

Food and Drug Administration Operating Plan for FY 2020 <i>Dollars in Millions</i>			
Activities	FY 2019	FY 2020	
	Final	Final	FY 20 Final +/- FY 19 Final
Foods Program 1/	1,070.851	1,099.970	29.119
Foods, BA	1,059.980	1,088.881	28.901
Foods, User Fees	10.871	11.089	.218
Center.....	328.294	342.315	14.021
BA 2/.....	327.462	341.466	14.004
Food Safety [non-add].....	327.462	341.466	14.004
Other Budget Authority 2/.....	292.667	299.117	6.450
National Integrated Food Safety System [non-add].....	8.000	4.280	-3.720
Cannabidiol (CBD) Activities [non-add].....	.000	1.000	1.000
Office of Dietary Supplement Programs [non-add].....	6.600	9.600	3.000
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	5.000	6.274	1.274
Standard of Identity and Product Labeling [non-add].....	2.550	3.550	1.000
Imported Seafood Safety Pilot (Machine Learning) [non-add].....	.000	5.000	5.000
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add] 3/.....	1.100	1.100	.000
User Fees.....	.832	.849	.017
Food and Feed Recall User Fee.....	.243	.248	.005
Voluntary Qualified Importer Program.....	.243	.248	.005
Third Party Auditor Program.....	.346	.353	.007
Field.....	742.557	757.655	15.098
BA 2/.....	732.518	747.415	14.897
Food Safety [non-add].....	732.518	747.415	14.897
Other Budget Authority 2/.....	608.730	609.041	.311
National Integrated Food Safety System (Farm Data) [non-add].....	48.562	55.747	7.185
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	.000	4.601	4.601
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add].....	13.900	13.900	.000
Food Import Safety [non-add].....	57.912	60.712	2.800
User Fees.....	10.039	10.240	.201
Food and Feed Recall User Fee.....	1.000	1.020	.020
Food Reinspection User Fee.....	4.575	4.667	.092
Voluntary Qualified Importer Program.....	4.320	4.406	.086
Third Party Auditor Program.....	.144	.147	.003
Human Drugs	1,880.935	1,973.122	92.187
Human Drugs, BA	662.907	683.195	20.288
Human Drugs, User Fees	1,218.234	1,289.927	71.693
Center.....	1,675.475	1,734.133	58.658
BA.....	524.738	507.726	-17.012
Medical Product Safety [non-add].....	524.738	507.726	-17.012
Other Budget Authority.....	318.207	259.845	-58.362
Compounding (including Bulk Drug Substances) [non-add].....	19.554	26.254	6.700
Medical Counter-measures [non-add].....	6.020	7.020	1.000
Combating the Opioids Epidemic [non-add].....	57.511	30.511	-27.000
Opioids Activities including SUPPORT Act.....	47.000	20.000	-27.000
Modernizing Generic Drug Development and Review [non-add].....	25.100	27.000	1.900
User Fees.....	1,150.943	1,226.407	75.464
Prescription Drug User Fee Act.....	732.096	788.576	56.480
Generic Drug User Fee.....	382.803	400.252	17.449
Biosimilars User Fee Act.....	35.416	36.938	1.522
Outsourcing Facility.....	.628	.641	.013
Field.....	205.460	238.989	33.529
BA.....	138.169	175.469	37.300
Medical Product Safety [non-add].....	138.169	175.469	37.300
Opioids [non-add].....	9.500	44.500	35.000
Compounding Bulk Substances [non-add].....	7.822	10.122	2.300
User Fees.....	67.291	63.520	-3.771
Prescription Drug User Fee Act.....	9.003	8.536	-.467
Generic Drug User Fee.....	56.808	53.124	-3.684
Biosimilars User Fee Act.....	1.100	1.472	.372
Outsourcing Facility.....	.380	.388	.008

