

**Food and Drug Administration**  
**Operating plan for FY 2022**

*Dollars in Millions*

Activities	FY 2021	FY 2022	
	Final	FY 2022 Final	FY22 Final +/- FY21 Final
<b>Foods Program.....</b>	<b>1,110,471</b>	<b>1,144,712</b>	<b>34,241</b>
<b>Foods, BA.....</b>	<b>1,099,160</b>	<b>1,133,176</b>	<b>34,016</b>
<b>Foods, User Fees.....</b>	<b>11,311</b>	<b>11,536</b>	<b>.225</b>
Center.....	344,155	370,420	25,765
BA/1.....	343,289	369,537	25,748
Food Safety [non-add].....	343,289	369,537	25,748
Cannabis and Cannabis Derivatives Activities [non-add].....	3,000	3,000	.000
New Era of Smarter Food Safety (including AI and other Emerging Technologies) [non-add].....	1,073	2,793	1,720
Maternal and Infant Health and Nutrition [non-add].....	2,000	13,000	11,000
Emerging Chemical and Toxicological Issues [non-add]/3.....	.000	5,000	5,000
Dietary Supplements [non-add]/3.....	3,000	5,000	2,000
Standards of Identity [non-add].....	3,000	4,500	1,500
Animal Feed Reviews [non-add].....	.000	1,000	1,000
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.200	.200
Pay Costs [non-add].....	.000	2,731	2,731
Essential Services [non-add].....	.000	.400	.400
User Fees.....	.866	.883	.017
Food and Feed Recall User Fee.....	.253	.258	.005
Voluntary Qualified Importer Program.....	.253	.258	.005
Third Party Auditor Program.....	.360	.367	.007
Field.....	766,316	774,292	8,476
BA/1.....	755,871	763,639	8,268
Food Safety [non-add].....	755,871	763,639	8,268
Cannabis and Cannabis Derivatives Activities [non-add].....	2,000	2,000	.000
New Era of Smarter Food Safety (including AI and other Emerging Technologies) [non-add].....	1,456	2,776	1,320
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.426	.426
Inspections [non-add].....	.000	1,860	1,860
Pay Costs [non-add].....	.000	4,318	4,318
User Fees.....	10,445	10,653	.208
Food and Feed Recall User Fee.....	1,040	1,061	.021
Food Reinspection User Fee.....	4,760	4,855	.095
Voluntary Qualified Importer Program.....	4,495	4,584	.089
Third Party Auditor Program.....	.150	.153	.003
<b>Human Drugs.....</b>	<b>1,997,174</b>	<b>2,116,086</b>	<b>118,912</b>
<b>Human Drugs, BA.....</b>	<b>689,195</b>	<b>713,888</b>	<b>24,693</b>
<b>Human Drugs, User Fees.....</b>	<b>1,307,979</b>	<b>1,402,198</b>	<b>94,219</b>
Center.....	1,753,685	1,851,466	97,781
BA.....	510,226	517,675	7,449
Medical Product Safety [non-add].....	510,226	517,675	7,449
Orphan Products Grants Program [non-add].....	2,500	5,000	2,500
Rare Diseases [non-add].....	10,000	10,300	.300
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.941	.941
Pay Costs [non-add].....	.000	2,808	2,808
Essential Services [non-add].....	.000	.400	.400
Advancing the Goal of Ending the Opioid Crisis (Opioids Activities including SUPPORT Act) [non-add].....	20,000	20,500	.500
User Fees.....	1,243,459	1,333,791	90,332
Prescription Drug User Fee Act.....	800,637	878,206	77,569
Generic Drug User Fee.....	404,241	419,210	14,969
Biosimilars User Fee Act.....	37,928	35,709	-2,219
Outsourcing Facility.....	.653	.666	.013
Field.....	243,489	264,620	21,131
BA.....	178,969	196,213	17,244
Medical Product Safety [non-add].....	178,969	196,213	17,244
