

Food and Drug Administration Operating Plan for FY 2019 Dollars in Millions			
Activities	FY 2018	FY 2019	
	Final	Final	FY 19 Final+/- FY 18 Final
Foods Program 1/	1,052.486	1,070.851	18.365
Foods, BA	1,041.615	1,059.980	18.365
Foods, User Fees	10.871	10.871	.000
Center.....	317.438	328.294	10.856
BA.....	316.606	327.462	10.856
Food Safety [non-add].....	316.606	327.462	10.856
Food Safety.....	316.106	327.462	11.356
Other Budget Authority.....	297.700	292.667	-5.033
Cosmetics [non-add].....	8.106	8.106	.000
Office of Cosmetics and Colors [non-add].....	7.200	7.200	.000
National Integrated Food Safety System [non-add] 2/.....	6.000	8.000	2.000
Biotech Education [non-add].....	1.500	3.000	1.500
Botanical Drugs and Dietary Supplements Interaction [non-add].....	.500	.500	.000
Seafood Decomposition Study [non-add].....	2.800	.000	-2.800
Strengthening Food Outbreaks [non-add].....	.000	5.000	5.000
Standard of Identity and Product Labeling [non-add].....	.550	2.550	2.000
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add] 3/.....	1.100	1.100	.000
Food Import Safety [non-add].....	6.539	6.539	.000
User Fees.....	.832	.832	.000
Food and Feed Recall User Fee.....	.243	.243	.000
Voluntary Qualified Importer Program.....	.243	.243	.000
Third Party Auditor Program.....	.346	.346	.000
Field.....	735.048	742.557	7.509
BA.....	725.009	732.518	7.509
Food Safety [non-add].....	725.009	732.518	7.509
Other Budget Authority.....	673.033	608.730	-64.303
Cosmetics [non-add].....	3.414	3.414	.000
National Integrated Food Safety System [non-add].....	48.562	48.562	.000
National Integrated Food Safety System (Farm Data) [non-add].....	5.000	5.000	.000
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add] 3/.....	12.864	13.900	1.036
Food Import Safety [non-add].....	57.912	57.912	.000
User Fees.....	10.039	10.039	.000
Food and Feed Recall User Fee.....	1.000	1.000	.000
Food Reinspection User Fee.....	4.575	4.575	.000
Voluntary Qualified Importer Program.....	4.320	4.320	.000
Third Party Auditor Program.....	.144	.144	.000
Human Drugs	1,618.814	1,880.935	262.121
Human Drugs, BA	495.603	662.907	167.304
Human Drugs, User Fees	1,123.211	1,218.028	94.817
Center.....	1,419.991	1,675.475	255.484
BA.....	359.396	524.738	165.342
Medical Product Safety [non-add].....	359.396	524.738	165.342
Other Budget Authority.....	326.376	318.207	-8.169
Antimicrobial Resistance (includes CARB) [non-add].....	10.277	10.277	.000
Over-the-Counter Drugs (includes sunscreen) [non-add].....	12.263	12.263	.000
Precision Medicine Initiative [non-add].....	.700	.700	.000
Botanical Drugs and Dietary Supplements Interaction [non-add].....	.500	.500	.000
Critical Path Initiatives [non-add].....	2.200	2.200	.000
Compounding Bulk Drug Substances [non-add].....	2.779	2.779	.000
Medical Counter-measures [non-add].....	6.020	6.020	.000
Counterfeit Drugs [non-add].....	.360	.360	.000
Combatting the Opioids Epidemic [non-add] 4/.....	10.511	57.511	47.000
Data Warehouse [non-add].....	.000	20.000	20.000
Promote Domestic Manufacturing [non-add].....	.000	24.800	24.800
New Domestic Drug Industry [non-add].....	.000	10.000	10.000
New Medical Data Enterprise [non-add].....	.000	10.700	10.700
New Platform for Drug Development [non-add].....	.000	38.300	38.300
Modernizing Generic Drug Development and Review [non-add].....	.000	25.100	25.100
Investment and Innovation for Rare Diseases [non-add].....	.000	10.000	10.000
User Fees.....	1,060.595	1,150.737	90.142
Prescription Drug User Fee Act.....	654.835	731.961	77.126
Generic Drug User Fee.....	369.065	382.737	13.672
Biosimilars User Fee Act.....	36.116	35.411	-.705
Outsourcing Facility 7/.....	.579	.628	.049
Field.....	198.823	205.460	6.637
BA.....	136.207	138.169	1.962
Medical Product Safety [non-add].....	136.207	138.169	1.962
Counterfeit Drugs [non-add].....	4.185	4.185	.000
New Domestic Drug Industry [non-add].....	.000	2.000	2.000
User Fees.....	62.616	67.291	4.675
Prescription Drug User Fee Act.....	8.038	9.003	.965
Generic Drug User Fee.....	53.104	56.808	3.704
Biosimilars User Fee Act.....	1.120	1.100	-.020
Outsourcing Facility 7/.....	.354	.380	.026

