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The Food and Drug Administration (FDA) Budget: Fact Sheet

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Summary

The Food and Drug Administration (FDA) regulates the safety of foods (including dietary supplements), cosmetics, and radiation-emitting products; the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices; and public health aspects of tobacco products. Seven centers within FDA represent the broad program areas for which the agency has responsibility: the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the National Center for Toxicological Research (NCTR), and the Center for Tobacco Products (CTP). Several other offices have agency-wide responsibilities.

FDA's budget has two funding streams: annual appropriations (i.e., discretionary budget authority, or BA) and industry user fees. In FDA's annual appropriation, Congress sets both the total amount of appropriated funds and the amount of user fees that the agency is authorized to collect and obligate for that fiscal year.

Between FY2012 and FY2016, FDA's total program level increased from $3.832 billion to $4.745 billion. Although congressionally appropriated funding increased by 9% over that time period, user fee revenue increased more than 50%. The President's FY2017 budget request was for a *total program level* of $4.826 billion, an increase of $81 million (+2%) over the FY2016 enacted appropriation of $4.745 billion. Both the House and Senate Appropriations Committees have reported their FY2017 Agriculture appropriations bills (H.R. 5054, S. 2956). This report will be updated with information on FDA funding for FY2017 once legislative action on appropriations for the new fiscal year is completed.

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FDA Overview

The Food and Drug Administration (FDA) regulates the safety of foods (including dietary supplements), cosmetics, and radiation-emitting products; the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices; and public health aspects of tobacco products.[1] Although FDA has been a part of the Department of Health and Human Services (HHS) since 1940, the Committees on Appropriations do not consider FDA within the rest of HHS under their Subcommittees on Labor, Health and Human Services, and Education, and Related Agencies. Jurisdiction over FDA's budget remains with the Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, reflecting FDA's beginnings as part of the Department of Agriculture.

FDA Centers

Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Drug Evaluation and Research (CDER)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
National Center for Toxicological Research (NCTR)
Center for Tobacco Products (CTP)

Seven centers within FDA represent the broad program areas for which the agency has responsibility, along with various other offices that have agency-wide responsibilities. **Table 1** is organized in a format consistent with the Administration's budget request as presented in the FDA Congressional Justification, as well as with the materials of the Committees on Appropriations—each program area includes funding (FY2012-FY2016, as well as the FY2017 President's request) designated for the responsible FDA center (e.g., CDER or CFSAN) and the portion of funding for the FDA-wide Office of Regulatory Affairs that is committed to that program area.

Funding Sources

FDA's *total program level*, the amount that FDA can spend, is composed of *direct appropriations* (also referred to as budget authority) and *user fees*.[2] In FDA's annual appropriation, Congress sets both the amount of appropriated funds and the amount of user fees that the agency is authorized to collect and obligate for that fiscal year. Appropriated funds are largely for the Salaries and Expenses account, with a much smaller amount for the Buildings and Facilities account. The different user fees contribute only to the Salaries and Expenses account.

The largest and oldest FDA user fee that is linked to a specific program was first authorized by the Prescription Drug User Fee Act (PDUFA, P.L. 102-571) in 1992. After PDUFA, Congress added user fee authorities regarding medical devices, animal drugs, animal generic drugs, tobacco products, priority review, food reinspection, food recall, voluntary qualified food importer, generic drugs, biosimilars, and, most recently, outsourcing facilities (related to drug compounding) and some wholesale distributors and third-party logistics providers (related to pharmaceutical supply chain security).[3] Each of the medical product fee authorities requires

[1] Several CRS reports have information on FDA authority and activities: CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, and CRS Report R42130, *FDA Regulation of Medical Devices*.

[2] Beginning with the Prescription Drug User Fee Act (PDUFA, P.L. 102-571) in 1992, Congress has authorized FDA to collect fees from industry sponsors of certain FDA-regulated products and to use the revenue to support statutorily defined activities, such as the review of product marketing applications.

[3] CRS Report R42366, *Prescription Drug User Fee Act (PDUFA): 2012 Reauthorization as PDUFA V*, by (name redacted) ; CRS Report R42508, *The FDA Medical Device User Fee Program*, by (name redacted) ; CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*, coordinated by (name redacted) ; CRS Report R42680, *The* (continued...)

