Food and Drug Administration
Object Class Detail
Budget Authority
(Dollars in Thousands)

Direct Obligations PERSONNEL COMPENSATION:	FY 2005 Estimate	FY 2005 Actuals	FY 2006 Enacted	FY 2007 Estimate	Increase or Decrease
11.1 Full-time permanent	$ 640,592,000	$ 551,841,000	$ 590,980,003	$ 648,049,000	$ 57,068,997
11.3 Other than full-time perm	39,417,000	68,709,000	73,582,076	40,286,000	(33,296,076)
11.5 Other personnel comp	22,078,000	21,798,000	23,343,582	22,378,000	(965,582)
11.7 Military Personnel Compensation	36,246,000	42,598,000	45,618,907	36,832,000	(8,786,907)
11.8 Special personal svcs pay	166,000	370,000	396,114	172,000	(224,114)
Subtotal Personnel Comp	**$ 738,499,000**	**$ 685,316,000**	**$ 733,920,682**	**$ 747,717,000**	**$ 13,796,318**
12.1 Civilian Personnel Benefits	156,464,000	167,121,000	178,974,241	158,664,000	(20,310,241)
12.2 Military Personnel Benefits	17,156,000	24,100,000	25,809,684	17,470,000	(8,339,684)
13.0 Benefits -former personnel	27,000	(50,000)	(53,193)	27,000	80,193
Subtotal Pay Costs	**$ 912,146,000**	**$ 876,487,000**	**$ 938,651,414**	**$ 923,878,000**	**$ (14,773,414)**
21.0 Travel & Transportation of persons	$ 24,306,000	$ 22,939,000	$ 21,355,694	$ 27,655,000	$ 6,299,306
22.0 Transportation of things	4,663,000	6,410,000	5,967,838	5,306,000	(661,838)
23.1 Rental payments to GSA	113,479,000	112,285,000	117,579,000	124,598,000	7,019,000
23.2 Rent payments to others	4,478,000	2,981,000	2,775,229	5,094,000	2,318,771
23.3 Communication, Util & Misc Services	24,468,000	27,249,000	25,367,963	27,839,000	2,471,037
24.0 Printing & Reproduction	2,262,000	3,220,000	2,997,541	2,573,000	(424,541)
Contractual Costs:					
25.1 Advisory and Assistance Services	$ 41,371,000	$ 42,859,000	$ 39,901,156	$ 47,071,000	$ 7,169,844
25.2 Other Services	82,901,000	62,848,000	58,510,391	94,323,000	35,812,609
25.3 Purchase of Goods & Svcs from Govt Acts	80,093,000	88,400,000	82,298,261	91,128,000	8,829,739
25.4 Operation & Maintenance of Facilities	50,316,000	47,176,000	43,919,971	57,249,000	13,329,029
25.5 Research & Development Contracts	19,688,000	33,108,000	30,823,183	22,401,000	(8,422,183)
25.7 Operation & Maintenance of Equipment	22,295,000	30,332,000	28,238,579	25,367,000	(2,871,579)
25.8 Subsistence and support of persons		-	-		
Subtotal Contractual Costs	**$ 296,664,000**	**$ 304,723,000**	**$ 283,691,540**	**$ 312,437,000**	**$ 28,745,460**
26.0 Supplies & Materials	19,261,000	22,977,000	21,391,458	21,915,000	523,542
31.0 Equipment	24,962,000	45,132,000	42,016,911	28,401,000	(13,615,911)
32.0 Land & Structure	7,230,000	2,555,000	2,378,606	8,227,000	5,848,394
41.0 Grants, subsidies & contributions	22,921,000	25,783,000	24,002,967	26,080,000	2,077,033
42.0 Ins claims & indemnities	45,000	1,548,000	1,440,838	52,000	(1,388,838)
62.0 Receivables collected	(6,788,000)		-	(7,723,408)	(7,723,408)
Subtotal Non-Pay Costs	**537,951,000**	**577,802,000**	**550,965,586**	**607,555,000**	**56,589,414**
TOTAL DIRECT OBLIGATION	**$ 1,450,097,000**	**$ 1,454,289,000**	**$ 1,489,617,000**	**$ 1,531,433,000**	**$ 41,816,000**
FTE [1/]	**8,585**	**8,182**	**8,377**	**8,280**	**(97)**

[1/] FTE levels do not include reimbursable FTE (65 for FY 2005, 2006, and 2007).

Food and Drug Administration
Object Class Detail
User Fees
(Dollars in Thousands)

Reimbursable Obligations **PERSONNEL COMPENSATION:**	**FY 2005 Estimate**	**FY 2005 Actuals**	**FY 2006 Enacted**	**FY 2007 Estimate**	**Increase or Decrease**
11.1 Full-time permanent	$ 143,891,000	$ 125,454,000	$ 135,275,494	$ 150,586,647	$ 150,587,000
11.3 Other than full-time perm	10,834,000	16,037,000	17,227,875	18,946,091	18,946,000
11.5 Other personnel comp	5,437,000	6,558,000	6,998,011	7,904,280	7,904,000
11.7 Military Personnel Compensation	8,737,000	9,484,000	10,237,416	11,233,703	11,234,000
11.8 Special personal svcs pay	32,000	306,000	321,083	193,704	194,000
Subtotal Personnel Comp	**$ 168,931,000**	**$ 157,839,000**	**$ 170,059,878**	**$ 188,864,424**	**$ 188,865,000**
12.1 Civilian Personnel Benefits	35,905,000	38,418,000	41,907,981	46,460,727	46,461,000
12.2 Military Personnel Benefits	4,338,000	4,897,000	5,372,225	5,921,375	5,921,000
13.0 Benefits -former personnel	1,000	-	-	27,323	26,000
Subtotal Pay Costs	**$ 209,175,000**	**$ 201,154,000**	**$ 217,340,084**	**$ 241,273,849**	**$ 241,273,000**
21.0 Travel & Transportation of persons	$ 7,840,000	$ 4,029,000	$ 5,731,510	$ 6,213,346	$ 6,213,000
22.0 Transportation of things	771,000	289,000	443,386	774,242	774,000
23.1 Rental payments to GSA	15,229,000	15,170,000	16,516,000	21,947,000	21,947,000
23.2 Rent payments to others	825,000	377,000	442,975	336,903	337,000
23.3 Communication, Util & Misc Services	3,036,000	2,777,000	5,290,011	5,532,901	5,533,000
24.0 Printing & Reproduction	260,000	374,000	481,052	435,235	435,000
Contractual Costs:					
25.1 Advisory and Assistance Services	$ 3,579,000	$ 10,471,000	$ 13,180,933	$ 13,049,038	$ 13,026,000
25.2 Other Services	53,628,000	39,526,000	54,744,809	55,082,787	55,083,000
25.3 Purchase of Goods & Svcs from Govt	16,291,000	16,034,000	22,071,671	24,065,964	24,066,000
25.4 Operation & Maintenance of Facilities	2,301,000	10,879,000	13,482,976	10,012,612	10,013,000
25.5 Research & Development Contracts	3,562,000	819,000	1,685,588	2,075,604	2,076,000
25.7 Operation & Maintenance of Equipment	8,464,000	6,002,000	9,290,777	15,391,545	15,392,000
25.8 Subsistence and support of persons					
Subtotal Contractual Costs	**$ 87,825,000**	**$ 83,731,000**	**$ 114,456,754**	**$ 119,677,550**	**$ 119,656,000**
26.0 Supplies & Materials	8,630,000	4,010,000	5,756,467	6,597,474	6,597,000
31.0 Equipment	16,729,000	12,812,000	14,681,022	7,630,897	7,631,000
32.0 Land & Structure	10,000	-	13,697	46,570	47,000
41.0 Grants, subsidies & contributions	97,000	117,000	241,387	262,219	262,000
42.0 Ins claims & indemnities	16,000	371,000	368,654	68,813	92,000
62.0 Receivables collected		-	-	-	
Subtotal Non-Pay Costs	**$ 141,268,000**	**$ 124,057,000**	**$ 164,422,916**	**$ 169,523,151**	**$ 169,524,000**
TOTAL REIMBURSABLE OBLIGATION	**$ 350,443,000**	**$ 325,211,000**	**$ 381,763,000**	**$ 410,797,000**	**$ 410,797,000**
FTE [1/]	**1,796**	**1,728**	**1,843**	**1,843**	**1,956**

[1/] FTE levels do not include reimbursable FTE (65 for FY 2005, 2006, and 2007).

Food and Drug Administration
Object Class Detail
Program Level
(Dollars in Thousands)

Direct Obligation PERSONNEL COMPENSATION:	FY 2005 Estimate	FY 2005 Actuals	FY 2006 Enacted	FY 2007 Estimate	Increase or Decrease
11.1 Full-time permanent	$ 784,483,000	$ 677,295,000	$ 726,255,497	$ 798,635,647	207,655,997
11.3 Other than full-time perm	$ 50,251,000	$ 84,746,000	90,809,951	59,232,091	-14,350,076
11.5 Other personnel comp	$ 27,515,000	$ 28,356,000	30,341,593	30,282,280	6,938,418
11.7 Military Personnel Compensation	$ 44,983,000	$ 52,082,000	55,856,323	48,065,703	2,447,093
11.8 Special personal svcs pay	$ 198,000	$ 676,000	717,197	365,704	-30,114
Subtotal Personnel Comp	**$ 907,430,000**	**$ 843,155,000**	**$ 903,980,560**	**$ 936,581,424**	**202,661,318**
12.1 Civilian Personnel Benefits	$ 192,369,000	$ 205,539,000	220,882,222	205,124,727	26,150,759
12.2 Military Personnel Benefits	$ 21,494,000	$ 28,997,000	31,181,909	23,391,375	-2,418,684
13.0 Benefits -former personnel	$ 28,000	$ (50,000)	(53,193)	54,323	106,193
Subtotal Pay Costs	**$ 1,121,321,000**	**$ 1,077,641,000**	**$ 1,155,991,498**	**$ 1,165,151,849**	**226,499,586**
21.0 Travel & Transportation of persons	$ 32,146,000	$ 26,968,000	$ 27,087,204	$ 33,868,346	12,512,306
22.0 Transportation of things	5,434,000	6,699,000	6,411,224	6,080,242	112,162
23.1 Rental payments to GSA	128,708,000	127,455,000	134,095,000	146,545,000	28,966,000
23.2 Rent payments to others	5,303,000	3,358,000	3,218,204	5,430,903	2,655,771
23.3 Communication, Util & Misc Services	27,504,000	30,026,000	30,657,975	33,371,901	8,004,037
24.0 Printing & Reproduction	2,522,000	3,594,000	3,478,593	3,008,235	10,459
Contractual Costs:					
25.1 Advisory and Assistance Services	$ 44,950,000	$ 53,330,000	$ 53,082,089	$ 60,120,038	20,195,844
25.2 Other Services	136,529,000	102,374,000	113,255,200	149,405,787	90,895,609
25.3 Purchase of Goods & Svcs from Govt Acts	96,384,000	104,434,000	104,369,932	115,193,964	32,895,739
25.4 Operation & Maintenance of Facilities	52,617,000	58,055,000	57,402,947	67,261,612	23,342,029
25.5 Research & Development Contracts	23,250,000	33,927,000	32,508,771	24,476,604	-6,346,183
25.7 Operation & Maintenance of Equipment	30,759,000	36,334,000	37,529,355	40,758,545	12,520,421
25.8 Subsistence and support of persons		-			
Subtotal Contractual Costs	**$ 384,489,000**	**$ 388,454,000**	**$ 398,148,294**	**$ 457,216,550**	**148,401,460**
26.0 Supplies & Materials	27,891,000	26,987,000	27,147,926	28,512,474	7,120,542
31.0 Equipment	41,691,000	57,944,000	56,697,933	36,031,897	-5,984,911
32.0 Land & Structure	7,240,000	2,555,000	2,392,303	8,273,570	5,895,394
41.0 Grants, subsidies & contributions	23,018,000	25,900,000	24,244,354	26,342,219	2,339,033
42.0 Ins claims & indemnities	61,000	1,919,000	1,809,492	120,813	-1,296,838
62.0 Receivables collected		$ (7,575,000)			
Subtotal Non-Pay Costs	**$ 686,007,000**	**$ 701,859,000**	**$ 715,388,502**	**$ 784,802,151**	**226,113,414**
TOTAL DIRECT OBLIGATION	**$ 1,807,328,000**	**$ 1,779,500,000**	**$ 1,871,380,000**	**$ 1,949,954,000**	**452,613,000**
FTE [1/]	**10,381**	**9,910**	**10,220**	**10,123**	**1,859**

Food and Drug Administration
Object Class Detail
Salaries and Expenses -- Budget Authority
(Dollars in Thousands)

Direct Obligation **PERSONNEL COMPENSATION:**	**FY 2005 Estimate**	**FY 2005 Actuals**	**FY 2006 Enacted**	**FY 2007 Estimate**	**Increase or Decrease**
11.1 Full-time permanent	$ 640,592,000	$ 551,841,000	590,980,003	648,049,000	$ 57,068,997
11.3 Other than full-time perm	39,417,000	68,709,000	73,582,076	40,286,000	$ (33,296,076)
11.5 Other personnel comp	22,078,000	21,798,000	23,343,582	22,378,000	$ (965,582)
11.7 Military Personnel Compensation	36,246,000	42,598,000	$ 45,618,907	$ 36,832,000	$ (8,786,907)
11.8 Special personal svcs pay	166,000	370,000	396,114	172,000	$ (224,114)
Subtotal Personnel Comp	**$ 738,499,000**	**$ 685,316,000**	**733,920,682**	**747,717,000**	**$ 13,796,318**
12.1 Civilian Personnel Benefits	156,464,000	167,121,000	178,974,241	158,664,000	(20,310,241)
12.2 Military Personnel Benefits	17,156,000	24,100,000	25,809,684	17,470,000	(8,339,684)
13.0 Benefits -former personnel	27,000	(50,000)	$ (53,193)	$ 27,000	80,193
Subtotal Pay Costs	**$ 912,146,000**	**$ 876,487,000**	**938,651,414**	**923,878,000**	**$ (14,773,414)**
21.0 Travel & Transportation of persons	$ 24,306,000	$ 22,939,000	$ 21,355,694	$ 27,655,000	$ 6,299,306
22.0 Transportation of things	4,663,000	6,410,000	$ 5,967,838	$ 5,306,000	$ (661,838)
23.2 Rent payments to others	4,478,000	2,981,000	$ 2,775,229	$ 5,094,000	$ 2,318,771
23.3 Communication, Util & Misc Services	24,468,000	27,249,000	$ 25,367,963	$ 27,839,000	$ 2,471,037
24.0 Printing & Reproduction	2,262,000	3,220,000	$ 2,997,541	$ 2,573,000	$ (424,541)
Contractual Costs:					
25.1 Advisory and Assistance Services	$ 41,371,000	$ 42,859,000	39,901,156	47,071,000	$ 7,169,844
25.2 Other Services	82,901,000	62,848,000	58,510,391	94,323,000	$ 35,812,609
25.3 Purchase of Goods & Svcs from Govt Acts	80,093,000	88,400,000	82,298,261	91,128,000	$ 8,829,739
25.4 Operation & Maintenance of Facilities	50,316,000	47,176,000	43,919,971	57,249,000	$ 13,329,029
25.7 Operation & Maintenance of Equipment	22,295,000	30,332,000	28,238,579	25,367,000	$ (2,871,579)
Subtotal Contractual Costs	**$ 276,976,000**	**$ 271,615,000**	**252,868,357**	**315,138,000**	**$ 62,269,643**
26.0 Supplies & Materials	19,261,000	22,977,000	21,391,458	21,915,000	$ 523,542
Subtotal Non-Pay Costs	**$ 356,414,000**	**$ 357,391,000**	**$ 332,724,081**	**$ 405,520,000**	**$ 72,795,919**
TOTAL DIRECT OBLIGATION	**$ 1,268,560,000**	**$ 1,233,878,000**	**$ 1,271,375,495**	**$ 1,329,398,000**	**$ 58,022,505**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2005 Actuals	PREMARKET												PREMARKET TOTAL		OU COOI
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION DOMESTIC		PREMARKET OUTREACH/COORDINATION FOREIGN		PREMARKET INSPECTIONS DOMESTIC		PREMARKET INSPECTIONS FOREIGN				CON
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
FOODS															
Center for Food Safety & Applied Nutrition	27,115	168	6,159	33	6,251	56	1,441	12	0	0	0	0	40,966	269	60,
Field Activities													-	-	56,6
FOODS TOTAL	**27,115**	**168**	**6,159**	**33**	**6,251**	**56**	**1,441**	**12**	**-**	**-**	**-**	**-**	**40,966**	**269**	**117,2**
HUMAN DRUGS															
Center for Drug Evaluation & Research	276,661	1,544	14,277	62	34,680	232	5,885	30	10,353	55	3,219	17	345,075	1,940	43,2
Field Activities	4,271	36							14,860	120	5,385	44	24,516	200	20,3
PDUFA (non-add): Center	*151,983*	*897*			*11,538*	*66*	*1,836*	*9*	*8,056*	*43*	*867*	*5*	*174,280*	*1,020*	*11,2*
Field									*4,573*	*26*	*522*	*6*	*5,095*	*32*	
HUMAN DRUGS TOTAL	**280,932**	**1,580**	**14,277**	**62**	**34,680**	**232**	**5,885**	**30**	**25,213**	**175**	**8,604**	**61**	**369,591**	**2,140**	**63,5**
BIOLOGICS															
Center for Biologics Evaluation & Research	101,080	578	10,450	60	13,365	76	482	3	741	4	-	-	126,118	721	15,7
Field Activities									3,199	25	366	3	3,565	28	3,7
PDUFA (non-add): Center	*35,676*	*211*	*-*	*-*	*4,792*	*28*	*100*	*1*	*249*	*1*	*-*	*-*	*40,817*	*241*	*3*
Field									*1,043*	*7*			*1,043*	*7*	
MDUFMA (non-add): Center	*4,635*	*19*	*-*	*-*	*461*	*2*	*8*	*-*	*55*	*-*	*-*	*-*	*5,159*	*21*	*1*
Field									*97*	*1*			*97*	*1*	
BIOLOGICS TOTAL	**101,080**	**578**	**10,450**	**60**	**13,365**	**76**	**482**	**3**	**3,940**	**29**	**366**	**3**	**129,683**	**749**	**19,4**
ANIMAL DRUGS & FEEDS										-					
Center for Veterinary Medicine	28,659	191	4,091	27	825	12							*33,575*	*230*	21,6
Field Activities	62	1							*1,657*	*13*	*294*	*2*	2013	16	6,3
ADUFA (non-add): Center	*7,538*	*39*											*9,489*	*54*	
ANIMAL DRUGS & FEEDS TOTAL	**36,259**	**231**	**4,091**	**27**	**825**	**12**	**-**	**-**	**1,657**	**13**	**294**	**2**	**43,126**	**285**	**28,0**
DEVICES AND RADIOLOGICAL HEALTH															
Center for Devices & Radiological Health	89,849	566	10,156	58	5,448	37	1,335	9					106,788	670	60,3
Field Activities									5,957	41	266	2	6,223	43	18,1
MQSA (non-add): Center													*6,223*	*43*	*4,3*
Field													-	-	*4,8*
MDUFMA (non-add): Center	*15,492*	*108*											15,492	108	
Field									*869*	*7*			869	7	
DEVICES TOTAL	**89,849**	**566**	**10,156**	**58**	**5,448**	**37**	**1,335**	**9**	**5,957**	**41**	**266**	**2**	**113,011**	**713**	**78,5**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**24,928**	**117**									**24,928**	**117**	
OTHER ACTIVITIES															
Other Activities	**40,005**	**229**	**2,649**	**20**	**4,527**	**30**	**683**	**4**	**2,748**	**19**	**712**	**5**	**51,325**	**307**	**22,6**
USER FEES (non-add): PDUFA													-	-	
MQSA (Other Activities)													-	-	
MDUFMA													-	-	
ADUFA															
OTHER ACTIVITIES TOTAL	**40,005**	**229**	**2,649**	**20**	**4,527**	**30**	**683**	**4**	**2,748**	**19**	**712**	**5**	**51,325**	**307**	**22,6**
SUB-TOTAL:	**575,240**	**3,352**	**72,710**	**377**	**65,096**	**443**	**9,826**	**58**	**39,515**	**277**	**10,242**	**73**	**772,630**	**4,580**	**329,8**
Total Center	534,772	3,086	68,619	350	64,271	431	9,826	58	15,499	91	4,225	24	697,213	4,040	209,0
Total Field	11,809	75	-	-	-	-	-	-	24,016	186	6,017	49	41,842	310	99,1
(PDUFA, MQSA and MDUFMA User Fees - non add)	*207,786*	*1,235*	*-*	*-*	*16,791*	*96*	*1,944*	*10*	*14,942*	*85*	*1,389*	*11*	*242,852*	*1,437*	*20,9*
Plus:															
Other Rent and Rent-Related															
Other Rent and Rent Related MDUFMA(non-add)															
GSA Rent															
GSA Rent PDUFA (non-add)															
GSA Rent MDUFMA (non-add)															
Other Current Law User Fees															
Buildings and Facilities															
TOTAL S&E PROGRAM:															

UNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2005 Actuals	POSTMARKET									POSTMARKET TOTAL		TOTAL ALL FDA	
	POSTMARKET RATORY ANALYSES			POSTMARKET INSPECTIONS									
	STIC	IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS													
Center for Food Safety & Applied Nutrition	34	5,134	41	1,605	7	2,121	17	687	0	111,294	615	152,260	884
Field Activities	212	46,792	359	60,384	461	2,544	20	72,887	524	283,257	2,059	283,257	2,059
FOODS TOTAL	**246**	**51,926**	**400**	**61,989**	**468**	**4,665**	**37**	**73,574**	**524**	**394,551**	**2,674**	**435,517**	**2,943**
HUMAN DRUGS													
Center for Drug Evaluation & Research	7	241	1	3,250	18	2,269	7	240	1	50,961	280	396,036	2,220
Field Activities	42	1,740	17	25,020	200	2,955	24	6,421	50	61,582	498	86,098	698
PDUFA (non-add): Center										*11,275*	*29*	*185,555*	*1,049*
Field										-	-	*5,095*	*32*
HUMAN DRUGS TOTAL	**49**	**1,981**	**18**	**28,270**	**218**	**5,224**	**31**	**6,661**	**51**	**112,543**	**778**	**482,134**	**2,918**
BIOLOGICS													
Center for Biologics Evaluation & Research	-	0	0	1,174	7	-	-	-	-	16,912	97	143,030	818
Field Activities				18,519	148	885	7	935	7	24,089	195	27,654	223
PDUFA (non-add): Center	-	-	-	-	-	-	-	-	-	*358*	*2*	*41,175*	*243*
Field										-	-	*1,043*	*7*
MDUFMA (non-add): Center	-	-	-	-	-	-	-	-	-	*101*	*1*	*5,260*	*22*
Field										-	-	*97*	*1*
BIOLOGICS TOTAL	**-**	**-**	**-**	**19,693**	**155**	**885**	**7**	**935**	**7**	**41,001**	**292**	**170,684**	**1,041**
ANIMAL DRUGS & FEEDS							-						
Center for Veterinary Medicine										*29,323*	*139*	*62,898*	*369*
Field Activities	*29*	*1,668*	*13*	*16,019*	*96*	*180*	*2*	*4,169*	*33*	33111	225	35124	241
ADUFA (non-add): Center										*33,111*	*225*		
ANIMAL DRUGS & FEEDS TOTAL	**29**	**1,668**	**13**	**16,019**	**96**	**180**	**2**	**4,169**	**33**	**62,434**	**364**	**98,022**	**610**
DEVICES AND RADIOLOGICAL HEALTH													
Center for Devices & Radiological Health	82									*76,369*	*434*	183,157	1,104
Field Activities	22	2,888	25	22,067	140	3,482	23	4,996	32	54,902	369	61,125	412
MQSA (non-add): Center										*4,373*	*26*	*4,373*	*26*
Field				*3,749*	*4*					*8,586*	*8*	*8,586*	*8*
MDUFMA (non-add): Center										-	-	*15,492*	*108*
Field										-	-	*869*	*7*
DEVICES TOTAL	**104**	**2,888**	**25**	**22,067**	**140**	**3,482**	**23**	**4,996**	**32**	**131,271**	**803**	**244,282**	**1,516**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH								**-**	**-**	**15,278**	**70**	**40,206**	**187**
OTHER ACTIVITIES													
Other Activities	**31**	**4,370**	**33**	**11,065**	**79**	**1,079**	**7**	**6,752**	**47**	**52,877**	**348**	**104,202**	**655**
USER FEES (non-add): PDUFA										-	-	-	-
MQSA (Other Activities)										-	-	-	-
MDUFMA										-	-	-	-
ADUFA													
OTHER ACTIVITIES TOTAL	**31**	**4,370**	**33**	**11,065**	**79**	**1,079**	**7**	**6,752**	**47**	**52,877**	**348**	**104,202**	**655**
SUB-TOTAL:	**459**	**62,833**	**489**	**159,103**	**1,156**	**15,515**	**107**	**97,087**	**694**	**809,955**	**5,329**	**1,575,047**	**9,870**
Total Center	183	11,413	88	33,113	207	5,649	33	11,848	81	356,802	2,069	1,054,015	6,109
Total Field	276	51,420	401	125,990	949	9,866	74	85,239	613	423,830	3,121	465,672	3,431
(PDUFA, MQSA and MDUFMA User Fees - non add)	-	-	-	*3,749*	*4*	-	-	-	-	*24,693*	*66*	*267,545*	*1,503*
Plus:													
Other Rent and Rent-Related												65,500	-
Other Rent and Rent Related MDUFMA(non-add)													
GSA Rent												127,495	-
GSA Rent PDUFA (non-add)													-
GSA Rent MDUFMA (non-add)													
Other Current Law User Fees												6,931	43
Buildings and Facilities												2,199	-
TOTAL S&E PROGRAM:												**1,777,173**	**9,913**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2006 Enacted	PREMARKET														
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION				PREMARKET INSPECTIONS				PREMARKET TOTAL		OUT COOR COM
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN				
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
FOODS															
Center for Food Safety & Applied Nutrition	26,546	168	6,750	33	6,183	56	1,425	12	0	-	-	-	40,904	269	59,2
Field Activities	-												-	-	67,7
FOODS TOTAL	**26,546**	**168**	**6,750**	**33**	**6,183**	**56**	**1,425**	**12**	**0**	**-**	**-**	**-**	**40,904**	**269**	**126,9**
HUMAN DRUGS															
Center for Drug Evaluation & Research	305,406	1,713	15,000	62	38,192	214	5,931	20	10,376	55	3,265	17	378,170	2,081	46,9
Field Activities	874	7							11,296	87	4,148	32	16,318	126	25,2
PDUFA (non-add): Center	*176,496*	*925*			*13,015*	*62*	*1,802*	*9*	*7,933*	*43*	*867*	*5*	*200,113*	*1,044*	*13,7*
Field	*-*	*-*							*4,189*	*19*	*1,744*	*10*	*5,933*	*29*	
HUMAN DRUGS TOTAL	**306,280**	**1,720**	**15,000**	**62**	**38,192**	**214**	**5,931**	**20**	**21,672**	**142**	**7,413**	**49**	**394,488**	**2,207**	**71,7**
BIOLOGICS															
Center for Biologics Evaluation & Research	119,113	636	9,332	52	15,757	84	572	3	872	5	-	-	145,646	780	18,1
Field Activities	-								3,728	20	200	1	3,928	21	6,9
PDUFA (non-add): Center	*38,932*	*199*	*-*	*-*	*5,229*	*27*	*109*	*1*	*272*	*1*	*-*	*-*	*44,542*	*228*	*3*
Field									*2,742*	*12*			*2,742*	*12*	
MDUFMA (non-add): Center	*7,414*	*26*	*-*	*-*	*737*	*3*	*12*	*-*	*87*	*-*	*-*	*-*	*8,250*	*29*	*1*
Field									*389*	*2*			*389*	*2*	
BIOLOGICS TOTAL	**119,113**	**636**	**9,332**	**52**	**15,757**	**84**	**572**	**3**	**4,600**	**25**	**200**	**1**	**149,574**	**801**	**25,**
ANIMAL DRUGS & FEEDS															
Center for Veterinary Medicine	*30,373*	*221*	*4,082*	*26*	*823*	*12*							*35,278*	*259*	*21,2*
Field Activities									1340	9	662	4	2002	13	10
ADUFA (non-add): Center	*9,301*	*76*											*9,301*	*76*	
ANIMAL DRUGS & FEEDS TOTAL	**39,674**	**297**	**4,082**	**26**	**823**	**12**	**-**	**-**	**1,340**	**9**	**662**	**4**	**46,581**	**348**	**31,9**
DEVICES AND RADIOLOGICAL HEALTH															
Center for Devices & Radiological Health	97,863	598	10,245	58	5,536	37	1,357	9					115,001	702	61,9
Field Activities									6,125	37	356	2	6,481	39	17,
MQSA (non-add): Center													-	-	*5,3*
Field													-	-	*6,3*
MDUFMA (non-add): Center	*22,173*	*124*											*22,173*	*124*	
Field									*805*	*8*			*805*	*8*	
DEVICES TOTAL	**97,863**	**598**	**10,245**	**58**	**5,536**	**37**	**1,357**	**9**	**6,125**	**37**	**356**	**2**	**121,482**	**741**	**78,7**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**25,996**	**128**									**25,996**	**128**	
OTHER ACTIVITIES															
Other Activities	**47,376**	**268**	**2,649**	**20**	**5,344**	**32**	**1**	**0**	**2,711**	**17**	**694**	**4**	**58,775**	**341**	**26,4**
USER FEES (non-add): PDUFA													-	-	
MQSA (Other Activities)													-	-	
MDUFMA													-	-	
ADUFA															
OTHER ACTIVITIES TOTAL	**47,376**	**268**	**2,649**	**20**	**5,344**	**32**	**1**	**0**	**2,711**	**17**	**694**	**4**	**58,775**	**341**	**26,4**
SUB-TOTAL:	**636,852**	**3,687**	**74,054**	**379**	**71,835**	**435**	**9,286**	**44**	**36,448**	**230**	**9,325**	**60**	**837,800**	**4,835**	**361,4**
Total Center													-	-	233,6
Total Field													-	-	127,7
(PDUFA, MQSA and MDUFMA User Fees - non add)													-	-	*26,0*
Plus:															
Other Rent and Rent-Related															
Other Rent and Rent Related MDUFMA(non-add)															
GSA Rent															
GSA Rent PDUFA (non-add)															
GSA Rent MDUFMA (non-add)															
GSA Rent ADUFA (non-add)															
Other Current Law User Fees															
Buildings and Facilities															
TOTAL S&E PROGRAM:															

UNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2006 Enacted	POSTMARKET									POSTMARKET TOTAL		TOTAL ALL FDA	
	POSTMARKET RATORY ANALYSES			POSTMARKET INSPECTIONS									
	STIC	IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS													
Center for Food Safety & Applied Nutrition	34	5,078	41	1,587	7	2,098	17	680	-	113,103	612	153,568	881
Field Activities	196	51,567	353	53,080	363	1,541	11	67,561	463	285,153	1,962	285,153	1,962
FOODS TOTAL	**230**	**56,645**	**394**	**54,667**	**370**	**3,639**	**28**	**68,241**	**463**	**398,256**	**2,574**	**438,721**	**2,843**
HUMAN DRUGS													
Center for Drug Evaluation & Research	7	235	1	3,309	16	2,258	7	234	1	53,535	279	431,705	2,360
Field Activities	56	2,525	22	24,820	192	3,180	25	6,171	48	69,534	538	85,852	664
PDUFA (non-add): Center										*13,795*	*37*	*213,908*	*1,081*
Field										*0*	-	*5,933*	*29*
HUMAN DRUGS TOTAL	**63**	**2,760**	**23**	**28,129**	**208**	**5,438**	**32**	**6,405**	**49**	**122,766**	**817**	**517,557**	**3,024**
BIOLOGICS													
Center for Biologics Evaluation & Research	-	-	-	1,356	7	-	-	-	-	19,531	103	165,177	883
Field Activities				17,459	140	976	7	964	7	26,387	206	30,315	227
PDUFA (non-add): Center	-	-	-	-	-	-	-	-	-	*391*	*2*	*44,933*	*230*
Field										-	-	*2,742*	*12*
MDUFMA (non-add): Center	-	-	-	-	-	-	-	-	-	*162*	*1*	*8,412*	*30*
Field										-	-	*389*	*2*
BIOLOGICS TOTAL	**-**	**-**	**-**	**18,815**	**147**	**976**	**7**	**964**	**7**	**45,918**	**309**	**195,492**	**1,110**
ANIMAL DRUGS & FEEDS													
Center for Veterinary Medicine										*28,762*	*126*	*64,040*	*385*
Field Activities	23	1406	9	12033	77	78	1	4417	28	32840	215	34842	228
ADUFA (non-add): Center										-	-		
ANIMAL DRUGS & FEEDS TOTAL	**23**	**1,406**	**9**	**12,033**	**77**	**78**	**1**	**4,417**	**28**	**61,602**	**341**	**98,882**	**613**
DEVICES AND RADIOLOGICAL HEALTH													
Center for Devices & Radiological Health	82									*77,713*	*434*	192,714	1,136
Field Activities	10	2,342	14	31,028	137	3,529	20	4,902	50	61,308	368	67,789	407
MQSA (non-add): Center										*5,337*	*26*	*5,337*	*26*
Field				*5,231*	*3*					*11,624*	*8*	*11,624*	*8*
MDUFMA (non-add): Center										-	-	*22,173*	*124*
Field										-	-	*805*	*8*
DEVICES TOTAL	**92**	**2,342**	**14**	**31,028**	**137**	**3,529**	**20**	**4,902**	**50**	**139,021**	**802**	**260,503**	**1,543**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH								**-**	**-**	**14,744**	**78**	**40,740**	**206**
OTHER ACTIVITIES													
Other Activities	**32**	**5,076**	**35**	**11,627**	**74**	**1,098**	**7**	**6,826**	**47**	**58,652**	**368**	**117,427**	**709**
USER FEES (non-add): PDUFA										-	-	-	-
MQSA (Other Activities)										-	-	-	-
MDUFMA										-	-	-	-
ADUFA													
OTHER ACTIVITIES TOTAL	**32**	**5,076**	**35**	**11,627**	**74**	**1,098**	**7**	**6,826**	**47**	**58,652**	**368**	**117,427**	***709***
SUB-TOTAL:	**440**	**68,229**	**475**	**156,300**	**1,013**	**14,758**	**95**	**91,754**	**644**	**840,959**	**5,289**	**1,669,322**	**10,048**
Total Center	155	10,389	77	17,880	104	5,454	31	7,739	48	366,040	2,000	366,040	2,000
Total Field	285	57,840	398	138,420	909	9,304	64	84,015	596	474,919	3,289	474,919	3,289
(PDUFA, MQSA and MDUFMA User Fees - non add)	-	-	-	*5,231*	*3*	-	-	-	-	*31,309*	*74*	*316,256*	*74*
Plus:													
Other Rent and Rent-Related												57,938	
Other Rent and Rent Related MDUFMA(non-add)													
GSA Rent												133,677	
GSA Rent PDUFA (non-add)													
GSA Rent MDUFMA (non-add)													
GSA Rent ADUFA (non-add)													
Other Current Law User Fees												7,640	46
Buildings and Facilities												7,920	
TOTAL S&E PROGRAM:												**1,876,497**	**10,094**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2007 Request	PREMARKET													
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION				PREMARKET INSPECTIONS				PREMARKET TOTAL	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN			
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS														
Center for Food Safety & Applied Nutrition	21,350	137	7,264	31	6,241	56	1,439	12	0	-	-	-	36,293	236
Field Activities													-	-
FOODS TOTAL	**21,350**	**137**	**7,264**	**31**	**6,241**	**56**	**1,439**	**12**	**-**	**-**	**-**	**-**	**36,293**	**236**
HUMAN DRUGS														
Center for Drug Evaluation & Research	314,358	1,704	17,136	79	38,584	216	6,097	27	10,558	55	3,342	16	390,075	2,097
Field Activities	874	7							11,296	87	4,148	32	16,318	126
PDUFA (non-add): Center	*183,681*	*945*			*14,106*	*62*	*1,802*	*9*	*7,933*	*43*	*867*	*5*	*208,389*	*1,064*
Field									*4,462*	*20*	*1,744*	*10*	*6,206*	*30*
HUMAN DRUGS TOTAL	**315,232**	**1,711**	**17,136**	**79**	**38,584**	**216**	**6,097**	**27**	**21,854**	**142**	**7,490**	**48**	**406,393**	**2,223**
BIOLOGICS														
Center for Biologics Evaluation & Research	129,752	674	8,399	47	17,168	90	625	3	950	5	-	-	156,894	819
Field Activities									4,173	23	200	1	4,373	24
PDUFA (non-add): Center	*40,724*	*207*	-	-	*5,470*	*28*	*114*	*1*	*284*	*1*	-	-	*46,592*	*237*
Field									*2,868*	*13*	*2,868*	*13*	*5,736*	*26*
MDUFMA (non-add): Center	*8,042*	*28*	-	-	*800*	*3*	*14*	*1*	*95*	-	-	-	*8,951*	*32*
Field									*422*	*2*			*422*	*2*
BIOLOGICS TOTAL	**129,752**	**674**	**8,399**	**47**	**17,168**	**90**	**625**	**3**	**5,123**	**28**	**200**	**1**	**161,267**	**843**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	*33,368*	*238*	*4,134*	*26*	*838*	*12*							*38,340*	*276*
Field Activities									1340	9	662	4	2002	13
ADUFA (non-add): Center	*9,537*	*76*											*9,537*	*76*
ANIMAL DRUGS & FEEDS TOTAL	**33,368**	**238**	**4,134**	**26**	**838**	**12**	**-**	**-**	**1,340**	**9**	**662**	**4**	**40,342**	**289**
DEVICES AND RADIOLOGICAL HEALTH														
Center for Devices & Radiological Health	101,393	615	11,996	59	5,772	38	1,368	9					120,529	721
Field Activities									5,626	37	356	2	5,982	39
MQSA (non-add): Center													-	-
Field													-	-
MDUFMA (non-add): Center	*24,058*	*131*											*24,058*	*131*
Field									*873*	*9*			*873*	*9*
DEVICES TOTAL	**101,393**	**615**	**11,996**	**59**	**5,772**	**38**	**1,368**	**9**	**5,626**	**37**	**356**	**2**	**126,511**	**760**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**-**	**-**	**23,965**	**139**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**23,965**	**139**
OTHER ACTIVITIES														
Other Activities	**47,639**	**258**	**2,649**	**20**	**5,437**	**31**	**755**	**4**	**2,690**	**17**	**690**	**4**	**59,860**	**334**
USER FEES (non-add): PDUFA													-	-
MQSA (Other Activities)													-	-
MDUFMA													-	-
ADUFA													-	-
OTHER ACTIVITIES TOTAL	**47,639**	**258**	**2,649**	**20**	**5,437**	**31**	**755**	**4**	**2,690**	**17**	**690**	**4**	**59,860**	**334**
SUB-TOTAL:	**648,734**	**3,633**	**75,543**	**401**	**74,040**	**443**	**10,284**	**55**	**36,633**	**233**	**9,398**	**59**	**854,631**	**4,824**
Total Center	647,860	3,626	75,543	401	74,040	443	10,284	55	14,198	77	4,032	20	825,956	4,622
Total Field	874	7	-	-	-	-	-	-	22,435	156	5,366	39	28,675	202
(PDUFA, MQSA, MDUFMA, ADUFA			-	-	*20,376*	*93*	*1,930*	*11*	*16,937*	*88*			*39,243*	*192*
User Fees - non add)														
Plus:														
Other Rent and Rent-Related														
Other Rent and Rent Related MDUFMA (non-add)														
Other Rent and Rent Related PDUFA (non-add)														
GSA Rent														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
Other Current Law User Fees														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2007 Request	POSTMARKET														POSTMARKET TOTAL		TOTAL ALL FDA	
	OUTREACH COORDINATION		POSTMARKET APPLIED		POSTMARKET LABORATORY ANALYSES				POSTMARKET INSPECTIONS									
	COMPLIANCE		RESEARCH		DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS																		
Center for Food Safety & Applied Nutrition	55,761	330	38,874	152	8,344	34	5,125	41	1,602	7	2,117	17	686	-	112,510	581	148,363	817
Field Activities	70,079	542	1,100	10	52,575	230	51,567	353	58,797	348	1,541	11	65,665	446	301,324	1,940	301,324	1,940
FOODS TOTAL	**125,840**	**872**	**39,974**	**162**	**60,919**	**264**	**56,692**	**394**	**60,399**	**355**	**3,658**	**28**	**66,351**	**446**	**413,834**	**2,521**	**449,687**	**2,757**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	50,202	242	1,382	11	1,081	7	234	1	3,405	16	2,338	7	244	1	58,886	285	448,961	2,382
Field Activities	25,354	189	-	-	7,329	57	2,828	22	24,820	192	3,180	25	6,171	48	69,682	533	86,000	659
PDUFA (non-add): Center	*15,363*	*41*													*15,363*	*41*	*223,752*	*1,105*
Field																	*6,206*	*30*
HUMAN DRUGS TOTAL	**75,556**	**431**	**1,382**	**11**	**8,410**	**64**	**3,062**	**23**	**28,225**	**208**	**5,518**	**32**	**6,415**	**49**	**128,568**	**818**	**534,961**	**3,041**
BIOLOGICS																		
Center for Biologics Evaluation & Research	19,579	102	-	-	-	-	-	-	1,461	8	-	-	-	-	21,040	110	177,934	929
Field Activities	6,166	45			-				19,142	153	1,421	9	964	7	27,693	214	32,066	238
PDUFA (non-add): Center	*409*	*2*	-	-	-	-	-	-	-	-	-	-	-	-	409	2	*47,001*	*239*
Field															-	-	*5,736*	*26*
MDUFMA (non-add): Center	*176*	*1*	-	-	-	-	-	-	-	-	-	-	-	-	176	1	*9,127*	*33*
Field															-	-	*422*	*2*
BIOLOGICS TOTAL	**25,745**	**147**	**-**	**-**	**-**	**-**	**-**	**-**	**20,603**	**161**	**1,421**	**9**	**964**	**7**	**48,733**	**324**	**210,000**	**1,167**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	*22,511*	*94*	*8,402*	*36*											*30,913*	*130*	*69,253*	*406*
Field Activities	12293	75			4258	31	1405	9	11325	72	78	1	4417	29	33776	217	35778	230
ADUFA (non-add): Center															-	-	*9,537*	*76*
ANIMAL DRUGS & FEEDS TOTAL	**34,804**	**169**	**8,402**	**36**	**4,258**	**31**	**1,405**	**9**	**11,325**	**72**	**78**	**1**	**4,417**	**29**	**64,689**	**347**	**105,031**	**636**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	61,590	339	2,478	15	15,883	83									79,951	437	200,480	1,158
Field Activities	17,156	130			2,351	16	2,342	14	33,628	149	4,278	23	5,354	50	65,109	382	71,091	421
MQSA (non-add): Center	*5,445*	*26*													*5,445*	*26*	*5,445*	*26*
Field	*6,630*	*5*							*5,231*	*3*					*11,861*	*8*	*11,861*	*8*
MDUFMA (non-add): Center															-	-	*24,058*	*131*
Field															-	-	*873*	*9*
DEVICES TOTAL	**78,746**	**469**	**2,478**	**15**	**18,234**	**99**	**2,342**	**14**	**33,628**	**149**	**4,278**	**23**	**5,354**	**50**	**145,060**	**819**	**271,571**	**1,579**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**-**	**-**	**10,275**	**60**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**10,275**	**60**	**34,240**	**199**
OTHER ACTIVITIES																		
Other Activities	**27,001**	**160**	**1,182**	**9**	**7,243**	**35**	**5,033**	**34**	**12,219**	**72**	**1,185**	**7**	**6,618**	**44**	**60,481**	**361**	**120,341**	**695**
USER FEES (non-add): PDUFA															-	-	-	-
MQSA (Other Activities)															-	-	-	-
MDUFMA															-	-	-	-
ADUFA															-	-	-	-
OTHER ACTIVITIES TOTAL	**27,001**	**160**	**1,182**	**9**	**7,243**	**35**	**5,033**	**34**	**12,219**	**72**	**1,185**	**7**	**6,618**	**44**	**60,481**	**361**	**120,341**	**695**
SUB-TOTAL:	**367,692**	**2,248**	**63,693**	**293**	**99,064**	**493**	**68,534**	**474**	**166,399**	**1,017**	**16,138**	**100**	**90,119**	**625**	**871,640**	**5,250**	**1,725,831**	**10,074**
Total Center	236,644	1,267	62,593	283	32,551	159	10,392	76	18,687	103	5,640	31	7,548	45	374,056	1,964	1,200,012	6,586
Total Field	131,048	981	1,100	10	66,513	334	58,142	398	147,712	914	10,498	69	82,571	580	497,584	3,286	526,259	3,488
(PDUFA, MQSA, MDUFMA, ADUFA	*28,023*	*75*	-	-	-	-	-	-	*5,231*	*3*	-	-	-	-	*33,254*	*78*		*270*
User Fees - non add)																		
Plus:																		
Other Rent and Rent-Related																	62,007	
Other Rent and Rent Related MDUFMA (non-add)																		
Other Rent and Rent Related PDUFA (non-add)																		
GSA Rent																	146,013	
GSA Rent PDUFA (non-add)																		
GSA Rent MDUFMA (non-add)																		
GSA Rent ADUFA (non-add)																		
Other Current Law User Fees																	8,481	50
Buildings and Facilities																	4,950	
TOTAL S&E PROGRAM:																	**1,947,282**	**10,124**

Special Requirements

Unified Financial Management System (UFMS). UFMS is being implemented to replace five legacy accounting systems currently used across the Operating Divisions (Agencies). The UFMS will integrate the Department's financial management structure and provide HHS leaders with a more timely and coordinated view of critical financial management information. The system will also facilitate shared services among the Agencies and thereby, help management reduce substantially the cost of providing accounting service throughout HHS. Similarly, UFMS, by generating timely, reliable and consistent financial information, will enable the component agencies and program administrators to make more timely and informed decisions regarding their operations. UFMS has reached a major milestone in April 2005 with the move to production for the Center for Disease Control (CDC) and the Food and Drug Administration (FDA). FDA's FY 2007 budget includes $2,328,000 for this purpose.

Accounting Operations. Operations and Maintenance (O & M) activities for UFMS commenced in FY 05. The Program Support Center will provide the O & M activities needed to support UFMS. The scope of O & M services includes post deployment support and ongoing business and technical operations services. Post-deployment services include supplemental functional support, training, change management and technical help-desk services. On-going business operation services involve core functional support, training and communications, and help desk services. On-going technical services include the operations and maintenance of the UFMS production and development environments, on-going development support, and backup and disaster recovery services. FDA's FY 2007 budget includes $3,163,000 for this purpose.

Automating Administrative Activities. HHS agencies have been working to implement automated solutions for a wide range of administrative activities. As UFMS development and implementation move toward completion, there are added opportunities to improve efficiency through automating the transfer of information from administrative systems to the accounting system. FDA's FY 2007 budget includes $1,482,000 to support coordinated development of these improved automated linkages and administrative systems.

Food and Drug Administration
Extramural Grant Research - FY 2005

GRANTEE INSTITUTION	STATE	PROJECT TITLE	AMOUNT
University of Cincinnati	OH	Cultured Skin Substitutes for Closure of Burn Wounds	$427,524
Case Western Reserve University	OH	Implanted Neuroprostesis for Standing after SCI	$362,236
Johns Hopkins University	MD	Investigation of Dose/Efficacy Properties of Intraventicular rt-PA in IVH	$365,704
Medical University of South Carolina	SC	Phase II Study of Alendronate in Juvenile Osteoporosis	$352,543
Los Angeles Biomedical Research Institute	CA	L-glutamine Therapy for Sickle Cell Anemia	$347,409
Children's Research Institute	DC	Phase I Study of Pirfenidone in Children with PNS in NF1	$295,823
Johns Hopkins University	MD	Phase II Trial of Moxifloxacin for TB	$390,480
University of Michigan	MI	MIBG plus Intensive Chemotherapy for Neroblastoma	$351,289
Drexel University College of Med	PA	Controlled Study of Olanzapine in Children with Autism	$407,489
Children's Hospital	MA	Clotrimazole Enemas for Pouchitis in Childrens and Adults	$18,324
University of California	CA	Immune Monitor for COG Trial of Anti-GD2 in Neuroblastoma	$281,300
Vanderbilt University Medical Center	TN	Inhibition of NF-kB Signaling in Melanoma Therapy	$276,949
Case Western Reserve University	OH	Restoration of Hand-Arm Function with Neuroprosthese	$228,131
Pennsylvania State University	PA	Treatment of Advanced Pancreatic Cancer with Opioid Growth Factor	$318,371
Children's Hospital Medical Center	OH	Anti-IL-5 for Hypereosinophilia	$234,119
University of Michigan	MI	Treatment of Graft-vs-Host Disease Using Enbrel	$228,016
Kennedy Krieger Research Institute	MD	Dextromethorphan in Rett Syndrome	$454,886
Columbia University Health Sciences	NY	Treatment of Hypoparathyroidism with Parathyroid Hormone	$446,250
John Hopkins University	MD	Phase II Study of Rapamycin in Pancreatic Cancer	$429,155
Duke University Medical Center	NC	PEG-uricase as Therapy for Refractory Gout	$462,000
Retina Foundation of Southwest	TX	High Dose DHA and X-Linked Retinitis Pigmentosa	$343,885
University of Pittsburgh	PA	DC Tumor conjugate Accine for the Immunotherapy of CTCL	$116,128
Massachusetts General Hospital	MA	IMURAN Dose Ranging Study in Crohn's Disease	$377,950
Children's Hospital Boston	MA	Inhaled NO Pediatric Painful Sickle Crisis	$251,958
Children's Hospital Boston	MA	Inhaled NO Pediatric Painful Sickle Crisis	$8,944
Johns Hopkins University	MD	Growth Hormone use in Pseudohypoparathyroidism Type 1A	$172,981
University of Iowa	IA	Phase I Trial of 90Y-DOTA-tyr3-Octreotide in Children	$174,150
Mt. Sinai School of Medicine	NY	Fluoxetine in Pediatric Body Dysmorphic Disorder	$401,485
Missouri Dept of Health and Sr Services	MO	Missouri Food Safety Task Force Conference Grant	$6,955
New York State Dept. Agriculture & Markets	NY	New York Food Safety Task Force Meeting	$7,000
Arizona Department of Agriculture	AZ	Arizona Food Safety Task Force	$7,000
State of New Hampshire	NH	NH State Food Safety Task Force Meetings	$7,000
Minnesota State Dept. of Agriculture	MN	State Food Safety Task Force Meetings	$7,000
Nebraska Department of Agriculture	NE	Nebraska Food Safety Task Force Conference	$7,000
CO Dept of Public Health & Environment	CO	Colorado State Food Safety Task Conference	$7,000
Rhode Island Department of Health	RI	Support for Rhode Island State Food Safety Task Force Conference/Meetings	$7,000
Iowa Department of Inspection & Appeals	IA	Iowa State Food Safety Meetings	$7,000
Nevada State Dairy Commission	NV	Nevada Food Safety Task Force	$7,000
North Carolina Division of Public Health	NC	North Carolina Food Safety and Security Task Force Meetins	$7,000
California Department of Health Services	CA	California Food Safety and Security Agency Team Conference	$7,000
Va Dept of Agriculture and Consumer Srvs	VA	Virginia Food Safety Task Force Meetings	$7,000
Kansas Department of Health and Environment	KS	Kansas Food Safety Task Force	$7,000
D.C. Department of Health	DC	District of Columbia Food Safety Task Force	$7,000
University of Texas Medical Branch	TX	Response to Phenylketonuria to Tetrahydrobiopterin	$373,358
CRCPD	KY	Assuring Radiation Protection	$453,000
World Health Organization		International programme on Chemical Safety	$90,000
Illinois Institute of Technology	IL	National Center for Food Safety and Technology	$175,500
Illinois Institute of Technology	IL	National Center for Food Safety and Technology	$3,000,000
Interestate Shellfish Sanitation Conference	SC	Shellfish Safety Assistance Project	$325,000
University of Maryland, College Park	MD	Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition	$607,100
Iowa State University	IA	Veterinary Antimicrobial Decision Support System (VADS)	$249,617
New Mexico State University	NM	Improving Safety of Fresh Fruits & Vegetables - Design Contest	$106,000
Univeristy of Mississippi	MS	Botnical Dietary Supplements: Science-Base for Authentication	$855,881
University of Mississippi	MS	Botnical Dietary Supplements: Science-Base for Authentication	$493,453
Tennessee State University	TN	Protein Markers for Verifying Inactivation of TSE Agents	$122,332
Agentase LLC	PA	Biocatalytic Polymer Indicators of Fish Freshness	$365,269
BioSense Technologies, Inc.	MA	Rapid Detection of Bacterial Contamination in Platelets	$48,595
Saigene Corporation	WA	Rapid On-Site Human fecal Contamination Biosensor	$80,136
Trevigen, Inc.	MD	Sensitive Detection of Food and Water Borne Path	$100,000
Tennessee Department of Health	TN	Communication and Cooperation with state and local	$6,974
Pennsylvania Department of Agric	PA	PA Act 315 Members Meeting	$7,000
Wyoming Department of Agriculture	WY	Food Safety Task Force Conference Grant	$5,000
Massachusetts Department of Health	MA	Food Safety Task Force Conference Grant	$5,000
Oklahoma Dept of Agriculture	OK	Food Safety Task Force Conference Grant	$7,000
Indiana Dept of Health	IN	Food Safety Task Force Conference Grant	$7,000
New Jersey Dept of Health and Senior Services	NJ	Food Safety Task Force Conference Grant	$7,000
Michigan Dept of Agriculture	MI	Food Safety Task Force Conference Grant	$7,000
Delaware Health and Social Services	DE	Food Safety Task Force Conference Grant	$7,000
West Virginia Dept of Health and Human Serv	WV	Food Safety Task Force Conference Grant	$7,000
Hawaii Dept of Health	HI	Food Safety Task Force Conference Grant	$7,000
Alaska Dept of Environmental Conservation	AK	Food Safety Task Force Conference Grant	$7,000
Georgia Dept of Agriculture	GA	Food Safety Task Force Conference Grant	$7,000
South Carolina Department of Agriculture	SC	Safety Council	$7,000
Florida Dept of Agriculture and Consumer	FL	Food Safety and Food Security Advisory Council	$7,000
Arkansas Dept of Health and Human Services	AR	Food Safety and Standardization Task Force Workshop	$5,000
Texas Department of Health	TX	Food Safety Task Force Conference Grant	$7,000
University of Michigan	MI	Phase III Trial of Tetrathiomolybdate in Primary Biliary Cirrhosis	$296,514
Duke University Medical Center	NC	Dose Study of Thymus Transplantation	$461,612
University of Texas Medical Branch	TX	Hydroxychloroquine vs. Phlebotomy for PCT	$262,263
DOR BioPharma, Inc.	FL	Oral BDP for the Treatment of GI GVHD	$318,750
Children's Hospital Los Angeles	CA	MND-ADA Transduced CD34+Cells for ADA-SCID	$456,900
Beckman Research Institute City of Hope	CA	Phase I/II Study of Nelfinavir in Liposarcoma	$253,500

