

**Food and Drug Administration**  
**Operating plan for FY 2021**

*Dollars in Millions*

Activities	FY 2020	FY 2021	
	Final	FY 2021 Final	FY21 Final +/- FY20 Final
<b>Foods Program.....</b>	<b>1,098.470</b>	<b>1,110.471</b>	<b>12.001</b>
<b>Foods, BA.....</b>	<b>1,087.381</b>	<b>1,099.160</b>	<b>11.779</b>
<b>Foods, User Fees.....</b>	<b>11.089</b>	<b>11.311</b>	<b>.222</b>
Center.....	335.815	344.655	8.840
BA.....	334.966	343.789	8.823
<i>Food Safety [non-add] 1/.....</i>	334.966	343.789	8.823
<i>Cannabis and Cannabis Derivatives Activities [non-add].....</i>	1.000	3.000	2.000
<i>Strengthening Response Capabilities for Foodborne Outbreaks [non-Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add]</i>	6.274	7.274	1.000
<i>Shrimp Import Pilot [non-add].....</i>	1.100	1.100	.000
<i>Allergen [non-add].....</i>	.000	3.000	3.000
<i>AI and other Emerging Technologies [non-add].....</i>	.000	1.250	1.250
<i>Cosmetics [non-add].....</i>	7.472	7.472	.000
User Fees.....	.849	.866	.017
<i>Food and Feed Recall User Fee.....</i>	.248	.253	.005
<i>Voluntary Qualified Importer Program.....</i>	.248	.253	.005
<i>Third Party Auditor Program.....</i>	.353	.360	.007
Field.....	762.655	.360	-762.295
BA.....	752.415	755.371	2.956
<i>Food Safety [non-add] 1/.....</i>	752.415	755.371	2.956
<i>Strengthening Response Capabilities for Foodborne Outbreaks [non-add]</i>	4.601	4.601	.000
<i>Imported Seafood Safety Pilot (Machine Learning) [non-add].....</i>	5.000	.000	-5.000
<i>Inspections of Foreign Seafood Manufacturers and Field Examinations of Imported Seafood [non-add]</i>	13.900	13.900	.000
<i>Shrimp Import Pilot [non-add].....</i>	.000	3.000	3.000
<i>Cannabis and Cannabis Derivatives Activities [non-add].....</i>	.000	2.000	2.000
<i>AI and other Emerging Technologies [non-add].....</i>	.000	1.456	1.456
<i>Cosmetics [non-add].....</i>	5.500	5.500	.000
User Fees.....	10.240	10.445	.205
<i>Food and Feed Recall User Fee.....</i>	1.020	1.040	.020
<i>Food Reinspection User Fee.....</i>	4.667	4.760	.093
<i>Voluntary Qualified Importer Program.....</i>	4.406	4.495	.089
<i>Third Party Auditor Program.....</i>	.147	.150	.003
<b>Human Drugs.....</b>	<b>1,973.122</b>	<b>1,997.174</b>	<b>24.052</b>
<b>Human Drugs, BA.....</b>	<b>683.195</b>	<b>689.195</b>	<b>6.000</b>
<b>Human Drugs, User Fees.....</b>	<b>1,289.927</b>	<b>1,307.979</b>	<b>18.052</b>
Center.....	1,734.133	1,753.685	19.552
BA.....	507.726	510.226	2.500
<i>Medical Product Safety [non-add]</i>	507.726	510.226	2.500
<i>Other Budget Authority.....</i>	259.845	259.845	.000
<i>Compounding (including Bulk Drug Substances) [non-add].....</i>	26.254	28.254	2.000