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Biologics	359.614	402.144	42.530
Biologics, BA	215.443	240.138	24.695
Biologics, User Fees	144.171	162.006	17.835
Center.....	316.625	358.355	41.730
BA.....	174.052	198.132	24.080
Medical Product Safety [non-add].....	174.052	198.132	24.080
Other Budget Authority.....	166.235	167.315	1.080
FDASIA Implementation [non-add].....	1.930	1.930	.000
Antimicrobial Resistance (includes CARB) [non-add].....	3.492	3.492	.000
Medical Counter-measures [non-add].....	2.395	2.395	.000
Promote Domestic Manufacturing [non-add].....	.000	10.000	10.000
New Medical Data Enterprise [non-add].....	.000	13.000	13.000
User Fees.....	142.573	160.223	16.650
Prescription Drug User Fee Act.....	127.961	144.529	16.568
Medical Devices User Fee Act.....	13.405	14.444	1.039
Generic Drug User Fee.....	1.032	1.072	.040
Biosimilars User Fee Act.....	.175	.178	.003
Field.....	42.989	43.789	.800
BA.....	41.391	42.006	.615
Medical Product Safety [non-add].....	41.391	42.006	.615
Other Budget Authority.....	40.286	40.901	.615
FDASIA Implementation [non-add].....	1.105	1.105	.000
User Fees.....	1.598	1.783	.185
Prescription Drug User Fee Act.....	1.397	1.566	.169
Medical Devices User Fee Act.....	.201	.217	.016
Animal Drugs and Feeds	198.171	224.530	26.359
Animal Drugs and Feeds, BA	172.552	178.934	6.382
Animal Drugs and Feeds, User Fees	25.619	45.596	19.977
Center	132.175	157.442	25.267
BA.....	107.905	113.419	5.514
Food Safety [non-add].....	64.049	64.549	.500
National Integrated Food Safety System [non-add].....	2.500	2.500	.000
National Antimicrobial Resistance Monitoring System [non-add].....	.000	.500	.500
Medical Product Safety [non-add].....	43.856	47.856	4.000
Supporting Animal Drug and Medical Device Review [non-add].....	13.400	13.400	.000
New Medical Data Enterprise [non-add].....	.000	4.000	4.000
Antimicrobial Resistance (includes CARB) [non-add] 5/.....	20.296	20.296	.000
National Antimicrobial Resistance Monitoring System.....	10.800	10.800	.000
User Fees.....	24.270	44.023	19.753
Animal Drugs User Fee Act.....	15.890	27.267	11.377
Animal Generic Drug User Fee Act.....	8.268	16.644	8.376
Third Party Auditor Program.....	.112	.112	.000
Field.....	65.996	67.088	1.092
BA.....	64.647	65.515	.868
Food Safety [non-add].....	61.756	61.756	.000
Food Safety Import [non-add].....	3.475	3.475	.000
Medical Product Safety [non-add].....	2.891	2.891	.000
Import Safety [non-add].....	3.075	3.075	.000
National Integrated Food Safety System [non-add].....	4.200	4.200	.000
User Fees.....	1.349	1.573	.224
Animal Drugs User Fee Act.....	.307	.431	.124
Animal Generic Drug User Fee Act.....	.235	.335	.100
Food Reinspection User Fee.....	.807	.807	.000
Devices and Radiological Health	507.466	576.609	69.143
Devices, BA /	330.064	386.743	56.679
Devices, User Fees	177.402	189.866	12.464
Center.....	407.752	475.369	67.617
BA.....	246.319	301.738	55.419
Medical Product Safety [non-add].....	246.319	300.319	54.000
Antimicrobial Resistance (includes CARB) [non-add].....	3.768	3.768	.000
Precision Medicine Initiative [non-add].....	3.800	3.800	.000
Supporting Animal Drug and Medical Device Review [non-add].....	.711	.711	.000
Pediatric Device Review [non-add].....	6.000	6.000	.000
Medical Counter-measures [non-add].....	4.001	4.001	.000
MedTech Manufacturing [non-add].....	.000	6.000	6.000
New Medical Data Enterprise [non-add].....	.000	23.000	23.000
Growth and Transformation of Digital Health [non-add].....	.000	25.000	25.000
User Fees.....	161.433	173.631	12.198
Prescription Drug User Fee Act.....	1.237	1.401	.164
Medical Devices User Fee Act.....	153.819	165.795	11.976
Mammography Quality Standards Act.....	6.377	6.435	.058
Field.....	99.714	101.240	1.526
BA.....	83.745	85.005	1.260
Medical Product Safety [non-add].....	83.745	83.745	.000
FDASIA Implementation [non-add].....	1.965	1.965	.000
Medical Device Postmarket Safety/Shipments Delays [non-add].....	1.300	1.300	.000
User Fees.....	15.969	16.235	.266
Medical Devices User Fee Act.....	2.077	2.240	.163
Mammography Quality Standards Act.....	13.892	13.995	.103