PTC Therapeutics, Inc.	NJ	PTC 124 as a Therapy for Nonsense-Mutation-Mediated CF	$298,999
Massachusetts General Hospital	MA	Phase 2 Trial of Recombinant Human Prolactin for Lactation Induction	$219,396
Point Therapeutics, Inc.	MA	Phase 2 Trial: Talabostat in Chronic Lymphocytic Leukemia	$300,000
Orphan Therapeutics, LLC	NJ	Terlipressin in HRS Type 1 (Phase 3)	$290,765
Massachusetts General Hospital	MA	Double Blind Study of Minocycline in HD	$361,319
Children's Hospital Medical Center	OH	Oxandrolone for the Treatment of Marrow Aplasia in Fanconi Anemia	$128,466
Arizona Department of Health Services	AR	Arizona Food Safety and Security Monitoring Project	$350,000
Florida Dept of Agriculture and Consumer	FL	Florida Food Safety and Security Monitoring of FERN	$350,000
Virginia Dept of General Services	VA	Virginia Food Safety and Security Monitoring Project	$310,000
Minnesota State Dept. of Agriculture	MN	Minnesota Food Safety and Security Monitoring Project	$334,950
Connecticut Agricultural Experiment Station	CT	FERN Food Safety Activiites at CAES	$232,324
New Hampshire Dept of Health & Human Services	CT	New Hampshire Food Safety (FERN)	$264,546
University of Iowa	IA	Iowa Food Safety in the Heartland	$301,655
University of California	CA	LC/MS,GC/MS and ICP/MS analysis for sceening and id of toxic subs in food	$349,740
Wisconsin Dept of Agriculture	WI	Wisconsin Expansion of DATCP's BSE Surveillance	$156,721
Minnesota State Dept. of Agriculture	MN	Minnesota Animal Feed Safety & BSE Prevention	$239,999
Illinois Department of Agriculture	IL	Illinois Ruminant Feed Ban Support Project	$233,528
Kansas Department of Agriculture	KS	Kansas BSE Inspection Program	$211,106
Nebraska Department of Agriculture	NE	Nebbraska Ruminant Feed Ban Support Project	$250,000
Texas Agricultural Experiment Station	TX	Texas Stte Chemist BSE Prevention Program	$249,852
Michigan Dept of Agriculture	MI	Michigan Ruminant Feed Ban Support	$250,000
Florida Dept of Agriculture and Consumer	FL	Florida Ruminant Feed Ban Enhancement Project	$239,688
Holles Labs	MA	Topical Dehydrex in Treating Recurrent Corneal Erosion	$62,500
Children's Hospital & Reg Med Ctr	WA	Triostat in Children During CPB	$350,000
Cincinnati Children's Hospital Med Ctr	OH	Triptorelin for Ovary Protection in Childhood Lupus	$400,757
Boston University School of Med	MA	Erythropoiesis & Pulse Arginine Buytrate in Sickle Cell Disease	$453,578
			$25,428,077

Food and Drug Administration
Significant Items

House Report 109-102 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2006 -- Significant Items

Item

Generic Drugs- The base funding includes not less than $56,228,000 in funding for the Generic Drugs Program. This is a vital program and the Committee is concerned that its potential as part of the solution to high quality and affordable health care is not realized. (Page 80)

Action Taken or To Be Taken

The Committee provided base funding includes not less than $56,228,000 in funding for the Generic Drugs Program. FDA has made significant progress in recent years in expediting the review of generic drug applications and will strive to maintain that progress. FDA will include base funding includes not less than $55,666,000 in funding for the Generic Drugs Program. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $56,228,000 specified in the Congressional report.

Item

Bovine Spongiform Encephalophathy (BSE)- The Committee provides the total amount requested, $29,566,000 for BSE prevention activities, primarily to continue enforcement of the 1997 feed ban. (Page 80)

Action Taken or to be Taken

The Committee provides the total amount requested, $29,566,000 for BSE prevention activities, primarily to continue enforcement of the 1997 feed ban. In FY 2006, FDA will devote no less than $29,260,000 BSE prevention activities, primarily to continue enforcement of the 1997 feed ban. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $29,566,000 specified in the Congressional report.

Item

Women's health- The Committee recommendation includes not less than $4,000,000 for the Office of Women's Health. The Committee continues to be committed to this function, and in particular activities related to cardiovascular disease in women and the hormone therapy education program. (Page 81)

Action Taken or to be Taken

The Committee recommendation includes not less than $4,000,000 for the Office of Women's Health. The Committee continues to be committed to this function, and in particular activities related to cardiovascular disease in women and the hormone therapy education program. The Office of Women's Health has identified heart disease in women as a high priority. FDA will monitor the progress and review the results of the

research projects funded in prior fiscal years and generate consumer friendly information for women on hormone therapy. FDA will spend $3,960,000 for the Office of Women's Health. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $4,000,000 specified in the Congressional report.

Item

Orphan products- The Committee directs that no less than $15,000,000 be available for grants and contracts awarded under section 5 of the Orphan Drug Act, the same amount as fiscal year 2005. (Page 81)

Action Taken or to be Taken

The Committee directs that no less than $15,000,000 be available for grants and contracts awarded under section 5 of the Orphan Drug Act, the same amount as fiscal year 2005. FDA will spend $14,549,000 for Orphan Product Grants. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $14,696,000 specified in the Conference Language.

Item

Financial management- In the fiscal year 2005 appropriations Act, Congress directed that the funding level for the Unified Financial Management System (UFMS) was at the same level as in fiscal year 2004. In response to the Questions for Record submitted to the Committee in April 2005, FDA reports that spending for the UFMS was $9,389,000 in fiscal year 2004 and is expected to be $13,582,000 in fiscal year 2005, a 45 percent increase. The Committee has not received the required notification of this increase. For fiscal year 2006, the Committee directs that no more than $9,389,000 is available for UFMS, and requires a quarterly report on the expenditures. The Committee reiterates that any additional costs for this purpose, either direct or by transfer, are subject to approval by the Committee. (Page 81)

Action Taken or to be Taken

Action Taken or to be Taken

The Committee directs that no more than $9,389,000 is available for UFMS, and requires a quarterly report on the expenditures. FDA is aware of the Congressional concern to stay within the appropriated limits for the Unified Financial Management System (UFMS). As provided in the conference agreement, FDA will not spend more than $12,896,094 for UFMS in FY 2006. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $13,026,357 specified in the FY2006 Congressional report. Quarterly spending reports will be prepared and submitted one month after the end of each quarter

Item

Consolidation- The Committee directs DHHS to include all future consolidations that impact FDA in the President's budget request submitted to Congress.

Action Taken or to be Taken

The Committee directs DHHS to include all future consolidations that impact FDA in the President's budget request submitted to Congress. FDA will submit all planned consolidations that impact the President's budget request to the Committee.

Item

Fees—The Committee directs that none of the funds made available to FDA in this bill be for any assessments, fees, or charges by DHHS or any other Department or Office unless such assessments, fees, or charges are identified in the FDA budget justification and expressly provided by Congress, or approved by Congress in the official reprogramming process as required in the General Provisions of this bill.

Action Taken or to be Taken

The Committee directs that none of the funds made available to FDA in this bill be for any assessments, fees, or charges by DHHS or any other Department or Office unless such assessments, fees, or charges are identified in the FDA budget justification and expressly provided by Congress, or approved by Congress in the official reprogramming process as required in the General Provisions of this bill. FDA has included a table and exhibit in this document, the Congressional Justification, entitled "DHHS Charges and Assessments." This table and exhibit list the actual and estimated fees or charges from DHHS. We have also included an exhibit on "Funding from Outside Sources." Any significant changes to these estimates will be handled through an official reprogramming.

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 not less than $250,000 for this effort. In addition, the Committee expects that FDA will continue its work with ISSC through a memorandum of understanding, and that FDA will devote not less than $200,000 to that work. The Committee expects the FDA to require all states to work cooperatively in conformity with the National Shellfish Sanitation Program implemented by the ISSC. (Page 82)

Action Taken or to be Taken

Committee expects that FDA will continue its work with ISSC through a memorandum of understanding, and that FDA will devote not less than $200,000 to that work. FDA continues to work with the Interstate Shellfish Sanitation Conference (ISSC) to address *Vibrio vulnificus* and work cooperatively with all relevant states in conformity with the ISSC's National Shellfish Sanitation Program at a level of $198,000.00. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $200,000 specified in the Congressional report. These joint efforts include actions to encourage the use of post-harvest treatment by the shellfish industry (e.g., improvements in validation of treatment methods, marketability studies), education of at-risk consumers on the risks posed by the organism, and monitoring of the frequency of occurrence of *V. vulnificus* illnesses.

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 not less than $250,000 for this effort. FDA will provide $248,000 to ISSC for education and outreach programs on *V. vulnificus.* The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $250,000 specified in the Congressional report. Since the initiation of the ISSC *V. vulnificus* illness reduction goal, the Gulf oyster industry has made great strides in the post-harvest treatment of oysters, with the capacity to treat in excess of 25 percent of the Gulf production. The impact of Hurricanes Katrina and Rita remain unclear.

Item

Food safety- The Committee recognizes the contributions which the National Center for Food Safety and Technology (NCFST) is making toward ensuring the security of the nation's food supply. The Committee directs that FDA continue to provide $3,000,000 to NCFST through the cooperative agreement. The $3,000,000 in funding shall be exclusive of any additional initiative funds that FDA may award to NCFST. (Page 82)

Action Taken to be Taken

The Committee directs that FDA continue to provide $3,000,000 to NCFST through the cooperative agreement. The National Center for Food Safety and Technology (NCFST) continues to make contributions toward ensuring the security of the nation's food supply. A five year renewal of the cooperative agreement with NCFST was completed in FY 2004. FDA will continue to provide funding of $2,970,000 to NCFST. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,000,000 specified in the Congressional report.

Item

Test method evaluation- The Committee directs that the agency continue its contract to conduct method evaluation of rapid test methods of fresh fruits and vegetables for microbiological pathogens with New Mexico State University's Physical Science Laboratory at the fiscal year 2005 level. (Page 82)

Action Taken or to be Taken

The Committee directs that the agency continue its contract to conduct method evaluation of rapid test methods of fresh fruits and vegetables for microbiological pathogens with New Mexico State University's Physical Science Laboratory at the fiscal year 2005 level. FDA will spend $2,358,972 in a contract for New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory. Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $2,382,800 specified in the Congressional report. Under contract to FDA, New Mexico State University (NMSU) Physical Science Laboratory has provided method assessment, development and validation data for targeted commodities identified as high profile/high risk for implementation into national food safety and food defense programs.

NMSU is evaluating rapid test methods for microbiological analyses in food samples under the Rapid Commercial Test Kit Evaluation Program. NMSU's evaluation includes the assessment of rapid test methods for a particular analyte(s) or food commodity to be

measured against the FDA Bacteriological Analytical Manual. This comparison is necessary prior to the Agency adopting a rapid test method for use for Food Safety.

Additionally, NMSU is also being utilized to examine the use of these rapid test methods in the arena of Food Defense. Interim counter terrorism methods have been developed for the rapid identification of agents of bioterrorism, but require further evaluation against food matrices of interest. NMSU serves to provide the validation of these counterterrorism methods. FDA's contract with NMSU enhances and complements the Agency's ability to be responsive in our food defense responsibilities and activities, especially those that involve field food import examinations and the associated testing of those commodities in the Field and/or at the border.

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 at the fiscal year 2005 level. (Page 82)

Action Taken or to be Taken

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 at the fiscal year 2005 level. In FY 2006, FDA will fund $98,200 to a grant awarded in 1995 to continue support for WERC and its work in food safety technology verification and education. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $99,200 specified in the Congressional report.

Item

Hearing on budget request.--The Committee has taken the step of withholding five percent of the funds provided to the central offices at FDA until there is a public hearing with the head of the agency on the fiscal year 2006 budget request. The Committee appreciates the willingness of the agency's head to present the budget request in March 2005, and regrets that the administration insisted on postponing his scheduled appearance. The Committee wants to make it clear to the administration that it will insist on a hearing with the agency's head before providing it the funds requested in the budget. (Page 83)

Action Taken or to be Taken

The Committee wants to make it clear to the administration that it will insist on a hearing with the agency's head before providing it the funds requested in the budget. FDA plans to have the Acting Commissioner present the budget request to the House Appropriations Subcommittee at the hearing scheduled for February 16, 2006.

Item

Direct to consumer advertising.--The Committee provides an increase of $884,000 for the review of direct-to-consumer drug ads. Because staff levels for these activities, under the Division of Drug Marketing, Advertising and Communication in the Center for Drug

Evaluation and Research in FDA, have remained flat for some time, despite the growth of direct to consumer ads, the Committee believes this increase is needed. (Page 83)

Action Taken or to be Taken

The Committee provides an increase of $884,000 for the review of direct-to-consumer drug ads. In FY 2006, FDA will spend an additional $875,160 for the review of direct-to-consumer drug ads. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $884,000 specified in the Congressional report.

FDA's goal is to promote and protect the health of Americans by ensuring that drug advertisements and the promotional materials are truthful and balanced. We operate a comprehensive program of education, surveillance and enforcement about drug advertising and promotion. FDA appreciates the Committee's recognition of the need for additional resources to regulate direct-to-consumer advertising. These additional resources will bolster our existing review staff in the Division of Drug Marketing, Advertising, and Communication (DDMAC) who are responsible for monitoring and evaluating promotional materials.

Senate Report 109-092 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2006 – Significant Items

Item

Budget Structure - The Committee does not approve the proposed restructuring of FDA's budget for the field activities, rent activities, and other activities accounts. The Committee directs the Agency to submit the fiscal year 2007 budget request in a format that follows the same account structure as the fiscal year 2005 budget request unless otherwise approved by the Committee. (Page 148)

Action Taken or to be Taken

The Committee does not approve the proposed restructuring of FDA's budget for the field activities, rent activities, and other activities accounts. The Committee directs the Agency to submit the fiscal year 2007 budget request in a format that follows the same account structure as the fiscal year 2005 budget request unless otherwise approved by the Committee. FDA has presented the FY 2007 President's Budget in a format that follows the same account structure as the FY 2005 budget.

Item

Codex Alimentarius - Within the total funding available, at least $2,500,000 is for FDA activities in support of Codex Alimentarius. (Page 148)

Action Taken or to be Taken

The Committee directs $2,500,000 is for FDA activities in support of Codex Alimentarius. In FY 2006, FDA will devote $2,475,000 in resources in order to continue its leadership role to provide scientifically sound international public health standards. Congressional directive in Public Law 109-148 applied a 1 percent rescission to the

2,500,000 specified in the Congressional report. This will be accomplished by heading US delegations, continuing interactions with other key government leads, strategic meetings with regional groups of countries, public outreach meetings in the US, coordination with US codex office and Rome secretariats, and assuring adequate FDA participation in Codex committee and commission sessions. In FY 2006, FDA will provide U.S. delegate to one Codex Commissioner Session, six cross-cutting general subject committee, and two commodity committee meetings.

Item

Bovine Spongiform Encephalopathy- The Committee provides $29,556,000 for Bovine Spongiform Encephalopathy [BSE]. The Committee understands that this funding will be used to conduct yearly inspections of all renderers and feed mills processing products containing prohibited materials; extend BSE inspections into targeted segments of industries subject to the BSE Feed regulation but previously minimally inspected; validate test methods for the detection of bovine-derived proteins in animal feed; and continue to conduct research on Transmissible Spongiform Encephalopathies in FDA's product centers. (Page 148)

Action Taken or to be Taken

The Committee provides $29,556,000 for Bovine Spongiform Encephalopathy (BSE). In FY 2006, FDA will devote no less than $29,260,000 BSE prevention activities, primarily to continue enforcement of the 1997 feed ban. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $29,566,000 specified in the Congressional report.

Item

Agricultural Products Food Safety Laboratory- The Committee provides an increase of $250,000 above the fiscal year 2005 funding level for the FDA to expand its contract with New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory, which conducts evaluation and development of rapid screening methodologies, technologies, and instrumentation; and to provide technology deployment, modeling, and data analysis for food safety and product safety, including advanced risk-based systems for screening and inspection, to facilitate FDA's regulations and responsibilities in food safety, product safety, homeland security, bioterrorism, and other initiatives. (Page 148)

Action Taken or to be Taken

The Committee provides an increase of $250,000 above the fiscal year 2005 funding level for the FDA to expand its contract with New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory. FDA will spend $2,358,972 in a contract for New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory. Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $2,382,800 specified in the Congressional report. Under contract to FDA, New Mexico State University (NMSU) Physical Science Laboratory has provided method assessment,

development and validation data for targeted commodities identified as high profile/high risk for implementation into national food safety and food defense programs.

Item

Waste Management Education and Research Consortium - 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 at no less than the fiscal year 2005 level. (Page 148)

Action Taken or to be Taken

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 at the fiscal year 2005 level. In FY 2006, FDA will award a $98,200 grant to the Waste Management Educational Research Consortium to continue its support for the Waste Management Education and Research Consortium (WERC) and its work in food safety technology verification and education. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $99,200 specified in the Congressional report.

Item

National Center for Food Safety and Technology- 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 includes $3,000,000 for the National Center to continue the important work done there. (Page 148)

Action Taken or to be Taken

The Committee includes $3,000,000 for the National Center to continue the important work done at the National Center for Food Safety and Technology (NCFST). NCFST continues to make contributions toward ensuring the security of the nation's food supply. A five year renewal of the cooperative agreement with NCFST was completed in FY 2004. FDA will continue to provide funding of $2,970,000 to NCFST. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,000,000 specified in the Congressional report.

Item

Seafood Safety- The Committee urges FDA to promote the development of new food safety technologies such as irradiation, flash freezing, high-pressure processing, or others that can cost-effectively reduce the incidence of pathogens, and technologies that can ensure constant safe temperatures of seafood throughout the food chain. (Page 149)

Action Taken or to be Taken

The Committee urges FDA to promote the development of new food safety technologies such as irradiation, flash freezing, high-pressure processing, or others that can cost-

effectively reduce the incidence of pathogens, and technologies that can ensure constant safe temperatures of seafood throughout the food chain. Food Safety is one of the Agencies top priorities and FDA will continue promote the development of new food safety technologies that can cost-effectively reduce the incidence of pathogens.

Item

Vibrio Vulnificus - The Committee supports the ongoing work of the Interstate Shellfish Sanitation Conference and its joint efforts with the FDA and the shellfish industry to formulate shellfish safety regulations through the National Shellfish Sanitation Program. The Committee recommends no less than $200,000 be directed through the Office of Seafood Inspection to continue these activities, and directs that $250,000 be directed to the Interstate Shellfish Sanitation Conference for the *Vibrio Vulnificus* Education Program. The Committee is concerned that FDA has not taken effective action to address foodborne illness risks from the consumption of raw shellfish. In particular, the Committee is concerned that Interstate Shellfish Sanitation Conference's [ISSC] proposed steps to reduce the rates of death and illness due to consumption of *Vibrio vulnificus*-contaminated raw shellfish may not effectively address public health concerns. (Page 149)

Action Taken or to be Taken

The Committee recommends no less than $200,000 be directed through the Office of Seafood Inspection to continue these activities, and directs that $250,000 be directed to the Interstate Shellfish Sanitation Conference for the *Vibrio Vulnificus* Education Program. FDA continues to work with the Interstate Shellfish Sanitation Conference (ISSC) to address *Vibrio vulnificus* and work cooperatively with all relevant states in conformity with the ISSC's National Shellfish Sanitation Program at a level of $198,000.00. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $200,000 specified in the Congressional report. These joint efforts include actions to encourage the use of post-harvest treatment by the shellfish industry (e.g., improvements in validation of treatment methods, marketability studies), education of at-risk consumers on the risks posed by the organism, and monitoring of the frequency of occurrence of *V. vulnificus* illnesses. FDA will provide $247,500 to ISSC for education and outreach programs on *V. vulnificus.* The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $250,000 specified in the Congressional report. Since the initiation of the ISSC *V. vulnificus* illness reduction goal, the Gulf oyster industry has made great strides in the post-harvest treatment of oysters, with the capacity to treat in excess of 25 percent of the Gulf production. The impact of Hurricanes Katrina and Rita remain unclear.

Item

Hazard Analysis Critical Control Point - The Committee also continues its concern with the agency's failure to bring FDA-regulated seafood into compliance with Hazard Analysis Critical Control Point [HACCP] standards. However, the Committee is aware that special or unique circumstances may exist for particular seafood processors. While ultimate HAACP compliance is not in question, the Committee is specifically aware of Hawaii's lengthy and culturally important history of hook-and-line fisheries, auction

markets, and the high consumption of raw tuna and other pelagic fish in Hawaii, and strongly encourages the Agency to take into account both the history and the industry's practical experience in approving a plan that is consistent with healthy seafood products and national standards for seafood safety. (Page 149)

Action Taken to be Taken

The Committee strongly encourages the Agency to take into account both the history and the industry's practical experience in approving a plan that is consistent with healthy seafood products and national standards for seafood safety. FDA's seafood HACCP program is designed to allow processors to design preventive controls that best accommodate their own circumstances so long as they provide an appropriate assurance of product safety. Of course, the level of safety assurance cannot be compromised based on cultural or traditional processing practices at the point of origin.

The special or unique circumstances involve proper handling practices on board fishing vessels to insure that tuna do not form scombrotoxin as a result of time/temperature abuse. Scombrotoxin is one of the three most frequently reported illnesses from seafood in the United States and is completely avoidable with proper care of the catch. Once a tuna dies, it can begin to decompose and form scombrotoxin if not properly chilled.

FDA's Office of Seafood has engaged in a continuing dialog with the auction house in Hawaii on how it can most effectively and practically ensure the control of scombrotoxin as a result of the death of tuna and other species while still on the line. During 2005, the Hawaiian seafood industry, NMFS and FDA collaborated in an important study on the conditions under which large, longline-caught tuna will form histamine. At present, the samples collected during this study are being analyzed and FDA anticipates using this data to refine its recommendations to the Hawaiian industry and other scombroid fishing industries on appropriate controls for this hazard.

Item

Imported Farmed Salmon - The Committee has been advised that farmed salmon imported from overseas is fed feed with chemical additives to change the color of its flesh or the flesh is artificially dyed. A lawsuit was filed against national grocery chains alleging they do not adequately label the fish which are dyed. The Committee directs the Food and Drug Administration to continue to monitor information concerning the safety of the use of such additives and dyes in seafood and to more aggressively enforce the clear and conspicuous disclosure of such additives and dyes to consumers on consumer packaging. (Page 149)

Action Taken to be Taken

The Committee directs the Food and Drug Administration to continue to monitor information concerning the safety of the use of such additives and dyes in seafood and to more aggressively enforce the clear and conspicuous disclosure of such additives and dyes to consumers on consumer packaging. Under the Federal Food, Drug and Cosmetic Act, retailers are required to label salmon that has been colored by the use of astaxanthin or canthaxanthin to clearly denote that the food has had color added. The FDA will

continue to monitor information concerning the safety of the use of such additives in seafood.

Item

Alaska -The funding provided for food safety will ensure the continuation of food contract inspections in the State of Alaska. Specifically, it will allow the FDA to renew its contract with the State of Alaska for inspections of food and seafood processors operating in Alaska. A new contract became effective on July 1, 2005. It funds at least 292 inspections, approximately 272 seafood/HACCP inspections and 20 other food inspections. The establishments to be inspected will be mutually agreed upon by FDA and the State of Alaska. (Page 149)

Action Taken to be Taken

He Committee directs the funding provided for food safety will ensure the continuation of food contract inspections in the State of Alaska. The funding provided for food safety will ensure the continuation of food contract inspections in the State of Alaska. Specifically, it will allow the FDA to renew its contract with the State of Alaska for inspections of food and seafood processors operating in Alaska. A new contract will be negotiated in July 2006. Its goal will be to fund at least 292 inspections, approximately 272 seafood/HACCP inspections and 20 other food inspections. The establishments to be inspected will be mutually agreed upon by FDA and the State of Alaska.

