Resistant Campylobactor	$194,750
GA	University of Georgia Research Found.	Foodborne Protozoa: Inoculation & Inactivation Methods	$103,125
IA	University of Iowa Hospitals and Clinics	OK-432 Sclerotherapy - A Multicenter Trial	$265,800
IA	Iowa State University	Veterinary Antimicrobial Decision Support System (VADS)	$249,253
IL	Northwestern University	Multi-Center Trial of TPN-Associated Liver Disease	$252,481
IL	Illinois Institute Technology	National Center for Food Safety & Technology (NCFST)	$3,060,375
IN	Indiana University	Indiana University Clinical Pharmacology	$649,995
IN	Purdue Research Foundation	Effect of Inoculation on Efficacy of Chlorine Dioxide Gas	$111,021
KY	Phoenix Pharmacologics, Inc.	Testing of ADI-PEG in Metastatic melanoma	$143,675
LA	Tulane School of Public Health	Phase I Studies of an Investigational Aminoquinoline	$148,500
MA	Boston University	Arginine Butyrate & Ganciclovir in Epstein Barr Virus	$163,000
MA	Dana-Farber Cancer Institute	Defibrotide for Severe Hepatic Veno-occlusive	$386,314
MA	Children's Hospital	Effect Inhaled Nitric Oxide Pediatric Sickle Pain Crisis	$141,977
MA	Massachusetts General Hospital	Minocycline Dosing & Safety in Huntington's Disease	$320,318
MA	Massachusetts General Hospital	TheraDerm Administration in Women with Hypopituitarism	$471,088
MA	Holles Laboratories, Inc.	Topical DEHYDREX in Treating Recurrent Corneal Erosion	$250,000
MA	Trustees of Boston University	Studies of Adverse Effects of marketed Drugs	$300,000
MD	Johns Hopkins University	Eff. of Abendazole Therapy in Epilepsy due to Cysticercosis	$18,000
MD	Chen Ophthalmic Laboratories	Trial on Safety/Efficacy of a New Cornea Storage Media	$30,588
MD	Johns Hopkins University	Enbrel in Wegener's Granulomatosis Phase Ii	$253,575
MD	John Hopkins University	Intraventricular Hemorrhage Thrombolysis Trial	$376,511
MD	Sigma-Tau Pharmaceuticals, Inc.	Cysteamine Hydrochloride Eye Drops	$89,100
MD	Johns Hopkins University	Intraventricular rt-PA Pharmacokinetic and Pharmcodynamic Study	$170,211
MD	University of Maryland	Joint Inst. for Food Safety & Applied Nutrition (JIFSAN)	$2,782,800
MI	University of Michigan	Prevention of TPN-Chloestasis with Cholecystokinin	$68,175
MI	University of Michigan	Etanercept for Non-Infectious Lung Injury following Bone Marrow	$213,067
MI	University of Michigan	Keratinocyte Growth Factor to Prevent Acute GVHD	$220,780
MI	Univ. of Michigan	Therapy of Wilson's Disease with Tetrathiomolybdate	$71,156
MI	Michigan State University	Transfer Coefficients for Listeria Cross-Contamination	$147,142
MN	Mayo Clinic Rochester	Giant Cell Myocaritis Treatment Trial Pilot Study	$175,531
MO	Washington University	Efficacy & Toxicity of Infusional Arsenic Trioxide in APML	$155,489
MO	University of Missouri - Columbia	Effect of Genistein on the Nasal Potential Diff. In C.F.	$28,836
MS	University of Mississippi	Botanical Dietary Supplements: Science-Base for Authentication	$839,611
MX	Fundacion Mexicana para la Salud	Susceptibility of Foodborne pathogens from Humans/Food/Animals	$388,823
NC	Duke University Medical Center	Intrathecal busulfan Therapy of Neoplastic Meningtis	$19,276

STATE	RECIPIENT	PROJECT TITLE	AMOUNT
NC	North Carolina State University	Antimicrobial Resistance of Salmonella Isolated from Swine	$118,514
NC	University of North Carolina at Chapel Hill	Development of Viral Extraction Processing & Detection Methods	$186,657
NC	Research Triangle Institute	Consumer Storage Length Practices for Ready-to-Eat Foods	$139,980
NJ	Rutgers University	Irrigation Water Quality	$101,347
NM	New Mexico State University	WERC Design Contest	$100,000
NY	State University of New York	Collagenase in the Treatment of Dupuytren's Disease	$72,167
NY	Mount Sinai School of Medicine	Fluoxetine vs. Placebo in Adult Autistic Disorder	$345,392
NY	Mount Sinai School of Medicine	IL-2 in Common Variable Immunodeficiency	$254,250
NY	Mount Sinai Medical Center	Liquid Fluoxetine vs. Placebo in Child Autism	$193,852
NY	Research Foundation at SUNY	Cyclophosphamide to Mycophenolate Mofetil	$301,943
NY	University of Rochester Medical Center	Mexiletine Treatment of Myotonic Dystrophy	$345,604
NY	Sloan-Kettering Institute for Cancer Res.	Phase II Trial of Bryostatin-1 & Paclitaxel in Patients with Espo.	$333,000
OH	University of Cincinnati	Cultured Skin Substitutes for Closure of Burn Wounds	$302,382
OH	Case Western Reserve University	Implantable FNS System for Standing Transfers	$259,975
OH	Children's Hospital Medical Center	Anti-resorptive Bone Therapy for Osteopenia In Gaucher Disease	$74,000
OH	Children's Hospital Medical Center	Multisite Trial of Pergolide in Children with Tourette's	$245,410
OH	Case Western Reserve University	Electrical Activation of Diaphragm for Ventilatory Assist	$191,868
OH	Cleveland Clinic Foundation	Trial of Gm-CSF for Alveolar Proteinosis	$384,433
OH	Ohio State University Research Foundation	Clinical Trials of Albuterol & Oxandrolone in FSH Dystrophy	$320,013
OH	BIOMEC Systems, Inc.	Nitroprusside Autoinfusor	$82,213
PA	University of Pittsburgh	Calcitriol & Dexamethasone for Myelodysplastic Syndrome	$423,606
SC	Medical University of South Carolina	Phase II Study of Alendronate in Juvenile Osteopooroosis	$154,892
TN	Vanderbilt University Medical Center	Growth Hormone in Renal Failure	$27,000
TN	Tennessee State University	Home Refirgeration Knowledge and Practaices of Consumers	$188,364
TN	Tennessee State University	Role of Irrigation Methods on Microbial Food Safety	$144,659
TX	Retina Foundation of the Southwest	DHA Supplementation & X-linked Retinitis Pigmentosa	$13,924
TX	University of Texas Medical Branch	Tin Mesoporphyrin and Heme Therapy in Acute Porphyria	$72,450
TX	University of Texas SW Medical Center	Phase I Trials of d-MSH	$153,984
TX	University of Texas MD Anderson Cancer	Development of ATRAGEN (Liposomal Tretinoin) for Pts with Relapsed	$291,188
TX	University of Texas MD Anderson Cancer	Subcutaneous Homoharringtonine in Chronic Myelogenous Leukemia	$193,664
TX	University of Texas MD Anderson Cancer Cntr	HHT, IFN-A & Ara-C in Early Chronic Myelogenous Leukemia	$240,000
TX	University of Texas MD Anderson Cancer	Clofarabine in Chronic Lymphocytic Leukemia	$220,968
TX	Texas A&M University	Development of Cell and Nanoparticle Based Sensors for BSE	$100,635
VA	Lighthouse Instruments LLC	Validation of a Rapid and Nondestructive Gas Analyzer	$401,017
WA	University of Washington	Treatment of Tyrosinemia-I with NTBC	$203,646
WA	Children's Hospital and Regional Medical Center	Triostat in Children During CPB	$405,080
WA	Washington State University	Livestock Feeds as a Means of Dissemination of Antimicrobial	$197,473
WI	Third Wave Technologies, Inc.	DNA-based Detection of Genetically Modified Organisms	$99,770
	TOTAL		**$24,259,177**

SIGNIFICANT ITEMS FROM HOUSE, SENATE, AND CONFERENCE REPORTS APPROPRIATIONS SUBCOMMITTEES FY 2002 BUDGET

House Report No. 107-116

Item

Dietary Supplement Adverse Event Reports -- The July 1999 General Accounting Office report (GGD 99 90) on dietary supplements found that the Adverse Event Report system used by the FDA needs to be improved. Furthermore, the GAO made specific recommendations to the FDA on what action should be taken to address this situation. More recently, in April 2001, the Office of the Inspector General (OIG) of the Department of Health and Human Services made further recommendations for enhancing the quality and capability of the FDA's AER system for dietary supplements. The Committee is concerned that the FDA has not taken proper steps to address the concerns outlined in the GAO and OIG reports. Therefore, the Committee directs the FDA to follow the recommendations made by these reports as a part of the agency's overall plan to consolidate and improve the AER system.

Action Taken or To Be Taken

GAO/OIG concluded that without further development of the overall regulatory framework for dietary supplements, the potential of the system to serve as a consumer safeguard is inherently limited. The program simply cannot serve as an adequate safety valve until other measures are taken that will allow FDA to generate and confirm signals of possible public health concerns. They encourage FDA to seek the authority it needs to require manufacturer and product registration and mandatory manufacturer reporting of adverse events.