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Activities	FY 2018	FY 2019	
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National Center for Toxicological Research.....	63.331	66.712	3.381
BA.....	63.331	66.712	3.381
Food Safety [non-add].....	10.233	10.233	.000
Other Budget Authority.....	10.053	10.053	.000
Cosmetics [non-add].....	.180	.180	.000
Medical Product Safety [non-add].....	53.098	55.298	2.200
Antimicrobial Resistance [includes CARB] [non-add].....	1.805	1.805	.000
Promote Domestic Manufacturing [non-add].....	.000	2.200	2.200
Center for Tobacco Products	625.646	666.832	41.186
Tobacco, BA.....	.000	.000	.000
Tobacco, User Fees.....	625.646	666.832	41.186
Center.....	611.096	652.065	40.969
BA.....	.000	.000	.000
User Fees.....	611.096	652.065	40.969
Family Smoking Prevention and Tobacco Control Act.....	611.096	652.065	40.969
Field.....	14.550	14.767	.217
BA.....	.000	.000	.000
User Fees.....	14.550	14.767	.217
Family Smoking Prevention and Tobacco Control Act.....	14.550	14.767	.217
Other Activities	335.847	317.767	-18.080
BA.....	194.775	186.569	-8.206
Food Safety [non-add].....	73.400	76.200	2.800
Food Import Safety [non-add].....	.000	2.800	2.800
Medical Product Safety [non-add].....	103.875	110.375	6.500
Promote Domestic Manufacturing [non-add].....	.000	1.500	1.500
Foreign High-Risk Inspections [non-add].....	7.500	7.500	.000
Medical Counter-measures [non-add].....	10.312	10.312	.000
Counterfeit Drugs [non-add].....	.275	.275	.000
OIG Transfer [non-add].....	.000	.000	.000
Oncology Center of Excellence [non-add] 6/.....	15.000	20.000	5.000
User Fees.....	141.072	131.198	-9.874
Prescription Drug User Fee Act.....	56.236	56.585	.349
Medical Devices User Fee Act.....	10.373	8.483	-1.890
Generic Drug User Fee.....	44.859	35.309	-9.550
Biosimilars User Fee Act.....	1.659	.637	-1.022
Animal Drugs User Fee Act.....	.654	1.004	.350
Animal Generic Drug User Fee Act.....	.267	.785	.518
Family Smoking Prevention and Tobacco Control Act.....	25.508	27.012	1.504
Mammography Quality Standards Act.....	.253	.092	-.161
Food and Feed Recall User Fee.....	.075	.075	.000
Food Reinspection User Fee.....	.480	.480	.000
Voluntary Qualified Importer Program.....	.277	.277	.000
Third Party Auditor Program.....	.039	.039	.000
Outsourcing Facility 7/.....	.392	.420	.028
White Oak Consolidation	50.559	50.587	.028
BA.....	43.044	43.044	.000
User Fees.....	7.515	7.543	.028
Prescription Drug User Fee Act.....	3.597	3.810	.213
Family Smoking Prevention and Tobacco Control Act.....	3.918	3.733	-.185
Other Rent and Rent-Related.....	121.919	123.735	1.816
BA.....	71.943	71.943	.000
Food Safety [non-add].....	36.300	36.300	.000
Medical Product Safety [non-add].....	35.643	35.643	.000
Precision Medicine Initiative [non-add].....	.145	.145	.000
Medical Counter-measures [non-add].....	.936	.936	.000
User Fees.....	49.976	51.792	1.816
Prescription Drug User Fee Act.....	24.672	26.127	1.455
Medical Devices User Fee Act.....	5.187	5.239	.052
Generic Drug User Fee.....	12.946	13.075	.129
Biosimilars User Fee Act.....	.805	1.070	.265
Animal Drugs User Fee Act.....	.720	.790	.070
Animal Generic Drug User Fee Act.....	.273	.264	-.009
Family Smoking Prevention and Tobacco Control Act.....	4.898	4.752	-.146
Food and Feed Recall User Fee.....	.043	.043	.000
Food Reinspection User Fee.....	.204	.204	.000
Voluntary Qualified Importer Program.....	.170	.170	.000
Third Party Auditor Program.....	.024	.024	.000
Outsourcing Facility 7/.....	.034	.034	.000
GSA Rent	238.487	238.665	.178
BA.....	170.208	170.208	.000
Food Safety [non-add].....	79.477	79.477	.000
Medical Product Safety [non-add].....	90.731	90.731	.000
Other Budget Authority.....	.000	.000	.000
Precision Medicine Initiative [non-add].....	.247	.247	.000
Medical Counter-measures [non-add].....	.888	.888	.000
User Fees.....	68.279	68.457	.178
Prescription Drug User Fee Act.....	33.373	35.341	1.968
Medical Devices User Fee Act.....	8.229	8.312	.083
Generic Drug User Fee.....	12.594	12.720	.126
Biosimilars User Fee Act.....	.339	.451	.112
Animal Drug User Fee Act.....	.522	.839	.317
Animal Generic Drug User Fee Act.....	.376	.307	-.069
Family Smoking Prevention and Tobacco Control Act.....	12.030	9.671	-2.359
Food and Feed Recall User Fee.....	.073	.073	.000
Food Reinspection User Fee.....	.348	.348	.000
Voluntary Qualified Importer Program.....	.290	.290	.000
Third Party Auditor Program.....	.047	.047	.000
Outsourcing Facility 7/.....	.058	.058	.000