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Biologics	402.144	419.302	17.158
Biologics, BA	240.138	252.138	12.000
Biologics, User Fees	162.006	167.164	5.158
Center.....	358.355	375.583	17.228
BA.....	198.132	210.132	12.000
Medical Product Safety [non-add].....	198.132	210.132	12.000
Other Budget Authority.....	167.315	167.315	.000
Medical Countermeasures [non-add].....	2.395	4.395	2.000
Compounding [non-add].....	.352	.352	.000
Integrated Pathogen Reduction of the Blood Supply.....	.000	10.000	10.000
User Fees.....	160.223	165.451	5.228
Prescription Drug User Fee Act.....	144.529	149.267	4.738
Medical Devices User Fee Act.....	14.444	14.578	.134
Generic Drug User Fee.....	1.072	.960	-.112
Biosimilars User Fee Act.....	.178	.646	.468
Field.....	43.789	43.719	-.070
BA.....	42.006	42.006	.000
Medical Product Safety [non-add].....	42.006	42.006	.000
Compounding [non-add].....	.102	.102	.000
User Fees.....	1.783	1.713	-.070
Prescription Drug User Fee Act.....	1.566	1.485	-.081
Medical Devices User Fee Act.....	.217	.228	.011
Animal Drugs and Feeds	224.530	238.678	14.148
Animal Drugs and Feeds, BA	178.934	190.869	11.935
Animal Drugs and Feeds, User Fees	45.596	47.809	2.213
Center.....	157.442	168.474	11.032
BA.....	113.419	122.099	8.680
Food Safety [non-add].....	65.079	73.759	8.680
National Integrated Food Safety System [non-add].....	2.500	2.780	.280
National Antimicrobial Resistance Monitoring System [non-add].....	.500	1.000	.500
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	.000	2.125	2.125
Promoting Innovation and Emerging Technology [non-add].....	.000	5.000	5.000
Cannabidiol (CBD) Activities [non-add].....	.000	.500	.500
Medical Product Safety [non-add].....	48.340	48.340	.000
Compounding [non-add].....	1.682	1.682	.000
User Fees.....	44.023	46.375	2.352
Animal Drugs User Fee Act.....	27.267	27.670	.403
Animal Generic Drug User Fee Act.....	16.644	18.591	1.947
Third Party Auditor Program.....	.112	.114	.002
Field.....	67.088	70.204	3.116
BA.....	65.515	68.770	3.255
Food Safety [non-add].....	62.602	65.857	3.255
National Integrated Food Safety System [non-add].....	4.200	7.455	3.255
Medical Product Safety [non-add].....	2.913	2.913	.000
Compounding [non-add].....	.352	.352	.000
User Fees.....	1.573	1.434	-.139
Animal Drugs User Fee Act.....	.431	.383	-.048
Animal Generic Drug User Fee Act.....	.335	.228	-.107
Food Reinspection User Fee.....	.807	.823	.016
Devices and Radiological Health	576.609	599.940	23.331
Devices, BA	386.743	395.168	8.425
Devices, User Fees	189.945	204.772	14.827
Center.....	475.369	501.296	25.927
BA.....	301.738	310.163	8.425
Medical Product Safety [non-add].....	300.319	308.319	8.000
Pediatric Device Review [non-add].....	6.000	7.000	1.000
Medical Counter-measures [non-add].....	4.001	5.001	1.000
MedTech Manufacturing [non-add].....	6.000	8.000	2.000
Transform Medical Device Safety, Cybersecurity, Review, and Innovation [non-add].....	25.000	29.000	4.000
User Fees.....	173.710	191.133	17.423
Prescription Drug User Fee Act.....	1.460	4.162	2.702
Medical Devices User Fee Act.....	165.815	180.073	14.258
Mammography Quality Standards Act.....	6.435	6.898	.463
Field.....	101.240	98.644	-2.596
BA.....	85.005	85.005	.000
Medical Product Safety [non-add].....	83.745	83.745	.000
User Fees.....	16.235	13.639	-2.596
Medical Devices User Fee Act.....	2.240	2.358	.118
Mammography Quality Standards Act.....	13.995	11.281	-2.714