CFSAN is developing a new adverse event report system, called the CFSAN Adverse Event Reporting System (CAERS). CAERS is being designed to capture and analyze all reports of consumer complaints and adverse events related to CFSAN-regulated products, including functional foods and dietary supplements. This system will incorporate all existing Center adverse events reporting systems into one state-of-the-art reporting and monitoring system. CAERS will capture information received from various formats, including electronic submissions through the field offices and other Center systems, paper submissions, telephone calls and Congressional inquiries

In FY 2001, FDA completed the development of the 1st prototype model of CAERS. The development of the CAERS prototype will allow a small group of selected users to test the CAERS system and determine its functionality, practicality and quality. Results of this testing will allow for further enhancements and modifications to be made to the system.

In FY 2002, FDA will (1) develop standard operating procedures and pilot test new systems for the processing of adverse events and (2) establish a system that makes adverse event reports promptly available to manufacturers, including the timely redaction of confidential information.

Item

Food Safety -- To enhance food safety, the Committee supports the expedited review of food additive petitions that are designed to decrease the risk of foodborne illness. FDA has implemented an expedited review process for such petitions. The Committee notes that despite this effort, unacceptable delays persist regarding actions that would permit the expanded use of pathogen-reducing technologies. The Committee directs FDA to explore additional activities that would permit the expanded use of pathogen-reducing technologies, particularly including more timely review, food additive petition process enhancements such as premarket consultations for petitions for new uses of irradiation, and developing irradiation labeling that is better understood by the general public.

Action Taken or To Be Taken

To further expedite the review of food additive petitions, especially those relating to pathogen-reducing technology, the Agency will develop guidance for pre-filing consultations for new petitions and notifications. In addition, FDA will communicate with prospective submitters to encourage pre-filing consultations for new petitions and notifications. Finally, FDA will implement a system for electronic submission of food and color additive petitions, provide general guidance for all types of submissions in electronic format, and provide appropriate training to submitters.

Item

Labeling of Irradiated Foods -- FDA is in the process of developing a proposed rule related to the current labeling requirements for foods that are treated with ionizing radiation. The Committee understands that FDA regulations currently permit labeling that explains why the food is being irradiated, as long as the labeling is truthful and not misleading. The Committee believes that any required disclosure should not be perceived as a warning or give rise to inappropriate consumer anxiety. The Committee believes the FDA should consider as part of its rulemaking process a proposal to include only those labeling alternatives that are easily understood by the general public.

Action Taken or To Be Taken

FDA conducted focus group research to understand how consumers react to alternative formats of irradiation labeling. Two focus group meetings were conducted in Maryland on June 18; two groups in California on July 9; and two groups in Minnesota on July 11. Each group consisted of 7 to 10 people recruited at random by telephone from large lists of the general population. A

final report on the irradiation labeling focus groups will be finalized and made available on the Center for Food Safety and Applied Research 's (CFSAN) Web site in FY 2002. Following completion of the report, FDA will report the findings to Congress.

Item

Shellfish Safety -- The Committee expects that FDA will continue its work with the Interstate Shellfish Sanitation Commission (ISSC) to promote educational and research activities related to shellfish safety in general, and Vibrio vulnificus in particular. The Committee directs the use of $250,000 for this effort from within sums provided for food safety. In addition, the Committee understands that FDA's Office of Seafood has a memorandum of understanding with ISSC to work on assuring the safety and quality of shellfish, including regulation development when needed. The Committee directs that FDA continue this work with the ISSC, and that FDA continue to devote not less than $200,000 to these efforts.

Action Taken or To Be Taken

FDA's laboratory at Dauphin Island, Alabama, is almost entirely dedicated to research projects designed to improve safety measures for molluscan shellfish. Such safety measures would be applied through control strategies adopted by the ISSC for use by state programs. CFSAN will continue funding in FY 2002.

Item

Shellfish Safety Goals -- While the Committee supports the efforts by the Food and Drug Administration in reducing the rate of illness due to Vibrio vulnificus, it is concerned about the achievability of the illness rate reduction goals and the severity of consequences for failure in reaching those goals being proposed by the Interstate Shellfish Sanitation Conference (ISSC). The Committee encourages FDA and the ISSC to work with the state regulatory authorities and industry to ensure that the impact to the affected states is understood and mitigated as these reduction goals are developed, consistent with latest scientific information available. Furthermore, the Committee supports the continued emphasis on education of at-risk individuals and their medical caretakers.

Action Taken or To Be Taken

FDA incorporated the Congressional request relating to shellfish safety goals into CFSAN's FY2002 Program Priority Workplan as an "A-list" goal. By doing so, FDA is committed to meeting the illness rate reduction goals proposed by the ISSC. CFSAN's FY 2002 Program Priority Workplan represents CFSAN work product expectations for the current fiscal year. It contains three tiers of goals in the document: the "A" list, B* list, and the "B" list. Our "A" list tier includes those goals that CFSAN must accomplish within the current fiscal year. CFSAN has given this report its highest priority and intends to respond to Congress before the end of FY

2002. FDA and ISSC will continue to work with the state regulatory authorities and industry in re-emphasizing the risk factors involved with Vibrio vulnificus.

Item

Secondary Wholesale Pharmaceutical Industry -- The Committee supports the recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until April 1, 2002. The Committee is concerned about the potential impact of the proposed revisions on the secondary wholesale pharmaceutical industry. Specifically, the Committee is concerned that the rule in its current form may disproportionately favor a few large distributors at the expense of consumers and genuine competition in the marketplace. The Committee urges the FDA to revise the rule to address the Committee's concerns.

Action Taken or To Be Taken

The Agency expects to publish a Federal Register notice in the early part of 2002 that will further delay the effective date of the requirements relating to wholesale distribution of prescription drugs by distributors until mid-year 2003.

FDA has prepared a report for congress and concluded that although FDA can address some of industry's concerns with the PDMA regulation through regulatory changes, other concerns would have to be addressed by congress through legislative action. The further delay is necessary to give congress time to consider the information and conclusions contained in the agency's report, and to determine if legislative action is appropriate. The further delay will also give the agency additional time to consider whether regulatory changes are appropriate and, if so, to initiate such changes.

Item

Breast Implants -- The Committee is concerned about a recent FDA study revealing alarmingly high rupture rates in silicone breast implants and the agency's decision to approve saline breast implants in spite of high complication and failure rates--particularly among mastectomy patients. The Committee advises the agency to carefully monitor breast implant manufacturers' patient brochures, informed consent documents, and package inserts to ensure they reflect accurate information about such implants, and to work with manufacturers to ensure women receive full and accurate information before enrolling in any study or undergoing surgery.

Action Taken or To Be Taken

FDA has various avenues for providing the latest information about breast implants to assist patients in making an informed decision about whether or not to have breast implants.

For any approved breast implant (to date there are only two - Mentor Corporation and McGhan Medical saline breast implants), patient labeling is required, typically in the form of a patient

brochure. Unlike the informed consent document, this includes actual study results for that given implant. Mentor and McGhan should provide all physician customers with patient labeling that physicians may disseminate to all prospective patients seeking breast implant information. As a condition of approval for their Premarket Approval (PMA) Device Applications, Mentor and McGhan completed a focus group study to improve the patient labeling. Modifications based on the focus group's study findings have been made and the updated patient labeling will be finalized after incorporation of 5-year study data from their post-approval studies. Mentor and McGhan's package inserts are directed to the physician and contain much of the same information in the patient labeling. The package inserts will also be revised to reflect 5-year post-approval study results.

For any investigational breast implant, whether, silicone gel, saline, or an alternative filler, FDA requires an informed consent document as part of the Investigational Device Exemption (IDE) application. The manufacturer may also choose, but is not required, to have supplemental patient labeling; however, this is not typical for the breast implant IDEs because of what the agency now requires in informed consent documents. Manufacturers provide informed consent documents to the participating IDE investigators. In accordance with the IDE protocol, the investigators must have the patient sign the informed consent document prior to surgery. In the past, FDA required the manufacturer to update their informed consent documents to reflect current published information on rupture/deflation rates. As necessary, we would request additional updates. In addition, each manufacturer has a study monitor to assure compliance with their IDE protocol. FDA's Bioresearch Monitoring Program (BIMO) periodically performs inspections to check the compliance with the IDE protocol.

To improve the dissemination of information to patients, the agency continues to update its FDA breast implant website at http://www.fda.gov/cdrh/breastimplants. This website includes, among other things, the approved patient labeling for the Mentor and McGhan saline breast implants and summaries of FDA breast implant studies. Additionally, the website includes FDA's updated consumer handbook, "Breast Implants - An Informational Update - 2000," available at http://www.fda.gov/cdrh/breastimplants/indexbip.html. This handbook includes more information regarding potential local breast implant complications and their reported frequency, as well as important factors for patients to consider in their decision whether or not to receive breast implants. Along with the publication of the breast implant consumer handbook, FDA also published a risk brochure in October 2000 to provide information about complications associated with the use of breast implants. This risk brochure is also available on our FDA breast implant website.

In FY 2001, FDA issued a revised breast implant guidance entitled, "Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry." This guidance provides important preclinical, clinical, and labeling information that should be presented in an investigational device exemptions (IDE), a premarket approval (PMA), or a product development protocol (PDP) application.

Item

Import Inspections -- The Committee remains concerned that the FDA physically inspects less than one percent of products imported into our country. The Committee is also concerned about the increasing and tremendous strain on inspection resources brought about by the flood of new imports coming into this country as a result of free trade agreements. The Committee encourages the FDA to consider the import program a priority in the agency's risk-based inspection system.