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Activities	FY 2018	FY 2019	
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Other Indefinite User Fees.....	22,507	22,444	-.063
Color Certification.....	10,125	10,062	-.063
Export Certification.....	4,696	4,696	.000
Priority Review Vouchers Pediatric Disease.....	7,686	7,686	.000
Buildings & Facilities.....	11,788	11,788	.000
21st Century Cures.....	60,000	70,000	10,000
Continuous manufacturing initiative.....	10,000	10,000	.000
Opioids - International Mail Facilities.....	94,000	.000	-94,000
Totals	.000	.000	.000
Discretionary Budget Authority.....	2,964,366	3,148,966	184,600
Food Safety (BA only) [non-add].....	1,366,830	1,377,330	10,500
Cosmetics [non-add].....	11,700	11,700	.000
National Integrated Food Safety System [non-add] 2/.....	61,262	63,262	2,000
Food Import Safety [non-add] 8/.....	67,926	70,726	2,800
Strengthening Food Outbreaks [non-add].....	.000	5,000	5,000
Standard of Identity and Product Labeling [non-add].....	.550	2,550	2,000
Biotech Education [non-add].....	1,500	3,000	1,500
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add].....	13,964	15,000	1,036
Medical Product Safety (BA only) [non-add] 9/.....	1,525,204	1,698,804	173,600
High Risk Inspections [non-add].....	7,500	7,500	.000
Antimicrobial Resistance (includes CARB) [non-add].....	39,638	40,138	500
National Antimicrobial Resistance Monitoring System [non-add] 10/.....	10,800	11,300	500
Precision Medicine Initiative [non-add].....	4,892	4,892	.000
FDASIA Implementation [non-add].....	5,000	5,000	.000
Over-the-Counter Drugs (includes sunscreen) [non-add].....	12,263	12,263	.000
Biotech Education [non-add].....	1,500	3,000	1,500
Supporting Animal Drug and Medical Device Review [non-add].....	14,111	14,111	.000
Pediatric Device Review [non-add].....	6,000	6,000	.000
Medical Device Postmarket Safety/Shipments Delays [non-add].....	1,300	1,300	.000
Botanical Drugs and Dietary Supplements Interaction.....	1,000	1,000	.000
Seafood Decomposition Study [non-add] 1/.....	2,800	.000	-2,800
Critical Path Initiatives [non-add].....	2,200	2,200	.000
Oncology Center of Excellence [non-add] 6/.....	15,000	20,000	5,000
Compounding Bulk Drug Substances [non-add].....	2,779	2,779	.000
Counterfeit Drugs [non-add].....	4,820	4,820	.000
Buildings & Facilities.....	11,788	11,788	.000
Medical Counter-measures.....	24,552	24,552	.000
Combatting the Opioids Epidemic [non-add] 11/.....	10,511	57,511	47,000
Data Warehouse [non-add].....	.000	20,000	20,000
Promote Domestic Manufacturing [non-add].....	.000	38,500	38,500
New Domestic Drug Industry [non-add].....	.000	12,000	12,000
MedTech Manufacturing [non-add].....	.000	6,000	6,000
New Medical Data Enterprise [non-add].....	.000	50,700	50,700
Growth and Transformation of Digital Health [non-add].....	.000	25,000	25,000
New Platform for Drug Development [non-add] 12/.....	.000	38,300	38,300
Modernizing Generic Drug Development and Review [non-add].....	.000	25,100	25,100
Investment and Innovation for Rare Diseases [non-add].....	.000	10,000	10,000
21st Century Cures.....	60,000	70,000	10,000
Opioids - International Mail Facilities.....	94,000	.000	-94,000
User Fees.....	2,396,269	2,574,633	178,364
Total Program Level.....	5,360,635	5,723,599	362,964
Total, Program Level with Reprogrammings.....	5,360,635	5,723,599	362,964