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Activities	FY 2019	FY 2020	
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National Center for Toxicological Research.....	66.712	66.712	.000
BA.....	66.712	66.712	.000
Food Safety [non-add].....	10.317	10.317	.000
Medical Product Safety [non-add].....	56.395	56.395	.000
Center for Tobacco Products.....	666.832	661.739	-5.093
Tobacco, BA.....	.000	.000	.000
Tobacco, User Fees.....	666.832	661.739	-5.093
Center.....	652.065	647.055	-5.010
BA.....	.000	.000	.000
User Fees.....	652.065	647.055	-5.010
Family Smoking Prevention and Tobacco Control Act.....	652.065	647.055	-5.010
Field.....	14.767	14.684	-.083
BA.....	.000	.000	.000
User Fees.....	14.767	14.684	-.083
Family Smoking Prevention and Tobacco Control Act.....	14.767	14.684	-.083
Other Activities.....	296.823	317.987	21.164
BA.....	186.569	183.920	-2.649
Food Safety [non-add].....	64.075	53.239	-10.836
Food Import Safety [non-add].....	2.800	.000	-2.800
Cannabidiol (CBD) Activities [non-add].....	.000	.500	.500
Medical Product Safety [non-add].....	104.994	113.181	8.187
Medical Counter-measures [non-add].....	10.312	13.312	3.000
Compounding [non-add].....	2.100	2.100	.000
OIG Transfer [non-add].....	.000	.000	.000
Oncology Center of Excellence [non-add] 3/.....	20.000	25.000	5.000
Office of Laboratory Safety.....	1.500	2.500	1.000
User Fees.....	130.913	134.067	3.154
Prescription Drug User Fee Act.....	56.391	56.756	.365
Medical Devices User Fee Act.....	8.463	9.219	.756
Generic Drug User Fee.....	35.243	32.834	-2.409
Biosimilars User Fee Act.....	.632	1.331	.699
Animal Drugs User Fee Act.....	1.004	.914	-.090
Animal Generic Drug User Fee Act.....	.785	.756	-.029
Family Smoking Prevention and Tobacco Control Act.....	27.012	30.867	3.855
Mammography Quality Standards Act.....	.092	.074	-.018
Food and Feed Recall User Fee.....	.075	.077	.002
Food Reinspection User Fee.....	.480	.489	.009
Voluntary Qualified Importer Program.....	.277	.283	.006
Third Party Auditor Program.....	.039	.040	.001
Outsourcing Facility.....	.420	.427	.007
White Oak Consolidation.....	50.587	53.913	3.326
BA.....	43.044	45.914	2.870
User Fees.....	7.543	7.999	.456
Prescription Drug User Fee Act.....	3.810	3.848	.038
Family Smoking Prevention and Tobacco Control Act.....	3.733	4.151	.418
Other Rent and Rent-Related.....	123.735	132.970	9.235
BA.....	71.943	80.173	8.230
Food Safety [non-add].....	36.300	40.450	4.150
Medical Product Safety [non-add].....	35.643	39.723	4.080
Compounding [non-add].....	.379	.379	.000
User Fees.....	51.792	52.797	1.005
Prescription Drug User Fee Act.....	26.127	26.389	.262
Medical Devices User Fee Act.....	5.239	5.291	.052
Generic Drug User Fee.....	13.075	13.206	.131
Biosimilars User Fee Act.....	1.070	1.081	.011
Animal Drugs User Fee Act.....	.790	.797	.007
Animal Generic Drug User Fee Act.....	.264	.266	.002
Family Smoking Prevention and Tobacco Control Act.....	4.752	5.283	.531
Food and Feed Recall User Fee.....	.043	.044	.001
Food Reinspection User Fee.....	.204	.208	.004
Voluntary Qualified Importer Program.....	.170	.173	.003
Third Party Auditor Program.....	.024	.024	.000
Outsourcing Facility.....	.034	.035	.001
GSA Rent.....	238.665	240.549	1.884
BA.....	170.208	171.208	1.000
Food Safety [non-add].....	79.477	79.947	.470
Medical Product Safety [non-add].....	90.731	91.261	.530
Compounding [non-add].....	1.290	1.290	.000
User Fees.....	68.457	69.341	.884
Prescription Drug User Fee Act.....	35.341	35.695	.354
Medical Devices User Fee Act.....	8.312	8.395	.083
Generic Drug User Fee.....	12.720	12.847	.127
Biosimilars User Fee Act.....	.451	.455	.004
Animal Drug User Fee Act.....	.839	.847	.008
Animal Generic Drug User Fee Act.....	.307	.310	.003
Family Smoking Prevention and Tobacco Control Act.....	9.671	9.960	.289
Food and Feed Recall User Fee.....	.073	.074	.001
Food Reinspection User Fee.....	.348	.355	.007
Voluntary Qualified Importer Program.....	.290	.296	.006
Third Party Auditor Program.....	.047	.048	.001
Outsourcing Facility.....	.058	.059	.001