Item

Chloramphenicol.—The Committee continues to have serious concerns regarding seafood safety issues posed by banned antibiotic contamination in farm-raised shrimp imports. In addition, the Committee is concerned that the FDA inspects less than 2 percent of shrimp being imported into the United States. Therefore, the Committee provides an increase of $500,000 for the FDA to develop, in cooperation with State testing programs, a program for increasing the inspection of imported shrimp, possibly including coldstorage inventories, for banned antibiotics, including chloramphenicol. (Page 150)

Item

National Antimicrobial Resistance Monitoring System- The Committee supports the work of the National Antimicrobial Resistance Monitoring System [NARMS] and its collaborative relationship between FDA, USDA, and the Centers for Disease Control. The Committee expects the coordination of activities among these three areas of government to result in the most unbiased presentation of timely, accurate data in the best interest of public health, and encourages FDA to equally divide research funding among the three branches of the program. The Committee directs FDA to provide a detailed financial report as well as an executive summary of 2004 NARMS data and a preliminary report on 2005 data to the Committee by March 1, 2006 in a format that is accessible to users of the data. Further, the Committee directs FDA to perform a review of all components of the NARMS program to ensure that the program remains scientifically sound and relevant to public health. (Page 150)

Action Taken or to be Taken

FDA strongly supports NARMS and all its components. FDA believes that all three arms are integral to the success of the NARMS program and are necessary to achieve the benefits envisioned at its inception and agreed upon by all three agencies. FDA has funded NARMS since it was conceived in 1996 and is committed to the continued funding of this program to the extent possible without compromising other core programs.

FDA met with a panel of outside experts for an external review of all three arms of the NARMS program in order to review key elements and establish future directions. FDA has begun implementing several of these recommendations. A FDA Science Board Peer Review is currently appraising the NARMS program.

FDA will continue efforts to maximize cooperation and communication between FDA, USDA, and CDC and strengthen data reporting to increase efficient use of resources. FDA is in the process of preparing a report on the NARMS program requested by Congress in the conference committee report.

Item

Dietary Supplements- The Committee includes total funding of approximately $5,560,000 for the CFSAN Adverse Events Reporting System [CAERS], of which approximately $1,700,000 is for dietary supplements. This is $1,060,000 more than the amount in the budget request. The Committee is aware that efforts are underway to authorize a mandatory adverse event reporting system for dietary supplements. The Committee requests, within 90 days of the enactment of this Act, a report on the cost of such a system. (Page 150)

Action Taken or to be Taken

The Committee includes total funding of approximately $5,560,000 for the CFSAN Adverse Events Reporting System [CAERS], of which approximately $1,700,000 is for dietary supplements. This is $1,060,000 more than the amount in the budget request. The conference agreement includes total funding of $5,360,000 for the CFSAN Adverse Events Reporting System. FDA will include base funding includes not less than $5,306,400 in funding for the CFSAN Adverse Events Reporting System. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $5,360,000 specified in the Congressional report.

Item

Orphan Products Grants- Included in the Center for Drug Evaluation and Research is $14,392,000 for the Orphan Products Grants Program. (Page 150)

Action Taken or to be Taken

The Committee includes in the Center for Drug Evaluation and Research is $14,392,000 for the Orphan Products Grants Program. FDA will spend $14,549,000 for Orphan Product Grants. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $14,696,000 specified in the Conference Language.

Item

Dietary Supplement Health and Education Act of 1994 - The Committee is encouraged by the FDA's recent activities to enforce provisions contained within the Dietary Supplement Health and Education Act of 1994 [DSHEA] (Public Law 103-417). The Committee has included funding to continue enforcement of the provisions contained in DSHEA. It is the Committee's intent that these funds be prioritized by the agency to step up activities against products that are clearly in violation of DSHEA. In addition, the Committee is concerned that Current Good Manufacturing Practice [CGMP] regulations, which have been under development for some time, have not been issued. Accordingly, the Committee requests that FDA issue the dietary supplement CGMP regulations. (Page 150)

Action Taken or to be Taken

The Committee has included funding to continue enforcement of the provisions contained in DSHEA. FDA will work to ensure dietary supplements are not in violation of DSHEA and take action on violators. Public comments have been reviewed and a draft of the Current Good Manufacturing Practice regulations are in the final stages of clearance.

Item

National Center for Natural Products Research - FDA has indicated that the ability to identify and analyze specific components in ingredients, including botanical ingredients, is an essential component of research and regulatory programs directed at ensuring the safety and effectiveness of dietary supplements. The Committee provides an increase of $500,000 for review of botanicals in dietary supplements. This work is being carried out by FDA in collaboration with the National Center for Natural Products Research, Oxford, MS. (Page 150)

Action Taken to be Taken

The Committee provides an increase of $500,000 for review of botanicals in dietary supplements. This work is being carried out by FDA in collaboration with the National Center for Natural Products Research, Oxford, MS. As directed in the conference report FDA will spend $3,243,240 for research at the National Center for Natural Products Research in Oxford, MS, which is an increase of $300,000 over the FY 2005 level of $2,976,000. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,276,000 specified in the Conference Language. In FY 2005 FDA will continue to identify and obtain botanical dietary ingredients of concern to FDA from a safety perspective, and determine research needs to support comprehensive safety evaluations. FDA will continue to acquire and characterize authenticated botanical materials, including raw plant materials, processed plant materials, and purified natural products. FDA scientists will continue to exchange technical and scientific information, methods, and botanical materials with NCNPR scientists and continue to build international network of botanical experts to meet needs for sourcing and identification.

Item

Standards of Identity- The Committee is aware of the ongoing debate surrounding increased importation and use of milk protein concentrate. A General Accounting Office investigation highlighted a dramatic increase in milk protein concentrate imports. The Committee remains concerned with FDA's current lack of enforcement of standards of identity as it relates to the potential illegal use of milk protein concentrate in standardized cheese. (Page 150)

Action Taken to be Taken

The Committee remains concerned with FDA's current lack of enforcement of standards of identity as it relates to the potential illegal use of milk protein concentrate in standardized cheese. In response to complaints, FDA conducted inspections at specific cheese manufacturing sites to determine compliance with the cheese standards and to document the use of MPC in standardized cheeses and cheese products. As a result of these inspections, FDA sent warning letters to two cheese manufacturers, Kraft Foods North America, Inc. and Lactoprot USA, advising them that standardized cheeses and cheese products containing MPCs are in violation of the misbranding provisions of the FD&C Act.

Both firms responded to the warning letters outlining the actions they were taking. Kraft Foods indicated that it would no longer label products containing MPC as a standardized cheese. Lactoprot USA announced that it would remove MPC as an ingredient in its standardized cheese products. FDA will continue to monitor to ensure that MPCs are not being used in standardized cheeses and cheese products.

Item

Office of Women's Health- The Committee believes that it is imperative for FDA to pay sufficient attention to gender-based research, ensuring that products approved by the FDA are safe and effective for women as well as men. The Committee notes that in the budget request, the Office of Women's Health at FDA is funded at not less than $4,000,000 for program operation and oversight. The Committee encourages FDA to ensure that the Office of Women's Health is sufficiently funded to carry out its activities, and to enhance its funding if necessary. (Page 150)

Action Taken or to be Taken

The Committee encourages FDA to ensure that the Office of Women's Health is sufficiently funded to carry out its activities, and to enhance its funding if necessary. The Office of Women’s Health is committed to conducting gender-based research, ensuring that products approved by the FDA are safe for women as well as men. FDA will spend at least $3,960,000 for the Office of Women’s Health. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $4,000,000 specified in the Congressional report.

Item

Rare Diseases Clinical Trials and Drug Evaluation- The Committee supports rapid access to therapeutics for children and adults with rare diseases. It is the view of the

Committee that improvements can be made with respect to clinical trial design and FDA Advisory Committees. The Committee encourages the FDA to make the best possible use of FDA's Advisory Committee members in FDA's considerations of clinical trial design and allow the same panel to participate in final review meetings, when feasible. The Committee supports utilization of qualified independent consultants as reflected in the draft guidance document `Independent Consultants for Biotechnology Clinical Protocols' issued by CBER/CDER on May 12, 2003. The Committee encourages enhanced exploration of potential surrogate endpoints and use of FDAMA's fast-track provision, where appropriate, to make drugs available as early as possible for serious and life-threatening orphan diseases that have no treatment. The Committee believes these policy enhancements will lead to more efficient and timely evaluation of rare disease therapeutics and further stimulate private sector investment in rare disease research. (Page 151)

Action Taken or To Be Taken

The Committee encourages the FDA to make the best possible use of FDA's Advisory Committee members in FDA's considerations of clinical trial design and allow the same panel to participate in final review meetings, when feasible. FDA supports development of drugs to treat rare diseases and we have a very good track record for prompt assessment of such drugs. Regarding the issue of clinical trial design, FDA has an ongoing program for orphan product protocol and product development assistance that has helped many sponsors develop appropriate clinical trials. The FDA also welcomes pre-IND, end of phase 2 and pre-NDA meetings. It should be noted that sponsors usually consult with recognized experts in the orphan disease and bring them to meetings with FDA. Indeed, such experts usually conduct the studies.

In addition, FDA supports the use of advisory committees to provide advice on approaches to clinical trial design and analysis for orphan and rare diseases, particularly where there is uncertainty over the appropriate course of action and/or likely disagreement between company and FDA.

We will continue to work with sponsors and outside experts to ensure that development programs for rare diseases are based on sound science and focus on increasing the availability of treatment options to patients while also ensuring that patients are not put at unnecessary risk of harm. To that end, we support the use of surrogate markers provided that they have biological and medical plausibility. Reliance on a surrogate endpoint must be determined case by case. Under our accelerated approval rule and FDAMA, for serious diseases with no good treatment, FDA can rely on surrogate endpoints that have been validated with definitive clinical data to be obtained after the drug is marketed.

Item

Perchlorate- The Committee directs the FDA to continue conducting perchlorate surveys of food and bottled water and to report back to Congress the findings of these surveys. The surveys should include a variety of produce and fluid milk samples and should identify level of contamination in order to determine the need for risk management strategies. The Committee believes it is important to assess produce, milk, and bottled

water produced in areas with known perchlorate contamination, with naturally occurring perchlorate, or grown near sites where perchlorate was or is used. (Page 153)

Action Taken or to be Taken

The Committee directs the FDA to continue conducting perchlorate surveys of food and bottled water and to report back to Congress the findings of these surveys. In February 2005, FDA issued an expanded survey assignment to determine perchlorate levels in 450 samples of various domestic and imported foods. The first phase of the assignment called for collection and analysis of 240 food samples that include fresh fruits and vegetables, fruit juices, and grain products. The second phase of the assignment called for collection and analysis of additional samples of fresh fruits and vegetables, fruit juices, and grain products and seafood.

FDA also expanded application of methods for perchlorate analysis to additional high priority foods (e.g., grain products, fruit juices, fish fillets) requested for collection in the FDA 2005 perchlorate field assignments.

In FY2006, the agency is planning to analyze relevant foods collected for 4 market baskets of FDA's Total Diet Study. In addition, FDA will perform exposure assessments on the data from its analyses.

Item

Glucose Monitoring- The Committee encourages the FDA to support a workshop to provide a forum for the developers of continuous glucose monitoring technologies to discuss ways in which promising continuous glucose monitoring technologies can be expeditiously reviewed. (Page 153)

Action Taken or To Be Taken

The Committee encourages the FDA to support a workshop to provide a forum for the developers of continuous glucose monitoring technologies to discuss ways in which promising continuous glucose monitoring technologies can be expeditiously reviewed. FDA, in conjunction with NIH and the Juvenile Diabetes Research Foundation held an open public workshop entitled "Obstacles and Opportunities on the Road to an Artificial Pancreas: Closing the Loop" on December 19, 2005. This program was attended by more then 100 participants from government, industry, academia and the consumer community. Obstacles to development of new technologies for diabetes monitoring were discussed and suggestions made for how to deal with them.

FDA has offered to review research proposals from JDRF to assist them in launching and managing a new research initiative in the area of non-invasive glucose testing. In addition to this activity, FDA continues to work directly with medical device manufacturers to encourage development and help expedite new technologies to the marketplace.

Item

Diabetes Product Characteristics- The Committee urges FDA to develop guidance, initiate collaborations, and promote consensus development activities to evaluate the utility and need for additional biomarkers and surrogate endpoints that will assist manufacturers' efforts to demonstrate efficacy of diabetes product characteristics with clinical outcomes, and where need exists, to aid in their development and validation. Where there is a demonstrated need, the Committee urges FDA to work with diabetes stakeholders to refine therapeutic endpoints. (Page 153)

Action Taken or to be Taken

The Committee urges FDA to work with diabetes stakeholders to refine therapeutic endpoints the agency is currently developing guidance for industry on demonstrating efficacy of diabetes products. In addition to input from within the agency, we have received input from external special interest groups, including NIH and the Juvenile Diabetes Research Foundation International. The document will be published for comment once it has completed the clearance process. We are planning to publish the draft document sometime this year.

Item

HIV/AIDS Vaccines- The Committee recognizes the importance of ensuring that promising HIV/AIDS vaccines are tested in infants and youth as early as is medically and ethically appropriate. The Committee requests that the Commissioner of the Food and Drug Administration, in consultation with appropriate public and private entities, consider the logistical, regulatory, medical and ethical issues presented by pediatric testing of these vaccines so that children can share in the benefit of any advances in vaccine research. The Committee urges FDA to issue guidance not later than 6 months after the enactment of this Act on the minimum requirements for obtaining FDA approval to test an HIV vaccine in pediatric populations and the minimum requirements for obtaining FDA approval of a pediatric indication of an HIV vaccine. (Page 153)

Action taken or to be taken

The Committee urges FDA to issue guidance not later than 6 months after the enactment of this Act on the minimum requirements for obtaining FDA approval to test an HIV vaccine in pediatric populations and the minimum requirements for obtaining FDA approval of a pediatric indication of an HIV vaccine. Vaccine development in the U.S. occurs in a stepwise fashion, starting with clinical studies in adults and then proceeding to children, as appropriate. This development pathway has led to the licensure of numerous pediatric vaccines over the past decade, including new vaccines against whooping cough, chickenpox, hepatitis A, pneumococcus, influenza, and meningococcus. The same development pathway applies to HIV vaccines. The regulatory issues that relate to pediatric drug and biological product development are well outlined in the Pediatric Research Equity Act of 2003 (PREA). PREA requires that the application for any new product must include an assessment of safety and effectiveness in pediatric patients except in a limited number of defined situations. A draft FDA guidance document on the implementation of PREA was issued in September 2005. This guidance document applies to both drugs and biologics (including vaccines). Also, FDA has

guidance on the Clinical Investigation of Medicinal Products in the Pediatric Population (ICH E11), which is intended to facilitate timely pediatric product development.

FDA is currently working to meet the timeline in the legislation to provide guidance for the development of pediatric HIV vaccines. While the Agency recognizes the importance of developing HIV vaccines, the absence of an HIV-specific guidance document is not preventing clinical development of HIV vaccines for pediatric populations in the U.S. Rather, the HIV virus has presented significant scientific challenges to vaccine development. We are not aware of even preliminary evidence of efficacy for any preventive HIV vaccine in adults from any trial, in the U.S. or elsewhere. Identifying promising HIV vaccine candidates (for any population) has been difficult, due to profound scientific impediments (lack of understanding of what aspect of the immune system will confer protection, etc.).

Item

Foodborne Illness- The Committee is pleased that the FDA, USDA, and CDC recently reported declines in foodborne infections due to common bacterial pathogens, including E. coli 0157, campylobacter, and salmonella infections. The Committee is aware of the effective work of the Partnership for Food Safety Education, in collaboration with these agencies, to provide information to the general public about simple, commonsense suggestions regarding safe food preparation and handling. Currently, the Partnership for Food Safety Education is working to develop a public education campaign aimed at populations vulnerable to listeria, including pregnant women and adults with weakened immune systems. The Committee believes this is a worthwhile effort, and encourages FDA to continue working with the Partnership for Food Safety Education in executing this education campaign. In addition, the Committee encourages the FDA to provide funding, as appropriate, to support this collaborative effort. (Page 154)

Action Taken or to be Taken

He Committee encourages FDA to continue working with the Partnership for Food Safety Education in executing this education campaign. As specified by the Memorandum of Understanding (MOU) between FDA and the Partnership for Food Safety Education (the Partnership), FDA continues to fulfill its coordination and programmatic participation and supply in-kind services and materials to promote food safety measures. The Partnership has established three work groups to carry out its initiatives. They are: public relations and web activities; program evaluation; and outreach.

In FY 2006 FDA played an active role in the update of the Fight BAC!® Brochure which now includes more food safety information about FDA–regulated foods and participates in developing E-cards to its BAC Fighters list serve, a database of state, local and Federal health educators, food industry staff, teachers and consumer activists. All 19 of the education projects conducted by FDA Public Affairs Specialists around the country emphasize the Partnership's four basic food safety messages and utilize Fight BAC!® materials extensively. FDA's *Reduce the Risk of Foodborne Listeria* campaign and *Food Safety for Moms-To-Be* campaign strongly support the Partnership's Listeria prevention initiative.

The Partnership has begun a review and renovation of its web site and FDA is playing an active role in this project which will be completed in 2006. With FDA's participation the USDA's Food Safety and Inspection Service (FSIS) and the Partnership issued a statement on consumption of poultry & poultry products, addressing consumers' questions about whether there could be a danger of getting "bird flu" through consumption of poultry or eggs.

Item

Global Evaluation Scale- The Committee notes that there has been public criticism about the Global Evaluation Scale used in studies submitted to FDA to determine efficacy of acne products. The Committee has been assured that, to date, FDA has not adopted this scale, the matter has been presented to the Advisory Committee, and will be addressed in guidance developed with the benefit of public comment. The Committee urges FDA to complete this guidance development process prior to adopting this scale as a preferred method of evaluating acne products. (Page 154)

Action Taken or to be Taken

The Committee urges FDA to complete this guidance development process prior to adopting this scale as a preferred method of evaluating acne products. On September 19, 2005, CDER published Draft Guidance for Industry on Acne Vulgaris: Developing Drugs for Treatment. This guidance can be accessed at http://www.fda.gov/cder/guidance/6499dft.htm to facilitate additional public input before any final guidance document is issued.

A number of comments on the draft guidance were submitted to the public docket. We are in the process of reviewing these comments and modifying the Draft Guidance for Industry, including re-evaluating the assessment scales for acne. The Agency will fully consider all comments received on the draft guidance before developing and publishing a final guidance.

Item

Collaborative Drug Safety Research- The Committee commends FDA for its work in developing the Critical Path Initiative to foster collaboration with outside researchers and develop new tools to both promote drug safety and accelerate the development of innovative new therapies. The Committee further commends the C-Path Institute, founded by the University of Arizona, for its innovative research efforts to develop more efficient tools for medical product development and drug safety. For this important effort, the Committee provides $750,000, to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. This research would help address the critical public health threat of heart failure which affects over 5 million Americans, with over 250,000 dying annually from this condition. The Committee understands the research would involve identifying candidate genes and proteins in University of Utah databases, designing and conducting genomic and proteomic biomarker validation experiments by the C-Path Institute, the University of Utah, FDA and manufacturers, determining which biomarkers identify

heart failure patients who are most likely to respond favorably to drug therapy and those at highest risk of adverse events. The Committee expects that this research will enhance patient safety, reduce the number of patients necessary for clinical testing, and enable manufacturers to accelerate drug development and bring safer, innovative life-saving drugs to market more quickly. (Page 154)

Action Taken or To Be Taken

The Committee provides $750,000, to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. In FY 2006, FDA will spend an $742,500 to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $750,000 specified in the Congressional report. The FDA has initiated discussions with the C-Path Institute and the University of Utah to clarify the terms of this collaborative research (e.g., defining the roles and responsibilities of each participant), including use of the University of Utah databases to identify candidate cardiovascular safety biomarkers, collaborative design of validation research, and conduct of that research. FDA is also in the process of identifying the appropriate contracting vehicle or vehicles for execution of the collaboration.

Item

Ocular Health- The Committee has included a general provision to promote the ocular health of contact lens wearers by barring the use of funds to facilitate a practice 32 State Attorneys General alleged to be illegal and detrimental to patient health.

The FDA has recognized the importance of timely replacement of contact lenses, advising consumers to comply with the wearing schedules established by their eye care providers. Federal and State regulators have reported that as contact lenses become less expensive and more convenient to replace, consumers will replace them more frequently, leading to increased patient safety, including decreases in eye infections and inflammation. In the 1990s, 32 State Attorneys General, citing these health benefits, sued to stop major contact lens manufacturers from engaging in the practice of limiting distribution of their lenses to eye care providers. Since contact lens prescriptions are branded, with no substitutions allowed, this practice was designed to increase prices and limit consumers' options for obtaining replacement lenses. A consent decree was reached between the parties involved. The provision effectively codifies the consent decrees reached with the Attorneys General. (Page 155)

Action Taken or to be Taken

The Committee has included a general provision to promote the ocular health of contact lens wearers by barring the use of funds to facilitate a practice 32 State Attorneys General alleged to be illegal and detrimental to patient health. It is within FDA's mission to assure that medical devices, including contact lenses, meet the statutory requirements for safety and effectiveness. It is not within FDA's mission to prevent medical device manufacturers from engaging in anticompetitive practices that have no relation to health or safety. Reining in anticompetitive practices is ordinarily the responsibility of the FTC

and the Department of Justice. FDA believes it is not in the best interest of public health and safety to divert it from its mission.

FDA does not believe that it has the expertise or the resources to determine whether contact lens manufacturers are marketing their lenses in a "non-discriminatory" manner. If a manufacturer were to sign a statement certifying that it makes its lenses available in a "non-discriminatory" manner, FDA could not confirm the truth of such a statement without diverting its limited enforcement resources to examining contact lens sales practices. FDA's enforcement professionals are not trained for, and FDA believes they should not be required to investigate anti-competitive marketing.

Item

Authorized Generics- The Committee is aware that amendments to the Hatch-Waxman Act (Public Law 98-417) provided 180 day marketing exclusivity to a generic drug that successfully challenges the patent of a name brand pharmaceutical company, and that the purpose of this exclusivity was to provide incentives to bring lower cost generic drugs to the market as quickly as possible. Recently, the Committee has been informed that `authorized' generics are entering the market at the same time as generic drugs, and is concerned that this practice may have the ultimate effect of decreasing the number of generic drugs that enter the market, keeping prices ultimately higher for the consumer. Therefore, the Committee strongly encourages FDA to work to ensure that incentives for generic drugs, which are currently written into law, are protected, and that consumers continue to have access to safe, effective generic drugs at the earliest possible time. (Page 155)

Action Taken or To Be Taken

The Committee strongly encourages FDA to work to ensure that incentives for generic drugs, which are currently written into law, are protected, and that consumers continue to have access to safe, effective generic drugs at the earliest possible time. Please be assured that FDA continues to work to ensure that incentives for generic drugs, which are currently written into law, are protected, and that consumers continue to have access to safe, effective generic drugs at the earliest possible time.

FDA stated in a July 2, 2004 response to two citizen petitions submitted by Teva Pharmaceuticals (the world’s largest generic drug manufacturer) and Mylan Pharmaceuticals (another of the largest generics), that the Agency does not have the legal authority to prohibit or delay the marketing of authorized generics during the 180-day exclusivity period. In June 2005 in a suit brought by Teva, the DC Circuit confirmed FDA's reading of the statute. Teva Pharmaceutical Industries Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005). A federal district court for West Virginia has also confirmed FDA's reading. Mylan Pharms. Inc. v. FDA, No. 1:04cv00242-IMK, 2005 WL 2411674, (N.D. W.Va. Sept. 29, 2005). That decision is currently on appeal to the Fourth Circuit.

Discussion of authorized generics has focused on the competitive effects of their being marketed during the 180-day exclusivity period. This exclusivity period can be awarded to the first applicants seeking approval under an abbreviated new drug application,

ANDA, that challenge (as invalid or not infringed by their products) a patent claiming the approved drug they wish to copy. ANDA applicants that challenge a patent can sometimes obtain approval to market their products before the patent expires, and if those applicants are also eligible for 180-day exclusivity, they can sometimes market their products for six months before other ANDA applicants can have their applications approved.

The prospect of 180-day exclusivity provides an extra incentive (in addition to that of possibly being able to enter the market before a patent expires) for generic drug manufacturers to challenge patents. Marketing of authorized generics during a 180-day exclusivity period could increase competition, reducing the value of this incentive. FDA recognizes that there is concern that potentially reducing the value of 180-day exclusivity might have a "chilling" effect on generics challenging drug patents (and thereby exposing themselves to patent infringement litigation risk). FDA further recognizes that there is concern that authorized generics might slow the rate at which generic versions of drugs come to market.

Item

Influenza- Most experts estimate that there will be a lag time of 6 to 9 months before a vaccine can be produced in sufficient quantities to protect individuals against a pandemic strain of influenza to which most people will have no natural immunity. While issues around vaccine manufacturing, distribution, safety and access are complex; the United States and other nations are putting protocols in place now with respect to creating a rapid-response approval process for a pandemic flu vaccine. The Committee understands that FDA's Center for Biologics Evaluation and Research is engaging potential manufacturers of influenza vaccines and that FDA is writing a guidance document for the clinical development of new influenza vaccines, including pandemic influenza vaccines. The Committee encourages the Food and Drug Administration's Center for Biologics Evaluation and Research to continue its efforts in working with potential influenza vaccine manufacturers to facilitate the development of influenza vaccines for a pandemic. (Page 156)

Action Taken or to be Taken

The Committee encourages the Food and Drug Administration's Center for Biologics Evaluation and Research to continue its efforts in working with potential influenza vaccine manufacturers to facilitate the development of influenza vaccines for a pandemic. The FDA are actively engaged with sponsors and manufacturers interested in developing new technologies for influenza vaccine manufacture, including antigen sparing vaccines using both alum and novel adjuvants (a nonspecific simulator of immune response), as well as cell-culture based and recombinant (combining DNA from two or more sources) vaccines. The Agency has extensive experience in overseeing the development and licensure of cell-culture based and recombinant vaccines including those for prevention of other infectious diseases, such as chicken pox, polio, rubella, and hepatitis A and B. In November 2005, FDA convened the Vaccines and Related Biological Products Advisory Committee to discuss the use of Madin Darby Canine Kidney cell cultures, including those that are highly tumorigenic, in the manufacture of inactivated influenza vaccines.

FDA scientists work with manufacturers throughout the year to collect information on the capability of new influenza viruses to be used for large-scale production of influenza virus vaccines. FDA has initiated annual inspections of licensed influenza manufacturers, which may eliminate the need for additional inspections in an emergent circumstance. FDA is working with NIAID and manufacturers to determine what additional studies are needed pertaining to influenza virus subtypes with pandemic potential.

CONFERENCE REPORT (House Report 109-255) - MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2006, AND FOR OTHER PURPOSES – Significant Items

Item

Direct-To-Consumer Advertising - The conference agreement provides $884,000 for activities related to direct-to-consumer advertising.

