

**Food and Drug Administration
Operating Plan for FY2017**

Dollars in Millions

Activities	FY2016	FY2017	
	FY2016 Final	FY2017 Final	FY17 Final +/- FY16 Final
Foods Program	1,013.914	1,037.089	23.175
Foods, BA 1/	1,002.328	1,025.503	23.175
Foods, User Fees	11.586	11.586	.
Center.....	304.544	311.544	7.
BA.....	303.994	310.994	7.
<i>Food Safety [non-add]</i>	303.994	310.994	7.
<i>Food Safety</i>	303.994	310.994	7.
<i>Other Budget Authority</i>	289.451	288.888	-.563
<i>Cosmetics [non-add]</i>	8.106	8.106	.
<i>National Integrated Food Safety System [non-add]</i>	3.168	6.	2.832
<i>Biotech Education 2/ [non-add]</i>	3.	3.
User Fees.....	.55	.55	.
<i>Food and Feed Recall User Fee</i>243	.243	.
<i>Voluntary Qualified Importer Program</i>243	.243	.
<i>Third Party Auditor Program</i>064	.064	.
Field.....	709.37	725.545	16.175
BA.....	698.334	714.509	16.175
<i>Food Safety [non-add]</i>	698.334	714.509	16.175
<i>Other Budget Authority</i>	655.343	638.695	-16.648
<i>Cosmetics [non-add]</i>	3.414	3.414	.
<i>National Integrated Food Safety System [non-add]</i>	28.756	38.062	9.306
<i>Import Safety [non-add]</i>	10.821	34.338	23.518
User Fees.....	11.036	11.036	.
<i>Food and Feed Recall User Fee</i>	1.	1.	.
<i>Food Reinspection User Fee</i>	4.575	4.575	.
<i>Voluntary Qualified Importer Program</i>	4.32	4.32	.
<i>Third Party Auditor Program</i>	1.141	1.141	.
Human Drugs	1,394.827	1,326.652	-68.175
Human Drugs, BA 3/	491.503	488.628	-2.875
Human Drugs, User Fees	903.324	838.024	-65.3
Center.....	1,189.531	1,125.411	-64.12
BA.....	355.296	352.421	-2.875
<i>Medical Product Safety</i>	359.573	355.996	-3.577
<i>Other Budget Authority</i>	346.08	316.221	-29.859
<i>Antimicrobial Resistance (includes CARB) [non-add]</i>	10.277	10.277	.
<i>Orphan Product Development Grants Program [non-add]</i>	16.535	16.535	.
<i>Over-the-Counter Drugs (includes sunscreen) [non-add]</i>	12.263	12.263	.
<i>Precision Medicine Initiative [non-add]</i>7	.7
User Fees.....	834.235	769.415	-64.82
<i>Prescription Drug User Fee Act</i>	601.643	533.134	-68.509
<i>Generic Drug User Fee</i>	215.867	219.018	3.151
<i>Biosimilars User Fee Act</i>	16.298	16.706	.408
<i>Outsourcing Facility</i>427	.557	.13
Field.....	205.296	204.816	-.48
BA.....	136.207	136.207	.
<i>Medical Product Safety</i>	136.207	136.207	.
User Fees.....	69.089	68.609	-.48
<i>Prescription Drug User Fee Act</i>	12.276	10.878	-1.398
<i>Generic Drug User Fee</i>	55.167	55.973	.806
<i>Biosimilars User Fee Act</i>	1.382	1.416	.034
<i>Outsourcing Facility</i>264	.342	.078