1/The Foods total assumes the \$2.8M in proposed savings reflected in the conference report for Seafood Decomposition. The Operating Plan reflects that reduction, including through a reprogramming. The reprogrammed amount is below the statutory notification threshold.

2/Reflects increase of \$2 million for FSMA cooperative grants.

3/The bill states that for the Foods program no less than \$15,000,000 shall be used for inspections of foreign seafood manufacturers and field examination of import seafood.

4/The Drugs total includes an increase of \$47 million in funding to combat the opioid epidemic for regulatory science, enforcement and innovation activities. Included in the total of \$47 million for opioids, \$20 million set aside to create a large-scale data warehouse to perform data analytics.

5/The Center for Veterinary Medicine Antimicrobial Resistance was realigned to Medical Product Safety in the FY 2016 Congressional Justification.

6/The bill includes an additional \$5 million in funding for the Oncology Center for Excellence for a total of \$20 million.

7/FY 2019 Enacted reflects the amount specified in the August 2018 FR Notice for Outsourcing Facility Fees.

8/Total reflects an increase of \$2.8 million in Other Activities.

9/The FY 2018 total includes one-time, no-year funding of \$94 million for opioids international mail facilities activities. The FY 2019 total includes the authorized increase for CURES of \$10 million.

10/The report provides an increase of \$500,000 to conduct pilot studies to assess types and levels of antibiotic resistance in zoonotic bacteria on food products of species not currently tested

11/Reflects only funding associated with opioids activities within the Center for Drug Evaluation and Research.

12/The operating plan displays \$5 million of the total increase within the Oncology Center for Excellence as specified by the conference report.

**The conference appropriates user fees for the Over-the-Counter Monograph User Fee contingent upon the enactment of the Over-the-Counter Monograph User Fee Act of 2019.