<i>Opioids Activities including SUPPORT Act.....</i>	20.000	20.000	.000
<i>Pandemic Influenza (including Modernizing Influenza Vaccines)[non-add].....</i>	4.364	4.864	.500
User Fees.....	1,226.407	1,243.459	17.052
<i>Prescription Drug User Fee Act.....</i>	788.576	800.637	12.061
<i>Generic Drug User Fee.....</i>	400.252	404.241	3.989
<i>Biosimilars User Fee Act.....</i>	36.938	37.928	.990
<i>Outsourcing Facility.....</i>	.641	.653	.012
Field.....	238.989	243.489	4.500
BA.....	175.469	178.969	3.500
<i>Medical Product Safety [non-add]</i>	175.469	178.969	3.500
<i>Opioids [non-add].....</i>	44.500	44.500	.000
<i>Opioids-International Mail Facilities [non-add].....</i>	35.000	35.000	.000
<i>Opioids-Regulatory Science [non-add].....</i>	9.500	9.500	.000
<i>Foreign Human Drug Inspection Pilot [non-add].....</i>	.000	3.500	3.500
<i>Compounding [non-add].....</i>	10.122	10.122	.000
User Fees.....	63.520	64.520	1.000
<i>Prescription Drug User Fee Act.....</i>	8.536	8.707	.171
<i>Generic Drug User Fee.....</i>	53.124	54.096	.972
<i>Biosimilars User Fee Act.....</i>	1.472	1.322	-.150
<i>Outsourcing Facility.....</i>	.388	.395	.007
<b>Biologics.....</b>	<b>419.044</b>	<b>437.071</b>	<b>18.027</b>
<b>Biologics, BA .....</b>	<b>252.138</b>	<b>254.138</b>	<b>2.000</b>
<b>Biologics, User Fees.....</b>	<b>166.906</b>	<b>182.933</b>	<b>16.027</b>
Center.....	375.325	393.322	17.997
BA.....	210.132	212.132	2.000
<i>Medical Product Safety [non-add]</i>	210.132	212.132	2.000
<i>Other Budget Authority.....</i>	167.315	167.315	.000
<i>Compounding [non-add].....</i>	.352	.352	.000
<i>Pandemic Influenza (including Modernizing Influenza Vaccines)[non-add].....</i>	29.233	31.233	2.000
User Fees.....	165.193	181.190	15.997
<i>Prescription Drug User Fee Act.....</i>	149.493	164.951	15.458
<i>Medical Devices User Fee Act.....</i>	14.549	14.981	.432
<i>Generic Drug User Fee.....</i>	.929	.983	.054
<i>Biosimilars User Fee Act.....</i>	.222	.275	.053
Field.....	43.719	43.749	.030
BA.....	42.006	42.006	.000
<i>Medical Product Safety [non-add]</i>	42.006	42.006	.000
<i>Pandemic Influenza [non-add].....</i>	1.400	1.425	.025
<i>Compounding [non-add].....</i>	.102	.102	.000
User Fees.....	1.713	1.743	.030
<i>Prescription Drug User Fee Act.....</i>	1.485	1.514	.029
<i>Medical Devices User Fee Act.....</i>	.228	.229	.001
<b>Animal Drugs and Feeds.....</b>	<b>238.678</b>	<b>245.307</b>	<b>6.629</b>
<b>Animal Drugs and Feeds, BA .....</b>	<b>190.869</b>	<b>192.369</b>	<b>1.500</b>
<b>Animal Drugs and Feeds, User Fees.....</b>	<b>47.809</b>	<b>52.938</b>	<b>5.129</b>