Biologics	354.901	339.618	-15.283
Biologics, BA 4/	215.443	215.443	.
Biologics, User Fees	139.458	124.175	-15.283
Center.....	311.209	296.181	-15.028
BA.....	174.052	174.052	.
<i>Medical Product Safety</i>	175.312	174.052	-1.26
<i>Other Budget Authority</i>	169.89	16.863	-153.027
<i>FDASIA Implementation [non-add]</i>	1.93	1.93	.
<i>Antimicrobial Resistance (includes CARB) [non-add]</i>	3.492	3.492	.
User Fees.....	137.157	122.129	-15.028
<i>Prescription Drug User Fee Act</i>	123.801	109.704	-14.097
<i>Medical Devices User Fee Act</i>	11.475	10.508	-.967
<i>Generic Drug User Fee</i>	1.072	1.088	.016
<i>Biosimilars User Fee Act</i>809	.829	.02
Field.....	43.692	43.437	-.255
BA.....	41.391	41.391	.
<i>Medical Product Safety</i>	41.391	41.391	.
<i>Other Budget Authority</i>	40.286	36.194	-4.092
<i>FDASIA Implementation [non-add]</i>	1.105	1.105	.
User Fees.....	2.301	2.046	-.255
<i>Prescription Drug User Fee Act</i>	2.084	1.847	-.237
<i>Medical Devices User Fee Act</i>217	.199	-.018
Animal Drugs and Feeds	188.632	195.059	6.427
Animal Drugs and Feeds, BA 5/	158.652	162.852	4.2
Animal Drugs and Feeds, User Fees	29.98	32.207	2.227
Center.....	122.508	128.876	6.368
BA.....	94.005	98.205	4.2
<i>Food Safety [non-add]</i>	63.549	64.049	.5
<i>Antimicrobial Resistance (includes CARB) [non-add]</i>	20.296	20.296	.
<i>National Integrated Food Safety System [non-add]</i>	2.	2.5	.5
<i>Medical Product Safety</i>	30.456	34.156	3.7
<i>Supporting Animal Drug and Medical Device Review [non-add]</i>	3.7	3.7
User Fees.....	28.503	30.671	2.168
<i>Animal Drugs User Fee Act</i>	20.125	20.879	.754
<i>Animal Generic Drug User Fee Act</i>	8.378	9.792	1.414
<i>Food and Feed Recall User Fee</i>
Field.....	66.124	66.183	.059
BA.....	64.647	64.647	.
<i>Food Safety [non-add]</i>	61.756	61.756	0
<i>Medical Product Safety</i>	2.891	2.891	.
User Fees.....	1.477	1.536	.059
<i>Animal Drugs User Fee Act</i>411	.427	.016
<i>Animal Generic Drug User Fee Act</i>259	.302	.043
<i>Food Reinspection User Fee</i>807	.807	.
Devices and Radiological Health	450.304	448.197	-2.107
Devices, BA 6/	323.253	329.764	6.511
Devices, User Fees	127.051	118.433	-8.618
Center.....	352.048	348.846	-3.202
BA.....	240.808	246.319	5.511
<i>Medical Product Safety</i>	117.008	110.095	-6.913
<i>Other Budget Authority</i>	238.308	.	-238.308
<i>Antimicrobial Resistance (includes CARB) [non-add]</i>	3.768	3.768	.
<i>Precision Medicine Initiative [non-add]</i>	2.	3.8	1.8
<i>Supporting Animal Drug and Medical Device Review [non-add]</i>711	.711
<i>Pediatric Device Review [non-add] 8/</i>	3.	6.	3.
User Fees.....	111.24	102.527	-8.713
<i>Medical Devices User Fee Act</i>	104.991	96.15	-8.841
<i>Mammography Quality Standards Act</i>	6.249	6.377	.128
Field.....	98.256	99.351	1.095
BA.....	82.445	83.445	1.
<i>Medical Product Safety</i>	82.445	83.445	1.
<i>Other Budget Authority</i>	80.48	.	-80.48
<i>FDASIA Implementation [non-add]</i>	1.965	1.965	.
<i>Medical Device Postmarket Safety [non-add]</i>	1.	1.
User Fees.....	15.811	15.906	.095
<i>Medical Devices User Fee Act</i>	2.199	2.014	-.185
<i>Mammography Quality Standards Act</i>	13.612	13.892	.28