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.121	.121
Inspections [non-add].....	.000	3,990	3,990
Pay Costs [non-add].....	.000	1,133	1,133
Advancing the Goal of Ending the Opioid Crisis (including other Opioid activities) [non-add].....	44,500	51,500	7,000
Foreign Unannounced Human Drug Inspection Pilots [non-add].....	3,500	8,500	5,000
User Fees.....	64,520	68,407	3,887
Prescription Drug User Fee Act.....	8,707	9,312	.605
Generic Drug User Fee.....	54,096	57,205	3,109
Biosimilars User Fee Act.....	1,322	1,487	.165
Outsourcing Facility.....	.395	.403	.008
<b>Biologics.....</b>	<b>437,071</b>	<b>456,882</b>	<b>19,811</b>
<b>Biologics, BA.....</b>	<b>254,138</b>	<b>260,118</b>	<b>5,980</b>
<b>Biologics, User Fees.....</b>	<b>182,933</b>	<b>196,764</b>	<b>13,831</b>
Center.....	393,322	410,198	16,876
BA.....	212,132	215,321	3,189
Medical Product Safety [non-add].....	212,132	215,321	3,189
Data Modernization and Enhanced Technology Initiative [non-add].....	.000	.200	.200
Rare Diseases [non-add].....	.000	1,200	1,200
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.280	.280
Pay Costs [non-add].....	.000	1,109	1,109
Essential Services [non-add].....	.000	.400	.400
User Fees.....	181,190	194,877	13,687
Prescription Drug User Fee Act.....	164,951	178,620	13,669
Medical Devices User Fee Act.....	14,981	14,886	-.095
Generic Drug User Fee.....	.983	1,103	.120
Biosimilars User Fee Act.....	.275	.268	-.007
Field.....	43,749	46,684	2,935
BA.....	42,006	44,797	2,791
Medical Product Safety [non-add].....	42,006	44,797	2,791
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.036	.036
Inspections [non-add].....	.000	2,394	2,394
Pay Costs [non-add].....	.000	.361	.361
User Fees.....	1,743	1,887	.144
Prescription Drug User Fee Act.....	1,514	1,649	.135
Medical Devices User Fee Act.....	.229	.238	.009
<b>Animal Drugs and Feeds.....</b>	<b>245,307</b>	<b>255,230</b>	<b>9,923</b>
<b>Animal Drugs and Feeds, BA.....</b>	<b>192,369</b>	<b>201,792</b>	<b>9,423</b>
<b>Animal Drugs and Feeds, User Fees.....</b>	<b>52,938</b>	<b>53,438</b>	<b>.500</b>
Center.....	175,083	181,351	6,268
BA.....	123,599	129,406	5,807
Food Safety [non-add].....	74,146	77,408	3,262
Cannabis and Cannabis Derivatives Activities [non-add].....	1,000	1,000	.000
New Era of Smarter Food Safety [non-add].....	.280	2,650	2,370
Medical Product Safety [non-add].....	49,453	51,998	2,545
CVM Medical Product Supply Chain [non-add].....	.000	1,500	1,500
Data Modernization and Enhanced Technology Initiative [non-add].....	.000	.500	.500
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.084	.084
Pay Costs [non-add].....	.000	.906	.906
Essential Services [non-add].....	.000	.400	.400
User Fees.....	51,484	51,945	.461
Animal Drugs User Fee Act.....	30,117	28,648	-1,469
Animal Generic Drug User Fee Act.....	21,250	23,178	1,928
Third Party Auditor Program.....	.117	.119	.002
Field.....	70,224	73,879	3,655
BA.....	68,770	72,386	3,616
Food Safety [non-add].....	65,857	69,451	3,594
New Era of Smarter Food Safety [non-add].....	3,255	6,195	2,940
Medical Product Safety [non-add].....	2,913	2,935	.022
Data Modernization and Enhanced Technologies Enterprise Wide [non-add].....	.000	.050	.050