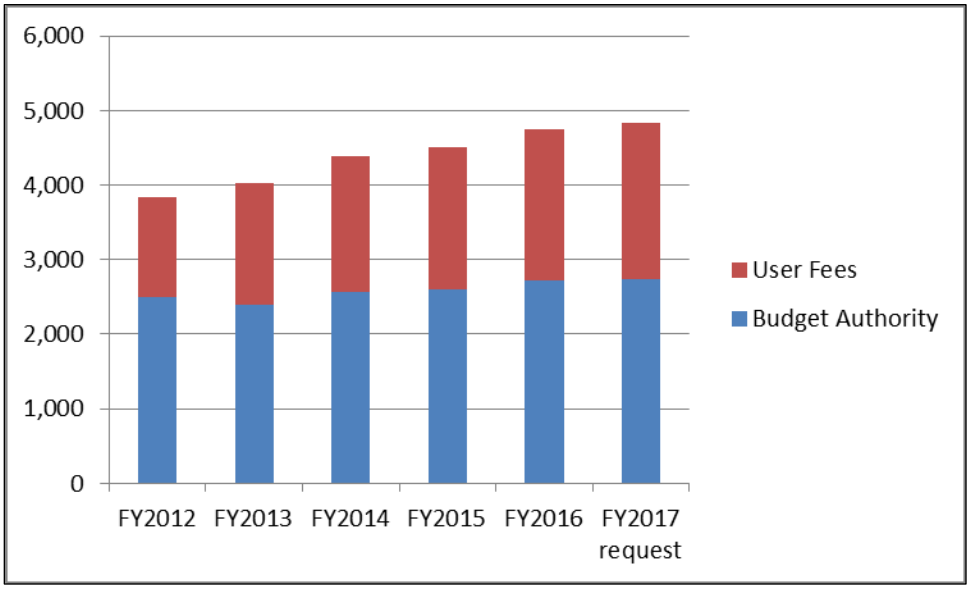
reauthorization every five years. Several indefinite authorities apply to fees for mammography inspection, color additive certification, export certification, and priority review vouchers.

FDA Recent Funding History and the FY2017 Request

Between FY2012 and FY2016, FDA's *total program level* increased from $3.832 billion to $4.745 billion. Although congressionally appropriated funding increased by 9% over that time period, user fee revenue increased more than 50%. In FY2016, user fees account for 42% of FDA's total program level; in the FY2017 President's budget request, authorized user fees account for 43% of the request.

Figure 1. FDA Budget, by Source, FY2012-FY2017

(in millions of dollars)



Sources: FY2012 amounts are from the Sequestration Operating Plan. FY2013 and FY2014 amounts are from the FDA FY2014 Operating Plan. FY2013 figures reflect sequestration. The enacted FY2015 amounts are from the FDA FY2015 Operating Plan, and FY2016 amounts are from the FY2016 enacted appropriations bill (P.L. 114-113). The President's FY2017 Request amount is from the FY2017 FDA Congressional Justification.

The President's FY2017 budget request was for a *total program level* of $4.826 billion, an increase of $81 million (+2%) over the FY2016 enacted appropriation of $4.745 billion.[4] The FY2017 President's request includes $2.743 billion in *direct appropriations*—an increase of $15 million (+0.5%) over the FY2016 enacted level of $2.728 billion. *For user fees,* the FY2017 President's request was for $2.084 billion (an increase of $67 million or 3% over the enacted FY2016 amount of $2.017 billion) in fees to be collected through authorized programs to support specified agency activities regarding prescription drugs, medical devices, animal drugs, animal generic drugs, tobacco products, generic human drugs, biosimilars, mammography quality, color

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Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144), coordinated by (name redacted), and CRS Report R43290, *The Proposed Drug Quality and Security Act (H.R. 3204)*, by (name redacted)

[4] Note that the total program level of $4.826 billion does not include the $202 million in proposed user fees or the $75 million in new mandatory resources to support the Cancer Moonshot Initiative.

certification, export certification, food reinspection, food recall, the voluntary qualified importer program, outsourcing facilities, priority review vouchers, and third-party auditors.[5] In addition to the $2.084 billion in user fees from currently authorized programs, the President had requested $202 million in as yet unauthorized fees to support international courier, food establishment registration and inspection, export certification, food imports, cosmetics, and food contact notification activities. With those proposed fees, the President's total user fee request was $2.286 billion, bringing the program level request to $5.029 billion.