Action Taken or To Be Taken

The conference agreement provides $884,000 for activities related to direct-to-consumer advertising. In FY 2006, FDA will spend an additional $875,160 for the review of direct-to-consumer drug ads. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $884,000 specified in the Congressional report. We promote and protect the health of Americans by influencing drug companies directly and indirectly so that they ensure their drug advertisements and other promotional materials are truthful and balanced. We operate a comprehensive program of education, surveillance and enforcement about drug advertising and promotion. FDA appreciates the Committee's recognition of the need for additional resources to regulate direct-to-consumer advertising. These additional resources will bolster our existing review staff in the Division of Drug Marketing, Advertising, and Communication (DDMAC) who are responsible for monitoring and evaluating promotional materials. (Page 100)

Item

New Mexico State University - The Conference Agreement provides an increase of $200,000 for agricultural product testing at the Physical Science Laboratory at New Mexico State University. (Page 100)

Action Taken or to be Taken

The Conference Agreement provides an increase of $200,000 for agricultural product testing at the Physical Science Laboratory at New Mexico State University. FDA will spend $2,358,972 in a contract for New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory. Congressional

directive in Public Law 109-148 applied a 1 percent rescission to the $2,332,800 specified in the Congressional report. Under contract to FDA, New Mexico State University (NMSU) Physical Science Laboratory has provided method assessment, development and validation data for targeted commodities identified as high profile/high risk for implementation into national food safety and food defense programs.

Item
Orphan Product grants - The conference agreement provides $14,696,000 for Orphan Product grants. (Page 100)

Action Taken or to be Taken
The conference agreement provides $14,696,000 for Orphan Product grants.
FDA will spend $14,549,000 for Orphan Product Grants. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $14,696,000 specified in the Conference Language.

Item
Office of Women's Health - The conference agreement provides not less than $4,000,000 for the Office of Women's Health. (Page 100)

Action Taken or to be Taken
The conference agreement provides not less than $4,000,000 for the Office of Women's Health. FDA will spend $3,960,000 for the Office of Women's Health. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $4,000,000 specified in the Congressional report.

Item
Generic Drugs – The conference agreement provides not less than $56,228,000 for the generic drug program. (Page 100)

Action Taken or To Be Taken
Generic Drugs – The conference agreement provides not less than $56,228,000 for the generic drug program. FDA has made significant progress in recent years in expediting the review of generic drug applications and will strive to maintain that progress. FDA will include base funding includes not less than $55,666,000 in funding for the Generic Drugs Program. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $56,228,000 specified in the Congressional report.

Item
Bovine Spongiform Encephalopathy - The conference agreement provides no less than $29,556,000 for Bovine Spongiform Encephalopathy (BSE), as requested. The conferees understand that this funding will support agency-wide BSE activities including conducting yearly inspections of all renderers and feed mills processing products containing prohibited materials, extending BSE inspections into targeted segments of industries subject to the BSE Feed regulation, validating test methods for the detection of

bovine-derived proteins in animal feed, and continuing to conduct research on Transmissible Spongiform Encephalopathies in FDA's product centers. (Page 100)

Action Taken or to be Taken

The conference agreement provides no less than $29,556,000 for Bovine Spongiform Encephalopathy (BSE), as requested. In FY 2006, FDA will devote no less than $29,260,000 BSE prevention activities, primarily to continue enforcement of the 1997 feed ban. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $29,566,000 specified in the Congressional report. This funding will support agency-wide BSE activities including conducting inspections of renderers and feed mills processing products containing prohibited materials, extending BSE inspections into targeted segments of industries subject to the BSE Feed regulation, validating test methods for the detection of bovine-derived proteins in animal feed, and continuing to conduct research on Transmissible Spongiform Encephalopathies in FDA's product centers.

Item

Chloramphenicol - The conferees have serious concerns regarding seafood safety issues posed by banned antibiotic contamination in farm-raised shrimp imports. In addition, the conferees are concerned that the FDA inspects less than 2 percent of shrimp being imported into the United States. The conferees recommend that the FDA, in cooperation with any state testing programs, continue testing of farm-raised shrimp imports for chloramphenicol and other related harmful antibiotics. (Page 101)

Action Taken or to be Taken

The conferees recommend that the FDA, in cooperation with any state testing programs, continue testing of farm-raised shrimp imports for chloramphenicol and other related harmful antibiotics. FDA will continue to work in cooperation with the states in evaluating farm-raised shrimp imports for chloramphenicol and other related harmful antibiotics.

Item

CFSAN Adverse Events Reporting System - The conference agreement includes total funding of $5,360,000 for the CFSAN Adverse Events Reporting System, of which approximately $1,500,000 is for dietary supplements. This is $860,000 more than the amount in the budget request.

Action Taken or to be Taken

The conference agreement includes total funding of $5,360,000 for the CFSAN Adverse Events Reporting System. FDA will include base funding includes not less than $5,306,400 in funding for the CFSAN Adverse Events Reporting System. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $5,360,000 specified in the Congressional report.

Item

NARMS - The conferees support the work of the National Antimicrobial Resistance Monitoring System (NARMS) and its collaborative relationship between FDA, USDA, and the Centers for Disease Control. The conferees expect the coordination of activities among these three areas of government to result in the most unbiased presentation of timely, accurate data in the best interest of public health, and encourage FDA to equally divide research funding among the three branches of the program. Further, the conferees direct that FDA perform a review of all components of the NARMS program to analyze the program's scientific soundness and relevance to public health, the criteria utilized to evaluate the program, the transparency of the program, opportunities for public input, and report the result to the Committees. (Page 101)

Action Taken or to be Taken

The conferees expect the coordination of activities among these three areas of government to result in the most unbiased presentation of timely, accurate data in the best interest of public health, and encourage FDA to equally divide research funding among the three branches of the program. Further, the conferees direct that FDA perform a review of all components of the NARMS program to analyze the program's scientific soundness and relevance to public health, the criteria utilized to evaluate the program, the transparency of the program, opportunities for public input, and report the result to the Committees. FDA strongly supports NARMS and all its components. FDA believes that all three arms are integral to the success of the NARMS program and to achieve the benefits envisioned at its inception and agreed upon by all three agencies. FDA has funded NARMS since it was conceived in 1996 and is committed to the continued funding of this program to the extent possible without compromising other core programs.

FDA met with a panel of outside experts for an external review of all three arms of the NARMS program in order to review key elements and establish future directions. FDA has begun implementation of several of these recommendations. The NARMS program is also being currently appraised by the FDA Science Board Peer Review.

FDA will continue efforts to maximize cooperation and communication between FDA, USDA, and CDC and strengthen data reporting to increase efficient use of resources. FDA is in the process of preparing a conference report to Congress on the NARMS program.

Item

National Center for Natural Products Research - The conference agreement provides an increase of $300,000 to enhance the collaboration between FDA and the National Center for Natural Products Research and allow increased participation by FDA staff in the research on botanicals and dietary supplements being conducted at the National Center for Natural Products Research in Oxford, MS. (Page 101)

Action Taken or to be Taken

The conference agreement provides an increase of $300,000 to enhance the collaboration between FDA and the National Center for Natural Products Research and allow increased participation by FDA staff in the research on botanicals and dietary supplements being conducted at the National Center for Natural Products Research in Oxford, MS. FDA will spend $3,243,240 for research at the National Center for Natural Products Research in Oxford, MS, which is an increase of $300,000 over the FY 2005 level of $2,976,000. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $3,276,000 specified in the Conference Language.

Item

Imports of Ethnic Foods -The conferees are aware of concerns about the regulation of imports of ethnic foods in the Los Angeles district. Concerns include the issues of communication to importers about shipments being held by FDA, the amount of time that shipments are held, and proper declaration of products. The conferees understand that in 2004 FDA's Los Angeles District implemented new operating procedures and held a public meeting on these issues. Since two years have elapsed, the conferees suggest that FDA now review the performance of the program and solicit input from the import community. (Page 102)

Action Taken or to be Taken

The conferees suggest that FDA now review the performance of the program and solicit input from the import community. In 2004 FDA's Los Angeles District implemented new operating procedures and held a public meeting on shipments being held by FDA, the amount of time that shipments are held, and proper declaration of products. FDA will review the performance of the program and solicit further input from the import community on how imported food is handled by FDA.

Item

Abuse-Resistant Drugs - The conferees note that FDA may use available funds to support review and action on new drug applications and supplements seeking approval for replacement or alternative abuse-resistant formulations of currently-available drug products that include an active ingredient that is a listed chemical under the Controlled Substances Act. Further, it is the understanding of the conferees that these applications may be considered under the expedited, priority review process at FDA. (Page 102)

Action Taken or To Be Taken

The conferees note that FDA may use available funds to support review and action on new drug applications and supplements seeking approval for replacement or alternative abuse-resistant formulations of currently-available drug products that include an active ingredient that is a listed chemical under the Controlled Substances Act. Drugs that are less prone to abuse would not generally meet the criteria for an expedited, priority review. Products regulated by CDER are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease. Products that are modified or reformulated to be “abuse-resistant” are considered, by regulations, to be the same active pharmaceutical ingredients

as the original approved products, and therefore do not meet the criteria for expedited review, because for the intended population, they do not offer a significant improvement compared to the originally marketed product.

However, if CDER received a new drug application for a product for which there is reasonable evidence or scientific basis to conclude it would be safer and have a lower abuse potential in people other than the intended population, compared to an already marketed product, we would work with the company to achieve an expedited action.

Item

Sunscreen Monographs- The conferees are aware that the FDA issued a monograph for sunscreen products in 2002, and the monograph was stayed shortly thereafter so that FDA could address the issue of measuring protection against UVA rays, which cause skin cancer. Since that time, no further official action has been taken by the FDA, although skin cancer rates continue to rise, especially among young persons and women. The conferees believe that a comprehensive monograph would be useful to consumers. Therefore, the conferees direct FDA to issue a comprehensive final monograph for over-the-counter sunscreen products, including UVA and UVB labeling requirements, within six months of enactment of this Act. (Page 102)

Action Taken or to be Taken

The conferees direct FDA to issue a comprehensive final monograph for over-the-counter sunscreen products, including UVA and UVB labeling requirements. FDA concurs with the conferees that a comprehensive monograph will be very useful to consumers. We are in the process of developing a comprehensive monograph for over-the-counter sunscreen products, including UVA and UVB labeling requirements, and expect to have the proposed rule for a monograph published soon. FDA will then address comments we receive on the proposed rule in an effort to publish the final rule.

Item

Commissioner's Testimony - The conferees do not include language in the House bill that withheld five percent of the funds provided to FDA's central offices pending a public hearing with the agency head on the fiscal year 2006 budget, because this requirement was satisfied by former Commissioner Crawford's testimony before the House subcommittee in July. However, the conferees expect the head of the agency to testify before the House and Senate subcommittees on the fiscal year 2007 budget during the regular course of budget hearings. (Page 102)

Action Taken or to be Taken

The conferees expect the head of the agency to testify before the House and Senate subcommittees on the fiscal year 2007 budget during the regular course of budget hearings. FDA plans to have the Acting Commissioner present the budget request to the House Appropriations Subcommittee at the hearing scheduled for February 16, 2006.

Item

Budget Structure - The conferees appreciate the detailed information provided in the budget justification prepared by the Food and Drug Administration and rely heavily on this information when considering budget proposals. These materials have traditionally been prepared for the sole use of the Committees on Appropriations in a format consistent with the structure of the Appropriations Act. The account organization in the fiscal year 2006 budget request does not present information in a format that is useful to the Committees. Therefore, the conferees do not approve the proposed restructuring of FDA's budget for the field activities, rent activities, and other activities accounts. The conferees direct the Agency to submit the fiscal year 2007 budget request in a format that follows the same account structure as the fiscal year 2005 budget request unless otherwise approved by the Committees. (Page 102)

Action Taken or to be Taken

The conferees do not approve the proposed restructuring of FDA's budget for the field activities, rent activities, and other activities accounts. The conferees direct the Agency to submit the fiscal year 2007 budget request in a format that follows the same account structure as the fiscal year 2005 budget. FDA has presented the FY 2007 President's Budget in a format that follows the same account structure as the FY 2005 budget.

Item

Consolidations -- The conferees direct the Department of Health and Human Services (HHS) to include all anticipated consolidations that impact FDA in the FDA budget request submitted to Congress. Further, the conferees direct that none of the funds made available to FDA in this Act be used for any assessments, fee, or charges by HHS unless such assessments, fees, or charges are identified in the FDA budget justification and expressly provided by Congress, or approved by Congress in the official reprogramming process as required in the General Provisions of this Act. The conferees further direct HHS to include in the fiscal year 2007 budget submission all sources of funding projected to be received by FDA from all other federal agencies in fiscal years 2006 and 2007, by agency, with a brief description of the reason for which the funds are to be provided to FDA. (Page 103)

Action Taken or to be Taken

The conferees direct the Department of Health and Human Services (HHS) to include all anticipated consolidations that impact FDA in the FDA budget request submitted to Congress. FDA has included a table and exhibit in this document, the Congressional Justification, entitled "DHHS Charges and Assessments." This table and exhibit list the actual and estimated fees or charges from DHHS. We have also included an exhibit on "Funding from Outside Sources."

Item

Research, Development and Evaluation - In its fiscal year 2006 budget, FDA requested $146,213,000 for `research, development and evaluation' (RD&E) activities. This amounts to about 10 percent of the agency's discretionary request. FDA provided only general descriptions of its planned RD&E activities within the context of its

strategic plan, without specifying the dollars requested, and provided only total proposed expenditures for each `research theme.' The conferees direct FDA to provide the same level of budget justification for its research activities in the fiscal year 2007 budget as it does other activities, including a justification of both base spending and any proposed increases by activity within center or office. (Page 103)

Action Taken or to be Taken

The conferees direct FDA to provide the same level of budget justification for its research activities in the fiscal year 2007 budget as it does other activities, including a justification of both base spending and any proposed increases by activity within center or office. FDA has included information on research and development in our program resource change, justification of base and accomplishment sections of the program narratives.

Item

The conference agreement provides $750,000 to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. The conferees understand the research would involve identifying candidate genes and proteins in University of Utah databases, designing and conducting genomic and proteomic biomarker validation experiments by the C-Path Institute, the University of Utah, FDA and manufacturers, determining which biomarkers identify heart failure patients who are most likely to respond favorably to drug therapy and those at highest risk of adverse events.

Action Taken or to be Taken

The conference agreement provides $750,000 to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. In FY 2006, FDA will spend an $742,500 to support collaborative research with the C-Path Institute and the University of Utah on cardiovascular biomarkers predictive of safety and clinical outcomes. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $750,000 specified in the Congressional report. The FDA has initiated discussions with the C-Path Institute and the University of Utah to clarify the terms of this collaborative research (e.g., defining the roles and responsibilities of each participant), including use of the University of Utah databases to identify candidate cardiovascular safety biomarkers, collaborative design of validation research, and conduct of that research. FDA is also in the process of identifying the appropriate contracting vehicle or vehicles for execution of the collaboration.

Item

The conferees remain concerned about the legal and regulatory issues relating to approval of drugs as both prescription and over the counter products, and urge FDA to expedite rulemaking on this topic.

Action Taken or To Be Taken
The conferees have expressed concern about legal and regulatory issues relating to the approval of drugs as prescription and over the counter products. FDA is evaluating these issues and the need for rulemaking, where necessary.

Item
St. Louis - SEC. 730. None of the funds made available to the Food and Drug Administration by this Act shall be used to close or relocate, or to plan to close or relocate, the Food and Drug Administration Division of Pharmaceutical Analysis in St. Louis, Missouri, outside the city or county limits of St. Louis, Missouri.

Action Taken or To Be Taken
None of the funds made available to the Food and Drug Administration by this Act shall be used to close or relocate, or to plan to close or relocate, the Food and Drug Administration Division of Pharmaceutical Analysis in St. Louis, Missouri, outside the city or county limits of St. Louis, Missouri. FDA has no plans to close or relocate or to plan to close or relocate the FDA Division of Pharmaceutical Analysis in St. Louis, Missouri.

Item
SEC. 795. (a) Subject to subsection (b), none of the funds made available in this Act may be used to-- (1) grant a waiver of a financial conflict of interest requirement pursuant to section 505(n)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)(4)) for any voting member of an advisory committee or panel of the Food and Drug Administration; or (2) make a certification under section 208(b)(3) of title 18, United States Code, for any such voting member.

(b) Subsection (a) shall not apply to a waiver or certification if-- (1) not later than 15 days prior to a meeting of an advisory committee or panel to which such waiver or certification applies, the Secretary of Health and Human Services discloses on the Internet website of the Food and Drug Administration-- (A) the nature of the conflict of interest at issue; and (B) the nature and basis of such waiver or certification (other than information exempted from disclosure under section 552 of title 5, United States Code (popularly known as the Freedom of Information Act)); or (2) in the case of a conflict of interest that becomes known to the Secretary less than 15 days prior to a meeting to which such waiver or certification applies, the Secretary shall make such public disclosure as soon as possible thereafter, but in no event later than the date of such meeting.

(c) None of the funds made available in this Act may be used to make a new appointment to an advisory committee or panel of the Food and Drug Administration unless the Commissioner of Food and Drugs submits a quarterly report to the Inspector General of the Department of Health and Human Services and the Committees on Appropriations of the House and Senate on the efforts made to identify qualified persons for such appointment with minimal or no potential conflicts of interest.

Action Taken or To Be Taken

The Committee directs that not later than 15 days prior to a meeting of an advisory committee or panel to which such waiver or certification applies, the Secretary of Health and Human Services discloses on the Internet website of the Food and Drug Administration. This information can be found at the following FDA website. *http://www.fda.gov/ohrms/dockets/ac/06acdocs.htm* The total number of waivers posted from November to December 31, 2005 is 32.

The Committee directs that none of the funds made available in this Act may be used to make a new appointment to an advisory committee or panel of the Food and Drug Administration unless the Commissioner of Food and Drugs submits a quarterly report to the Inspector General of the Department of Health and Human Services and the Committees on Appropriations of the House and Senate on the efforts made to identify qualified persons for such appointment with minimal or no potential conflicts of interest. FDA will submit the required quarterly reports to the Inspector General of the Department of Health and Human Services and the Committees on Appropriations of the House and Senate on the efforts made to identify qualified persons for such appointment with minimal or no potential conflicts of interest.

Item

Buildings and Facilities - The conference agreement provides $8,000,000 for the Food and Drug Administration Buildings and Facilities instead of $5,000,000 as proposed by the House and $7,000,000 as proposed by the Senate. Of the total, $4,000,000 is for the repair and improvement of existing buildings and facilities, and $4,000,000 is to complete the final phase of the Arkansas Regional Laboratory.

Action taken or to be taken

The conference agreement provides $8,000,000 for the Food and Drug Administration Buildings and Facilities. FDA will spend $3,960,000 for repair and improvement of existing buildings and facilities nation-wide. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $4,000,000 specified in the Congressional report. FDA will spend $3,960,000 for the final phase of Building 50 of the Arkansas Regional Laboratory. Funds will be utilized to develop the program, design and complete the fit-out of the remaining floors. This will complete the Arkansas Regional Laboratory Facility project. The Congressional directive in Public Law 109-148 applied a 1 percent rescission to the $4,000,000 specified in the Congressional report.

Food and Drug Administration
HIV/AIDS
(Dollars in Thousands)

Program	FY 2004 Current Estimate [1]	FY 2005 Enacted [2]	FY 2006 Estimate [3]	FY 2007 Estimate
HIV/AIDS				
Human Drugs	*$22,145*	*$33,930*	34,087	34,087
Biologics	*$28,150*	*$31,090*	26,816	26,816
Medical Devices	*$2,120*	*$2,302*	2,567	2,567
Other Acticities	*$4,015*	*$3,607*	4,862	4,862
Field Activity	*$17,417*	*$16,732*	21,091	21,091
Total HIV/AIDS	**$73,847**	**$87,661**	**89,423**	**89,423**

[1/] Includes 0.59% rescission

[2/] Includes 0.8% rescission

[3/] Includes 1.0% recission.

FDA Authorizing Legislation

FDA is requesting the authorization of two new user fees. The first will authorize FDA to collect user fees for Export Certificates for foods and animal feeds. The second user fee is for re-inspections and follow-up work when a regulated firm fails to meet good manufacturing practices or other regulatory requirements.

1. Authorize the Collection of User Fees for Export Certificates for Foods and Animal Feed

Current Law: FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). However, there is no similar authority for collecting user fees for export certificates for foods and animal feed.

Proposal: Amend the Act to authorize the Secretary to recover costs of food and animal feed export certificate-related activities through user fees and to use the fees to hire staff (above normal FTE ceiling) for these activities. The Administration proposes the following legislative language: Amend Section 801(e)(4)(A) by inserting "food and animal feed," before each appearance of the words "drug, animal drug, or device."

Estimated User Fee Collections for Food and Animal Feed Export Certificates

Program	FY 2006		FY 2007	
	FTE	$	FTE	$
Foods	0	$0	6	$906,000
Foods Field	0	$0	17	$2,567,000
Center for Veterinary Medicine	0	$0	0	$63,000
Total	0	$0	23	$3,536,000

2. Authorization of User Fees for re-inspections and follow-up work due to failure to meet Good Manufacturing Practice regulations and other requirements

Current Law: Reinspections of FDA-regulated firms are currently funded from appropriations.

Proposal: Amend the Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. FDA conducts follow-up inspection to verify that a firm implements action to correct violations discovered during an inspection or when we issue a warning letter. When FDA finds violations during an inspection, the agency conducts a follow-up inspection to ensure the firm has corrected the violation. When FDA issues warning letters, the agency usually conducts follow-up inspections within 90 days.

Estimated User Fee Collections for Re-Inspections and Follow-Up Work

Program	FY 2006		FY 2007	
	FTE	$	FTE	$
Foods Field	0	$0	44	$5,215,000
Human Drugs Field	0	$0	16	$2,009,000
Biologics Field	0	$0	3	$410,000
Animal Drugs and Feeds Field	0	$0	17	$2,050,000
Devices and Radiological Health Field	0	$0	22	$2,616,000
Office of the Commissioner	0	$0	10	$2,000,000
Office of Management	0	$0	6	$5,100,000
GSA Rent and Other Rent Related	0	$0	0	$2,600,000
Total	0	$0	118	$22,000,000

FOOD AND DRUG ADMINISTRATION
Table of Estimates and Appropriations
S&E

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation*
1996	965,462,000[1]	904,694,000[2]	904,694,000[2]	904,694,000[2]
1997	969,519,000[3]	907,499,000[4]	907,499,000[4]	907,499,000[4]
1998	995,194,000[5]	945,174,000[6]	935,175,000[6]	948,705,000[6]
1999	1,159,055,000[7]	1,003,722,000[8]	1,072,640,000[9]	1,096,445,000[10]
2000	1,305,869,000[11]	1,218,384,000[12]	1,180,972,000[13]	1,183,095,000[14]
2001	1,359,481,000[15]	1,240,178,000[16]	1,216,796,000[17]	1,215,446,000[18]
2002	1,377,160,000[19]	1,342,339,000[20]	1,344,386,000[21]	1,496,486,000[22]
2003	1,633,605,000[23]	1,599,602,000[24]	1,628,895,000[25]	1,621,739,000[26]
2004	1,678,632,000[27]	1,675,713,000[28]	1,670,692,000[29]	1,665,258,000[30]
2005	1,820,849,000[31]	1,788,849,000[32]	1,791,599,000[33]	1,776,784,000[34]
2006	1,849,676,000[35]	1,837,928,000[36]	1,841,959,000[37]	1,825,751,000[38]
2007	1,916,329,000[39]			

* Appropriation contains salaries and expenses (S&E), PDUFA , MDUFMA and ADUFA only.

[1] Includes $823,795,000 in S&E, $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.

[2] Includes $819,971,000 in S&E, and $84,723,000 in PDUFA. Excludes $13,000,000 in MQSA.

[3] Includes $823,771,000 in S&E, $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.

[4] Includes $819,971,000 in S&E, and $87,528,000 for PDUFA. Excludes $13,403,000 for MQSA fee collections.

[5] Includes $750,922,000 in S&E, $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.

[6] Includes $857,971,000 in S&E, and $91,204,000 for PDUFA. Excludes $13,966,000 for MQSA fee collections.

[7] Includes $878,885,000 in S&E, $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.

[8] Includes $871,449,000 in S&E, and $132,273,000 for PDUFA ($5,428,000 for GSA rent). Excludes $14,385,000 for MQSA fee collections, and GSA budget authority rental payments of $82,866,000.

[9] Includes $940,367,000 in S&E (which includes $82,866,000 in budget authority GSA rent), and $132,273,000 for PDUFA ($5,428,000 for GSA rent) Excludes $14,385,000 for MQSA fee collections.

[10] Includes rescission of $1,695,000, S&E of $964,172,000, (which includes $82,866,000 for GSA Rent), and $132,273,000 for PDUFA ($5,428,000 for GSA rent). Excludes $14,385,000 for MQSA fee collections.

[11] Includes $1,109,950,000 (including $94,537,000 of GSA Rent) S&E, $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.

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

[13] Includes $1,035,538,000 (including $94,537,000 of GSA Rent) in S&E, and $145,434,000 for PDUFA ($5,643,000 is for GSA Rent). Excludes $14,817,000 for MQSA fee collections.

[14] Includes rescission of $2,977,000, S&E of $1,037,661,000 (including $94,311,000 of GSA Rent), and $145,434,000 for PDUFA ($5,643,000 is GSA Rent). Excludes $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.

[15] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in S&E, $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).

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

[17] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in S&E, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). Excludes $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[18] Includes rescission of $2,351,000, S&E 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). Excludes $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.

[19] Includes $1,173,673,000 (including $98,876,000 of GSA Rent) in S&E, $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. Excludes $2,950,000 million for drug importation that is not available until requested by the President.

[20] Includes $1,180,623,000 (including $98,876,000 of GSA Rent) in S&E, 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.

[21] Includes $1,182,670,000 (including $98,876,000 of GSA Rent) in S&E, and $161,716,000 for PDUFA ($6,240,000 is GSA rent) Excludes $15,590,000 for MQSA fee collections, and $6,181,000 in Export Certification and Color Certification.

[22] Includes $1,183,670,000 (including $98,876,000 of GSA Rent) in S&E, $161,716,000 for PDUFA ($6,240,000 is GSA rent). Excludes $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.

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

[24] Includes $1,376,702,000 (including $98,876,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent). Excludes $16,112,000for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[25] Includes $1,383,505,000 (including $98,556,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent) and $22,490,000 for MDUFMA. Excludes $16,112,000 for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[26] Includes $1,373,714,000 (including $98,233,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent), and $25,125 in MDUFMA fees ($1,591,000 is GSA rent). Excludes $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $5,237,000 in Color Certification.