Activities	FY 2021	FY 2022	
	Final	FY 2022 Final	FY22 Final +/- FY21 Final
Inspections [non-add]	.000	.160	.160
Pay Costs [non-add]	.000	.426	.426
User Fees	1.454	1.493	.039
Animal Drugs User Fee Act	.390	.393	.003
Animal Generic Drug User Fee Act	.224	.244	.020
Food Reinspection User Fee	.840	.856	.016
<b>Devices and Radiological Health</b>	<b>627.664</b>	<b>647.553</b>	<b>19.889</b>
<b>Devices, BA</b>	<b>408.108</b>	<b>419.543</b>	<b>11.435</b>
<b>Devices, User Fees</b>	<b>219.556</b>	<b>228.010</b>	<b>8.454</b>
Center	528.784	545.821	17.037
BA	323.103	332.055	8.952
Medical Product Safety [non-add]	323.103	332.055	8.952
Device Shortages and Supply Chain [non-add]	.000	5.000	5.000
Data Modernization and Enhanced Technology Initiative (including Transform Medical Device Safety, Cybersecurity, Review, and Innovation) [non-Advancing the Goal of Ending the Opioid Crisis [non-add]]	38.000	38.300	.300
BioFilm Regulatory Research [non-add]	.000	.500	.500
Data Modernization and Enhanced Technologies Enterprise Wide [non-add]	.000	.500	.500
Pay Costs [non-add]	.000	.328	.328
Essential Services [non-add]	.000	1.924	1.924
User Fees	.000	.400	.400
Prescription Drug User Fee Act	205.681	213.766	8.085
Medical Devices User Fee Act	4.446	5.361	.915
Mammography Quality Standards Act	194.199	201.228	7.029
Field	7.036	7.177	.141
BA	98.880	101.732	2.852
Medical Product Safety [non-add]	85.005	87.488	2.483
Data Modernization and Enhanced Technologies Enterprise Wide [non-add]	83.745	87.488	3.743
Inspections [non-add]	.000	.079	.079
Pay Costs [non-add]	.000	1.596	1.596
User Fees	.000	.790	.790
Medical Devices User Fee Act	13.875	14.244	.369
Mammography Quality Standards Act	2.368	2.507	.139
Mammography Quality Standards Act	11.507	11.737	.230
<b>National Center for Toxicological Research</b>	<b>66.712</b>	<b>70.348</b>	<b>3.636</b>
BA	66.712	70.348	3.636
Food Safety [non-add]	5.087	5.272	.185
New Era of Smarter Food Safety [non-add]	.000	.150	.150
Medical Product Safety [non-add]	61.625	65.076	3.451
Predictive Toxicology Roadmap [non-add]	.000	3.000	3.000
Data Modernization and Enhanced Technologies Enterprise Wide [non-add]	.000	.035	.035
Pay Costs [non-add]	.000	.402	.402
<b>Center for Tobacco Products</b>	<b>681.513</b>	<b>679.944</b>	<b>-1.569</b>
<b>Tobacco, BA</b>	<b>.000</b>	<b>.000</b>	<b>.000</b>
<b>Tobacco, User Fees</b>	<b>681.513</b>	<b>679.944</b>	<b>-1.569</b>
Center	658.906	652.459	-6.447
BA	.000	.000	.000
User Fees	658.906	652.459	-6.447
Family Smoking Prevention and Tobacco Control Act	658.906	652.459	-6.447
Field	22.607	27.485	4.878
BA	.000	.000	.000
User Fees	22.607	27.485	4.878
Family Smoking Prevention and Tobacco Control Act	22.607	27.485	4.878
<b>Other Activities</b>	<b>318.072</b>	<b>330.686</b>	<b>11.114</b>
BA	193.451	205.568	10.617
Food Safety [non-add]	56.239	59.665	3.426
Cannabis and Cannabis Derivatives Activities [non-add]	1.000	1.000	.000