Not included in any of these totals is $75 million in new mandatory resources to support the Cancer Moonshot Initiative.[6]

Both the House and Senate Appropriations Committees have reported their FY2017 Agriculture appropriations bills (H.R. 5054, S. 2956). The FY2017 House-reported bill, H.R. 5054, would provide a *total program level* of $4.824 billion, including $2.766 billion in *direct appropriations* and $2.058 in authorized *user fees*. The FY2017 Senate-reported bill, S. 2956, would provide a *total program level* of $4.854 billion, including $2.772 in *direct appropriations* and $2.083 billion in authorized *user fees*. Neither appropriations committee's recommendations included any proposed user fees. In addition to comments on specific amounts of funding, the House and Senate Committees on Appropriations lay out in the reports that accompanied their respectively reported bills their concerns with specific FDA activities, and provide various directives and encouragements to the agency. While directions and suggestions in the committee reports do not have statutory stature, they convey to the agency the concerns of committees that determine future appropriations.[7]

[5] Those who speak of FDA policy often use acronyms for the various user fee authorizing acts: Prescription Drug User Fee Act or Amendments (PDUFA), Medical Device User Fee Act or Amendments (MDUFA), Animal Drug User Fee Program (ADUFA), Animal Generic Drug User Fee Program (AGDUFA), Generic Drug User Fee Amendments (GDUFA), Biosimilar User Fee Act (BSUFA), and the Mammography Quality Standards Act (MQSA). Acronyms for others have not caught on: color certification, export certification, tobacco (from the Family Smoking Prevention and Tobacco Control Act), and food reinspection and food recall (both authorized by the FDA Food Safety Modernization Act [FMSA]). Several CRS reports describe FDA user fee programs. See, for example, CRS Report R42366, *Prescription Drug User Fee Act (PDUFA): 2012 Reauthorization as PDUFA V*, and CRS Report R42508, *The FDA Medical Device User Fee Program*.

[6] For additional information about the Vice President's Cancer Moonshot, see page 12 of the FDA FY2017 Justification of Estimates for Appropriations Committees, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM485237.pdf.

[7] Topics addressed in the FY2017 committee reports, by program area, follow. *Foods:* Artisanal Cheese, Center for Safety and Nutrition Centers of Excellence, Cosmetics, Cotton Ginning, Crop Biotechnology & Biotech Ingredients, Date Labels on Food, Donor Milk Supply, FDA Food Mission, FDA Partnerships under FSMA, Food Contact Notification User Fees, Food Packaging, Food Traceability, Funding for Food Safety, Laboratories Near High Volume Ports, Listeriosis, Local Port Cooperation, Medical Foods, Menu Labeling, Nutrient Content Claims, Nutrition Facts Label, Office of Cosmetics and Colors, Olive Oil, Packaged Ice, Private Accredited Laboratories, Proprietary Information, Protecting Proprietary Information, Ready-to-Eat Foods, Seafood Advisory, Shrimp Imports, Sodium Guidance, Spent Grains, State Inspections, Staffing at Land Ports of Entry, and Vibrio. *Human Drugs:* Active Pharmaceutical Ingredients, Antibiotics, Atypical Actives, Compassionate Use, Continued FDA Approval of Drug Safety Labeling, Drug Compounding, Drug Compounding Inspections, Drug Compounding of Allergen Extracts, Drug Shortages, Drug Vial Sizes, Duchenne Muscular Dystrophy, Experimental Drugs for Terminally-Ill Patients, Genomic Editing, Medical Gases, Medical Gas Rulemaking, Opioid Abuse, Opioid Overdose Prevention, Over-the-Counter (OTC) Drugs, OTC Monograph Resources, Patient Focused Drug Development Initiative, Pharmacy Compounding, Prescription Drug Labeling Inserts, Sunscreen Ingredients, and Surrogate Endpoints. *Biologics:* Biological Products, Biosimilars, and Blood Donor Policies. *Animal Drugs and Feeds*: Animal Drug Compounding, National Antimicrobial Resistance Monitoring System, and Pet Food Imports. *Devices:* FDA and CMS Parallel Review Pilot, Indoor Tanning Devices, Mammography Exam Reports, Mammography Quality Standards Act, Laboratory Developed Tests, Medical Devices, Medical Device Facility Inspections, Medical Device Performance, Pediatric Devices, and Pediatric Device Consortia Grants. *Medical Products:* Diabetes, Emerging Public Health Threat Funding, Human Tissue Models (continued...)