Activities	FY 2020	FY 2021	
	Final	FY 2021 Final	FY21 Final +/- FY20 Final
Center .....	168.474	175.083	6.609
BA.....	122.099	123.599	1.500
Food Safety [non-add]	73.759	74.259	.500
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	2.125	2.125	.000
Cannabis and Cannabis Derivatives Activities [non-add].....	.500	1.000	.500
Medical Product Safety [non-add]	48.340	49.340	1.000
Pandemic Influenza [non-add].....	.131	.134	.003
Antimicrobial Resistance 5-Year Plan [non-add].....	.000	1.000	1.000
Compounding [non-add].....	1.682	1.682	.000
User Fees.....	46.375	51.484	5.109
Animal Drugs User Fee Act.....	27.670	30.117	2.447
Animal Generic Drug User Fee Act.....	18.591	21.250	2.659
Third Party Auditor Program.....	.114	.117	.003
Field.....	70.204	70.224	.020
BA.....	68.770	68.770	.000
Food Safety [non-add]	65.857	65.857	.000
Medical Product Safety [non-add]	2.913	2.913	.000
Compounding [non-add].....	.352	.352	.000
User Fees.....	1.434	1.454	.020
Animal Drugs User Fee Act.....	.383	.390	.007
Animal Generic Drug User Fee Act.....	.228	.224	-.004
Food Reinspection User Fee.....	.823	.840	.017
<b>Devices and Radiological Health.....</b>	<b>599.940</b>	<b>627.664</b>	<b>27.724</b>
<b>Devices, BA /.....</b>	<b>395.168</b>	<b>408.108</b>	<b>12.940</b>
<b>Devices, User Fees.....</b>	<b>204.772</b>	<b>219.556</b>	<b>14.784</b>
Center.....	501.296	528.784	27.488
BA.....	310.163	323.103	12.940
Medical Product Safety [non-add].....	310.163	323.103	12.940
Transform Medical Device Safety, Cybersecurity, Review, and Innovation [non-add].....	29.000	38.000	9.000
Pediatric Device Review [non-add] .....	7.000	7.000	.000
AI and other Emerging Technologies [non-add].....	.000	3.440	3.440
Pandemic Influenza (including Modernizing Influenza Vaccines)[non-add]	4.215	4.715	.500
User Fees.....	191.133	205.681	14.548
Prescription Drug User Fee Act.....	4.162	4.446	.284
Medical Devices User Fee Act.....	180.073	194.199	14.126
Mammography Quality Standards Act.....	6.898	7.036	.138
Field.....	98.644	98.880	.236
BA.....	85.005	85.005	.000
Medical Product Safety [non-add].....	83.745	83.745	.000
User Fees.....	13.639	13.875	.236
Medical Devices User Fee Act.....	2.358	2.368	.010
Mammography Quality Standards Act.....	11.281	11.507	.226
<b>National Center for Toxicological Research.....</b>	<b>66.712</b>	<b>66.712</b>	<b>.000</b>
BA.....	66.712	66.712	.000
Food Safety [non-add].....	5.087	5.087	.000
Cosmetics [non-add].....	.475	.475	.000
Medical Product Safety [non-add].....	61.625	61.625	.000
Biofilm Regulatory Science Research [non-add].....	.000	.500	.500
<b>Center for Tobacco Products .....</b>	<b>680.437</b>	<b>681.513</b>	<b>1.076</b>
<b>Tobacco, BA.....</b>	<b>.000</b>	<b>.000</b>	<b>.000</b>
<b>Tobacco, User Fees.....</b>	<b>680.437</b>	<b>681.513</b>	<b>1.076</b>
Center.....	664.168	658.906	-5.262
BA.....	.000	.000	.000
User Fees.....	664.168	658.906	-5.262
Family Smoking Prevention and Tobacco Control Act .....	664.168	658.906	-5.262
Electronic Nicotine Delivery Systems (ENDS) Testing Standardization (non-add).....	.000	5.000	5.000
Field .....	16.269	22.607	6.338
BA.....	.000	.000	.000
User Fees.....	16.269	22.607	6.338
Family Smoking Prevention and Tobacco Control Act .....	16.269	22.607	6.338
<b>Other Activities.....</b>	<b>302.289</b>	<b>319.572</b>	<b>15.783</b>
BA .....	186.920	194.951	6.531
Food Safety [non-add].....	53.239	55.770	2.531
Cannabis and Cannabis Derivatives Activities [non-add].....	.500	1.000	.500
Cosmetics [non-add].....	.000	1.000	1.000
Medical Product Safety [non-add].....	113.181	117.681	4.500
Compounding [non-add].....	2.100	2.100	.000
Pandemic Influenza (including Modernizing Influenza Vaccines)[non-add].....	.689	2.689	2.000
OCE Rare Cancer [non-add].....	.000	2.500	2.500
OIG Transfer [non-add].....	.000	1.500	1.500
Office of Chief Counsel [non-add].....	15.896	16.896	1.000
AI and other Emerging Technologies [non-add].....	.000	1.031	1.031
User Fees.....	115.369	124.621	9.252
Prescription Drug User Fee Act.....	56.756	60.354	3.598
Medical Devices User Fee Act.....	9.219	10.459	1.240
Generic Drug User Fee.....	32.834	34.575	1.741
Biosimilars User Fee Act.....	1.331	1.417	.086
Animal Drugs User Fee Act.....	.914	1.172	.258
Animal Generic Drug User Fee Act.....	.756	.740	-.016
Family Smoking Prevention and Tobacco Control Act .....	12.169	14.485	2.316
Mammography Quality Standards Act.....	.074	.076	.002
Food and Feed Recall User Fee.....	.077	.078	.001
Food Reinspection User Fee.....	.489	.499	.010
Voluntary Qualified Importer Program.....	.283	.288	.005
Third Party Auditor Program.....	.040	.041	.001
Outsourcing Facility.....	.427	.437	.010
<b>White Oak Complex.....</b>	<b>53.913</b>	<b>52.944</b>	<b>-.969</b>
BA.....	45.914	45.914	.000