New Era of Smarter Food Safety (including AI and other Emerging Technologies) [non-add]	1.031	1.531	.500
Medical Product Safety [non-add]	119.712	126.903	7.191
Rare Cancer Therapeutics [non-add]	7.500	8.500	1.000
Data Modernization and Enhanced Technologies Enterprise Wide [non-add]	.000	.420	.420
Pay Costs [non-add]	.000	.992	.992
Office of Minority Health and Health Equity [non-add]	3.441	8.141	4.700
Office of Laboratory Safety [non-add]	2.500	4.000	1.500
Office of Chief Counsel [non-add]	17.051	19.251	2.200
OIG Transfer [non-add]	.000	1.500	.000
User Fees	124.621	125.118	.497
Prescription Drug User Fee Act	60.354	59.725	-.629
Medical Devices User Fee Act	10.459	10.652	.193
Generic Drug User Fee	34.575	35.561	.986
Biosimilars User Fee Act	1.417	1.009	-.408
Animal Drugs User Fee Act	1.172	.937	-.235
Animal Generic Drug User Fee Act	.740	.788	.048
Family Smoking Prevention and Tobacco Control Act	14.485	14.999	.514
Mammography Quality Standards Act	.076	.077	.001
Food and Feed Recall User Fee	.078	.080	.002
Food Reinspection User Fee	.499	.509	.010
Voluntary Qualified Importer Program	.288	.294	.006
Third Party Auditor Program	.041	.041	.000
Outsourcing Facility	.437	.446	.009
<b>White Oak Complex</b>	<b>52.944</b>	<b>53.832</b>	<b>.888</b>
BA	45.914	46.664	.750
User Fees	7.030	7.168	.138
Prescription Drug User Fee Act	3.886	3.925	.039
Family Smoking Prevention and Tobacco Control Act	3.144	3.243	.099
<b>Other Rent and Rent-Related</b>	<b>150.557</b>	<b>139.362</b>	<b>-11.195</b>
BA	98.262	86.762	-11.500
Food Safety [non-add]	49.577	43.774	-5.803
Medical Product Safety [non-add]	48.685	42.988	-5.697
User Fees	52.295	52.600	.305
Prescription Drug User Fee Act	26.652	26.919	.267
Medical Devices User Fee Act	5.344	5.398	.054
Generic Drug User Fee	13.338	13.472	.134
Biosimilars User Fee Act	1.092	1.102	.010
Animal Drugs User Fee Act	.805	.806	.001
Animal Generic Drug User Fee Act	.269	.272	.003
Family Smoking Prevention and Tobacco Control Act	4.301	4.128	-.173
Food and Feed Recall User Fee	.045	.046	.001
Food Reinspection User Fee	.212	.216	.004
Voluntary Qualified Importer Program	.177	.180	.003
Third Party Auditor Program	.025	.025	.000
Outsourcing Facility	.035	.036	.001
<b>GSA Rent</b>	<b>221.661</b>	<b>236.557</b>	<b>14.896</b>
BA	153.119	166.286	13.167
Food Safety [non-add]	71.500	77.648	6.148
Medical Product Safety [non-add]	81.619	88.638	7.019
User Fees	68.542	70.271	1.729
Prescription Drug User Fee Act	36.052	36.412	.360
Medical Devices User Fee Act	8.479	8.564	.085
Generic Drug User Fee	12.975	13.105	.130
Biosimilars User Fee Act	.460	.465	.005
Animal Drug User Fee Act	.856	.857	.001
Animal Generic Drug User Fee Act	.314	.316	.002
Family Smoking Prevention and Tobacco Control Act	8.557	9.686	1.129
Food and Feed Recall User Fee	.076	.077	.001
Food Reinspection User Fee	.362	.369	.007
Voluntary Qualified Importer Program	.302	.308	.006