The human drugs program comprises the largest portion of FDA's budget (29% in FY2016), followed by the foods program (21% in FY2016), and the tobacco program (12% in FY2016). **Table 1** displays, by program area, the budget authority (direct appropriations), user fees, and total program levels for FDA in previous years: FY2012 (as calculated in the sequestration operating plan), FY2013 and FY2014 (as calculated by the 2014 operating plan), FY2015 (as calculated by the 2015 operating plan), FY2016 (as enacted in P.L. 114-113), and the FY2017 President's budget request.

Consistent with the Administration and congressional committee formats, each program area in **Table 1** includes funding designated for the responsible FDA center (e.g., CDER or CFSAN) and the portion of effort budgeted for the agency-wide Office of Regulatory Affairs to commit to that area. It also apportions user fee revenue across the program areas as indicated in the Administration's request (e.g., 90% of the animal drug user fee revenue is designated for the animal drugs and feeds program, with the rest going to the categories of headquarters and Office of the Commissioner, General Services Administration [GSA] rent, and other rent and rent-related activities).

Table 1. Food and Drug Administration (FDA) Appropriations

(dollars in millions)

Program Area	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 Req.
Foods (CFSAN)	**883**	**814**	**900**	**914**	**999**	**1,024**
BA	866	797	883	903	987	1,013
Fees	17	17	17	10	12	12
Human drugs (CDER)	**979**	**1,187**	**1,289**	**1,339**	**1,395**	**1,408**
BA	478	439	466	482	492	492
Fees	501	748	823	856	903	916
Biologics (CBER)	**329**	**308**	**338**	**344**	**355**	**360**
BA	212	195	211	211	215	215
Fees	117	113	127	133	139	145
Animal drugs and feeds (CVM)	**166**	**155**	**173**	**175**	**189**	**193**
BA	138	126	142	148	159	162
Fees	28	29	32	27	30	31
Devices and radiological health (CDRH)	**376**	**384**	**428**	**440**	**450**	**460**
BA	323	296	321	321	323	326
Fees	53	88	107	119	127	134
Tobacco products (CTP)	**455**	**459**	**501**	**532**	**564**	**596**

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Including 3D Models, In Silico Clinical Trials, In Vitro Clinical Trials, Medical Countermeasures, and Medical Product Safety Funding. *Tobacco Products:* Harm Reduction and Premium Cigars. *Toxicological Research:* Nanotechnology. *FDA-wide:* Centers of Excellence in Regulatory Science and Innovation, Federal Employee Conduct, Foreign High Risk Inspections, Late Reports, President's Budget Submission to Congress, Oversight Activities, Public Disclosure, Scientific Integrity, User Fee Collections/Obligations, and White Oak Expansion.

Program Area	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017 Req.
BA	—	—	—	—	—	—
Fees	455	459	501	532	564	596
Toxicological research (NCTR)	**60**	**55**	**62**	**63**	**63**	**60**
BA	60	55	62	63	63	60
Fees	—	—	—	—	—	—
Headquarters/Commissioner's Office	**223**	**251**	**275**	**277**	**290**[a]	**286**
BA	154	160	172	173	182	178
Fees	69	91	103	104	108	108
GSA rent	**205**	**199**	**220**	**228**	**239**	**236**
BA	161	150	162	169	177	170
Fees	45	49	58	60	62	66
Other rent, rent-related activities[b]	**132**	**157**	**178**	**163**	**172**	**169**
BA	106	118	133	116	122	115
Fees	26	40	46	48	50	54
Export, color certification[c]	**11**	**12**	**12**	**13**	**13**	**15**
BA	—	—	—	—	—	—
Fees	11	12	12	13	13	15
Priority review voucher	**5**	**5**	**0**	**8**	**8**	**8**
BA	—	—	—	—	—	—
Fees	5	5	0	8	8	8
Food and drug safety[d]	—	**46**	**0**	**0**	**0**	**0**
BA	—	46	0	0	0	0
Fees	—	0	0	0	0	0
Buildings & Facilities	**9**	**5**	**9**	**9**	**9**	**12**
BA	9	5	9	9	9	12
Fees	—	—	—	—	—	—
Total Budget Authority	**2,506**	**2,386**	**2,561**	**2,596**[e]	**2,728**	**2,743**
Total User Fees	**1,326**	**1,645**	**1,826**	**1,909**[f]	**2,017**[g]	**2,084**[h]
Total Program Level	**3,832**	**4,031**	**4,387**	**4,505**	**4,745**	**4,826**[i]