National Center for Toxicological Research.....	63.331	63.331	
BA.....	63.331	63.331	
Food Safety [non-add].....	10.233	10.233	
Other Budget Authority.....	10.053		-10.053
Cosmetics [non-add].....	.18	.18	
Antimicrobial Resistance (includes CARB) [non-add].....	1.805	1.805	
Medical Product Safety.....	53.098	53.098	
Center for Tobacco Products	564.117	596.338	32.221
Tobacco, BA.....			
Tobacco, User Fees.....	564.117	596.338	32.221
Center.....	547.454	581.438	33.984
BA.....			
User Fees.....	547.454	581.438	33.984
Institute of Medicine Agreement	1		-1
Family Smoking Prevention and Tobacco Control Act.....	546.454	581.438	34.984
Field	16.663	14.9	-1.763
BA.....			
User Fees.....	16.663	14.9	-1.763
Family Smoking Prevention and Tobacco Control Act.....	16.663	14.9	-1.763
Other Activities 7J.....	289.562	289.103	-459
BA	181.587	188.662	7.075
Food Safety [non-add].....	77.212	77.212	
Foreign High-Risk Inspections [non-add].....	5	7.5	2.5
Office of the Commissioner.....	48.167	56.178	8.011
Other Budget Authority.....	47.667		-47.667
Food Safety.....	5		-5
Office of Foods and Veterinary Medicine.....	20.841	23.843	3.002
Other Budget Authority.....	17.943		-17.943
Food Safety.....	2.898		-2.898
Office of Medical Products and Tobacco.....	9.626	14.834	5.208
Office of Global Regulatory Operations and Policy.....	18.765	23.564	4.799
Other Budget Authority.....	13.765		-13.765
Office of Operations.....	30.735	38.015	7.28
Other Budget Authority.....	29.835		-29.835
Food Safety.....	9		-9
Office of the Chief Scientist.....	25.943	30.728	4.785
Central.....	27.51		-27.51
OIG Transfer.....			
User Fees.....	107.975	100.441	-7.534
Prescription Drug User Fee Act.....	52.139	46.202	-5.937
Medical Devices User Fee Act.....	6.259	5.732	-.527
Generic Drug User Fee.....	24.69	25.05	.36
Biosimilars User Fee Act.....	1.354	1.388	.034
Animal Drugs User Fee Act.....	.913	.947	.034
Animal Generic Drug User Fee Act.....	.388	.453	.065
Family Smoking Prevention and Tobacco Control Act.....	20.789	19.132	-1.657
Mammography Quality Standards Act.....	.248	.253	.005
Food and Feed Recall User Fee.....	.075	.075	
Food Reinspection User Fee.....	.48	.48	
Voluntary Qualified Importer Program.....	.277	.277	
Third Party Auditor Program.....	.073	.073	
Outsourcing Facility.....	.29	.379	.089
White Oak Consolidation	52.346	46.856	-5.49
BA.....	48.044	43.044	-5
Other Budget Authority.....	43.044		-43.044
Feasibility Report [non-add].....	5		-5
User Fees.....	4.302	3.812	-.49
Prescription Drug User Fee Act.....	4.302	3.812	-.49
Other Rent and Rent-Related.....	119.56	117.147	-2.413
BA.....	73.484	71.943	-1.541
Food Safety [non-add].....	37.078	36.3	-.778
Medical Product Safety.....	36.406	35.643	-.763
Other Budget Authority.....	36.261		-36.261
Precision Medicine Initiative [non-add].....	.145	.145	
User Fees.....	46.076	45.204	-.872
Prescription Drug User Fee Act.....	29.724	26.34	-3.384
Medical Devices User Fee Act.....	4.558	4.174	-.384
Generic Drug User Fee.....	6.862	6.962	.1
Biosimilars User Fee Act.....	.617	.633	.016
Animal Drugs User Fee Act.....	.228	.236	.008
Animal Generic Drug User Fee Act.....	.097	.113	.016
Family Smoking Prevention and Tobacco Control Act.....	3.502	6.25	2.748
Food and Feed Recall User Fee.....	.043	.043	
Food Reinspection User Fee.....	.204	.204	
Voluntary Qualified Importer Program.....	.17	.17	
Third Party Auditor Program.....	.045	.045	
Outsourcing Facility.....	.026	.034	.008