Activities	FY 2021	FY 2022	
	Final	FY 2022 Final	FY22 Final +/- FY21 Final
Third Party Auditor Program.....	.049	.050	.001
Outsourcing Facility.....	.060	.062	.002
<b>Other Indefinite User Fees.....</b>	<b>56.864</b>	<b>58.001</b>	<b>.529</b>
Color Certification <sup>4</sup> .....	10.469	10.678	-.399
Export Certification.....	4.886	4.983	.097
Priority Review Vouchers.....	13.109	13.372	.263
Over the Counter Monograph.....	28.400	28.968	.568
<b>Buildings &amp; Facilities.....</b>	<b>12.788</b>	<b>12.788</b>	<b>.000</b>
Building & Facilities One-time funding [non-add].....	.000	.000	.000
<b>21st Century Cures.....</b>	<b>70.000</b>	<b>50.000</b>	<b>-20.000</b>
<b>Seafood Safety Studies - GP Sec. 765 (no-Year).....</b>	<b>1.000</b>	<b>.000</b>	<b>-1.000</b>
<b>Totals</b>	<b>.000</b>	<b>.000</b>	<b>.000</b>
Discretionary Budget Authority.....	3,284.216	3,366.933	81.217
<b>Food Safety (BA only) [non-add]/1.....</b>	<b>1,422.566</b>	<b>1,466.394</b>	<b>43.828</b>
Cannabis and Cannabis Derivatives Activities [non-add].....	7.000	7.000	.000
New Era of Smarter Food Safety (including AI and other Emerging Technologies) [non-add].....	7.095	16.095	9.000
Maternal and Infant Health and Nutrition [non-add].....	2.000	13.000	11.000
Emerging Chemical and Toxicological Issues [non-add]/3.....	.000	5.000	5.000
Dietary Supplements [non-add]/3.....	3.000	5.000	2.000
Standards of Identity [non-add].....	3.000	4.500	1.500
Animal Feed Reviews [non-add].....	.000	1.000	1.000
<b>Medical Product Safety (BA only) [non-add]/2.....</b>	<b>1,785.448</b>	<b>1,822.087</b>	<b>36.639</b>
Device Shortages and Supply Chain [non-add].....	.000	5.000	5.000
CVM Medical Product Supply Chain [non-add].....	.000	1.500	1.500
Advancing the Goal of Ending the Opioid Crisis (including International Mail Facilities (IMF) and SUPPORT Act).....	64.500	72.500	8.000
Predictive Toxicology Roadmap [non-add].....	.000	3.000	3.000
Data Modernization and Enhanced Technology Initiative (including Transform Medical Device Safety, Cybersecurity, Review, and Innovation) [non-add].....	38.000	39.000	1.000
Orphan Products Grants Program [non-add].....	2.500	5.000	2.500
Rare Cancer Therapeutics [non-add].....	7.500	8.500	1.000
Foreign Unannounced Human Drug Inspection Pilots [non-add].....	3.500	8.500	5.000
Rare Diseases [non-add].....	10.000	11.500	1.500
BioFilm Regulatory Research [non-add].....	.000	.500	.500
Data Modernization and Enhanced Technologies Enterprise Wide [non-add]/5.....	.000	3.000	3.000
Inspections [non-add]/6.....	.000	10.000	10.000
Pay Costs [non-add].....	.000	17.900	17.900
Office of Minority Health and Health Equity [non-add].....	3.441	8.141	4.700
Office of Laboratory Safety [non-add].....	2.500	4.000	1.500
Office of Chief Counsel [non-add].....	17.051	19.251	2.200
Essential Services [non-add]/5.....	.000	2.000	2.000
Reagan-Udall Foundation Sec. 770(n).....	1.250	1.250	.000
Buildings & Facilities.....	12.788	12.788	.000
21st Century Cures.....	70.000	50.000	-20.000
Seafood Safety Studies - Sec. 765 (no-year).....	1.000	.000	-1.000
User Fees.....	2,765.582	2,885.048	118.858
<b>Total Program Level.....</b>	<b>6,049.798</b>	<b>6,251.981</b>	<b>200.075</b>
<b>Total, Program Level with Reprogrammings.....</b>	<b>6,049.798</b>	<b>6,251.981</b>	<b>200.075</b>

1/ The Operating Plan reflects a reallocation from CFSAN to ORA of \$500,000 through a reprogramming, which was also carried out in FY 2019-2021, to better align food safety resources. The reprogrammed amount is below the statutory notification threshold.

2/ Crosscutting initiatives are included as non-adds, but the increases are reflected within the Food Safety and Medical Product Safety totals.

3/ The Joint Explanatory Statement provided an increase of +\$7.0M for Emerging Chemical and Toxicological Issues, of which \$5.0M is reflected in Emerging Chemical and Toxicological Issues and \$2.0M in Dietary Supplements.

4/ The Operating Plan FY 2022 Final total reflects the sequestered amount for Color Certification. The Enacted amount for Color Certification is \$10.678M and the post-sequestration level is \$10.069M. FDA's total Program Level reflects the post-sequestration amount.

5/ Funding supports FDA's Working Capital Fund.

6/ Reflects funding increase in FY 2022 specific to the Joint Explanatory Statement for a crosscutting initiative related to inspections.