Sources: FY2012 amounts are from the FY2013 Sequestration Operating Plan. FY2013 and FY2014 amounts are from the FDA FY2014 Operating Plan. FY2013 figures reflect sequestration. The enacted FY2015 are from the FDA FY2015 Operating Plan, and FY2016 amounts are from the FY2016 enacted appropriations bill (P.L. 114-113). The President's FY2017 Request amount is from the FY2017 FDA Congressional Justification.

Notes: Consistent with the Administration and congressional committee formats, each program area includes funding designated for the responsible FDA center (e.g., the Center for Drug Evaluation and Research or the Center for Food Safety and Applied Nutrition) and the portion budgeted for agency-wide Office of Regulatory Affairs in that area. User fee revenue is apportioned as indicated in the Administration's request (e.g., 90% of the animal drug user fee revenue is designated for the animal drugs and feeds program, with the rest going to other [including Office of the Commissioner], GSA rent, and other rent and rent-related activities categories).

a. P.L. 114-113 required (for FY2016) that $1.5 million of the budget authority provided for "other activities" (e.g., Office of the Commissioner) be transferred to the HHS Office of Inspector General for FDA oversight.

b. Other rent and rent-related activities include White Oak consolidation.

c. The FY2012-FY2016 amounts reflect the color certification fees authorized by the Color Additive Amendments of 1960 (P.L. 86-618) and export certification for medical products authorized by the FDA Export Reform and Enhancement Act of 1996 (P.L. 104-134). The Food Safety Modernization Act (FSMA) of 2011 (P.L. 111-353) authorized FDA to collect export certification fees also for food. Note that the Appropriations Committees have not included funding for the export certification fees authorized by FSMA. The Administration's request includes funding for authorized export and color certification fees, as well as [proposed] export certification fees, which reflect FDA's legislative proposal to increase the statutory maximum for this fee in FY2017.

d. The FY2013 Sequestration Operating Plan notes food safety and drug safety items that had not been included in the program-level appropriations. Subsequent years' bills have not specified this distinct item.

e. Table VIII of P.L. 113-235 (for FY2015) provided an additional, one-time $25 million in direct appropriations to FDA for Ebola response and preparedness activities. Adding this $25 million to the FDA appropriations made in Title VI brought BA to $2.622 billion and the total program level to $4.525 billion for FY2015.

f. The FY2015 enacted bill included $1 million for fees related to pharmacy compounding that the President's request had not included in the FY2015 request submission.

g. The FY2016 enacted bill included $1 million for fees related to pharmacy compounding (CBO estimate) that the President's request had not included in the FY2016 request submission.

h. The President's FY2017 request includes $2.084 billion in user fees from currently authorized programs (prescription drug, medical device, animal drug, animal generic drug, tobacco product, generic drug, biosimilars, mammography quality, color certification, export certification, food reinspection, food and feed recall, pharmacy compounding, Voluntary Qualified Importer Program, third-party food import auditors, and outsourcing facility).

   The request included an additional $202 million in *proposed user fees* (export certification, food facility registration and inspection, food import, international courier, cosmetics, and food contact notification) that would require authorizing legislation to implement. The request allocated these across several FDA program areas (foods; human drugs; animal drugs and feeds; devices and radiological health; headquarters and Office of the Commissioner; GSA rent; other rent and rent-related activities; and export certification).

   For user fees in the Administration's FY2017 request, this column shows only those that have been authorized. Including the $202 million in proposed user fees, the President's total user fee request is $2.286 billion, yielding a total program level request of $5.029 billion.

i. This total does not include the $75 million in mandatory funding for the Vice President's Cancer Moonshot Initiative.

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