Action Taken or To Be Taken

FDA considers the import program a top priority in the Agency's risk-based inspection system and will continue to provide additional funding in support of its nationwide import coverage program. FDA is committed to supporting the Southwest Import District pilot which coordinates import activities on the southern border. Implementing reciprocal FDA and U.S. Customs training will improve product integrity of goods offered for import and increase enforcement actions by Customs to deter willful violations of U.S. laws and regulations. The Counter Terrorism supplemental budget in FY 2002 will allow for FDA to hire additional staff, including investigators stationed at the border who will be trained to conduct physical inspection of imports, compliance officers who will be able to take regulatory action against violative imported products, and laboratory analysts who will be trained to conduct laboratory analyses of imported products. These actions will eventually result in a dramatic increase in the number of imports physically examined.

Senate Report 107-41

Item

WERC -- The Committee expects the FDA to continue its support for the Waste Management Education and Research Consortium (WERC) and its work in food safety technology verification and education. With the growing threat of foodborne illness to the public health, the Committee believes that collaborative research in food safety should continue among government, academia, and private industry. The national model for that collaboration has been the National Center for Food Safety and Technology (NCFST) in Summit-Argo, Illinois. The Committee expects the FDA to maintain at least $3,000,000 as the annual base level of funding for the National Center to continue the important work done there.

Action Taken or To Be Taken

In FY 2002, CFSAN will continue support of the Waste Management Education and Research Consortium (WERC) through a cooperative agreement, and aims to reduce pathogenic bacteria from entering the food chain as environmental contaminants. The Agency will continue to provide at least $3,000,000 to support The National Center for Food Safety and Technology's (NCFST) collaborative research in the area of food safety. FDA continues to believe that NCFST is cost effective resource for developing and exploring new technologies. This cooperative arrangement benefits the Agency, industry, and academia by spreading the cost and risk of doing research, while providing the opportunity positive returns on investment.

Item

Biotechnology -- The Committee understands that the FDA frequently receives requests from foreign governments for FDA regulators to visit foreign countries to educate regulators on the evaluation of the safety of biotechnology. Providing information on the soundness of the U.S. regulatory process will promote the understanding of the benefits of biotechnology to human health and the environment and improve the climate for acceptance of U.S. agricultural products abroad. The Committee directs the FDA to allocate adequate funding so that agency representatives may perform this service.

Action Taken or To Be Taken

FDA gives high priority to requests made by foreign governments, particularly health authorities, for information about FDA's food biotechnology policy, and the Agency will make every effort to accommodate those requests. FDA also considers other requests, such as requests from other US agencies, based on our available resources. FDA will allocate the necessary resources to continue this activity through FY 2002.

Item

Biotechnology Labeling -- The Committee commends FDA for its ``Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Note Been Developed Using Bioengineering" (66 Federal Register 4839), released on January 18, 2001. The Committee urges FDA to expeditiously publish a final version of this guidance.

Action Taken or To Be Taken

CFSAN received a total of 150,000 comments to the ``Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Note Been Developed Using Bioengineering" (66 Fed. Reg. 4839) released on January 18, 2001. The Agency anticipates reviewing the comments during FY 2002. Once all comments have been reviewed, FDA will incorporate comments as appropriate and proceed with developing the final guidance.

Item

Blood product safety -- The Committee is concerned FDA has not moved forward in finalizing its proposed rule to require manufacturer tracking of blood-derived products and prompt patient notification of adverse events. The Committee urges FDA to complete implementation of this important blood product safety mechanism.

Action Taken or To Be Taken

We recognize the value of a Patient Safety Notification System for plasma derived products and have included this as part of our overall patient safety initiatives. We published an Advanced Notice of Proposed Rule Making and have collected and analyzed all comments received. Based on these comments, and further discussions, we have developed a proposed rule that we hope to publish in FY 2002. Pending an FDA regulation, Agency efforts were successful in prompting the plasma fractionation industry voluntarily to implement a patient notification system that is still in use. FDA's proposed requirements would further define and improve upon the existing voluntary system.

Item

Tissue Processing -- Over the past several years, there has been a growing concern about the transmission of CJD, vCJD and its related non-human counterpart mad cow disease. Processing multiple tissues from multiple donors could pose a substantial risk of transmitting CJD to those receiving tissue transplants. Pooling or batch processing could also result in transmission of many other diseases. For this reason, the American Association of Tissue Banks prohibits pooling of tissues for its members. The FDA has issued new rules regarding tissue processing. Those rules include a prohibition on pooling tissue from multiple donors but allow for a waiver under certain circumstances. FDA acknowledges that there is no scientific consensus at the present on how to inactivate CJD prions. Given this, the Committee believes FDA should

consider not granting proposed waivers from the pooling prohibition, unless the patient's safety can be guaranteed. The Committee also directs FDA to notify the House and Senate Committees on Appropriation prior to granting such a waiver.

Action Taken or To Be Taken

FDA solicited comments on its proposed rule for "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement," ("proposed good tissue practice rule"), published January 8, 2001, in the Federal Register. The proposed rule is part of the Agency's proposed comprehensive new system of regulating human cellular and tissue-based products ("the proposed approach"), announced in February 1997. The comment period ended May 8, 2001, and as of January 2002, the proposed rule has not yet been finalized. The proposed sections are 1271.220 (c) *Pooling,* and 1271.155 *Exemptions and alternatives.* FDA is reviewing the comments, and the Agency projects that the rule will be finalized in 2003. In finalizing the Good Tissue Practices (GTP) rule, the Agency will consider comments on the appropriate standards for granting exceptions to the pooling requirement.

Item

Tissue Processor Inspections -- Recently, the FDA instituted new regulations for tissue processors. All tissue banks are now required to register with the FDA. The number registering is substantially larger than the number known to exist prior to this rule. This means that a large number of facilities have been operating without any inspections by the FDA or another accrediting body. Therefore, the conditions under which tissues have been processed in these facilities are unknown. The Committee encourages FDA to move expeditiously to inspect all tissue facilities that have never been inspected by the agency by the end of fiscal year 2002.

Action Taken or To Be Taken

FDA regulations established a phased in registration system for tissue establishments. The establishments registering with FDA include establishments that recover, screen, test, process, store or distribute human tissue intended for transplantation. Not all of these are considered "banks" and many are not involved in processing. In addition to receiving registration from firms required to register by mid-2001, we are also voluntarily registering establishments that are not required to register until 2003, such as reproductive and stem cell establishments. Our strategy calls for inspecting firms required to register, with those that have not previously been inspected to take precedence over inspecting firms, which FDA previously inspected and found non-violative.

Item

Reused Medical Devices -- It has come to the Committee's attention that certain reprocessors of medical devices are obtaining devices for reprocessing by sorting through medical waste. The

Committee directs FDA to take enforcement action against reprocessors using inappropriate and unsanitary methods of collection of devices for reprocessing and to further ensure that all reprocessors are aware of what constitutes appropriate and sanitary collection.

Action Taken or To Be Taken

Currently, FDA is not aware of any commercial reprocessor (i.e., third party reprocessor) that is obtaining devices for reprocessing by sorting through medical waste.

However, FDA is aware that in 1999, Alliance Medical Corporation, a commercial reprocessor, maintained a decontamination station in Apopka, Florida, where employees used opened sharps containers to collect devices for reprocessing and reuse. When FDA learned of the activity occurring at Apopka, the Agency immediately issued an inspection of the facility. The inspection was conducted on November 17-19, 1999. Apparently, Alliance leased a room within the facilities of Stericycle/BFI Waste Systems where sharps containers were collected from local hospitals. The investigator determined that two Alliance personnel were assigned to sort and clean medical devices collected in disposable sharps containers. While performing these tasks, the employees were required to wear protective clothing (including surgical masks, safety goggles, latex gloves, heavy-duty gloves, gowns, foot covers, and hair covers). The devices were placed into two piles - one pile for devices found to be "acceptable" for reprocessing by Alliance and the second pile for devices "unacceptable" for reprocessing. The devices in the "acceptable" pile were cleaned and shipped to Alliance's Phoenix site for further processing. Devices in the "unacceptable" pile and the emptied disposable sharps containers were given to Stericycle/BFI to destroy by incineration.

At the conclusion of the inspection, FDA issued a list of Inspectional Observations that noted seven serious violations. As a result of the inspection, FDA issued a Warning Letter (dated December 23, 1999) to Alliance Medical. In a follow up inspection of the facility (on January 27, 2000), FDA determined that the objectionable conditions were corrected; however, Alliance Medical closed their Apopka facility shortly after FDA’s inspection.

Item

Device Reprocessing -- The Committee recognizes the important role that FDA plays in ensuring that every medical device used on a patient in the United States is both safe and effective for its intended use. Adhering to this principle, the FDA has issued new guidance for the reprocessing of single-use medical devices. The Committee is concerned that the FDA may consider allowing a single premarket submission for reprocessing of multiple models of a certain medical devices. FDA's own research indicates that minor modifications to a device can substantially alter the device's properties with regard to sterilization and reprocessing. This was stated by FDA's own scientists at the 1999 AAMI/FDA Conference entitled “The reuse of single-use devices.” Therefore, the Committee urges the FDA to require a premarket submission for every model that is to be reprocessed, if an application was required for the original manufactured device.

Action Taken or To Be Taken

FDA's premarket submission requirements are identical for all device manufacturers regardless of whether they are original equipment manufacturers or reprocessors of previously used devices intended by the original equipment manufacturers for single use. Also, one of the Agency's basic goals of the reuse of single use device policy is to regulate original equipment manufacturers and single use device reprocessors in the same manner. As such, FDA must allow reprocessors to include more than one model of the same device in a single premarket submission since this option is available to all original equipment manufacturers.