[27] Includes $1,394,617,000 (including $108,876,000 of GSA Rent) in S&E, $249,825,000 in proposed PDUFA fees ($8,646,000 is GSA rent) and $29,190,000 in MDUFMA fees ($2,273,000 is GSA rent) and $5,000,000 in proposed Animal Drug User Fees ($250,000 is GSA Rent). Excludes $16,576,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[28] Includes $1,389,234,000 (including $108,876,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA) ($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[29] Includes $1,384,213,000 (including $108,233,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[30] Includes $1,378,779,000 (including $107,594,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification. A$8,224,000 rescission is included.

[31] Includes $1,494,517,000 (including $107,594,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[32] Includes $1,462,517,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[33] Includes $1,465,267,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[34] Includes $1,450,098,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,354,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[35] Includes $1,492,726,000 (including $117,579,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,203,000 is GSA rent), and $11,318,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[36] Includes $1,480,978,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, and $11,318,000 in proposed ADUFA fees. Excludes $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), $1,371,000 in GSA Rent (ADUFA), $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[37] Includes $1,485,009,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, and $11,318,000 in proposed ADUFA fees. Excludes $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), $1,371,000 in GSA Rent (ADUFA), $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[38]Includes $1,468,801,000 (including $116,403,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,203,000 is GSA rent), and $11,318,000 in proposed Animal Drug User Fees (ADUFA) ($1,371 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[39] Includes $1,540,399,000 (including $126,871,000 of GSA Rent) in S&E, and $320,600,000 for PDUFA ($14,501,000 is GSA rent), $43,726,000 in MDUFMA fees ($3,323,000 is GSA rent), and $11,604,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

FOOD AND DRUG ADMINISTRATION
Table of Estimates and Appropriations
Rental Payments to GSA

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1995	48,575,000	46,294,000[1]	46,294,000	46,294,000[2]
1996	46,294,000	46,294,000	46,294,000	46,294,000[3]
1997	46,294,000	46,294,000	46,294,000	46,294,000[4]
1998	46,294,000[5]	46,294,000	46,294,000	46,294,000
1999	82,866,000[6]	82,866,000[7]		

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

[2] Includes an authorized reduction of $3,970,000 to cover Building Delegation expenses.

[3] Includes an authorized reduction of $3,957,000 to cover Building Delegation expenses.

[4] Includes an authorized reduction of estimated to be $4,705,000 to cover Building Delegation expenses.

[5] Includes an authorized reduction of estimated to be $4,832,000 to cover Building Delegation expenses.

[6] 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 Building Delegation expenses and $5,428,000 of PDUFA collections, which are included in S&E PDUFA.

[7] Does not include GSA Rent in the S&E Appropriation. Includes an authorized reduction of GSA rent payments estimated to be $4,917,000 to cover Building Delegation expenses. Excludes $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.

FOOD AND DRUG ADMINISTRATION
Table of Estimates and Appropriations
Buildings and Facilities

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1996	8,350,000	15,350,000	8,350,000	12,150,000[1]
1997	8,350,000	21,350,000	21,350,000	21,350,000[2]
1998	22,900,000[3]	21,350,000	22,900,000	21,350,000[4]
1999	8,350,000	11,350,000	12,350,000	11,350,000[5]
2000	31,750,000[6]	31,750,000	8,350,000	11,350,000
2001	31,350,000[7]	11,350,000	31,350,000	31,350,000
2002	34,281,000[8]	34,281,000	34,281,000	34,281,000
2003	8,000,000[9]	8,000,000	11,000,000[10]	7,948,000[11]
2004	11,500,000[12]	6,000,000	7,948,000	6,959,000 [13]
2005	-6,959,000 [14]	-6,959,000	-6,959,000	-6,959,000
2006	7,000,000	5,000,000	7,000,000	7,920,000
2007	4,950,000			

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

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

[3] Includes $13,000,000 for continuing modernization of the ARL.

[4] Includes $14,550,000 for continuing modernization of the ARL

[5] Includes $3,000,000 for continuing modernization of the ARL

[6] Includes $20,400,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL

[7] Includes $20,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL

[8] Includes $23,000,000 for construction of Phase II of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL

[9] Reflects a reduction of $26,281,000 to centralize of B&F construction activities at the Department.

[10] Includes $3,000,000 to complete ARL

[11] Includes $8,000,000 in Appropriated funds with a rescission of $52,000.

[12] Includes $3,500,000 to complete ARL.

[13] Includes Final Conference amount of $7,000,000 with a $41,000 rescission.

[14] Includes a $6,959,000 decrease to fund high priority programs.

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

Project	FY 2005 Actual	FY 2006 Enacted	FY 2007 Estimate
Center for Food Safety and Applied Nutrition	884	881	817
Center for Drug Evaluation and Research	2,220	2,360	2,382
Center for Biologics Evaluation and Research	818	883	929
Center for Veterinary Medicine	369	385	406
Center for Devices and Radiological Health	1,104	1,136	1,158
National Center for Toxological Research	187	206	199
Office of Regulatory Affairs	3,633	3,488	3,488
Other Activities			
Office of the Commissioner	256	259	251
Office of Management	257	314	310
Office of External Relations	74	73	73
Office of Planning and Policy	65	60	61
Other User Fees	43	46	50
TOTAL	**9,910**	**10,091**	**10,124**

Note: FY 2005 actuals exclude 82 reimbursable FTE. FY 2006 and 2007 actuals exclude 85 reimbursable FTE.

Five Year History of GS/GM Average Grade

Year	Grade
FY 2003	11.7
FY 2004	11.9
FY 2005	11.9
FY 2006	11.9
FY 2007	12.2

FOOD AND DRUG ADMINISTRATION
DETAIL OF FTE BY GRADE

	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate
Executive Level I……	-	-	-
Executive Level II……	-	-	-
Executive Level III……	-	-	-
Executive Level IV……	-	1	1
Executive Level V……	-	-	-
Total, Exec. Level	-	1	1
ES……	44	55	55
Total, ES	44	55	55
GS-15……	762	776	779
GS-14……	1,513	1,541	1,546
GS-13……	2,668	2,717	2,727
GS-12……	1,647	1,677	1,684
GS-11……	605	616	618
GS-10……	48	49	49
GS-9……	391	398	400
GS-8……	187	190	191
GS-7……	412	419	421
GS-6……	70	71	71
GS-5……	59	60	60
GS-4……	79	80	80
GS-3……	84	86	86
GS-2……	43	44	44
GS-1……	10	10	10
Subtotal, GS	**8,578**	**8,734**	**8,766**
AL……	1	1	1
ST/SL……	1	1	1
RS……	39	39	39
CC - 08/07/06……	203	206	206
CC - Other……	508	514	514
Subtotal, CC	**711**	**720**	**720**
AD (includes Title 42)……	553	560	561
Wage Grade……	54	54	54
Consultants……	11	11	11
Total FTE (End of Year) 1/	**9,992**	**10,176**	**10,209**
Average ES level……	-	-	-
Average ES Salary……	151,200	157,200	163,500
Average GS grade…….	12.2	12.2	12.2
Average GS salary…….	62,900	64,850	66,277

1/ FY 2005 FTE total reflects actual 113G year end total.

FOOD AND DRUG ADMINISTRATION
New Positions Requested for Appropriated and User Fee Funding

Program	Budget Authority		User Fee		
Job Category and Grade Series	**Center**	**Field**	**Center**	**Field**	**TOTAL**
FOODS					
Microbiologist GS-403 – 9/11	2				2
Microbiologist GS-403 – 12	2				2
Microbiologist GS-403 – 13	1				1
Foods Subtotal	**5**				**5**
HUMAN DRUGS					
Epidemiologist GS-0601-12/13/14	1		3		4
Lead Medical Officer GS-0602-15	1		1		2
Medical Officer GS-0602-12/13/14	6		6		12
Pharmacist GS-0660-12/13/14			4		4
Pharmacologist GS-0405-13			3		3
Project Management-GS-0601-14	1				1
Project Management-GS-0601-13	2				2
Regulatory Health Project Manager, GS-0601-12/13			5		5
Risk Management Scientific Analyst GS-0601-12/13/14			2		2
Scientist (Regulatory Scientist) GS-0601-12/13	1				1
Human Drugs Subtotal	**12**		**24**		**36**
BIOLOGICS					
Microbiologist GS-0403 11/12/13	7		1		8
Medical Officer GS-0602 12/13/14/15	12		3		15
Consumer Safety Officer GS-0696 11/12/13	19		4		23
Chemist GS-1320 9/11/12/13	7		1		8
Veterinary Medical Science GS-0701 13/14	1		0		1

Program	Budget Authority		User Fee		
Job Category and Grade Series	**Center**	**Field**	**Center**	**Field**	**TOTAL**
Biologist GS-0401 9/11/12/13/14	9		3		12
General Health Science GS-0601 9/11/12	5		0		5
Mathematical Statistician GS-1530 12/13/14	4		0		4
Biologics Subtotal	**64**		**12**		**76**
ANIMAL DRUGS					
Project Managers – GS-12/13	3				3
Biologists – GS-11/12	2				2
Chemist – GS-11/12	1				1
Consumer Safety Officers – GS-11/12	4				4
Microbiologists – GS-11/12	2				2
Pharmacologists – GS-11/12	4				4
Veterinary Medical Officers – GS-11/12	7				7
Animal Drugs Subtotal	**23**				**23**
DEVICES AND RADIOLOGICAL HEALTH					
Public Health Training Specialist GS-13	1				1
Interdisciplinary Scientists GS-7/9/11/12/13/14	3		4		7
Biologist/Radiation Biologist GS-13	1				1
Biomedical Engineer GS-7/9/11/12/13	2				2
Chem./Mech./Materials Engineer GS-7/9/11	2		2		4
Microbiologist GS-13	2				2
Radiologist/Medical Officer GS-12/13/14	2				2
Management/Program/Budget Analyst GS-11/13	1				1
Chemist GS-9/11	1				1
Consumer Safety Officer GS-9/11/			1		1
Devices Subtotal	**15**		**7**		**22**

Program	Budget Authority		User Fee		
Job Category and Grade Series	**Center**	**Field**	**Center**	**Field**	**TOTAL**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH					
NCTR has no new positions for FY2007	**0**				**0**
OTHER ACTIVITIES					
Medical Officer GS-0602-13/14	1				1
Consumer Safety Officer GS-0696-12-13	3				3
Project Management-GS-0696/0601-12-13			2		2
Operation Research Analyst 11,12-13			**2**		2
Other Activities Subtotal	**4**		**4**		**8**
Grand Total	**123**		**47**		**170**

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
DAUPHIN ISLAND - TOTAL ASSETS	CFSAN	0865 - DAUPHIN ISLAND	01 - AL	HEADQUARTERS FIELD	FDA OWNED
DAUPHIN ISLAND -Seafood Laboratory	CFSAN	0865 - DAUPHIN ISLAND	01 - AL	HEADQUARTERS FIELD	FDA OWNED
DAUPHIN ISLAND -Generator Buildings	CFSAN	0865 - DAUPHIN ISLAND	01 - AL	HEADQUARTERS FIELD	FDA OWNED
DAUPHIN ISLAND -Outer Buildings	CFSAN	0865 - DAUPHIN ISLAND	01 - AL	HEADQUARTERS FIELD	FDA OWNED
RESIDENT POST- MOBILE, AL	ORA	2100 - MOBILE	01 - AL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- MONTGOMERY, AL	ORA	2130 - MONTGOMERY	01 - AL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- BIRMINGHAM, AL	ORA	0350 - BIRMINGHAM	01 - AL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- ANCHORAGE, AK	ORA	0130 - ANCHORAGE	02 - AK	PACIFIC (OAKLAND)	GSA OWNED
DAYCARE BUILDING - SHARED USE	ORA	0130 - ANCHORAGE	02 - AK	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- TUCSON, AZ	ORA	0530 - TUCSON	04 - AZ	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- SAN LUIS, AZ	ORA	0417 - SAN LUIS	04 - AZ	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- DOUGLAS, AZ	ORA	0130 - DOUGLAS	04 - AZ	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- NOGALES, AZ	ORA	0330 - NOGALES	04 - AZ	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- SAN LUIS, AZ	ORA	0417 - SAN LUIS	04 - AZ	SOUTHWEST (DALLAS)	GSA OWNED
OCI PHOENIX RESIDENT OFFICE	OCI	0370 - PHOENIX	04 - AZ	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- NOGALES, AZ	ORA	0330 - NOGALES	04 - AZ	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- PHOENIX, AZ	ORA	0490 - TEMPE	04 - AZ	SOUTHWEST (DALLAS)	GSA LEASED
REGIONAL LABORATORY- ARKANSAS - BUILDING 26	ORA	2045 - JEFFERSON	05 - AR	SOUTHWEST (DALLAS)	FDA OWNED
JEFFERSON LABORATORY COMPLEX - TOTAL ASSETS	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON - Bldg. 16 - Paint Shop	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 6	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
		2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Guard Portable Shed Delivery	NCTR				
JEFFERSON -Bldg. 20 - Storage	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 9	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
		2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Guard Portable Shed Roadway	NCTR				
JEFFERSON -Bldg. 21 - Security Building	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 11	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 28 - Golf Cart Charging Station	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 10 - Library	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 31 - Communications and Copy Cente	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 13	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 32 - Storage	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 7	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 70 - Commons	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 14A	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 71 - Residence	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 14B	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 72 - Residence	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 14C	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 74 - Residence	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 12	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. 75 - Residence	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 15	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. T-45 - Modular Offices - Facility Maint.	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 17	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. T5 - Office Trailer	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 37	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Bldg. T-14 - Modular Offices	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 44 - Utilities	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 5A	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 45 - Maintenance	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 5D	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 46 - Utilities	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 5B	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 50	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 5C	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 51	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 85A	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 52 - Warehouse	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 85C	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 54	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 85B	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 58 - Main Corridors	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 53A	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 58B - Connecting Corridors	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 53B	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
		2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 60	NCTR				
JEFFERSON -Building 53C	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 62	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Building 53D	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Haz Mat Portable at 5B	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
JEFFERSON -Building 53E	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
JEFFERSON -Haz Mat Portable at 53C	NCTR	2045 - JEFFERSON	05 - AR	HEADQUARTERS FIELD	FDA OWNED
RESIDENT POST- LITTLE ROCK, AR	ORA	2320 - LITTLE ROCK	05 - AR	SOUTHWEST (DALLAS)	GSA OWNED
OCI LOS ANGELES FIELD OFFICE	OCI	3250 - SAN CLEMENTE	06 - CA	HEADQUARTERS FIELD	FDA LEASED
REGIONAL LABORATORY- PACIFIC SOUTHWEST/ DISTRICT OFFICE - LOS ANGELES	ORA	1713 - IRVINE	06 - CA	PACIFIC (OAKLAND)	FDA OWNED
Irvine Regional Laboratory - Regional Office and Laboratory	NCTR	1713 - IRVINE	06 - CA	PACIFIC (OAKLAND)	FDA OWNED
Irvine Regional Laboratory - Security Gate House	NCTR	1713 - IRVINE	06 - CA	PACIFIC (OAKLAND)	FDA OWNED
RESIDENT POST- STOCKTON, CA	ORA	3770 - STOCKTON	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- SACRAMENTO, CA	ORA	3150 - SACRAMENTO	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
REGIONAL FIELD OFFICE - PACIFIC (OAKLAND)	ORA	2480 - OAKLAND	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- OTAY MESA, CA	ORA	3260 - SAN DIEGO	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- SAN FRANCISCO AIRPORT, CA	ORA	3730 - SAN FRANCISCO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- CALEXICO, CA	ORA	0520 - CALEXICO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- CALEXICO, CA	ORA	0520 - CALEXICO	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
US BORDER STATION	ORA	3835 - TECATE	06 - CA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- CANOGA PARK, CA	ORA	1970 - CANOGA PARK	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SAN JOSE, CA	ORA	3340 - SAN JOSE	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SANTA BARBARA, CA	ORA	3430 - SANTA BARBARA	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SAN DIEGO, CA	ORA	3260 - SAN DIEGO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
DISTRICT OFFICE W/LAB- SAN FRANCISCO	ORA	0010 - ALAMEDA	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SAN PEDRO, CA	ORA	1970- SAN PEDRO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- LAX	ORA	1980 - LOS ANGELES	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- OTAY MESA, CA	ORA	2610 - OTAY	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- FRESNO, CA	ORA	1370 - FRESNO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
OCI SAN FRANCISCO RESIDENT OFFICE	OCI	2480 - OAKLAND	06 - CA	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST - ONTARIO, CA	ORA	2550 - ONTARIO	06 - CA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- CARSON, CA	ORA	0602 - CARSON	06 - CA	PACIFIC (OAKLAND)	USPS BLDG
RESIDENT POST- LONG BEACH, CA	ORA	1970 - LONG BEACH/San Pedro	06 - CA	PACIFIC (OAKLAND)	USPS BLDG
DISTRICT OFFICE W/LAB- DENVER	ORA	0600 - DENVER	08 - CO	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- HARTFORD, CT	ORA	0280 - HARTFORD	09 - CT	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- BRIDGEPORT, CT	ORA	0080 - BRIDGEPORT	09 - CT	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- WILMINGTON, DE	ORA	0490 - WILMINGTON	10 - DE	CENTRAL (PHILADELPHIA)	GSA LEASED
MARY E SWITZER BUILDING SW	OC	0010 - WASHINGTON	11 - DC	HEADQUARTERS	GSA OWNED
MIAMI RESIDENT POST STORAGE	ORA	2010 - MIAMI	12 - FL	SOUTHEAST (ATLANTA)	GSA OWNED
RESIDENT POST- FORT MYERS, FL	ORA	1070 - FORT MYERS	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- TAMPA, FL	ORA	2950 - TAMPA	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- JACKSONVILLE, FL	ORA	1510 - JACKSONVILLE	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- BOCA RATON, FL	ORA	0290 - BOCA RATON	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
OCI MIAMI FIELD OFFICE	OCI	2541 - PLANTATION	12 - FL	HEADQUARTERS FIELD	GSA LEASED
DISTRICT OFFICE- FLORIDA	ORA	1895 - MAITLAND	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- MIAMI, FL- DOMESTIC	ORA	2010 - MIAMI	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- TALLAHASSEE, FL	ORA	2940 - TALLAHASSEE	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- MIAMI, FL- IMPORT	ORA	2010 - MIAMI	12 - FL	SOUTHEAST (ATLANTA)	GSA LEASED
?	ORA	0280 - ATLANTA	13 - GA	SOUTHEAST (ATLANTA)	GSA OWNED
OCI ATLANTA RESIDENT OFFICE	OCI	0280 - ATLANTA	13 - GA	HEADQUARTERS FIELD	GSA OWNED
REGIONAL LABORATORY - SOUTHEAST	ORA	0280 - ATLANTA	13 - GA	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- SAVANNAH, GA	ORA	4910 - SAVANNAH	13 - GA	SOUTHEAST (ATLANTA)	GSA OWNED
RESIDENT POST- TIFTON, GA	ORA	5490 - TIFTON	13 - GA	SOUTHEAST (ATLANTA)	GSA LEASED
DISTRICT/REGION - ATLANTA	ORA	0280 - ATLANTA	13 - GA	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- HONOLULU, HI	ORA	2400 - HONOLULU	15 - HI	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- EASTPORT, ID	ORA	0445 - EASTPORT	16 - ID	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- BOISE, ID	ORA	0160 - BOISE	16 - ID	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- MOUNT VERNON, IL	ORA	5900 - MT VERNON	17 - IL	CENTRAL (CHICAGO)	GSA OWNED
RESIDENT POST- SPRINGFIELD, IL	ORA	8220 - SPRINGFIELD	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
REGIONAL FIELD OFFICE- CENTRAL (CHICAGO)	ORA	1670 - CHICAGO	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
OCI CHICAGO FIELD OFFICE	OCI	4867 - LISLE	17 - IL	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- HINSDALE, IL	ORA	3980 - HINSDALE	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- PEROIA, IL	ORA	6850 - PEORIA	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
MOFFETT CENTER	CFSAN	0610 - BEDFORD PARK	17 - IL	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- BENSENVILLE, IL	ORA	0740 - BENSENVILLE	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
UNION STATION PARKING	ORA	1670 - CHICAGO	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- GURNEE, IL	ORA	3670 - GURNEE	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
DISTRICT OFFICE- CHICAGO	ORA	1670 - CHICAGO	17 - IL	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- EVANSVILLE, IN	ORA	1480 - EVANSVILLE	18 - IN	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- INDIANAPOLIS, IN	ORA	2210 - INDIANAPOLIS	18 - IN	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- SOUTH BEND, IN	ORA	4580 - SOUTH BEND	18 - IN	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- SIOUX CITY, IA	ORA	7850 - SIOUX CITY	19 - IA	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- DES MOINES, IA	ORA	2260 - DES MOINES	19 - IA	SOUTHWEST (DALLAS)	GSA OWNED
AMPCO SYSTEM PARKING ONLY	ORA	2260 - DES MOINES	19 - IA	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- DAVENPORT, IA	ORA	2080 - DAVENPORT	19 - IA	SOUTHWEST (DALLAS)	GSA OWNED
CHILD CARE CENTER - SHARED USE	ORA	2260 - DES MOINES	19 - IA	SOUTHWEST (DALLAS)	GSA LEASED
OCI KANSAS CITY FIELD OFFICE	OCI	3705 - MISSION	20 - KS	HEADQUARTERS FIELD	GSA LEASED
DISTRICT OFFICE- ANNEX (LAB)	ORA	3080 - LENEXA	20 - KS	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- WICHITA, KS	ORA	5880 - WICHITA	20 - KS	SOUTHWEST (DALLAS)	GSA LEASED

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
DISTRICT OFFICE- KANSAS CITY	ORA	3080 - LENEXA	20 - KS	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- LOUISVILLE, KY	ORA	2090 - LOUISVILLE	21 - KY	CENTRAL (PHILADELPHIA)	GSA LEASED
Metairie Center	ORA	1545 - METAIRIE	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- BATON ROUGE, LA	ORA	0150 - BATON ROUGE	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- SHREVEPORT, LA	ORA	2130 - SHREVEPORT	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
DISTRICT OFFICE- NEW ORLEANS	ORA	1690 - NEW ORLEANS	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- LAFAYETTE, LA	ORA	1230 - LAFAYETTE	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
OCI NEW ORLEANS RESIDENT OFFICE	OCI	0510 - COVINGTON	22 - LA	HEADQUARTERS FIELD	GSA LEASED
Mandeville Square Shopping Center	ORA	1400 - MANDEVILLE	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
Old Bank Building	ORA	1400 - MANDEVILLE	22 - LA	SOUTHEAST (ATLANTA)	GSA LEASED
BORDER STATION - HOULTON, ME	ORA	3750 - HOULTON	23 - ME	NORTHEAST (NEW YORK)	GSA OWNED
BORDER STATION - HOULTON, ME	ORA	3750 - HOULTON	23 - ME	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- AUGUSTA, ME	ORA	0160 - AUGUSTA	23 - ME	NORTHEAST (NEW YORK)	GSA LEASED
BORDER STATION - CALAIS, ME	ORA	1250 - CALAIS	23 - ME	NORTHEAST (NEW YORK)	GSA LEASED
NICHOLSON LANE RESEARCH CENTER(DIRECT LEASE)	CBER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	FDA LEASED
FDA LABORATORY BUILDING 1(MOD1)	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
NIH BLDG 29	CBER	0130 - BETHESDA	24 - MD	HEADQUARTERS	DIRECT OWNED
NIH BLDG 29A	CBER/CDER	0130 - BETHESDA	24 - MD	HEADQUARTERS	DIRECT OWNED
NIH BLDG 29B	CBER/CDER	0130 - BETHESDA	24 - MD	HEADQUARTERS	DIRECT OWNED
NIH BLDG 14D	CBER	0130 - BETHESDA	24 - MD	HEADQUARTERS	DIRECT OWNED
BELTSVILLE RESEARCH FACILITY - TOTAL ALL ASSETS	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-02 Laboratory	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-03 Support	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-04 Carpentry Shop	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-05 Fitness Center	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-06 Hazmat Trailers	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
BELTSVILLE RESEARCH FACILITY-07 Block Building	CFSAN	0900 - LAUREL	24 - MD	HEADQUARTERS	FDA OWNED
RESIDENT POST- SALISBURY, MD	ORA	1380 - SALISBURY	24 - MD	CENTRAL (PHILADELPHIA)	GSA OWNED
METRO PARK NORTH 1	CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
ROCKWALL 2 BUILDING	CBER/CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
CRABB CVM BUILDING	CVM	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
METRO PARK NORTH 2	OC/OCI/CDER/CVM	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
WOODMONT OFFICE COMPLEX 1	CBER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
OAKGROVE BUILDING 2094	CDRH	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
PICCARD BUILDING 1350	CDRH	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
OAKGROVE BUILDING 2098	CDRH	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
WOODMONT OFFICE COMPLEX 2	CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
CORPORATE BUILDING	CDRH	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
CRABB BUILDING	ORA/OC	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
TECHNOLOGY CENTER	CDRH/OC	0630 - GAITHERSBURG	24 - MD	HEADQUARTERS	GSA LEASED
OCI TASK FORCE MARYLAND (SPECIAL PROSECUTION STAFF)	OCI	0100 - BELTSVILLE	24 - MD	HEADQUARTERS	GSA LEASED
CORPORATE BUILDING 2	CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
OCI OFFICE OF INTERNAL AFFAIRS	OCI	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
HARVEY W WILEY BUILDING	CFSAN	0370 - COLLEGE PARK	24 - MD	HEADQUARTERS	GSA OWNED
FDA LABORATORY BUILDING 2(MOD2)	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
B1-ANIMAL CARETAKERS	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
B2-RESEARCH FAC DOGS	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
B3-RESEARCH FAC LAMB	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
B4-RESEARCH FAC-SWIN	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
C1-ANIMAL CARETAKERS	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
8501G MUIRKIRK RD	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
C3-RESEARCH FAC COWS	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
C4-RESEARCH FAC/SHEE	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
C5-RESEARCH FAC-CATT	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
8501L MUIRKIRK RD	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
D2-FEED MIXING	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
E1-RESEARCH FAC-POUL	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
F1-QUARANTINE	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
H-AQUACULTURE	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
L-HAY STORAGE	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
M-ANIMAL LOAFING	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
8501T MUIRKIRK RD	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
N-PUMP EQUIPMENT	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
WASTE STORAGE AREA	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
PASTURE PADS	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
C6 RESEARCH FAC CATT	CVM	0900 - LAUREL	24 - MD	HEADQUARTERS	GSA OWNED
DISTRICT OFFICE- BALTIMORE	ORA	0050 - BALTIMORE	24 - MD	CENTRAL (PHILADELPHIA)	GSA LEASED