Activities	FY 2020	FY 2021	
	Final	FY 2021 Final	FY21 Final +/- FY20 Final
User Fees.....	7.999	7.030	-969
<i>Prescription Drug User Fee Act</i> .....	3.848	3.886	.038
<i>Family Smoking Prevention and Tobacco Control Act</i> .....	4.151	3.144	-1.007
<b>Other Rent and Rent-Related</b> .....	<b>132.970</b>	<b>136.257</b>	<b>3.287</b>
BA.....	80.173	84.262	4.089
<i>Food Safety [non-add]</i> .....	40.450	40.450	.000
<i>Medical Product Safety [non-add]</i> .....	39.723	39.723	.000
<i>Compounding [non-add]</i> .....	.379	.379	.000
User Fees.....	52.797	51.995	-.802
<i>Prescription Drug User Fee Act</i> .....	26.389	26.652	.263
<i>Medical Devices User Fee Act</i> .....	5.291	5.344	.053
<i>Generic Drug User Fee</i> .....	13.206	13.338	.132
<i>Biosimilars User Fee Act</i> .....	1.081	1.092	.011
<i>Animal Drugs User Fee Act</i> .....	.797	.805	.008
<i>Animal Generic Drug User Fee Act</i> .....	.266	.269	.003
<i>Family Smoking Prevention and Tobacco Control Act</i> .....	5.283	4.001	-1.282
<i>Food and Feed Recall User Fee</i> .....	.044	.045	.001
<i>Food Reinspection User Fee</i> .....	.208	.212	.004
<i>Voluntary Qualified Importer Program</i> .....	.173	.177	.004
<i>Third Party Auditor Program</i> .....	.024	.025	.001
<i>Outsourcing Facility</i> .....	.035	.035	.000
<b>GSA Rent</b> .....	<b>240.549</b>	<b>235.961</b>	<b>-4.588</b>
BA.....	171.208	167.119	-4.089
<i>Food Safety [non-add]</i> .....	79.947	79.947	.000
<i>Medical Product Safety [non-add]</i> .....	91.261	91.261	.000
<i>Compounding [non-add]</i> .....	1.290	1.290	.000
User Fees.....	69.341	68.842	-.499
<i>Prescription Drug User Fee Act</i> .....	35.695	36.052	.357
<i>Medical Devices User Fee Act</i> .....	8.395	8.479	.084
<i>Generic Drug User Fee</i> .....	12.847	12.975	.128
<i>Biosimilars User Fee Act</i> .....	.455	.460	.005
<i>Animal Drug User Fee Act</i> .....	.847	.856	.009
<i>Animal Generic Drug User Fee Act</i> .....	.310	.314	.004
<i>Family Smoking Prevention and Tobacco Control Act</i> .....	9.960	8.857	-1.103
<i>Food and Feed Recall User Fee</i> .....	.074	.076	.002
<i>Food Reinspection User Fee</i> .....	.355	.362	.007
<i>Voluntary Qualified Importer Program</i> .....	.296	.302	.006
<i>Third Party Auditor Program</i> .....	.048	.049	.001
<i>Outsourcing Facility</i> .....	.059	.060	.001
<b>Other Indefinite User Fees</b> .....	<b>27.905</b>	<b>57.520</b>	<b>28.959</b>
Color Certification.....	10.263	11.125	.206
Export Certification.....	4.790	4.886	.096
Priority Review Vouchers.....	12.852	13.109	.257
Over the Counter Monograph.....	.000	28.400	28.400
<b>Buildings &amp; Facilities</b> .....	<b>31.788</b>	<b>12.788</b>	<b>-19.000</b>
<i>Building &amp; Facilities One-time funding [non-add]</i> .....	20.000	.000	-20.000