FDA allows manufacturers and reprocessors to include more than one model of the device in a single premarket application, provided that all the models in a single premarket submission meet certain requirements. In fact, including more than one model of a device in one premarket submission occurs so routinely that the Agency has coined a phrase for this activity -- "bundling". One of the basic requirements that the Agency has imposed upon manufacturers who wish to include more than one model of the same device into one premarket submission is that all the models within one premarket submission must have the same intended use. In addition, the models must be of a similar design; configured from similar material; and have similar biomaterial compatibility profiles. Additional details regarding bundling are addressed in various premarket guidance documents that the Agency has published that are located on the Reuse of Single Use Devices Website at http://www.fda.gov/cdrh/reuse/reuse-contact.shtml.

In FY 2001, FDA received 101 reuse applications, including 5 PMA applications and 96 510k applications.

Item

Medical Device Application Review -- The Committee is aware that for the last several years, premarket approval applications for breakthrough medical technologies have taken more than a year despite the 180-day statutory maximum for approval or denial of such applications. Moreover, the medical technology industry has doubled the investment in research and development in the last decade. Such research and development investment promises to yield numerous and dramatic new technologies which must come through FDA's review process. As requested in the budget, the Committee provides an increase of $13,917,000 from the fiscal year 2001 level for FDA's Devices and Radiological Health program area. This amount is consistent with agency estimates for bringing review times within statutory requirements in the short term. The Center for Devices and Radiological Health is directed to develop accountability measures to ensure that these funds are used to support sustained progress toward compliance with statutory review times in the long term.

Action Taken or To Be Taken

FDA's Device and Radiological Health program will clearly benefit from the FY 2002 appropriated increase of $13,917,00; however, the majority of the resources were not provided to meet statutory requirements. Funds were provided in the areas of Patient Safety/Adverse Event

Reporting, Imports and Inspections, and Human Subject Protection. A portion of these funds, along with the cost of living increase, will benefit the Device Premarket Review program, and will contribute towards the Agency's effort to eventually meet all the device review statutory requirements in FDAMA for 510(k)s, PMAs, and PMA supplements. The FY 2002 appropriated increases, and additional resources in the future, will be used to give device reviewers the capability to do high quality, interactive, and timely reviews required by FDAMA, and allow the Agency to keep the public well informed about medical product safety associated with new technology and products reviewed by FDA.

In the area of PMA reviews, the FDAMA statutory requirement is to review and complete PMA first actions within 180 days. The FY 2002 FDA performance target is to meet the requirement 90 percent of the time. Another FY 2002 performance goal is to review and complete 90 percent of PMA supplement final actions within 180 days and the FDAMA statutory requirement is to review and complete PMA supplements within 180 days. Device technology advances is another factor that will impact performance. FDA anticipates that the FY 2002 submissions will be more complex and will take more time for review.

Senate Report 107-84

Item

Dietary Supplements -- The Committee recognizes the substantial role that dietary supplements can play in improving the health status of Americans….while the Food and Drug Administration (FDA) has spent resources to take action against a number of important healthful products, the Committee believes it has failed to take action against a number of clearly violative claims and inaccurate ingredient labels. The Committee is aware that funding for the Food and Drug Administration is in the Department of Agriculture appropriations bill. However, the Committee directs the Secretary to work with the FDA to undertake appropriate enforcement of DSHEA in areas relating to the accuracy of claims about dietary supplement ingredients, and prohibiting any dietary supplement claim that is false or misleading.

Action Taken or To Be Taken

FDA recently formed an intra-agency working group tasked with identifying those dietary supplements products/ingredients making claims that are false or misleading. The working group will then decide on appropriate enforcement actions to prohibit such claims.

Conference Report 107-275

Item

Interstate Shellfish Sanitary Commission (ISSC) -- The conferees expect that FDA will continue its work with the Interstate Shellfish Sanitary Commission (ISSC) to promote educational and research activities related to shellfish safety in general, and Vibrio vulnificus in particular. The conference agreement directs the use of $250,000 for this effort from within sums provided for food safety, the same amount proposed by the House and instead of $200,000 as proposed by the Senate. In addition, the conferees direct that the FDA continue to devote not less than $200,000 to its efforts in working with the ISSC on assuring the safety and quality of shellfish and development of shellfish regulations, as proposed by the House.

Action Taken or To Be Taken

CFSAN will continue funding in FY 2002. FDA will work with ISSC to persuade those most vulnerable to illness to avoid eating raw shellfish, and to decrease the number of illnesses and deaths from Vibrio vulnificus infection. Additionally, FDA will continue efforts with ISSC in support of the development of codes, laws, and regulations that may improve shellfish safety.

Item

Codex -- The conferees direct that at least $2,100,000 of the funds appropriated for FDA activities be used in support of Codex Alimentarius activities, as proposed by the Senate.

Action Taken or To Be Taken

FDA will participate in and raise visibility to those issues of relevance to the Agency or the nation within the 14 Codex committees, ad hoc task forces, and related drafting and working groups that FDA is a part of. Acceptance and utilization of international safety standards that satisfy U.S. consumer protection goals will improve product safety and public health, reduce FDA's import inspection burden, and help facilitate the import and export of foods.

Item

Catfish -- General Provisions: Section 755 None of the funds appropriated or otherwise made available by this Act to the Food and Drug Administration shall be used to allow admission of fish or fish products labeled wholly or in part as "catfish" unless the products are taxonomically from the family Ictaluridae.

Action Taken or To Be Taken

The Agency has been working to implement section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002. FDA field

offices are reviewing the labeling of imported seafood to ensure that products labeled with the term "catfish" are either from the Ictaluridae family or relabeled, exported, or destroyed. On January 17, 2002, FDA sent a letter to trade associations, foreign embassies, the trade press, and other relevant parties, as well as posting the letter on the Agency web site http://www.cfsan.fda.gov/~frf/slcf2002.html, informing them of section 755 of Public Law 107-76. The letter also explains how fish affected by the Section 755 may be relabeled so it no longer bears the term "catfish." FDA will continue to keep the Department of Health and Human Services and Congress informed of any developments relating to this issue.

Item

Generic Drugs -- The conference agreement provides increases for the generic drugs program and generic drug education, as proposed by both the House and the Senate. The conferees direct an increase of $2,500,000 above the fiscal year 2001 level for the generic drug program. This amount includes a $250,000 increase for generic drug education activities, for a total of $400,000 in fiscal year 2002 funding for that purpose.

Action Taken or To Be Taken

FDA expects to use the increase of $2,500,000 for the benefit of improving the generic drug review process and educating various audiences in the safe and effective use of generic drugs as a substitute to their brand-name counterparts. Increased efficiencies in the program can be accomplished by hiring additional staff, and thus eventually decreasing the total time to approval of abbreviated new drug applications. Additional hires will include an additional medical officer to increase the efficiency of assessments of bioequivalence trials having clinical endpoints, and an additional manager that has a background as an interdisciplinary scientist.

Item

Current Good Manufacturing Practice (CGMP) regulations -- The conferees are aware that FDA has never issued Current Good Manufacturing Practice (CGMP) regulations for medical oxygen and other medical gases despite the fact that the agency intended to do so in 1978. The conferees are concerned that FDA's interpretation of CGMP requirements pertaining to the validation of Air Separation Units (ASUs) would benefit from more extensive comment from, and interaction with, the regulated industry. Therefore, the conferees strongly encourage FDA to develop draft guidance on medical gas CGMPs that addresses ASU validation requirements and to report to the Committees on Appropriations regarding the status of these guidelines within six months of the enactment of this Act. The guidance development process should be fully consistent with the agency's good guidance practices and should allow for extensive industry input and interaction. In addition, FDA would be expected to address and respond to each significant comment received as it would in a rulemaking process.

Action Taken or To Be Taken

FDA's regulatory actions against medical gas producers are based upon the Current Good Manufacturing Practice (CGMP) regulations. FDA always appreciates input from the medical gases industry. In fact, the information contained in the Fresh Air workshops is a result of intensive input from the industry, and we look forward to continuing our interaction with the medical gases industry.

However, validation requirements of ASUs are consistent with the Agency's longstanding interpretation of the CGMPs with ample input from the industry, including the Compressed Gas Association (CGA). In 1998, following numerous meetings with the CGA, the CGA published a document (CGA P-8.2) that provides ASU validation guidelines and states, "FDA and the compressed gas industry have agreed that there is a need to perform validations in accordance with 21 CFR 211 and FDA guidelines at FDA-registered ASUs."

The absence of safety problems traced to ASUs cannot be the rationale for not applying CGMP regulations to ASUs. FDA does not believe the appropriate standard should be to wait until there are injuries. Medical gases are often intended for administration to seriously ill people in acute life threatening situations and to the chronically ill thus injuries and death often may not be reported as the cause of injury or death may be confounded by the seriousness of the underlying conditions. The application of CGMPs to ensure the identity, strength, quality and purity in these pharmaceutical products is of utmost importance. In addition, because the Federal Food, Drug, and Cosmetic Act and its CGMP requirement were designed to systematically prevent manufacturing quality problems that could impact the safety and effectiveness of drugs-rather than waiting until after a death or injury has resulted from inadequate quality control.

Finally, FDA is developing guidance on medical gas CGMP regulations that addresses Air Separation Units validation requirements that will supplement the CGA guidance in CGA p-8.2. The agency has been in contact with the CGA and is scheduling a meeting with the CGA to discuss ASU issues.

Item

Free Health Care Clinics -- The conferees are familiar with concerns that have been expressed regarding the impact of regulations promulgated by the Food and Drug Administration (21 CFR Sec. 203.39) on free health care clinics. The conferees encourage the agency to continue its review of the regulations' impacts and direct the agency to include a status report on this matter when it submits its budget request for the next fiscal year.