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
TWINBROOK BUILDING 12725	CDRH	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
FISHERS LANE 5630	CDER/OC	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
OCI METRO WASHINGTON FIELD OFFICE	OCI	0228 - CALVERTON	24 - MD	HEADQUARTERS	GSA LEASED
METRO PARK NORTH 4	CVM	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
METRO PARK NORTH 5	CVM	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
WHITE OAK ANIMAL FACILITY BUILDING 10	CDER/CDRH	1450 - SILVER SPRING	24 - MD	HEADQUARTERS	GSA OWNED
WHITE OAK LIFE SCIENCES BUILDING 64	CDER/CDRH	1450 - SILVER SPRING	24 - MD	HEADQUARTERS	GSA OWNED
NICHOLSON LANE RESEARCH CENTER(GSA LEASE)	CBER	0860 - KENSINGTON	24 - MD	HEADQUARTERS	GSA LEASED
AMMENDALE BUILDING	CDER/CFSAN	0100 - BELTSVILLE	24 - MD	HEADQUARTERS	GSA LEASED
MONTROSE METRO 2	ORA/CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
UNIVERSITY STATION	CFSAN	1330 - RIVERDALE	24 - MD	HEADQUARTERS	GSA LEASED
METRO PARK NORTH 6	CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
WHITE OAK CDER OFFICE BUILDING 21	CDER	1450 - SILVER SPRING	24 - MD	HEADQUARTERS	GSA OWNED
WHITE OAK CDER OFFICE BUILDING 22	CDER	1450 - SILVER SPRING	24 - MD	HEADQUARTERS	GSA OWNED
12345 PARKLAWN DRIVE	OC	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
RESIDENT POST- DUNDALK, MD - IMPORT	ORA	0050 - BALTIMORE	24 - MD	CENTRAL (PHILADELPHIA)	GSA LEASED
TWINBROOK BUILDINGS (1-5)	CDRH/CDER/ORA	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
PARKLAWN BUILDING	OC/ORA/CDER/CFSAN/NCTR	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
FDA WAREHOUSE/MAIL SCREENING FACILITY/DOCUMENT ROOMS	OC/CBER/CDER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
ROCKWALL BUILDING	CBER	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
PARK BUILDING	CDER/OC	1360 - ROCKVILLE	24 - MD	HEADQUARTERS	GSA LEASED
WINCHESTER ENGINEERING & ANALYTICAL CENTER - TOTAL ASSSETS	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC Engineering and Analytical Center	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC- Storage Warehouse 7	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC- Old Mouse House	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Storage Warehouse 1	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC- Fire Extinguisher Shed	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Hazmat Trailer 1	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Hazmat Trailer 2	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Hazmat Building	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Freezer 1	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
WEAC - Freezer 2	ORA	1503 - WINCHESTER	25 - MA	NORTHEAST (NEW YORK)	FDA OWNED
BORDER STATION - BOSTON, MA	ORA	0120 - BOSTON	25 - MA	NORTHEAST (NEW YORK)	GSA LEASED
DISTRICT OFFICE- NEW ENGLAND	ORA	1275 - STONEHAM	25 - MA	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- WORCHESTER, MA	ORA	1520 - WORCESTER	25 - MA	NORTHEAST (NEW YORK)	GSA LEASED
OCI BOSTON RESIDENT OFFICE	OCI	1000 - PEABODY	25 - MA	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- KALAMAZOO, MI	ORA	2520 - KALAMAZOO	26 - MI	CENTRAL (CHICAGO)	GSA OWNED
RESIDENT POST- DETROIT, MI	ORA	1260 - DETROIT	26 - MI	CENTRAL (CHICAGO)	GSA OWNED
RESIDENT POST- GRAND RAPIDS, MI	ORA	2010 - GRAND RAPIDS	26 - MI	CENTRAL (CHICAGO)	GSA LEASED
BORDER STATION - BLUEWATER BRIDGE, MI	ORA	4060 - PORT HURON	26 - MI	CENTRAL (CHICAGO)	GSA LEASED
DISTRICT OFFICE W/LAB- DETROIT	ORA	1260 - DETROIT	26 - MI	CENTRAL (CHICAGO)	GSA LEASED
DISTRICT OFFICE- MINNEAPOLIS	ORA	4760 - MINNEAPOLIS	27 - MN	CENTRAL (CHICAGO)	GSA OWNED
RESIDENT POST- INTERNATIONAL FALLS, MN	ORA	3480 - INTERNATIONAL FALLS	27 - MN	CENTRAL (CHICAGO)	GSA LEASED
COURTHOUSE MUNICIPAL PARKING RAMP	ORA	4760 - MINNEAPOLIS	27 - MN	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- JACKSON, MS	ORA	1220 - JACKSON	28 - MS	SOUTHEAST (ATLANTA)	GSA OWNED
JRA FACILITY NO 3 PARKING GARAGE	ORA	1220 - JACKSON	28 - MS	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- SPRINGFIELD, MO	ORA	7460 - SPRINGFIELD	29 - MO	SOUTHWEST (DALLAS)	GSA LEASED
DIVISION OF DRUG ANALYSIS	CDER	7080 - ST. LOUIS	29 - MO	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- ST LOUIS, MO	ORA	7080 - ST LOUIS	29 - MO	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- SWEETGRASS, MT	ORA	1125 - SWEETGRASS	30 - MT	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- HELENA MT	ORA	0590 - HELENA	30 - MT	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- OMAHA, NE	ORA	3620 - OMAHA	31 - NE	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- RENO, NV	ORA	0170 - RENO	32 - NV	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- LAS VEGAS, NV	ORA	0120 - LAS VEGAS	32 - NV	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- CONCORD, NH	ORA	0070 - CONCORD	33 - NH	NORTHEAST (NEW YORK)	GSA OWNED
OCI- NEW YORK FIELD OFFICE	OCI	1520 - JERSEY CITY	34 - NJ	HEADQUARTERS FIELD	FDA LEASED
RESIDENT POST- ELIZABETH, NJ	ORA	0860 - ELIZABETH	34 - NJ	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- NORTH BRUNSWICK, NJ	ORA	2140 - NORTH BRUNSWICK	34 - NJ	CENTRAL (PHILADELPHIA)	GSA LEASED
DISTRICT OFFICE- NEW JERSEY	ORA	2498 - PARSIPPANY	34 - NJ	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- VOORHEES, NJ	ORA	3465 - VOORHEES	34 - NJ	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- ALBUERQUE, NM	ORA	0030 - ALBUQUERQUE	35 - NM	SOUTHWEST (DALLAS)	GSA OWNED
FEDERAL PARKING GARAGE	ORA	0030 - ALBUQUERQUE	35 - NM	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- SANTA TERESA, NM	ORA	0735 - SANTA TERESA	35 - NM	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- SANTA TERESA, NM	ORA	0735 - SANTA TERESA	35 - NM	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- BINGHAMTON, NY	ORA	0540 - BINGHAMTON	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
PARKING	ORA	6010 - SYRACUSE	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
DIVISION OF PERSONEL- NEW YORK	ORA	4170 - MANHATTEN	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
PARKING	ORA	0750 - BUFFALO	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- ALEXANDRIA BAY, NY	ORA	0090 - ALEXANDRIA BAY	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- LONG ISLAND	ORA	1050 - CENTRAL ISLIP	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- MASSENA, NY	ORA	5275 - ROOSEVELTOWN	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
RESIDENT POST- CHAMPLAIN	ORA	1080 - CHAMPLAIN	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- CHAMPLAIN, NY	ORA	1080 - CHAMPLAIN	36 - NY	NORTHEAST (NEW YORK)	GSA OWNED
BORDER STATION - PEACE BRIDGE	ORA	0750 - BUFFALO	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- WHITE PLAINS, NY	ORA	6670 - WHITE PLAINS	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
BORDER STATION - LEWISTON BRIDGE	ORA	3220 - LEWISTON	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- SYRACUSE, NY	ORA	6010 - SYRACUSE	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
IMPORT OFFICE- BUFFALO	ORA	0750 - BUFFALO	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- ALBANY, NY	ORA	0050 - ALBANY	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
DISTRICT/REGION/REGIONAL LAB- NEW YORK	ORA	4170 - JAMAICA	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- ROCHESTER, NY	ORA	5230 - ROCHESTER	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- OGDENSBURG, NY	ORA	4420 - OGDENSBURG	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- NEW WINDSOR, NY	ORA	4130 - NEW WINDSOR	36 - NY	NORTHEAST (NEW YORK)	GSA LEASED
RESIDENT POST- RALEIGH, NC	ORA	3750 - RALEIGH	37 - NC	SOUTHEAST (ATLANTA)	GSA OWNED
TERRY SANFORD FEDERAL BUILDING, PARKING	ORA	3750 - RALEIGH	37 - NC	SOUTHEAST (ATLANTA)	GSA OWNED
RESIDENT POST- CHARLOTTE, NC	ORA	0870 - CHARLOTTE	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- GREENSBORO, NC	ORA	1940 - GREENSBORO	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- GREENVILLE, NC	ORA	1950 - GREENVILLE	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- ARDEN, NC	ORA	0131 - ARDEN	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
BORDER STATION - WILMINGTON, NC	ORA	5060 - WILMINGTON	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
MOORE SQUARE PARKING DECK	ORA	3750 - RALEIGH	37 - NC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- DUNSEITH, ND	ORA	3360 - WILLOW CITY	38 - ND	CENTRAL (CHICAGO)	DOMICILE
RESIDENT POST- FARGO, ND	ORA	1020 - FARGO	38 - ND	CENTRAL (CHICAGO)	GSA OWNED
RESIDENT POST- PEMBINA, ND	ORA	2500 - PEMBINA	38 - ND	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- BRUNSWICK, OH	ORA	1085 - BRUNSWICK	39 - OH	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- COLUMBUS, OH	ORA	1800 - COLUMBUS	39 - OH	CENTRAL (PHILADELPHIA)	GSA LEASED
DISTRICT OFFICE/FORENSIC CHEMISTRY - CINCINNATI	ORA	1610 - CINCINNATI	39 - OH	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- TOLEDO, OH	ORA	8120 - TOLEDO	39 - OH	CENTRAL (PHILADELPHIA)	GSA LEASED
OKC FEDERAL PARKING GARAGE	ORA	3550 - OKLAHOMA CITY	40 - OK	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- OKLAHOMA CITY, OK	ORA	3550 - OKLAHOMA CITY	40 - OK	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- TULSA, OK	ORA	4780 - TULSA	40 - OK	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- TULSA, OK	ORA	4780 - TULSA	40 - OK	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- BEAVERTON, OR	ORA	0180 - BEAVERTON	41 - OR	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- PORTLAND AIRPORT, OR	ORA	1650 - PORTLAND	41 - OR	PACIFIC (OAKLAND)	GSA LEASED
DISTRICT OFFICE/REGION W/LAB- PHILADELPHIA	ORA	6540 - PHILADELPHIA	42 - PA	CENTRAL (PHILADELPHIA)	GSA OWNED
RESIDENT POST- SCRANTON, PA	ORA	7460 - SCRANTON	42 - PA	CENTRAL (PHILADELPHIA)	GSA OWNED
RESIDENT POST- PITTSBURGH, PA	ORA	6600 - PITTSBURGH	42 - PA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- HARRISBURG, PA	ORA	3500 - HARRISBURG	42 - PA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- NORTH WALES, PA	ORA	6120 - NORTH WALES	42 - PA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- PROVIDENCE, RI	ORA	0057 - EAST PROVIDENCE	44 - RI	NORTHEAST (NEW YORK)	GSA LEASED
QUONSET HUT-BUILDING 336	N/A	0053 - DAVISVILLE	44 - RI	HEADQUARTERS	FDA OWNED
MJ PERRY JR PARKING GARAGE	ORA	0520 - COLUMBIA	45 - SC	SOUTHEAST (ATLANTA)	GSA OWNED
RESIDENT POST- COLUMBIA, SC	ORA	0520 - COLUMBIA	45 - SC	SOUTHEAST (ATLANTA)	GSA OWNED
RESIDENT POST- GREENVILLE, SC	ORA	1040 - GREENVILLE	45 - SC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- CHARLESTON, SC	ORA	0410 - CHARLESTON	45 - SC	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- SIOUX FALLS, SD	ORA	2450 - SIOUX FALLS	46 - SD	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- KNOXVILLE, TN	ORA	1300 - KNOXVILLE	47 - TN	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST-CHATTANOOGA, TN	ORA	0400 - CHATTANOOGA	47 - TN	SOUTHEAST (ATLANTA)	GSA LEASED
BORDER STATION - MEMPHIS, TN	ORA	1620 - MEMPHIS	47 - TN	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- MEMPHIS, TN	ORA	1620 - MEMPHIS	47 - TN	SOUTHEAST (ATLANTA)	GSA LEASED
DISTRICT OFFICE- NASHVILLE	ORA	1760 - NASHVILLE	47 - TN	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- AUSTIN, TX	ORA	0330 - AUSTIN	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- LAREDO LINCOLN JUAREZ BRIDGE II, TX	ORA	3899 - LAREDO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
BORDER ST - COLUMBIA BRIDGE	ORA	1470 - COLUMBUS	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- LOS INDIOS, TX	ORA	4111 - LOS INDIOS	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- PHARR, TX	ORA	5330 - PHARR	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- DEL RIO, TX	ORA	1820 - DEL RIO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- BROWNSVILLE, TX	ORA	0940 - BROWNSVILLE	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- LOS TOMATES, TX	ORA	0940 - BROWNSVILLE	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- FORT WORTH, TX	ORA	2450 - FORT WORTH	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- BOTA, TX	ORA	2190 - EL PASO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- EL PASO, TX	ORA	2190 - EL PASO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- EL PASO, TX	ORA	2190 - EL PASO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- YSLETTA, TX	ORA	2190 - EL PASO	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- HOUSTON, TX	ORA	3280 - HOUSTON	48 - TX	SOUTHWEST (DALLAS)	GSA OWNED
RESIDENT POST- SAN ANTONIO, TX	ORA	6090 - SAN ANTONIO	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
OCI AUSTIN RESIDENT OFFICE	OCI	0330 - AUSTIN	48 - TX	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- RIO GRANDE CITY, TX	ORA	5780 - RIO GRANDE CITY	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- EAGLE PASS, TX	ORA	2030 - EAGLE PASS	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- LAREDO WORLD TRADE BRIDGE, TX	ORA	3899 - LAREDO	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
DISTRICT/REGION/SW IMPORTS - DALLAS	ORA	1730 - DALLAS	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
BORDER STATION - DFW AIRPORT, TX	ORA	1730 - DALLAS	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- EL PASO, TX	ORA	2190 - EL PASO	48 - TX	SOUTHWEST (DALLAS)	GSA LEASED

FDA
Geographic Distribution of Facilities

Building Name	Organization	City	State	OP DIV Subdivision	Ownership
RESIDENT POST- SALT LAKE CITY, UT	ORA	1700 - SALT LAKE CITY	49 - UT	SOUTHWEST (DALLAS)	GSA LEASED
RESIDENT POST- ESSEX JUNCTION, VT	ORA	0200 - ESSEX JUNCTION	50 - VT	NORTHEAST (NEW YORK)	GSA OWNED
BORDER STATION - HIGHGATE SPRINGS, VT	ORA	0245 - HIGHGATE SPRINGS	50 - VT	NORTHEAST (NEW YORK)	GSA OWNED
RESIDENT POST- NORFOLK, VA-IMPORT	ORA	1760 - NORFOLK	51 - VA	CENTRAL (PHILADELPHIA)	FDA LEASED
PRIOR NOTICE CENTER	ORA	2034 - RESTON	51 - VA	HEADQUARTERS	GSA LEASED
RESIDENT POST- FALLS CHURCH, VA	ORA	0930 - FALLS CHURCH	51 - VA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- ROANOKE VA	ORA	2100 - ROANOKE	51 - VA	CENTRAL (PHILADELPHIA)	GSA LEASED
OCI ABINGDON	OCI	0010 - ABINGDON	51 - VA	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- RICHMOND, VA	ORA	2060 - RICHMOND	51 - VA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- HERNDON, VA	ORA	1220 - HERNDON	51 - VA	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- NORFOLK, VA	ORA	1760 - NORFOLK	51 - VA	CENTRAL (PHILADELPHIA)	GSA OWNED
RESIDENT POST- BAINBRIDGE ISLAND, WA	ORA	0111 - BAINBRIDGE ISLAND	53 - WA	PACIFIC (OAKLAND)	DOMICILE
RESIDENT POST- YAKIMA, WA	ORA	2590 - YAKIMA	53 - WA	PACIFIC (OAKLAND)	DOMICILE
DISTRICT OFFICE/REGIONAL LAB- SEATTLE	ORA	0170 - BOTHELL	53 - WA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- BLAINE, WA	ORA	0150 - BLAINE	53 - WA	PACIFIC (OAKLAND)	GSA OWNED
RESIDENT POST- OROVILLE, WA	ORA	1610 - OROVILLE	53 - WA	PACIFIC (OAKLAND)	GSA OWNED
PARK PLACE BUILDING (DAYCARE-JOINT USE)	ORA	1960 - SEATTLE	53 - WA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SEATTLE, WA	ORA	1960 - SEATTLE	53 - WA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- SPOKANE VALLEY, WA	ORA	2110 - SPOKANE VALLEY	53 - WA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- TACOMA, WA	ORA	2230 - TACOMA	53 - WA	PACIFIC (OAKLAND)	GSA LEASED
RESIDENT POST- CHARLESTON, WV	ORA	0480 - CHARLESTON	54 - WV	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- MORGANTOWN, WV	ORA	1840 - MORGANTOWN	54 - WV	CENTRAL (PHILADELPHIA)	GSA LEASED
RESIDENT POST- GREEN BAY, WI	ORA	2000 - GREEN BAY	55 - WI	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- WAUWATOSA, WI	ORA	5130 - WAUWATOSA	55 - WI	CENTRAL (CHICAGO)	GSA LEASED
RESIDENT POST- MADISON, WI	ORA	2780 - MADISON	55 - WI	CENTRAL (CHICAGO)	GSA LEASED
DISTRICT OFFICE W/LAB- SAN JUAN -TOTAL ASSETS	ORA	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - FDA Laboratory Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - New Administration Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Administration Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Conference Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Maintenance Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Generator Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Boat House Building	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
SAN JUAN - Guard Booth	NCTR	0930 - SAN JUAN	RQ - PR	SOUTHEAST (ATLANTA)	FDA OWNED
RESIDENT POST- MAYAGUEZ, PR	ORA	0650 - MAYAQUEZ	RQ - PR	SOUTHEAST (ATLANTA)	GSA LEASED
OCI SAN JUAN RESIDENT OFFICE	OCI	0930 - SAN JUAN	RQ - PR	HEADQUARTERS FIELD	GSA LEASED
RESIDENT POST- PONCE, PR	ORA	0760 - PONCE	RQ - PR	SOUTHEAST (ATLANTA)	GSA LEASED
RESIDENT POST- ST THOMAS, VI	ORA	0900 - ST. THOMAS	VQ - VI	SOUTHEAST (ATLANTA)	GSA OWNED

FOOD AND DRUG ADMINISTRATION
User Fee History
(Dollars in Thousands)

USER FEES: Appropriations

User Fees	FY 2003 Actual		FY 2004 Actual		FY 2005 Actual		FY 2006 Enacted		FY 2007 Estimate	
	FTE	$	FTE	$	FTE	$	FTE	$		
Definite Appropriations:										
PDUFA										
- Human Drugs	742	$125,103	972	$162,653	1,049	$185,555	1,081	$213,908	1,105	$223,752
- Biologics	269	$44,959	217	$40,170	243	$41,175	230	$44,933	239	$47,001
- Office of Regulartory Affairs	41	$5,629	41	$5,808	39	$6,138	41	$8,675	43	$9,074
- Other Activities	149	$15,745	122	$13,535	124	$14,020	133	$25,116	136	$26,272
- Other Rent and Rent Related Activities	0	$0	0	$3,770	0	$11,212	0	$0		$0
- GSA Rent		$8,719	0	$6,146	0	$11,334	0	$12,700		$14,501
Subtotal, PDUFA	**1,201**	**$200,155**	**1,352**	**$232,082**	**1,455**	**$269,434**	**1,485**	**$305,332**	**1,523**	**$320,600**
MDUFMA										
- Biologics	5	$2,157	21	$3,437	22	$5,260	30	$8,412	33	$9,127
- Medical Devices and Radiological Health	14	$10,661	100	$17,253	108	$15,492	124	$22,173	131	$24,058
- Office of Regulartory Affairs	4	$449	6	$676	8	$966	9	$1,194	10	$1,295
- Other Activities	10	$1,071	10	$1,142	15	$2,644	19	$4,535	20	$4,921
- Other Rent and Rent Related Activities	0	$100	0	$287	0	$562	0	$783		$1,055
- GSA Rent	0	$400	0	$1,080	0	$2,237	0	$3,203		$3,270
Subtotal, MDUFMA	**33**	**$14,838**	**137**	**$23,875**	**153**	**$27,161**	**182**	**$40,300**	**194**	**$43,726**
ADUFA										
- Animal Drugs and Feeds			3	$983	39	$7,538	76	$9,301	76	$9,537
- Other Activities			0	$0	3	$384	6	$646	6	$696
- GSA Rent			0	$100	0	$567	0	$1,371		$1,371
Subtotal, ADUFA			**3**	**$1,083**	**42**	**$8,489**	**82**	**$11,318**	**82**	**$11,604**
Indefininate Appropriations:										
MQSA										
- Devices and Radiological Health	36	$12,870	26	$4,039	26	$4,373	26	$5,337	26	$5,445
- Office of Regulartory Affairs			8	$8,463	8	$8,586	8	$11,624	8	$11,861
-Other Activities	2	$204	2	$214	2	$226	2	$212	2	$216
Subtotal, MQSA	**38**	**$13,074**	**36**	**$12,716**	**36**	**$13,185**	**36**	**$17,173**	**36**	**$17,522**
Export Certification	**13**	**$1,663**	**11**	**$1,806**	**8**	**$1,425**	**8**	**$1,639**	**11**	**$2,300**
Certification Fund	**32**	**$7,855**	**35**	**$6,128**	**35**	**$5,506**	**38**	**$6,001**	**39**	**$6,181**
Total, User Fees	**1,317**	**$237,585**	**1,574**	**$277,690**	**1,729**	**$325,200**	**1,831**	**$381,763**	**1,885**	**$401,933**

USER FEES: Obligations

	FY 2003 Actual		FY 2004 Actual		FY 2005 Actual	
	FTE	$	FTE	$	FTE	$
PDUFA:						
- Human Drugs	742	$125,103	972	$162,653	1,053	$185,888
- Biologics	269	$44,959	217	$40,170	228	$39,637
- Office of Regulartory Affairs	41	$5,629	41	$5,808	41	$7,343
- Other Rent and Rent Related Activities	149	$15,745	122	$13,535	0	$11,334
- Other Activities	0	$0	0	$3,770	101	$14,019
- GSA Rent		$8,719	0	$6,146	0	$11,212
Subtotal, PDUFA	**1,201**	**$200,155**	**1,352**	**$232,082**	**1,423**	**$269,434**
MDUFMA						
- Biologics	5	$2,157	21	$3,437	20	$5,232
- Medical Devices and Radiological Health	14	$10,661	100	$17,253	108	$15,481
- Office of Regulatory Affairs	4	$449	6	$676	8	$1,006
- Other Activities	10	$1,071	10	$1,142	0	$562
- Other Rent and Rent Related Activities	0	$100	0	$287	19	$2,654
- GSA Rent	0	$400	0	$1,080	0	$2,237
Subtotal, MDUFMA	**33**	**$14,838**	**137**	**$23,875**	**155**	**$27,171**
ADUFA						
- Animal Drugs and Feeds			3	$983	39	$7,538
- Other Activities			0	$0	3	$384
- GSA Rent			0	$100	0	$567
Subtotal, ADUFA			**3**	**$1,083**	**42**	**$8,489**
MQSA	38	$13,074	36	$12,716	36	$4,028
Export Certification	13	$1,663	11	$1,806	8	$1,425
Certification Fund	32	$7,855	35	$6,128	28	$5,506
Subtotal	83	$22,592	82	$20,650	72	$10,959
Total, FDA	**1,317**	**$237,585**	**1,574**	**$277,690**	**1,692**	**$316,053**

USER FEES: Collections

	FY 2003 Actual	FY 2004 Actual	FY 2005 Actual	FY 2006 Enacted	FY 2007 Estimate
	$	$	$	$	
PDUFA Collections	$348,489	$274,055	$307,959	$305,332	$320,600
MDUFMA Collections	$21,596	$27,169	$31,103	$40,300	$43,726
ADUFA Collections	$0	$4,866	$8,302	$11,318	$11,604
MQSA Collections	$12,295	$13,926	$13,922	$17,173	$17,522
Export Certification	$2,025	$1,806	$2,205	$1,639	$2,300
Certification Fund	$5,142	$5,180	$5,926	$6,001	$6,181
Total, User Fees	**$389,547**	**$327,002**	**$369,417**	**$381,763**	**$401,933**

FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services Charges and Assessments
Fiscal Year 2005

Assessments:

Quality of Worklife Initiative **$9,369**
The Quality of Work Life was created to help HHS employees deal with the multitude of changes impacting the worksite.

Safety Management Information System **$1,921**
TAP for a department-wide, computerized accident and injury reporting and analysis system required by the Department of Labor.

Safety, Health and Environmental Management **$11,711**
Agreement enables the Department to continue conducting program evaluations and environmental compliance assessments of occupational safety and health as required

Energy Program Review **$10,931**
Energy Efficiency and Water Conservation at Federal Facilities mandate a myriad of requirements from energy and water conservation in HHS facilities. HHS must ensure that all such requirements are met.

Health and Wellness Center **$668**
Funds from the Health and Wellness Center are used to provide a portion of the on-going operational costs of a healthy facility.

IT Access for Disable Persons **$31,855**
Federal agencies are required to ensure that individuals with disabilities have access to electronic and information technology systems and equipment that are comparable to the access enjoyed by people without disabilities.

Media Outreach **$5,625**
TAP provides funding to support Secretarial public affairs initiatives, including production and distribution of public services announcement and video news reports.

President's Council on Bioethics **$295,276**
TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology.

National Rural Development Partnership **$9,227**
TAP is managed by USDA's Rural Development Administration. Under the partnership, States develop State Rural Develop Councils which supports rural development through cooperation among Federal, State and Local governments

Federal Laboratory Consortium **$9,304**
TAP to fund FLC research and development. US Department of Commerce's National Institute of Standards and Technology (NIST) is the recipient of these funds on behalf of FLC.

Fees for Service:

PROGRAM SUPPORT CENTER/FOH/OS **$34,839,589**

Provides various services to the FDA. The following is a breakdown of costs.