<b>21st Century Cures</b> .....	<b>75.000</b>	<b>70.000</b>	<b>-5.000</b>
<b>Seafood Safety Studies - GP Sec. 765 (no-Year)</b> .....	<b>.000</b>	<b>1.000</b>	<b>1.000</b>
<b>Totals</b>			
Discretionary Budget Authority.....	3,266.466	3,285.716	17.750
Food Safety (BA only) [non-add] 2/.....	1,405.720	1,420.530	14.810
Strengthening Response Capabilities for Foodborne Outbreaks [non-add].....	13.000	14.000	1.000
Cannabis and Cannabis Derivatives Activities [non-add].....	2.000	7.000	5.000
Shrimp Import Pilot [non-add].....	.000	6.000	6.000
Cosmetics [non-add].....	13.447	14.447	1.000
Medical Product Safety (BA only) [non-add] 3/.....	1,762.544	1,783.984	21.440
Antimicrobial Resistance (includes CARB) [non-add].....	40.138	41.138	1.000
Pediatric Device Review [non-add].....	7.000	7.000	.000
Pandemic Influenza (including Modernizing Influenza Vaccines)[non-add]/6.....	40.032	45.060	5.028
Compounding (including Bulk Drug Substances) [non-add] 4/.....	42.632	44.632	2.000
Opioids Activities including International Mail Facilities (IMF) and SUPPORT Act 5/.....	64.500	64.500	.000
Transform Medical Device Safety, Cybersecurity, Review, and Innovation [non-add].....	29.000	38.000	9.000
Buildings & Facilities.....	11.788	12.788	1.000
21st Century Cures.....	75.000	70.000	-5.000
User Fees.....	2,674.351	2,766.238	91.231
<b>Total Program Level</b> .....	<b>5,940.817</b>	<b>6,051.954</b>	<b>108.981</b>
Total, Program Level with Reprogrammings.....	5,940.817	6,051.954	108.981

1/ 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.

2/ The increase above FY 2020 for food safety reflects the amount specified in the report Joint Explanatory Statement, less the savings of \$3M from Machine Learning Pilot and the shift of \$1M incorrectly allocated to NARMS, and the \$3.56M increase for AI activities.

3/ The increase above FY 2020 for medical product safety reflects the amount specified in the Joint Explanatory Statement, less the statutory change in Cures (-\$5M), the \$3.44M increase for AI activities, and the \$1M for the Antimicrobial Resistance 5-Year Plan.

4/ In FY 2021, FDA will dedicate \$44.6 million in total BA resources across the agency for compounding activities.

5/ In FY 2021, FDA will spend \$64.5 million in total dedicated BA resources across the agency for opioids activities consistent with the Drug Control Budget. FDA is also projected to utilize \$10.5M of unspecified base funding in the Human Drugs Center on Opioids related activities.

6/ This total includes \$5 million for Modernizing Influenza Vaccine within the Human Drugs, Biologics, and Devices and Radiological Health Centers, and FDA Office of the Commissioner. FDA will utilize additional base funding across the agency for broader Pandemic Influenza activities in FY 2021.