Action Taken or To Be Taken

FDA has decided that more information is needed regarding the potential burdens on free clinics as well as the risks from diversion if free clinics were to be relieved of some or all of the record-keeping requirements. FDA intends to conduct a study to obtain enough information to make an

informed regulatory judgment on this matter. While conducting this study, FDA intends to exercise our enforcement discretion and will not initiate enforcement actions based on 21 CFR 203.39 against free clinics that receive donated drug samples from licensed practitioners or other charitable institutions for the purpose of dispensing to patients. FDA intends to issue a final guidance document by the end of FY 2002 that will indicate our intention to exercise enforcement discretion while we gather the additional information.

Item

Financial Management System -- For other increases requested in the President's fiscal year 2002 budget, the conferees provide: $4,000,000 for the move of the Center for Drug Evaluation and Research to White Oak, Maryland; and $3,100,000 for financial management system priorities. The conferees direct that the priority use of the financial management system funds will be to support streamlining and centralizing FDA's existing financial management systems, rather than beginning investment in a new financial system.

Action Taken or To Be Taken

In FY 2002, FDA will perform numerous tasks related to its existing system in preparation for the migration to a new financial system that works in conjunction with other Department of Health and Human Services (DHHS) systems. Some of these tasks include: centralizing FDA's Accounting operations from 25 accounting points and 15 Agency Location Codes (ALC) to 7 accounting points and 1 ALC, and standardizing the financial systems being used throughout FDA. In order for FDA to minimize the migration effort, the Agency is standardizing the use of its systems to include the implementation of an already existing Accounts Payable system in headquarters to our field accounting points, and a Travel Manager system, a commercial off-the-shelf system used to reimburse FDA staff for their work related travel. FDA and DHHS are evaluating the impact of not receiving the full request and may submit a reprogramming letter later this year, if warranted.

Table of Estimates and Appropriations
Salaries and Expenses

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation*
1991	654,808,000[1]	654,808,000[2]	661,652,000[3]	656,519,000[4]
1992	734,604,000[5]	725,962,000[6]	704,734,000[7]	725,962,000
1993	757,038,000[8]	744,135,000[9]	744,135,000[10]	782,035,000[11]
1994	867,339,000[12]	867,339,000[13]	867,339,000[14]	869,623,000[15]
1995	935,141,000[16]	914,394,000[17]	917,956,000[18]	897,104,000[19]
1996	965,462,000[20]	904,694,000[21]	904,694,000[22]	904,694,000[23]
1997	969,519,000[24]	907,499,000[25]	907,499,000[26]	907,499,000[27]
1998	995,194,000[28]	945,174,000[29]	935,175,000[30]	948,705,000[31]
1999	1,159,055,000[32]	1,003,722,000[33]	1,072,640,000[34]	1,096,445,000[35]
2000	1,305,869,000[36]	1,218,384,000[37]	1,180,972,000[38]	1,183,095,000[39]
2001	1,359,481,000[40]	1,240,178,000[41]	1,216,796,000[42]	1,215,446,000[43]
2002	1,377,160,000[44]	1,342,339,000[45]	1,344,386,000[46]	1,496,486,000[47]
2003	1,656,095,000[48]			

* Appropriation contains salaries and expenses and PDUFA only.

[1] Includes $157,175,000 proposed to be available from user fees.

[2] Includes $157,175,000 proposed as user fees in salaries and expenses.

[3] Includes $157,175,000 proposed as user fees in salaries and expenses and an additional $6,844,000 over the budget authority request.

[4] Includes $8,535,000 that was subsequently sequestered.

[5] Includes $197,500,000 proposed to be available from user fees.

[6] Includes an additional $188,858,000 over the salaries and expenses request.

[7] Rejects proposed user fees of $197,500,000, but includes an additional $167,630,000 in salaries and expenses over the request.

[8] Includes $200,000,000 proposed to be available from user fees.

[9] Includes an additional $187,097,000 over the salaries and expenses request.

[10] Includes an additional $187,097,000 over the salaries and expenses request.

[11] Includes $746,035,000 in salaries and expenses and $36,000,000 in supplemental appropriations for the Prescription Drug User Fee Act. It does not include a $3,000,000 supplemental for Mammography Quality Standards Act (MQSA) to be transferred from HCFA, NIH and CDC.

[12] Includes $54,000,000 for the Prescription Drug User Fee Act (PDUFA), and $200,000,000 in proposed user fees.

[13] The allowance includes $867,339,000 in salaries and expenses, which contains $54,000,000 in PDUFA.

[14] Includes $54,000,000 in PDUFA, and $175,000,000 in other user fees.

[15] Includes $813,339,000 in salaries and expenses, and $56,284,000 for PDUFA, of which $2,284 was a supplemental appropriation.

[16] Includes $588,084,000 in salaries and expenses, $79,423,000 for PDUFA, other user fees of $228,000,000 $24,000,000 for Device User Fees, $6,500,000 for MQSA fee collections, $9,134,000 for Certification/FOIA, It does not include the transfer from Office of the Secretary, Office of General Counsel to FDA of $2,745,000 and 34 FTE.

[17] Includes an additional $248,438,000 over the salaries and expenses request. Includes $834,971,000 in salaries and expenses, and $79,423,000 in PDUFA.

[18] Includes $687,733,000 in salaries and expenses, $79,423,000 in PDUFA, and $150,800,000 in proposed new user fees. It does not include $6,500,000 in MQSA.

[19] Includes budget authority rescission of $2,990,000, $817,681,000 in salaries and expenses, and $79,423,000 for PDUFA. The amount does not include MQSA fee collections of $6,500,000.

[20] Includes $823,795,000 in salaries and expenses, $84,723,000 for PDUFA, $13,000,000 for MQSA fee collections, $23,740,00 for MDUFA, $15,000,000 for Import user fees, and $5,204,000 for the Certification Fund/FOIA.

[21] Includes $819,971,000 in salaries and expenses, and $84,723,000 in PDUFA. It does not include $13,000,000 in MQSA.

[22] Includes $819,971,000 in salaries and expenses, and $84,723,000 in PDUFA. It does not include $13,000,000 in MQSA.

[23] Includes $819,971,000 in salaries and expenses and $84,723,000 for PDUFA. It does not include $13,000,000 for MQSA fee collections.

[24] Includes $823,771,000 in salaries and expenses, $87,528,000 for PDUFA, $13,403,000 for MQSA fee collections, $24,476,000 for MDUFA, $15,000,000 for Import fees, and $5,341,000 for Certification/FOIA.

[25] Includes $819,971,000 in salaries and expenses, and $87,528,000 for PDUFA. It does not include $13,403,000 for MQSA fee collections.

[26] Includes $819,971,000 in salaries and expenses, and $87,528,000 for PDUFA. It does not include $13,403,000 for MQSA fee collections.

[27] Includes $819,971,000 in salaries and expenses, and $87,528,000 for PDUFA. It does not include $13,403,000 for MQSA fee collections.

[28] Includes $750,922,000 in salaries and expenses, $91,204,000 for PDUFA, $131,643,000 for new user fees, $13,966,000 for MQSA fee collections, $2,000,000 for Export Certification, and $5,459,000 for Certification/FOIA. It does not reflect proposed PDUFA Supplemental request of $25,618,000 requested with the FY 1999 President's Budget.

[29] Includes $857,971,000 in salaries and expenses, and $91,204,000 for PDUFA. It does not include $13,966,000 for MQSA fee collections.

[30] Includes $843,971,000 in salaries and expenses, and $91,204,000 for PDUFA. It does not include $13,966,000 for MQSA fee collections.

[31] Includes $857,501,000 in salaries and expenses and $91,204,000 for PDUFA. It does not include $13,966,000 for MQSA fee collections.

[32] Includes $878,885,000 in salaries and expenses, $132,274,000 for PDUFA, $14,385,000 for MQSA fee collections, $1,000,000 for Export Certification, $127,717,000 for new user fees, $1,030,000 for FOIA, and $3,764,000 for Certification. This does not include GSA budget authority rental payments of $82,866,000.

[33] Includes $871,449,000 in salaries and expenses, and $132,273,000 for PDUFA ($5,428,000 for GSA rent). It does not include $14,385,000 for MQSA fee collections, and GSA budget authority rental payments of $82,866,000.

[34] Includes $940,367,000 in salaries and expenses (which includes $82,866,000 in budget authority GSA rent), and $132,273,000 for PDUFA ($5,428,000 for GSA rent) It does not include $14,385,000 for MQSA fee collections.

[35] Includes rescission of $1,695,000, salaries and expenses of $964,172,000, (which includes $82,866,000 for GSA Rent), and $132,273,000 for PDUFA ($5,428,000 for GSA rent). It does not include $14,385,000 for MQSA fee collections.

[36] Includes $1,109,950,000 (including $94,537,000 of GSA Rent) salaries and expenses, $145,434,000 for PDUFA ($5,643,000 is GSA Rent), $14,817,000 for MQSA fee collections, $1,030,000 for Export Certification, $3,877,000 for Certification fund, $1,061,000 for FOIA, $12,700,000 for Seafood Transfer User Fees, and $17,000,000 for proposed new user fees.

[37] Includes $1,072,950,000 (including $94,537,000 of GSA Rent) in salaries and expenses, $145,434,000 for PDUFA ($5,643,000 is for GSA Rent). This does not include $14,817,000 for MQSA fee collections.