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Activities	FY 2019	FY 2020	
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Other Indefinite User Fees	22.444	27.905	5.461
Color Certification.....	10.062	10.263	.201
Export Certification.....	4.696	4.790	.094
Priority Review Vouchers Pediatric Disease.....	7.686	12.852	5.166
Buildings & Facilities	11.788	31.788	20.000
Building & Facilities One-time funding [non-add].....	.000	20.000	20.000
21st Century Cures	70.000	75.000	5.000
Totals			
Discretionary Budget Authority.....	3,148.966	3,264.966	116.000
Food Safety (BA only) [non-add] 4/.....	1,377.830	1,412.450	34.620
National Integrated Food Safety System [non-add].....	63.262	70.262	7.000
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	5.000	13.000	8.000
Standard of Identity and Product Labeling [non-add].....	2.550	3.550	1.000
Office of Dietary Supplement Programs [non-add].....	6.600	9.600	3.000
Imported Seafood Safety Pilot (Machine Learning) [non-add].....	.000	5.000	5.000
Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add].....	15.000	15.000	.000
Promoting Innovation and Emerging Technology [non-add]000	5.000	5.000
Cannabidiol (CBD) Activities [non-add].....	.000	2.000	2.000
Medical Product Safety (BA only) [non-add] 5/.....	1,698.804	1,757.314	58.510
Antimicrobial Resistance (includes CARB) [non-add].....	40.138	40.638	.500
National Antimicrobial Resistance Monitoring System [non-add] 10/.....	11.300	11.800	.500
Pediatric Device Review [non-add].....	6.000	7.000	1.000
Oncology Center of Excellence [non-add] 3/.....	20.000	25.000	5.000
Compounding (including Bulk Drug Substances) [non-add] 6/.....	33.632	42.632	9.000
Medical Countermeasures	24.552	31.552	7.000
Opioids Activities including International Mail Facilities (IMF) and SUPPORT Act 7/.....	67.011	75.011	8.000
MedTech Manufacturing [non-add].....	6.000	8.000	2.000
Transform Medical Device Safety, Cybersecurity, Review, and Innovation [non-add].....	25.000	29.000	4.000
Modernizing Generic Drug Development and Review [non-add].....	25.100	27.000	1.900
Integrated Pathogen Reduction of the Blood Supply.....	.000	10.000	10.000
Office of Laboratory Safety	1.500	2.500	1.000
Buildings & Facilities	11.788	31.788	20.000
21st Century Cures.....	70.000	75.000	5.000
User Fees.....	2,574.633	2,674.609	99.976
Total Program Level	5,723.599	5,939.575	215.976
Total, Program Level with Reprogrammings	5,723.599	5,939.575	215.976

1/ From FY 2017 - FY 2019, Congress directed FDA to obligate funding to support Biotechnology Education. The FY 2020 appropriation no longer continues this requirement.

2/ The Operating Plan reflects a reallocation between from CFSAN to ORA of \$500,000 through a reprogramming, which was also carried out in FY 2019, to better align food safety resources. The reprogrammed amount is below the statutory notification threshold.

3/ The increase above FY 2019 provided to the Oncology Center of Excellence will support rare cancer therapeutics.

4/ The increase above FY 2019 for food safety reflects both the amount specified in the report [ties to the report amount] and \$4.62 million for increases to rent and operation costs.

5/ The increase above FY 2019 for medical product safety reflects both the amount specified in the report [ties to the report amount] and \$4.61 million for increases to rent and operation costs.

6/ In FY 2020, FDA will dedicate \$42.6 million in total BA resources across the agency for compounding activities.

7/ In FY 2020, FDA will dedicate \$75.0 million in total BA resources across the agency for opioids activities.