Human Resources, Personnel and Payroll: 6,920,461

Administrative Operations Service: 22,795,893

Security	10,927,500
Building Operations	4,950,343
Transhare	970,044
Telecom	1,190,991
Library	363,000
Misc. – i.e. Product Distribution, Shipping & Handling, Shredding, Storage, Graphics, Conference Center, Strategic Systems, Property Disposal and mail	4,394,015

Financial Management Services: 255,356

Office of the Director (OD): 160,540

Employee related programs and Childcare.

Office of Secretary (OS): 3,452,341

Includes costs for Regional Health Administration, Audit Resolution, Contracts and Grants and Tracking Accounting in Government Grants. OS will include a portion of Commissioned Corp. Management costs in FY 04 and FY 05.

FOH: 1,130,000

FDA agency health units and services

NIH Management Fund **$13,215,000**

Agreement to support the Center for Biologics, Evaluation and Research activities on the NIH Campus. Includes Building Operations, Telecom, Utilities and various common services.

NIH Patents **$871,000**

Agreement with NIH for support developing patent applications for FDA.

JOINTLY FUNDED PROJECTS:

Enterprise Information Management **$7,120,000**
FDA's contribution to the HHS Enterprise Infrastructure Fund. The funds are used for Enterprise Information Tech programs/projects outlined in the Enterprise Info Tech Strategic Plan or which benefit the corporate enterprise, such as enterprise buys/licenses.

Unified Financial Management Systems (UFMS) **$4,782,176**
Interagency agreement with NIH to provide funding for UFMS.

Human Resource Center – Rockville $**14,031,164**

International Health Bilateral Agreement **$1,050,150**
Agreement to provide funding in support of the Bilateral Multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs

OPM Job Information Federal Assessment **$24,880**
OPM charges fees to Federal Agencies to cover costs associated with maintenance and enhancement to the USAJOBS website, outreach initiatives regarding public service through print ads and other materials.

Tri-Council Activities **$72,734**
AP to support government wide financial, information technology, procurement and other management activities.

Office of Pacific Health and Human Services **$14,467**
Agreement to support funding for health activities in support of the Office of Pacific Health and Human Services.

Motor Vehicle Information & Management **$7,000**
Agreement to support the MVIMS which generates reports on federal agency vehicle fleet expenditures.

NIH eRA Grants Management System **$176,118**
Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System

Financial Shared Services Study **$72,373**
Agreement to work on achieving projected milestones and offering recommendations to the senior leadership on the change management initiatives required to implement decisions.

DHHS Primary Health Care Policy Fellowship **$45,000**
Agreement with HRSA to support a DHHS Primary Health Care Policy Fellowship program and related staff support activities

Office of Public Health/Blood Safety **$495,850**
Agreement to provide funding for the advisory committee on Blood Safety.

Presidential Advisory Council on HIV/AIDS **$60,000**
Agreement to provide funding to the NIH Office of AIDS research

Core Support from National Academy of Science **$91,455**
Agreement for a group of standing bodies in a number of health areas that can be called upon to provide feedback on various issues or to conduct more deliberative seminars and studies on HHS programs

Federal Executive Board, Dallas **$19,382**
President's Management Council asked Federal agencies to fund the FEBs, and HHS agreed to support the Dallas-Fort Worth (DFW) FEB. This covers costs of the Executive Director position.

National Science Advisory Board for Biosecurity **$325,485**
Agreement with NIH to develop improved biosecurity measures for classes of legitimate biological research that could be misused to threaten public health or national security.

Interdepartmental Council on Native American Affairs **$11,600**
IAG with DHHS, Administration on Children and Families, for staff and administrative support for the Interdepartmental Council for Native American Affairs (ICNAA)**,** to conduct semi-annual Council meetings, Executive Committee meetings and assignments.

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2005 Actual, and FY 2006 and 2007 Estimates

Activity	FY 2005 Actual	FY 2006 Estimate	FY 2007 Estimate
DHHS ASSESSMENTS 1/	**426,334**	**439,124**	**452,298**
FEE FOR SERVICE	**42,518,964**	**43,082,232**	**43,936,069**
Program Support Center/FOH/OS	*27,632,264*	28,461,232	29,315,069
NIH Management Fund	*14,015,700*	13,750,000	13,750,000
NIH Patents	*871,000*	871,000	871,000
JOINTLY FUNDED PROJECTS	**31,843,038**	**31,857,078**	**31,311,856**
Enterprise Information Management	*7,120,000*	*7,120,000*	*7,120,000*
Unified Financial Management System	*8,388,096*	*7,557,563*	*6,973,126*
Human Resources Consoliation Costs	*14,015,700*	*14,822,200*	*14,822,200*
International Health - Bilateral Agreement	*1,050,150*	*1,050,150*	*1,050,150*
Other Jointly Funded Projects /2	*1,269,092*	*1,307,165*	*1,346,380*
Total	**74,788,336**	**74,939,310**	**75,247,925**

1/ FY 2006 and FY 2007 are estimates based on historical charges and assessments.
2/ Includes Jointly Funded Projects under $1,000,000.

Future Consolidations in the Department of Health and Human Services
Impacting on the Food and Drug Administration

Statement

In the FY 2006 Appropriation Conference Report 109-255, Congress directed the Department of Health and Human Services (DHHS) to include all future consolidations that impact the Food and Drug Administration (FDA) in the President's budget request submitted to Congress.

Response

The DHHS does not anticipate any consolidations that will impact on FDA in FY 2007.

Sources of Funding to FDA by Other Federal Agencies

Federal Agencies	FY 2006 Estimate	FY 2007 Estimate	Reason for Funds
Department of Health and Human Services			
National Institute of Environmental Health Sciences - NIH	$13,469,879	$13,766,216	Conduct toxicological assessments
National Institute of Environmental Health Sciences - NIH	$12,200	$12,468	Provide staff research
National Institutes of Health	$258,670	$264,361	Research for NIH Intramural AIDS Program
National Institutes of Health	$121,700	$124,377	Provide core Facility Biotechnology services
National Institutes of Health	$275,000	$281,050	Share expertise of selected NIDCR personnel
National Institutes of Health	$115,000	$117,530	Study genetic variants of HIV and other blood-borne viruses
National Institutes of Health	$175,000	$178,850	Develop a new HIV-1 EIA
National Institutes of Health	$30,092	$30,754	Provide miscellaneous services
National Institutes of Health	$200,000	$204,400	Assess the use of Ketamine in nonhuman primates
National Institutes of Health	$50,000	$51,100	Modification of ArrayTrack application to enable the importation of data files from CBES database
National Institutes of Health	$1,977,343	$2,020,845	Evaluation of genetic toxicity and behavioral effects of chrnic methylphenidate exposure
National Institutes of Health	$324,000	$331,128	Provide joint laboratories
National Institutes of Health	$1,200	$1,226	Provide Multimedia Services for Webcam
National Institutes of Health	$50,000	$51,100	Study the Image-Guided Interventional Therapeutics
National Institutes of Health	$43,434	$44,390	Study Computer-Aided Diagnostics
National Institutes of Health	$1,100	$1,124	Manage Presidential Task Force on Dietary Supplement
National Institutes of Health	$25,000	$25,550	Study Botanical Dietary Supplements in Raw Materials and Finished Products
National Institutes of Health	$274,000	$280,028	Assess the validities of Selected Analytical Protocols/Prototypes for Dietary Supplements
National Cancer Institute - NIH	$104,000	$106,288	Study Immunotherapy, Protection & Vaccines for Hepatitis C
National Cancer Institute - NIH	$13,000	$13,286	Provide miscellaneous services
National Cancer Institute - NIH	$46,482	$47,505	Provide assessment of the Computer Aided Diagnostics
National Cancer Institute - NIH	$1,622,000	$1,657,684	Provide medical and postdoctoral fellowship training to fellows
National Institute of Dental Research - NIH	$55,500	$56,721	Provide Core Facility Biotechnology services
National Institute of Allergy and Infectious Diseases - NIH	$668,600	$683,309	Conduct Biodefense Research Projects
National Institute of Allergy and Infectious Diseases - NIH	$100,000	$102,200	Produce pandemic influenza vaccine reagents
National Institute of Allergy and Infectious Diseases - NIH	$2,244,143	$2,293,514	Assess the safety of cell substrates and vaccine components
National Institute of Allergy and Infectious Diseases - NIH	$53,500	$54,677	Provide miscellaneous services
National Institute of Allergy and Infectious Diseases - NIH	$100,000	$102,200	Provide Computation Toxicology Services
National Institute of Allergy and Infectious Diseases - NIH	$1,300	$1,329	Provide miscellaneous services
Centers for Disease Control and Prevention	$236,500	$241,703	Develop a single Vaccine Adverse Events Reporting System
Centers for Disease Control and Prevention	$150,000	$153,300	Support Ranch Hand Committee
Centers for Disease Control and Prevention	$14,000	$14,308	Provide Support for Food Safety Task Force meetings
Centers for Disease Control and Prevention	$98,000	$100,156	Provide information on the relationship between the environment and health
Centers for Medicare and Medicaid Services	$2,895,000	$2,958,690	Support transfer of complexity categorization responsibilities under the Clinical Lab Improvement Amendments
Agency for Healthcare Research and Quality	$203,720	$208,202	Develop and maintain standards for medical devices
Indian Health Service	$44,945	$45,934	Provide support to Surgeon General's Office
Program Support Center	$130,400	$133,269	Implement and operate a customer call center
Office of Global Health Affairs	$247,415	$252,858	Participate in the Biotechnology Engagement Program Umbrella Agreement
Office of Global Health Affairs	$7,200	$7,358	Participate in the Biotechnology Engagement Program
Office of Global Health Affairs	$116,793	$119,362	Support of the President's emergency AIDS Relief Plan
Office of the Secretary	$1,264,160	$1,291,972	Provide research support to the National Vaccine Program
Office of the Secretary	$555,179	$567,393	Provide miscellaneous services
Office of the Assistant Secretary for Public Health and Emergency Preparedness	$600,000	$613,200	Develop critical medical countermeasures through the development of animal disease models
Office of the Assistant Secretary for Public Health and Emergency Preparedness	$7,149	$7,306	Provide employee assistance in the aftermath of Hurricane Katrina
DHHS total	**$28,982,604**	**$29,620,221**	
Environmental Protection Agency			
Environmental Protection Agency	$200,000	$204,400	Conduct testing of sporicidal chemicals using efficacy methods
Environmental Protection Agency	$193,000	$197,246	Coordinate the state activities of the Radiation Control Program
Environmental Protection Agency	$109,699	$112,112	Develop arsenic speciation methodology
EPA total	**$502,699**	**$513,758**	
Department of Defense			
Defense Medical Standardization Board	$1,200,000	$1,226,400	Conduct a program for testing the shelf-life of stored medical items
Defense Advance Research Projects Agency	$213,675	$218,376	Assist in the test bed development for deep bleeder acoustic coagulation program
Defense Advance Research Projects Agency	$280,000	$286,160	Develop a customized "Introduction to Product Development" course
Defense Advance Research Projects Agency	$4,600	$4,701	Joint funding of medical device sofware
Defense Advance Research Projects Agency	$23,925	$24,451	Determine the safety & efficiency of Baterical Ghost Mucosal
Air Force Office of Scientific Research	$81,535	$83,329	Provide Infrared Fiber Testing
Joint Medical Information Systems	$110,129	$112,552	Promote collaboration in IT Health
Navy	$10,000	$10,220	Support the Study of Molecular Pathogenesis of Enterpathogenic
US Army	$94,642	$96,724	Test and evaluate Magi Chips
Uniformed Services University of the Health Sciences	$193,000	$197,246	Provide an employee to work on the AIDS vaccine
DOD total	**$2,211,506**	**$2,260,159**	
Department of Homeland Security			
Department of Homeland Security	$1,681,520	$1,718,513	Test for microbiological and molecular identification of foodborne bioagents
Department of Homeland Security	$400,000	$408,800	Study the threat of imported food additives
Department of Homeland Security	$25,000	$25,550	Provide miscellaneous services
Federal Emergency Management Agency	$50,000	$51,100	Support the Radiological Emergency Preparedness Program
DHS total	**$2,156,520**	**$2,203,963**	
Nuclear Regulatory Commission	$110,000	$112,420	Provide miscellaneous services
National Oceanic and Atmospheric Administration	$75,000	$76,650	Support the Shellfish Safety Assistance Project
Department of Veterans Affairs	$34,034	$34,783	Provide mammography facility inspections
Department of Energy	$55,660	$56,885	Will provide installation and maintenance of the Security Network System
Department of Justice	$1,000,000	$1,022,000	Purchase investigative equipment
Department of Agriculture			
Department of Agriculture	$7,500	$7,665	Provide annual briefing with Executive Board of Directors
Department of Agriculture	$7,600	$7,767	Provide miscellaneous services
Department of Agriculture	$486,000	$496,692	Support the eLexnet Database
Ag Total	**$501,100**	**$512,124**	
Transportation Safety Administration	$100,000	$102,200	Assess prototype x-ray security systems for conformance
TOTAL	**$35,729,123**	**$33,515,471**	

Summary of Full Costs

(Dollars in Thousands)

Performance Program Area	FY 2005	FY 2006	FY 2007
Foods	$540	$548	$564
Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (11001)	$51	$51	$45
Percentage of the approximately 3,000 eligible state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards by October 1, 2007 and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards by October 1, 2007. (11010) (outcome)	$82	$80	$76
Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk. (11040) (output)	$9	$9	$9
Perform import food field exams on products with suspect histories. (11036) (output)	$89	$87	$87
Perform Filer Evaluations of import filers. (19015) (output)	$25	$24	$24
Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. (19016) (output)	$25	$24	$24
Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (output)	$171	$179	$186
Expand federal/ state/ local involvement in FDA's eLEXNET system by having laboratories submit data in the system; and, beginning in FY 2007, expand the capability of the system to provide automated notification of potential events. (19013) (outcome)	$2	$2	$2
Establish and maintain a quality system in the ORA Field laboratories which meets the requirements of ISSO 17025 (American Society for Crime Laboratory Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation.) (11041) (outcome)	$128	$136	$156
Human Drugs	$582	$605	$644
Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. (12001) (Output)	$283	$263	$275
Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. (12026) (Output)	$11	$12	$14

Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. (12003) (Outcome)	$64	$70	$75
Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available. (12048) (Output)	$18	$20	$21
Enhance the protection of the American public against the effects of terrorist agents by facilitating the development of and access to medical countermeasures, providing follow-up assessments on therapies, and engaging in emergency preparedness and response activities. (12045) (Output)	$11	$12	$14
Improve the Safe Use of Drugs in Patients and Consumers (12007) (Output)	$53	$75	$89
Increase the efficiency of the Adverse Event Reporting Process by reducing the average cost associated with turning a submitted Adverse Event Report into a verified record in the database. (efficiency goal)	$9	$9	$8
Increase risk-based compliance and enforcement activities to ensure drug product quality. (12020) (output)	$81	$87	$91
Biologics	$196	$224	$241
Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months; and review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (13001) (Output)	$52	$59	$64
Complete review and action on standard PDUFA efficacy supplements within 10 months; and review and act on priority PDUFA efficacy supplements within 6 months of receipt (13002) (Output)	$46	$52	$56
Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date. (13005) (Output)	$52	$55	$51
Increase manufacturing diversity and capacity for pandemic influenza vaccine production through interacting with vaccine researchers and developers and issuing guidance and other documents and through global vaccine response coordination to facilitate the development and expedite the evaluation of cell-based technologies and dose-sparing approaches, such as the use of adjuvants. (13030) (Output)	$0	$19	$36
Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) (Output)	$27	$30	$31
Animal Drugs and Feeds	$124	$126	$134

Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (14020) (output)	$42	$45	$49
Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) (output)	$66	$66	$70
Medical Devices and Radiological Health	$293	$330	$328
Percentage of Expedited PMAs reviewed and decided upon within 300 days; Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1 (15033) (Outcome)	$34	$38	$39
Percentage of 180 day PMA supplements reviewed and decided upon within 180 days./1 (15031) (Outcome)	$18	$20	$20
Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days./1 (15032) (Outcome)	$66	$73	$74
Percentage of an estimated 9,100 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (15007) (Outcome)	$30	$32	$32
Expand actively participating sites in MedSun Network. (15012) (Outcome)	$35	$40	$39
Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. (15025) (Output)	$12	$14	$14
Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005) (Output)	$65	$82	$78
National Center for Toxicological Research	$43	$44	$37
Use new technologies (toxicoinformatics, proteomics, metabolomics, and genomics) to study the risk associated with how an FDA-regulated compound or product interacts with the human body. (16014) (output)	$19	$19	$14
Develop computer-based models and infrastructure to predict the health risk of biologically active products. (16003) (output)	$6	$7	$12
Develop risk assessment methods and build biological dose-response models in support of Food Security. (16007) (output)	$9	$9	$7
Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. (16012) (output)	$8	$9	$4
Additional Program Management Performance Goals			
Increase the number of Commercial Activities that will be reviewed for competitive sourcing. (19003) (Efficiency)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		
FDA's implementation of HHS's Unified Financial Management System (19017) (Efficiency)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		

Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack. (19008) (Output)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		
Full Cost Total	$1,777	$1,876	$1,947

* Full cost data for the measures under each performance program area are shown as non-adds. The sum of full costs of performance measures may not equal the full cost of the performance program area, to the extent the program has elements for which there are no current measures. However, each program in FDA has performance goals that account for 90-95% of its full costs when you include the relevant "Field Activities" for each program.

GLOSSARY OF ACRONYMS

510(k)	Pre-market notification (Medical devices substantially equivalent to products already on the market)
513(g)	Written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device
AADA	Abbreviated Antibiotic Drug Application
AAFCO	American Association of Feed Control Officials
AAR	After Action Review
ABC	Activity Based Costing
ACE	Angiotensin-converting Enzyme
ADE	Adverse Drug Event
ADAA	Animal Drug Availability Act of 1996
ADR	Adverse Drug Report
ADIMS	Automated Drug Information Management System
ADUFA	Animal Drug User Fee Act
AER	Adverse Event Review
AERS	Adverse Events Reporting System
AFSS	Animal Feed Safety System
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
AMDUCA	Animal Medicinal Drug Use Clarification Act
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
ANPR	Advanced Notice of Proposed Rulemaking
ANSI	American National Standards Institute
APHIS	Animal Plant and Health Inspection Service (USDA)
AR	Anti-microbial Resistance
ARL	Arkansas Regional Laboratory
ASAM	Assistant Secretary for Grants and Acquisitions Management
AVMA	American Veterinary Medical Association
BAMSG	Bacteriology and Mycology Study Group
BCCP	Business Continuity and Contingency Plan
BIMO	Bioresearch Monitoring
BIMS	Biological Investigational New Drug Application Management System
BCCP	Business Continuity and Contingency Plan
BLA	Biologics License Application
BLT	Blood Logging and Tracking System
BPCA	Better Pharmaceuticals for Children Act
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
BSL	Biosafety Level
BT	Bioterrorism
CABS	Conformity Assessment Bodies
CAERS	CFSAN Adverse Event Reporting System
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)
CERTS	Center for Education and Research Therapeutics
CFO	Chief Financial Officer
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CGMPs	Current Good Manufacturing Practices
CHD	Coronary Heart Disease
CIP	Critical Infrastructure Protection
CJD	Creutzfeldt-Jakob disease
CLIA	Clinical Laboratory Improvement Amendments
CMC	Chemistry, Manufacturing, and Controls
CMS	Centers for Medicare and Medicaid
CMV	Cytomegalovirus
COMSTAS	Compliance Status Information System
COBOL	Common Business Oriented Language
COOP	Continuity of Operations
CPI	Consumer Price Index
CPI/U	Consumer Price Index/Urban
CRADA	Cooperative Research and Development Agreement
CRO	Contract Research Organization
CRS	Contamination Response System
CT	Counter Terrorism
CTS	Correspondence Tracking System
CVM	Center for Veterinary Medicine (FDA)
CWD	Chronic Wasting Disease
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOL	Department of Labor
DQRS	Drug Quality Reporting System
DRLS	Drug Registration and Listing System
DSaRM	Drug Safety and Risk Management
DSHEA	Dietary Supplement Health and Education Act
DTPA	Diaminopropanoltetraacetic acid
eCTD	Electronic Common Technical Document
EDR	Electronic Document Room
EDMS	Electronic Data Management System
EIP	Emerging Infection Program
EIR	Establishment Inspection Report
ELA	Establishment License Application
eLEXNET	Electronic Laboratory Exchange Network
EO	Emergency Operations
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
ERS	Economic Research Service
ETS	Environmental Tobacco Smoke
EU	European Union

FAA	Federal Aviation Administration
FACTS	Field Accomplishment and Compliance Tracking System
FAIR Act	Federal Activities Inventory Reform Act
FAO	Food and Agricultural Organization (United Nations)
FBI	Federal Bureau of Investigation
FAS	Foreign Agriculture Service (USDA)
FD	Food Defense
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act of 1997
FD&C Act	Federal Food, Drug and Cosmetic Act
FERN	Food Emergency Response Network
FES	Financial Enterprise Solutions
FHA	Federal Health Architecture
FIS	Field Information System
FLQ	Fluoroquinolone
FMD	Foot and Mouth Disease
FMFIA	Federal Manager's Financial Integrity Act
FORCG	Food Outbreak Response Coordination Group
FPL	Final Printed Label
FPLA	Fair Packaging and Labeling Act
FSI	Food Safety Initiative (National)
FSIS	Food Safety Inspection Service (USDA)
FSSS	Food Safety and Security Staff (CFSAN)
FTC	Federal Trade Commission
FTE	Full-time Equivalent
FURLS	FDA Unified Registration and Listing System
FY	Fiscal Year (October - September)
GAO	General Accounting Office
GAPs	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GeMCRIS	Genetic Modification Clinical Research Information System
GGPs	Good Guidance Practices
GLP	Good Laboratory Practices
GMO	Genetically Modified Organisms
GMPs	Good Manufacturing Practices
GphA	Generic Pharmaceutical Association
GPRA	Government Performance and Results Act of 1993
GRAS	Generally Recognized as Safe Food Ingredients
GSA	General Services Administration
GSFA	General Standards for Food Additives
GTIS	Gene Therapy Information System
HACCP	Hazard Analysis Critical Control Points
HCV	Hepatitis C Virus
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
HR	Human Resources
HSPD	Homeland Security Presidential Directive
HUD	Humanitarian Use Device

IAG	Interagency Agreement
ICAAC	Interscience Conference on Antimicrobial Agents and Chemotherapy
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IDSA	Infectious Disease Society of America
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
ISLI	International Life Sciences Institute
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
LRN	Laboratory Response Network
MALDI	Matrix Assisted Laser Desorption Ionization
MAB	Metastable Atom Bombardment
MATS	Management Assignment Tracking System
MBM	Meat and Bone Meal
MDAE	Medical Device Adverse Events
MDAER	Medical Device Adverse Event Reports
MDR	Medical Device Reporting System
MDUFMA	Medical Device User Fee and Modernization Act
MedSun	Medical Product Surveillance Network
MEO	Most Efficient Organization
MERS-TM	Medical Event Reporting System for Transfusion Medicine
MFA	Medicated Feed Application
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
MUMS	Minor Use/Minor Species
NADA	New Animal Drug Application
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group
NAHMS	National Animal Health Monitoring System
NARMS	National Antimicrobial Resistance Monitoring System
NAS	National Academy of Sciences
NASS	National Agricultural Statistics Survey

NAT	Nucleic Acid Test
NCCLS	National Committee on Clinical Laboratory Standards
NCFST	National Center for Food Safety and Technology (Moffett Center)
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
NIBSC	National Institute for Biological Standards and Control
NIDA	National Institute on Drug Abuse
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act
NME	New Molecular Entity
NOA	Notice of Availability
NOH	Notice of Hearing
NPR	National Partnership for Reinventing Government
NPRM	Notice of Proposed Rulemaking
NRC	National Research Council
NSCLC	Non-Small Cell Lung Cancer
NSE	Not Substantially Equivalent
NTP	National Toxicology Program
nvCJD	new variant Creutzfeldt-Jakob disease
NVPO	National Vaccine Program Office
OAI	Official Action Indicated
OARSA	Office of Applied Research and Safety Assessment (CFSAN)
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review (CBER)
OC	Office of Compliance (CFSAN)
OCD	Obsessive Compulsive Disorder
OCTGT	Office of Cellular, Tissues and Gene Therapies (CBER)
OFAS	Office of Food Additive Safety (CFSAN)
OGD	Office of Generic Drugs (CDER)
OM	Office of Management (FDA)
ONPLDS	Office of Nutritional Products, Labeling, and Dietary Supplements (CFSAN)
OPDFB	Office of Plant and Dairy Foods and Beverages (CFSAN)
OPDiv	Operating Division
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs (FDA)
ORISE	Oak Ridge Institute for Science and Education
OS	Office of Seafood (CFSAN)
OSAS	Office of Scientific Analysis and Support (CFSAN)
OSCI	Office of Science (CFSAN)
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)

PART	Program Assessment Rating Tool (PART)
PAS	Public Affairs Specialist (FDA)
PAT	Process Analytical Technology
PDPs	Product Development Protocols
PDUFA	Prescription Drug User Fee Act of 1992
PERV	Porcine endogenous retrovirus
PIFSI	Produce and Food Safety Initiative
PISI	Protocol Investigator Site Inspection
PLA	Product License Application
PMA	Premarket Approval (Application to market medical device that requires Premarket approval) or President's Management Agenda *(depending upon context)*
PMN	Premarket Notification
PODS	Project-Oriented Data System
PPP	Pregnancy Prevention Program
PQRI	Product Quality Research Initiative
QSAR	Quantitative Structure Activity Relationship
QSIT	Quality System Inspection Technique
QSR	Quality System Regulation
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
SAB	Science Advisory Board
SAMHSA	Substance Abuse and Mental Health Services Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SCC	Secretary's Command Center
SE	Salmonella Enteriditis
S.M.A.R.T.	System to Manage Accutane Related Teratogenicity
SN/AEMS	Special Nutritional Adverse Events Monitoring System
SSO	Shared Services Organization
STARS	Submission Tracking and Review System
StmDT104	Salmonella Tphimurium DT 104
TB	Tuberculosis
Tof	Time of flight
TRIMS	Tissue Residue Information System
TSE	Transmissible Spongiform Encephalopathy (includes BSE and CJD)
UFMS	Unified Financial Management System
UK	United Kingdom
UMCP	University of Maryland-College Park
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USC	United States Code
USDA	United States Department of Agriculture

VAERS	Vaccine Adverse Event Reporting System
VAI	Voluntary Action Indicated
vCJD	variant Creutzfeldt-Jakob disease
VEE	Venezuelean Equine Encephalitis
VFD	Veterinary Feed Directive
VICH	Veterinary International Cooperation on Harmonization
VFD	Veterinary Feed Directive
VICH	Veterinary International Conference on Harmonization
WHO	United Nations World Health Organization
WNV	West Nile Virus
WR	Written Request
WTO	World Trade Organization