[38] Includes $1,035,538,000 (including $94,537,000 of GSA Rent) in salaries and expenses, and $145,434,000 for PDUFA ($5,643,000 is for GSA Rent). It does not include $14,817,000 for MQSA fee collections.

[39] Includes rescission of $2,977,000, salaries and expenses of $1,037,661,000 (including $94,311,000 of GSA Rent), and $145,434,000 for PDUFA ($5,643,000 is GSA Rent). It does not include $14,817,000 for MQSA fee collections, $1,030,000 for Export Certification, $3,877,000 for Certification fund, $1,061,000 for FOIA, $12,700,000 for Seafood Transfer User Fees, $17,000,000 for new user fees, or $13,400,000 for Bioterrorism.

[40] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in salaries and expenses, $149,273,000 for PDUFA ($5,860,000 is GSA rent), $15,128,000 for MQSA fee collections, $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification, $4,492,000 for Certification fund, and $19,483,000 for proposed new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[41] Includes $1,090,905,000 (including $99,094,000 of GSA Rent) in salaries and expenses, $149,273,000 for PDUFA ($5,860,000 is GSA rent). This does not include $15,128,000 for MQSA fee collections.

[42] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in salaries and expenses, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). It does not include $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[43] Includes rescission of $2,351,000, salaries and expenses of $1,066,173,000 (including $98,876,000 of GSA Rent), and $149,273,000 for PDUFA (of which 5,860,000 is GSA rent). It does not include $14,947,000 for MQSA fee collections, $1,500,000 for Export Certification, or $22,950,000 million for drug importation that is not available until requested by the President. Also does not include $1,750,000 funded from PHSSEF for physical security counter-terrorism measures.

[44] Includes $1,173,673,000 (including $98,876,000 of GSA Rent) in salaries and expenses, $161,716,000 for PDUFA ($6,240,000 is GSA rent), $15,590,000 for MQSA fee collections, $1,500,000 for Export Certification, $4,681,000 for Certification fund, and $20,000,000 for proposed new user fees. Does not include $2,950,000 million for drug importation that is not available until requested by the President.

[45] Includes $1,180,623,000 (including $98,876,000 of GSA Rent) in salaries and expenses, and $161,716,000 for PDUFA ($6,240,000 is GSA rent). This does not include $15,590,000 for MQSA fee collections. This does not include the $2,950,000 the House provided for MEDSA.

[46] Includes $1,182,670,000 (including $98,876,000 of GSA Rent) in salaries and expenses, and $161,716,000 for PDUFA ($6,240,000 is GSA rent) It does not include $15,590,000 for MQSA fee collections, and $6,181,000 in Export Certification and Color Certification.

[47] Includes $1,183,670,000 (including $98,876,000 of GSA Rent) in salaries and expenses, $161,716,000 for PDUFA ($6,240,000 is GSA rent). It does not include $15,590,000 for MQSA fee collections, or $6,181,000 in Export Certification and Color Certification. Includes an additional $151,100,000 provided in the FY 2002 counter-terrorism supplemental.

[48] Includes $1,369,385,000 (including $98,556,000 of GSA Rent) in salaries and expenses, $264,220,000 in proposed PDUFA fees ($7,140,000 is GSA rent), $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $4,878,000 in Color Certification.

Table of Estimates And Appropriations
Rental Payments to GSA

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1991	25,612,000	25,612,000	25,612,000	25,612,000[1]
1992	25,612,000	25,612,000	25,612,000	25,612,000
1993	25,612,000	25,612,000	25,612,000	25,612,000
1994	48,575,000	48,575,000	48,575,000	48,575,000[2]
1995	48,575,000	46,294,000[3]	46,294,000	46,294,000[4]
1996	46,294,000	46,294,000	46,294,000	46,294,000[5]
1997	46,294,000	46,294,000	46,294,000	46,294,000[6]
1998	46,294,000[7]	46,294,000	46,294,000	46,294,000
1999	82,866,000[8]	82,866,000[9]		

[1] Does not reflect $333,000, which was subsequently sequestered.

[2] Includes $15,000,000 reserved for use by FDA for repairs and improvements to facilities.

[3] Reflects a GSA rent reduction of $2,281,000 to the rent cap.

[4] Includes an authorized reduction of GSA rent payments of $3,970,000 to cover FDA's Building Delegation expenses.

[5] Includes an authorized reduction of GSA rent payments of $3,957,000 to cover FDA's Building Delegation expenses.

[6] Includes an authorized reduction of GSA rent payments estimated to be $4,705,000 to cover FDA's Building Delegation expenses.

[7] Includes an authorized reduction of GSA rent payments estimated to be $4,832,000 to cover FDA's Building Delegation expenses.

[8] Increase in GSA Rent estimate reflects the real cost of rental payments. In previous years, Congress had imposed a ceiling on rental payments. Includes an authorized reduction of GSA rent payments estimated to be $4,917,0000 to cover FDA's Building Delegation expenses and $5,428,000 of PDUFA collections, which are included in S&E PDUFA.

[9] Does not include GSA Rent in the S&E Appropriation. Includes an authorized reduction of GSA rent payments estimated to be $4,917,0000 to cover FDA's Building Delegation expenses. Does not include $5,428,000 of PDUFA collections, which are included in S&E PDUFA. Beginning in FY 1999 the Senate Appropriation Committee and the final Appropriation included GSA Rent in the S&E Appropriation. For subsequent years, GSA Rent is included in S&E.

Table of Estimates And Appropriations
Buildings and Facilities

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1991	4,752,000	8,350,000	10,850,000	8,350,000
1992	10,000,000	10,350,000	8,350,000	8,350,000[1]
1993	8,350,000	8,350,000	8,350,000	8,350,000
1994	8,350,000[2]	8,350,000	8,350,000	8,350,000
1995	8,350,000[3]	18,150,000	8,350,000	18,150,000[4]
1996	8,350,000	15,350,000	8,350,000	12,150,000[5]
1997	8,350,000	21,350,000	21,350,000	21,350,000[6]
1998	22,900,000[7]	21,350,000	22,900,000	21,350,000[7]
1999	8,350,000	11,350,000	12,350,000	11,350,000[8]
2000	31,750,000[9]	31,750,000	8,350,000	11,350,000
2001	31,350,000[10]	11,350,000	31,350,000	31,350,000
2002	34,281,000[11]	34,281,000	34,281,000	34,281,000
2003	8,000,000[12]			

[1] Does not include $200,000,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1992 for consolidation of FDA headquarters facilities.

[2] Does not include $73,900,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1994 for consolidation of FDA headquarters facilities.

[3] Does not include $45,000,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1995 for consolidation of FDA headquarters facilities.

[4] Includes $9,800,000 to purchase land and begin engineering and design work for replacement of FDA's Los Angeles District office and laboratory,

[5] Includes $3,800,000 for continuing work on an Arkansas Regional Laboratory at Jefferson, AR.

[6] Includes $13,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[7] Includes $14,550,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[8] Includes $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[9] Includes $20,400,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[10] Includes $20,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[11] Includes $23,000,000 for construction of Phase II of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[12] Reflects a reduction of $26,281,000 in Buildings and Facilities for the centralization of B&F construction activities at the Department level.

APPROPRIATIONS NOT AUTHORIZED BY LAW

Pursuant to clause 3(f)(1) 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:

Program and last year of authorization	Authorization level	Appropriations in last year of authorization	Appropriations in this bill
The following programs are not currently authorized by law:			
FDA:			
PDUFA III	**N/A**	**$161,716,000** *1/*	**$264,220,000**
Accrual Costs	**N/A**	**N/A**	**$63,205,000** *2/*

1/ Reflects PDUFA II, authorized by the Food and Drug Modernization Act of 1997 (FDAMA) which expires September 30, 2002. FDA is negotiating with industry on a proposal to reauthorize PDUFA and make enhancements to it.

2/ The proposed Managerial Flexibility Act of 2001 requires agencies to pay the full share of accruing employee pensions and annuitant health benefits beginning in FY 2003. The proposed legislation will require agencies, beginning in FY 2003, to pay all the full Government share of the accruing cost of retirement and health benefit costs for current employees. The legislation will also require agencies to pay the accruing costs of post-retirement health benefits.

Food and Drug Administration
Detail of Full-Time Equivalent Employment (FTE)
Program Level

Project	FY 2001 Total	FY 2002 Current Est	FY 2003 Estimate
Center for Food Safety and Applied Nutrition	879	909	922
Center for Drug Evaluation and Research	1,784	1,906	2,034
Center for Biologics Evaluation and Research	809	935	1,010
Center for Veterinary Medicine	290	320	325
Center for Devices and Radiological Health	1,016	1,028	1,032
National Center for Toxological Research	206	237	238
Office of Regulatory Affairs	3,158	3,803	4,136
Other Activities			
Office of the Commissioner	113	118	122
Office of Senior Associate Commissioner	107	96	48
Office of Dep. Commissioner - Intl & Constituent Relations	72	66	66
Office of Policy, Legislation & Planning	100	97	63
Office of Management and Systems	407	416	412
Other User Fees	48	51	51
TOTAL	**8,989**	**9,982**	**10,459**

Note: Does not include 89 reimbursable FTEs. Totals do not reflect comparable adjustments as a result of FY 2003 Legislative/Public Affairs activities transfer to DHHS.

