

Food and Drug Administration Operating Plan for FY2018 <i>Dollars in Millions</i>			
Activities	FY2017	FY2018	
	FY2017 Final	FY2018 Final	FY18 Final +/- FY17 Final
Foods Program 1/	1,037.089	1,052.486	15.397
Foods, BA	1,025.503	1,041.615	16.112
Foods, User Fees	11.586	10.871	-.715
Center.....	311.544	317.438	5.894
BA.....	310.994	316.606	5.612
<i>Food Safety [non-add]</i>	310.994	316.606	5.612
<i>Food Safety</i>	310.994	316.106	5.112
<i>Other Budget Authority 2/</i>	288.888	297.7	8.812
<i>Cosmetics [non-add]</i>	8.106	8.106	.
<i>Office of Cosmetics and Colors [non-add]</i>	7.2	7.2	.
<i>National Integrated Food Safety System [non-add]</i>	6.	6.	.
<i>Biotech Education [non-add]</i>	3.	1.5	-1.5
<i>Botanical Drugs and Dietary Supplements Interaction [non-add]</i>5	.5
<i>Seafood Decomposition Study [non-add]</i>	2.8	2.8
User Fees.....	.55	.832	.282
<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	.346	.282
Field.....	725.545	735.048	9.503
BA.....	714.509	725.009	10.5
<i>Food Safety [non-add]</i>	714.509	725.009	10.5
<i>Other Budget Authority</i>	638.695	673.033	34.338
<i>Cosmetics [non-add]</i>	3.414	3.414	.
<i>National Integrated Food Safety System [non-add] 6/</i>	38.062	48.562	10.5
<i>National Integrated Food Safety System (Farm Data) [non-add]</i>	5.	5.	.
User Fees.....	11.036	10.039	-.997
<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	.144	-.997
Human Drugs	1,326.652	1,618.814	292.162
Human Drugs, BA	488.628	495.603	6.975
Human Drugs, User Fees	838.024	1,123.211	285.187
Center.....	1,125.411	1,419.991	294.58
BA 4/.....	352.421	359.396	6.975
<i>Medical Product Safety [non-add]</i>	355.996	359.396	3.4
<i>Other Budget Authority</i>	329.951	326.376	-3.575
<i>Antimicrobial Resistance (Includes CARB) [non-add]</i>	10.277	10.277	.
<i>Over-the-Counter Drugs (Includes sunscreen) [non-add]</i>	12.263	12.263	.
<i>Precision Medicine Initiative [non-add]</i>7	.7	.
<i>Oncology Center of Excellence Transfer [non-add]</i>	-3.575	.	3.575
<i>Botanical Drugs and Dietary Supplements Interaction [non-add]</i>5	.5
<i>Critical Path Initiatives [non-add]</i>	1.8	2.2	.4
<i>Compounding [non-add] 3/</i>279	2.779	2.5
<i>Medical Counter-measures [non-add]</i>	6.02	6.02	.
<i>Counterfeit Drugs [non-add]</i>36	.36	.
User Fees.....	769.415	1,060.595	291.18
<i>Prescription Drug User Fee Act</i>	533.134	654.835	121.701
<i>Generic Drug User Fee</i>	219.018	369.065	150.047
<i>Biosimilars User Fee Act</i>	16.706	36.116	19.41
<i>Outsourcing Facility</i>557	.579	.022
Field.....	204.816	198.823	-5.993
BA.....	136.207	136.207	.
<i>Medical Product Safety [non-add]</i>	136.207	136.207	.
<i>Counterfeit Drugs [non-add]</i>	4.185	4.185	.
User Fees.....	68.609	62.616	-5.993
<i>Prescription Drug User Fee Act</i>	10.878	8.038	-2.84
<i>Generic Drug User Fee</i>	55.973	53.104	-2.869
<i>Biosimilars User Fee Act</i>	1.416	1.12	-.296
<i>Outsourcing Facility</i>	-.342	-.354	-.012