GSA Rent	224.105	231.293	7.188
BA /3.....	161.683	170.208	8.525
Food Safety [non-add].....	67.5	79.477	11.977
Medical Product Safety.....	94.183	90.731	-3.452
Other Budget Authority.....	.	.	.
Precision Medicine Initiative [non-add].....	.247	.247	.
User Fees.....	62.422	61.931	-.491
Prescription Drug User Fee Act.....	25.512	22.607	-2.905
Medical Devices User Fee Act.....	7.978	7.306	-.672
Generic Drug User Fee.....	14.705	14.92	.215
Biosimilars User Fee Act.....	1.08	1.107	.027
Animal Drug User Fee Act.....	1.141	1.184	.043
Animal Generic Drug User Fee Act.....	.583	.681	.098
Family Smoking Prevention and Tobacco Control Act.....	10.592	13.28	2.688
Food and Feed Recall User Fee.....	.073	.073	.
Food Reinspection User Fee.....	.348	.348	.
Voluntary Qualified Importer Program.....	.29	.29	.
Third Party Auditor Program.....	.077	.077	.
Outsourcing Facility.....	.043	.058	.015
Other Indefinite User Fees	20.9	22.064	1.165
Color Certification.....	8.518	9.682	1.165
Export Certification.....	4.696	4.696	.
Priority Review Vouchers Pediatric Disease.....	7.686	7.686	.
Buildings & Facilities	8.788	11.788	3.
21st Century CURES	20.	20.
MCMi	10.	10.
Totals	0	0	0
Discretionary Budget Authority.....	2,728.096	2,799.666	71.57
Food Safety [non-add].....	1,319.656	1,354.53	34.874
Cosmetics [non-add].....	11.7	11.7	.
Antimicrobial Resistance (includes CARB) [non-add].....	39.638	39.638	.
High Risk Inspections [non-add].....	5.	7.5	2.5
Precision Medicine Initiative [non-add].....	2.392	4.892	2.5
FDASIA Implementation [non-add].....	5.	5.	.
Over-the-Counter Drugs (includes sunscreen) [non-add].....	12.263	12.263	.
Orphan Product Development Grants Program [non-add].....	16.535	16.535	.
White Oak Feasibility [non-add].....	5.	.	-5.
National Integrated Food Safety System [non-add].....	38.999	50.762	11.763
Import Safety [non-add].....	15.999	42.413	26.414
Biotech Education [non-add].....	.	3.	3.
Supporting Animal Drug and Medical Device Review [non-add].....	.	4.411	4.411
Pediatric Device Review [non-add].....	3.	6.	3.
Buildings & Facilities.....	8.788	11.788	3.
21st Century CURES.....	.	20.	20.
MCMi.....	.	10.	10.
User Fees.....	2,017.191	1,954.215	-62.975
Total Program Level	4,745.287	4,753.881	8.595
<i>Total, Program Level with Reprogrammings</i>	4,745.287	4,753.881	8.595

1/The Operating Plan reflects a previously notified transfer in FY 2017 of \$3.575 million from the Human Drugs Program to the Office of Medical Products and Tobacco within Headquarters.

2/The Medical Device Postmarket Safety amount reflects an increase above surveillance activities FDA already carries out using base resources.

3/The Omnibus provides \$170 million in budget authority for GSA Rent. This reflects a reduction of \$6.5 million relative to FY 2016 Enacted level of \$177 million.

*The FY 2017 Omnibus provides FDA the authority to collect fees under the Medical Countermeasure Priority Review Voucher program. FDA continues to develop estimates for the fee levels anticipated to be collected in FY 2017.

**The FY 2017 total for the National Integrated Food Safety System and Import Safety reflect the total amount of increases provided by Congress in FY 2016 and FY 2017 for these activities. The allocation of the FY 2017 totals may change as final grant, cooperative agreement, and contract awards are determined, and other administrative actions are determined. The FY 2016 Final Column reflects totals for National Integrated Food Safety System and Import Safety different than originally planned due to the timing of receiving the additional resources and being able to bring staff onboard.