Five Year History of GS/GM average grade

Year	Grade
FY 1999	11.7
FY 2000	11.7
FY 2001	11.8
FY 2002	11.8
FY 2003	11.8

REVISED AS OF 01/14/2002

FOOD AND DRUG ADMINISTRATION
DETAIL OF FTE BY GRADE

	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Executive Level I.....	-	-	-
Executive Level II.....	-	-	-
Executive Level III.....	-	-	-
Executive Level IV.....	-	1	1
Executive Level V.....	-	-	-
Total, Exec. Level Salaries	-	1	1
ES-6.....	-	1	1
ES-5.....	6	6	5
ES-4.....	17	18	18
ES-3.....	8	7	7
ES-2.....	5	5	5
ES-1.....	14	13	14
Total, ES Salaries	50	50	50
GS/GM - 15.....	606	678	712
GS/GM - 14.....	1,327	1,485	1,559
GS/GM - 13.....	2,560	2,864	3,002
GS-12.....	1,446	1,618	1,698
GS-11.....	480	537	564
GS-10.....	83	93	98
GS-9.....	469	525	551
GS-8.....	234	262	275
GS-7.....	534	597	627
GS-6.....	159	178	187
GS-5.....	118	132	139
GS-4.....	69	77	81
GS-3.....	36	40	42
GS-2.....	16	18	19
GS-1.....	6	7	7
Subtotal, GS Salaries	**8,143**	**9,111**	**9,561**
AL.....	1	1	1
ST.....	2	1	1
RS.....	45	46	48
CC - 08/07/06.....	200	210	221
CC - Other.....	270	284	298
Subtotal, CC Salaries	**470**	**494**	**519**
AD (includes Title 42).....	290	290	290
Wage Grade.....	67	67	67
Consultants.....	10	10	10
Total FTE (End of Year) 1/	**9,078**	**10,071**	**10,548**
Average ES level.....	2.9	3.0	3.0
Average ES Salary.....	131,000	135,700	140,600
Average GS/GM grade.....	11.8	11.8	11.8
Average GS/GM salary.....	58,200	61,400	64,400

1/ FTE total includes reimbursable FTEs. Totals do not reflect comparable adjustments as a result of FY 2003 Legislative/Public Affairs activities transfer

NEW POSITIONS REQUESTED FOR APPROPRIATED & USER FEE FUNDING

Program Job Category Grade Series	Budget Authority 1/ Center	 Field	User Fee 1/ Center	 Field	TOTAL
FOODS					
Chemist/Biochemist					
GS-5/7/9/11/12		40			40
GS-13	7				7
Microbiologist					
GS-5/7/9/11/12	6	40			46
Consumer Safety Officer					
GS-5/7/9/11/12		558			558
GS-13	12				12
Computer Systems Analyst					
GS-7/9/11	3				3
Management Analyst					
GS-5/7/9/11	2				2
Criminal Investigator					
GS-13/14		29			29
Foods Subtotal	30	667	0	0	697
HUMAN DRUGS					
Regulatory Health Management					
GS-13	3		9		12
Project Manager					
GS-13	5		3		8
Contract Specialist					
GS-12	1				1
Microbiologist					
GS-5/7/9/11/12		1			1
GS-12	1				1
GS-13	1		1		2
Medical Officer/Pharmacololgist					
GS-13/14	8		52		60
Chemist					
GS-5/7/9/11/12	10	1			11
Consumer Safety Officer					
GS-5/7/9/11/12		2		12	14
GS-13			9		9
GS-14			1		1
Consumer Safety Technician					
GS-6	2				2
Compliance Officers/Technician					
GS-5/7/9/11	4				4
Computer Systems Analyst					
GS-7/9/11	3				3
Management Analyst					
GS-5/7/9/11	1				1
Program Support					
GS-5/7/9	4		7		11
Regulatory Counsel					
GS-13	2				2
Personnel Specialist					0
GS-9	1				1
Bioequivalence Reviewer					0
GS-13	2				2
Interdisciplinary Scientist					0
GS-13	2				2
Management Officer					0
GS-13	2				2
Pharmacist					0
GS-12/13/14	5				5
Associate Director Regulatory Affairs					0
GS-14	1				1
Division Director for Bioterrorism					0
GS-15	1				1
Office of Regulatory Policy					0
GS-13	1				1
Policy Analyst					0
GS-13	1		5		6
Criminal Investigator					
GS-13/14		2			2
Human Drugs Subtotal	61	6	87	12	166

BIOLOGICS					
Biologist					
GS-12	5		2		7
GS-13	4		1		5
GS-14	5		2		7
Chemist					
GS-5/7/9/11/12		3			3
GS-12	5		2		7
GS-13	7		3		10
GS-14	6		3		9
Consumer Safety Officer					
GS-5/7/9/11/12		2		4	6
GS-12	3		1		4
GS-13	4		2		6
GS-14	5		3		8
Epidemiologist					
GS-14	4		1		5
Medical Officer					
GS-14	10		5		15
GS-15	12		5		17
Microbiologist					
GS-5/7/9/11/12		3			3
GS-12	4		1		5
GS-13	8		3		11
GS-14	4		1		5
Compliance Officers/Technician					
GS-5/7/9/11	6				6
Program Analysts					
GS-13	2				2
GS-14	2				2
Computer Systems Analyst					
GS-13	1				1
Management Analyst					
GS-12/13	4		1		5
Program Support					
GS-5/7/9	2		1		3
Criminal Investigator					
GS-13/14		2			2
Biologics Subtotal	103	10	37	4	154
ANIMAL DRUGS AND FEED					
Veterinary Medical Officer					
GS-12	1				1
GS-13	2				2
Veterinary Toxicologist					
GS-12	1				1
Chemist					
GS-5/7/9/11/12	2	5			7
Animal Scientist					
GS-13	1				1
Computer Systems Analyst					
GS-9/11/12	1				1
Consumer Safety Officer					
GS-5/7/9/11/12		25			25
Microbiologist					
GS-5/7/9/11/12		5			5
Animal Drugs Subtotal	8	35	0	0	43

DEVICES AND RADIOLOGICAL HEALTH					
Public Health Advisor					
GS-12					
GS-13	1				1
Radiation Safety Analyst					
GS-5/7/9	2				2
GS-12/13	2				2
Scientific Reviewer					
GS-12/13	4				4
Chemist					
GS-5/7/9/11/12		1			1
Microbiologist					
GS-5/7/9/11/12		1			1
Consumer Safety Officer					
GS-5/7/9/11/12	2	2			4
GS-12/13	2				2
Devices Subtotal	13	4	0	0	17
NCTR					
Microbiologist					
GS-13	2				2
Computational Scientist					
GS-13	3				3
Chemist					
GS-13	3				3
NCTR Subtotal	8	0	0	0	8
OTHER ACTIVITIES					
Health Science Administrator					
GS-13/14	1				1
Regulatory Counsel					
GS-13/14	3				3
Safety/Security Personnel					
GS-13/14	3				3
Other Activities Subtotal	7	0	0	0	7
Total	**230**	**722**	**124**	**16**	**1092**

1/ Budget Authority new positions were calculated based on the crosswalk from the original FY 2002 Appropriation, not including the Counter Terrorism supplemental, to FY 2003 request level. User Fee new positions were calculated based on the user fee crosswalk summary of change to all purpose tables and the FTE only correspond to the additional $78,220,000 being requested for PDUFA III. Existing positions under PDUFA II are assumed to carry into PDUFA III.

Geographical Distribution of FDA Facilities

Location	Activities
Washington, D.C. area:	
Rockville, MD	FDA Headquarters and headquarters operations of the Human Drugs, Biologics, Animal Drugs, Device and Radiological Health products programs and laboratories.
Washington, D.C. and College Park, MD	Foods program headquarters and laboratories
Bethesda, MD	Human Drugs and Biologics laboratories
Beltsville, MD	Foods and Animal Drugs Research facilities
Field Operations Facilities:	
Jefferson, AR	Arkansas Regional Laboratory
Oakland, CA	Pacific Regional Office
Alameda, CA	San Francisco District Office and laboratory
Los Angeles, CA	Pacific Regional Laboratory Southwest
Irvine, CA	Los Angeles District Office
Denver, CO	Denver District Office and laboratory (special emphasis in animal drugs residue testing)
Maitland, FL	Florida District Office
Atlanta, GA	Southeast Regional Office, Southeast Regional Laboratory, and Atlanta District Office
Chicago, IL	Chicago District Office
Lenexa, KS	Kansas City District Office and laboratory (special emphasis in pesticides and total diet analysis)
New Orleans, LA	New Orleans District Office
Stoneham, MA	New England District Office
Winchester, MA	Winchester Engineering and Analytical Center (testing of Medical Devices and Radiological Health Research products)- Testing facility for Radionuclides and Radiopharmaceutics.
Baltimore, MD	Baltimore District Office
Detroit, MI	Detroit District Office and laboratory
Minneapolis, MN	Minneapolis District Office
Parsippany, NJ	New Jersey District Office
Jamaica, NY	Northeast Regional Office, Regional laboratory and New York District Office
Cincinnati, OH	Cincinnati District Office and Forensic Chemistry Center (elemental analysis)
Philadelphia, PA	Central Regional Office, Philadelphia District Office and laboratory (special emphasis on Human Drugs)
San Juan, PR	San Juan District Office and laboratory (special emphasis on human drugs products testing)
Dallas, TX	Southwest Regional Office and Dallas District Office
Bothell, WA	Seattle District Office and Pacific Regional Laboratory Northwest (special emphasis on seafood products testing)

Other Specialized facilities:

Dauphin Island, AL	Fishery research (CFSAN)
Jefferson, AR	National Center for Toxicological Research (NCTR)
St. Louis, MO	Specialized human drugs product testing laboratory (CDER)

FOOD AND DRUG ADMINISTRATION

User Fee History

(Dollars in Thousands)