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Biologics	339.618	359.614	19.996
Biologics, BA /.....	215.443	215.443	.
Biologics, User Fees	124.175	144.171	19.996
Center.....	296.181	316.625	20.444
BA.....	174.052	174.052	.
Medical Product Safety [non-add].....	174.052	174.052	.
Other Budget Authority.....	166.235	166.235	.
FDASIA Implementation [non-add].....	1.93	1.93	.
Antimicrobial Resistance (includes CARB) [non-add].....	3.492	3.492	.
Medical Counter-measures [non-add].....	2.395	2.395	.
User Fees.....	122.129	142.573	20.444
Prescription Drug User Fee Act.....	109.704	127.961	18.257
Medical Devices User Fee Act.....	10.508	13.405	2.897
Generic Drug User Fee.....	1.088	1.032	-.056
Biosimilars User Fee Act.....	.829	.175	-.654
Field.....	43.437	42.989	-.448
BA.....	41.391	41.391	.
Medical Product Safety [non-add].....	41.391	41.391	.
Other Budget Authority.....	36.194	40.286	4.092
FDASIA Implementation [non-add].....	1.105	1.105	.
User Fees.....	2.046	1.598	-.448
Prescription Drug User Fee Act.....	1.847	1.397	-.45
Medical Devices User Fee Act.....	.199	.201	.002
Animal Drugs and Feeds	195.059	198.171	3.112
Animal Drugs and Feeds, BA /.....	162.852	172.552	9.7
Animal Drugs and Feeds, User Fees	32.207	25.619	-6.588
Center.....	128.876	132.175	3.299
BA.....	98.205	107.905	9.7
Food Safety [non-add].....	64.049	64.049	.
Antimicrobial Resistance (includes CARB) [non-add] 7/.....	20.296	20.296	.
National Integrated Food Safety System [non-add].....	2.5	2.5	.
Medical Product Safety [non-add].....	34.156	43.856	9.7
Supporting Animal Drug and Medical Device Review [non-add] 5/.....	3.7	13.4	9.7
User Fees.....	30.671	24.27	-6.401
Animal Drugs User Fee Act.....	20.879	15.89	-4.989
Animal Generic Drug User Fee Act.....	9.792	8.268	-1.524
Third Party Auditor Program.....	.	.112	.112
Field.....	66.183	65.996	-.187
BA.....	64.647	64.647	.
Food Safety [non-add].....	61.756	61.756	.
Medical Product Safety [non-add].....	2.891	2.891	.
Import Safety [non-add].....	3.075	3.075	.
National Integrated Food Safety System [non-add].....	4.2	4.2	.
User Fees.....	1.536	1.349	-.187
Animal Drugs User Fee Act.....	.427	.307	-.12
Animal Generic Drug User Fee Act.....	.302	.235	-.067
Food Reinspection User Fee.....	.807	.807	.
Devices and Radiological Health	448.197	507.466	59.269
Devices, BA /.....	329.764	330.064	.3
Devices, User Fees	118.433	177.402	58.969
Center.....	348.846	407.752	58.906
BA.....	246.319	246.319	.
Medical Product Safety [non-add].....	246.319	246.319	.
Antimicrobial Resistance (includes CARB) [non-add].....	3.768	3.768	.
Precision Medicine Initiative [non-add].....	3.8	3.8	.
Supporting Animal Drug and Medical Device Review [non-add].....	.711	.711	.
Pediatric Device Review [non-add].....	6.	6.	.
Medical Counter-measures [non-add].....	4.001	4.001	.
User Fees.....	102.527	161.433	58.906
Prescription Drug User Fee Act.....	.	1.237	1.237
Medical Devices User Fee Act.....	96.15	153.819	57.669
Mammography Quality Standards Act.....	6.377	6.377	.
Field.....	99.351	99.714	.363
BA.....	83.445	83.745	.3
Medical Product Safety [non-add].....	83.445	83.745	.3
FDASIA Implementation [non-add].....	1.965	1.965	.
Medical Device Postmarket Safety/shipment Delays [non-add].....	1.	1.3	.3
User Fees.....	15.906	15.969	.063
Medical Devices User Fee Act.....	2.014	2.077	.063
Mammography Quality Standards Act.....	13.892	13.892	.