User Fees - Appropriations

	FY 1999 Appropriation		FY 2000 Appropriation		FY 2001 Appropriation		FY 2002 Appropriation		FY 2003 Request	
Current Law	**FTE**	**$**	**FTE**	**$**	**FTE**	**$**	**FTE**	**$**	**FTE**	**$**
PDUFA										
- Human Drugs	504	$88,003	620	$97,053	702	$99,298	722	$106,188	*	*
- Biologics	179	28,959	204	31,385	253	32,154	253	35,344	*	*
- Other Activities	107	9,514	127	11,353	127	11,961	127	13,944	*	*
- GSA Rent	0	5,428	0	5,643	0	5,860	0	6,240	*	*
Subtotal, PDUFA	790	131,904	951	145,434	1,082	149,273	1102	161,716		
MQSA	50	14,385	50	14,817	50	15,128	50	15,590	50	16,427
Export Certification	8	1,000	13	1,030	13	1,500	13	1,500	13	1,582
Certification Fund	35	3,764	35	3,877	38	4,492	38	4,681	38	5,117
Total, Current Law	883	151,053	1,049	165,158	1,183	170,393	1203	183,487	101	23,126
Proposed:										
PDUFA III:										
- Human Drugs									821	185,830
- Biologics									294	64,324
- Other Activities									127	14,744
- GSA Rent									0	7,140
Subtotal, PDUFA III									1,242	272,038
Total, FDA	**883**	**$151,053**	**1,049**	**$165,158**	**1,183**	**$170,393**	**1,203**	**183,487**	**1,343**	**$295,164** 1/

*** Included in PDUFA III Proposed User Fee**

User Fees - Obligations

	FY 1999 Actual		FY 2000 Actual		FY 2001 Actual	
	FTE	**$**	**FTE**	**$**	**FTE**	**$**
PDUFA:						
- Human Drugs	610	$77,876	671	$95,696	711	$103,965
- Biologics	198	29,342	211	34,584	255	38,927
- Other Activities	101	9,869	127	11,353	123	11,961
- GSA Rent	0	5,428	0	5,643	0	5,860
Subtotal, PDUFA	909	122,515	1,009	147,276	1,089	160,713
MQSA	50	13,373	48	12,767	47	12,439
Export Certification	13	1,315	12	1,344	13	1,479
Certification Fund	32	7,511	33	4,447	35	3,930
Subtotal	95	22,199	93	18,558	95	17,848
Total, FDA	**1,004**	**$144,714**	**1,102**	**$165,834**	**1,184**	**$178,561**

User Fees - Collections

	FY 1999 Actual	FY 2000 Actual	FY 2001 Actual	FY 2002 Current Estimate	FY 2003 Request
Current Law	**$**	**$**	**$**	**$**	**$**
PDUFA Collections	$126,580	$133,060	$138,761	$161,716	**
MQSA Collections	12,668	13,836	12,872	15,590	16,427
Export Certification	1,379	1,417	1,487	1,500	1,582
Certification Fund	4,435	4,097	4,521	4,681	5,117
Total, Current Law	145,062	152,410	157,641	183,487	23,126
Proposed:					
PDUFA III:					
- Human Drugs					185,830
- Biologics					64,324
- Other Activities					14,744
- GSA Rent					7,140
Subtotal, PDUFA III					272,038
Total, FDA	**$145,062**	**$152,410**	**$157,641**	**$183,487**	**$295,164** 1/

**** Included in PDUFA III Proposed User Fee**

1/ Includes Retirement Accural Costs. Without Accruals, the amounts requested are as follows: PDUFA - $264.220; MQSA - $16.112; Export Certification - $1.500; and Certification Fund - $4.878

GLOSSARY OF ACRONYMS

510(k)	Premarket notification (Medical devices substantially equivalent to products already on the market)
AADA	Abbreviated Antibiotic Drug Application
ADE	Adverse Drug Event
ADAA	Animal Drug Availability Act of 1996
ADR	Adverse Drug Report
AERS	Adverse Events Reporting System
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
ANDA	Abbreviated New Drug Application
ANSI	American National Standards Institute
APHIS	Animal Plant and Health Inspection Service (USDA)
BLA	Biologics License Application
BIMO	Bioresearch Monitoring
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
CABS	Conformity Assessment Bodies
CARS	Compliance Achievement Reporting System
CBER	Center for Biologics Evaluation and Research (FDA)
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CFO	Chief Financial Officer
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CGMPs	Current Good Manufacturing Practices
CJD	Creutzfeldt-Jakob Disease
CMC	Chemistry, Manufacturing, and Controls
COMSTAS	Compliance Status Information System
COBOL	Common Business Oriented Language
CRADA	Cooperative Research and Development Agreement
CRS	Contamination Response System
CTS	Correspondence Tracking System
CVM	Center for Veterinary Medicine (FDA)
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOL	Department of Labor
DQRS	Drug Quality Reporting System
DRLS	Drug Registration and Listing System
DSHEA	Dietary Supplement Health and Education Act
EDR	Electronic Document Room
EDMS	Electronic Data Management System
EIP	Emerging Infection Program
EIR	Establishment Inspection Report
ELA	Establishment License Application
EPA	Environmental Protection Agency

ERS	Economic Research Service
ETS	Environmental Tobacco Smoke
EU	European Union
FACTS	Field Accomplishment and Compliance Tracking System
FAO	Food and Agricultural Organization (United Nations)
FAS	Foreign Agriculture Service (USDA)
FDAMA	Food and Drug Administration Modernization Act of 1997
FFD&C Act	Federal Food, Drug and Cosmetic Act
FIS	Field Information System
FLQ	Fluoroquinolone
FORCG	Food Outbreak Coordination Response Group
FPL	Final Printed Label
FPLA	Fair Packaging and Labeling Act
FSI	Food Safety Initiative (National)
FSIS	Food Safety Inspection Service (USDA)
FTC	Federal Trade Commission
FTE	Full-time Equivalent
FY	Fiscal Year (October - September)
GAO	General Accounting Office
GAPs	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GPRA	Government Performance and Results Act of 1993
GMPs	Good Manufacturing Practices
GRAS	Generally Recognized as Safe Food Ingredients
GSFA	General Standards for Food Additives
HACCP	Hazard Analysis Critical Control Points
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
HUD	Humanitarian Use Device
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
IOM	Institute of Medicine
ISO	International Standards Organization
ISRS	Individual Safety Reports
IT	Information Technology
IVD	In Vitro Diagnostic
JECFA	Joint Expert Committee on Food Additives

JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JINAD	Generic Investigational New Animal Drug
LACF	Low Acid Canned Foods
LAN	Local Area Network
LBITF	Least Burdensome Industry Task Force
MATS	Management Assignment Tracking System
MDR	Medical Device Reporting System
MERS-TM	Medical Event Reporting System for Transfusion Medicine
MMBM	Mammalian Meat and Bone Meal
MOU	Memorandum of Understanding
MPRIS	Mammography Program Reporting and Information Systems
MQSA	Mammography Quality Standards Act
MRA	Mutual Recognition Agreement
NADA	New Animal Drug Application
NAFTA	North Atlantic Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group
NARMS	National Antimicrobial Resistance Monitoring System
NASS	National Agricultural Statistics Survey
NCI	National Cancer Institute
NCIE	Notice of Claimed Investigational Exemptions
NCTR	National Center for Toxicological Research (FDA)
NDA	New Drug Application
NDE/MIS	New Drug Evaluation Management Information System
NIAID	National Institute of Allergy and Infectious Diseases
NIDA	National Institute on Drug Abuse
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institute of Health
NLEA	Nutrition Labeling and Education Act
NME	New Molecular Entity
NPR	National Partnership for Reinventing Government
NPRM	Notice of Proposed Rulemaking
NRC	National Research Council
NTP	National Toxicology Program
NVPO	National Vaccine Program Office
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review (CBER)
OPA	Office of Premarket Approvals (CFSAN)
ORA	Office of Regulatory Affairs (FDA)
ORISE	Oak Ridge Institute for Science and Education
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
OTR	Office of Testing and Research (CDER)
OTRR	Office of Therapeutics Research and Review (CBER)
OVRR	Office of Vaccines Research and Review (CBER)
PAS	Public Affairs Specialist (FDA)
PDPs	Product Development Protocols

PDUFA	Prescription Drug User Fee Act of 1992
PIFSI	Produce and Food Safety Initiative
PLA	Product License Application
PMA	Premarket Approval (Application to market medical device that requires premarket approval)
PODS	Project-Oriented Data System
PQRI	Product Quality Research Initiative
QSIT	Quality System Inspection Technique
RA	Rheumatoid Arthritis
RCHSA	Radiation Control for Health and Safety Act
REGO	Reinventing Government Initiative
RIMS	Regulatory Information Management Staff (CBER)
RMS-BLA	Regulatory Management System-Biologics License Application
RVIS	Residue Violation Information System
SAB	Science Advisory Board
SAMHSA	Substance Abuse and Mental Health Services Administration
SE	Salmonella Enteriditis
SN/AEMS	Special Nutritional Adverse Events Monitoring System
STARS	Submission Tracking and Review System
StmDT104	Salmonella Tphimurium DT 104
TB	Tuberculosis
TRIMS	Tissue Residue Information System
UK	United Kingdom
UMCP	University of Maryland-College Park
USDA	United States Department of Agriculture
VAERS	Vaccine Adverse Event Reporting System
VFD	Veterinary Feed Directive
VICH	Veterinary International Conference on Harmonization
WHO	United Nations World Health Organization
WTO	World Trade Organization