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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 [non-add].....	53.098	53.098	.
Antimicrobial Resistance (includes CARB) [non-add].....	1.805	1.805	.
Center for Tobacco Products	596.338	625.646	29.308
Tobacco, BA.....	.	.	.
Tobacco, User Fees.....	596.338	625.646	29.308
Center.....	581.438	611.096	29.658
BA.....	.	.	.
User Fees.....	581.438	611.096	29.658
Family Smoking Prevention and Tobacco Control Act.....	581.438	611.096	29.658
Field.....	14.9	14.55	-.35
BA.....	.	.	.
User Fees.....	14.9	14.55	-.35
Family Smoking Prevention and Tobacco Control Act.....	14.9	14.55	-.35
Other Activities 2/.....	289.103	335.847	46.744
BA.....	187.162	194.775	7.613
Food Safety [non-add].....	77.212	73.4	-3.812
Medical Product Safety [non-add].....	88.875	103.875	15.
Foreign High-Risk Inspections [non-add].....	7.5	7.5	.
Medical Counter-measures [non-add].....	10.312	10.312	.
Counterfeit Drugs [non-add].....	.275	.275	.
Office of the Commissioner.....	56.178	60.103	3.925
Food Safety.....	.	.	.
Office of Foods and Veterinary Medicine.....	23.843	16.106	-7.737
Food Safety.....	.	.	.
Office of Medical Products and Tobacco.....	14.834	11.259	-3.575
Office of Global Regulatory Operations and Policy.....	23.564	23.564	.
Office of Operations.....	38.015	38.015	.
Food Safety.....	.	.	.
Office of the Chief Scientist.....	30.728	30.728	.
Central.....	.	.	.
OIG Transfer.....	.	.	.
Oncology Center of Excellence 4/.....	3.575	15.	11.425
User Fees.....	100.441	141.072	40.631
Prescription Drug User Fee Act.....	46.202	56.236	10.034
Medical Devices User Fee Act.....	5.732	10.373	4.641
Generic Drug User Fee.....	25.05	44.859	19.809
Biosimilars User Fee Act.....	1.388	1.659	.271
Animal Drugs User Fee Act.....	.947	.654	-.293
Animal Generic Drug User Fee Act.....	.453	.267	-.186
Family Smoking Prevention and Tobacco Control Act.....	19.132	25.508	6.376
Mammography Quality Standards Act.....	.253	.253	.
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	.039	-.034
Outsourcing Facility.....	.379	.392	.013
White Oak Consolidation	46.856	50.559	3.703
BA.....	43.044	43.044	.
User Fees.....	3.812	7.515	3.703
Prescription Drug User Fee Act.....	3.812	3.597	-.215
Family Smoking Prevention and Tobacco Control Act.....	.	3.918	3.918

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Activities	FY2017	FY2018	
	FY2017 Final	FY2018 Final	FY18 Final +/- FY17 Final
Other Rent and Rent-Related.....	117.147	121.919	4.772
BA.....	71.943	71.943	.
Food Safety [non-add].....	36.3	36.3	.
Medical Product Safety [non-add].....	35.643	35.643	.
Precision Medicine Initiative [non-add].....	.145	.145	.
Medical Counter-measures [non-add].....	.936	.936	.
User Fees.....	45.204	49.976	4.772
Prescription Drug User Fee Act.....	26.34	24.672	-1.668
Medical Devices User Fee Act.....	4.174	5.187	1.013
Generic Drug User Fee.....	6.962	12.946	5.984
Biosimilars User Fee Act.....	.633	.805	.172
Animal Drugs User Fee Act.....	.236	.72	.484
Animal Generic Drug User Fee Act.....	.113	.273	.16
Family Smoking Prevention and Tobacco Control Act.....	6.25	4.898	-1.352
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	.024	-.021
Outsourcing Facility.....	.034	.034	.
GSA Rent.....	232.139	238.487	6.348
BA.....	170.208	170.208	.
Food Safety [non-add].....	79.477	79.477	.
Medical Product Safety [non-add].....	90.731	90.731	.
Other Budget Authority.....	.	.	.
Precision Medicine Initiative [non-add].....	.247	.247	.
Medical Counter-measures [non-add].....	.888	.888	.
User Fees.....	61.931	68.279	6.348
Prescription Drug User Fee Act.....	22.607	33.373	10.766
Medical Devices User Fee Act.....	7.306	8.229	.923
Generic Drug User Fee.....	14.92	12.594	-2.326
Biosimilars User Fee Act.....	1.107	.339	-.768
Animal Drug User Fee Act.....	1.184	.522	-.662
Animal Generic Drug User Fee Act.....	.681	.376	-.305
Family Smoking Prevention and Tobacco Control Act.....	13.28	12.03	-1.25
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	.047	-.03
Outsourcing Facility.....	.058	.058	.
Other Indefinite User Fees.....	22.064	22.507	.443
Color Certification.....	9.682	10.125	.443
Export Certification.....	4.696	4.696	.
Priority Review Vouchers Pediatric Disease.....	7.686	7.686	.
Buildings & Facilities.....	11.788	11.788	.
21st Century CURES.....	20.	60.	40.
Emerging Public Health Threat.....	10.	.	-10.
Opioids.....	.	94.	94.
Totals	0	0	0
Discretionary Budget Authority.....	2,799.666	2,964.366	164.7
Food Safety (BA only) [non-add].....	1,354.53	1,366.83	12.3
Cosmetics [non-add].....	11.7	11.7	.
National Integrated Food Safety System [non-add].....	50.762	61.262	10.5
Antimicrobial Resistance (includes CARB) [non-add].....	39.638	39.638	.
Medical Product Safety (BA only) [non-add].....	1,372.804	1,525.204	152.4
High Risk Inspections [non-add].....	7.5	7.5	.
Precision Medicine Initiative [non-add].....	4.892	4.892	.
FDASIA Implementation [non-add].....	5.	5.	.
Over-the-Counter Drugs (includes sunscreen) [non-add].....	12.263	12.263	.
Biotech Education [non-add].....	3.	1.5	-1.5
Supporting Animal Drug and Medical Device Review [non-add].....	4.411	14.111	9.7
Pediatric Device Review [non-add].....	6.	6.	.
Medical Device Postmarket Safety/Shipments Delays [non-add].....	1.	1.3	.3
Botanical Drugs and Dietary Supplements Interaction.....	.	1.	1.
Seafood Decomposition Study.....	.	2.8	2.8
Critical Path Initiatives.....	1.8	2.2	.4
Oncology Center of Excellence.....	3.575	15.	11.425
Compounding.....	.279	2.779	2.5
Counterfeit Drugs [non-add].....	4.82	4.82	.
Buildings & Facilities.....	11.788	11.788	.
21st Century CURES.....	20.	60.	40.
Continuous manufacturing initiative (non-add).....	1.	10.	9.
Opioids.....	.	94.	94.
User Fees.....	1,954.215	2,396.269	442.054
Total Program Level.....	4,753.881	5,360.635	606.754
Total, Program Level with Reprogrammings.....	4,753.881	5,360.635	606.754

1/The Foods program totals for center and field are not reflected correctly in the explanatory statement; the correction is reflected in the Operating Plan (+\$.5 million center total, -\$0.5 million field total).

2/FDA has updated the FDA HQ Office of Foods and Veterinary Medicine and Office of the Commissioner PPAs consistent with the reorganization package submitted to the Hill in Dec 2017. The explanatory statement applied the net change of the reorganization to the OFVM PPA, but the OC PPA is also impacted by this reorganization. In addition, the net impact (\$3.812 million) of the reorganization to CFSAN is reflected consistent with the FY 2018 Omnibus and no updates were required to the CFSAN amounts.

3/The Drugs total includes a one-time increase of \$2.5 million for compounding (Bulks List).

4/The FY 2017 Final reflects a transfer of \$3.575 million from the Human Drugs Program to FDA Headquarters to establish the Oncology Center of Excellence (OCE). The FY 2018 column reflects \$15 million directly for OCE. As a result, FDA does not plan to continue the transfer of funding from the Human Drugs Program to OCE in FY 2018.

5/Reflects an increase of \$9.7 million above the FY 2017 final level will be dedicated to only animal drugs review.

6/Reflects an increase of \$10.5 million above the FY 2017 final level to support produce safety cooperative agreements with states.

7/The Center for Veterinary Medicine Antimicrobial Resistance total includes \$10.8 million in FYs 2017 and 2018 for the National Antimicrobial Resistance Monitoring System (NARMS).

*The FY 2018 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 2018.

***The FY 2018 Omnibus provides \$94 million for the FDA to expand its efforts related to addressing the Opioids crisis.

***The Operating Plan does not include \$7.6 million in one-time, no year funding for facilities and related costs included in the Further Additional Supplemental Appropriations for Disaster Relief and Requirement Act, 2018.