Food and Drug Administration Appropriations for FY2010

-name redacted-
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Summary

On October 21, 2009, the President signed into law, as P.L. 111-80, an Act making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2010, and for other purposes. This followed House and Senate agreement to the conference report. The law provides the Food and Drug Administration (FDA) with a program level of $3.28 billion for FY2010, dividing that total authorized spending into $2.36 billion in direct appropriations (which FDA refers to as budget authority) and $922 million in user fees.

The total, which includes $235 million in newly authorized user fees to support a new Center for Tobacco Products (and related activities of the agency-wide Office of Regulatory Affairs), is 22.9% higher than FY2009 appropriations for FDA. Excluding the new tobacco program, to provide a comparison of similar program responsibilities, FY2010 appropriations are 14.1% higher than FY2009 appropriations. Congress intends the increase to go toward enhanced food safety and medical product safety activities as well as cost-of-living personnel expenses.

Neither the signed legislation nor any of the House- and Senate-considered bills include $141 million in proposed user fees that the Administration included in its request. The proposed fees were intended for generic drug review, food export certification, reinspection, and food inspection and facility registration.

The versions of H.R. 2997 passed by the House and the Senate agreed on the appropriations to FDA. The conference agreement increased the appropriation to the human drugs program by $7 million. In its explanatory statement, the conference report includes directions and requests to FDA for studies and reports.

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Appropriations Process

The Food and Drug Administration (FDA) regulates the safety of foods (including animal feeds) and cosmetics, and the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices. The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill provides FDA's annual funding. The total amount that FDA can spend, its program level, consists of direct appropriations (which FDA calls budget authority) and other funds, most of them user fees.[1]

An appropriations bill specifies both the budget authority and user fee amounts each year. It also dictates the total for each of FDA's major program areas (Foods, Human Drugs, Biologics, Devices, Animal Drugs and Feeds, and Toxicological Research[2]) and several agency-wide support areas (Office of the Commissioner and other headquarter offices, rents to the General Services Administration, and other rent and rent-related activities). It also authorizes collections and spending from several specific other funds (relating to mammography quality standards, and color and export certification). Traditionally, the appropriations committees have used report language to recommend, urge, or request specific activities within major programs.

The standard appropriations procedure involves congressional passage of 12 annual regular appropriations acts, of which agriculture (including FDA) is one.[3] Except that final passage occurred after the start of the fiscal year, the FY2010 agriculture appropriations followed the standard process. **Table 1** provides a timeline of the administrative and congressional steps toward FY2010 appropriations for FDA.

For 7 of the previous 11 fiscal years, Congress had not completed that standard process and had passed omnibus or consolidated appropriations legislation, as shown in **Table 2**. For FY2009, Congress acted in the final days of FY2008 to provide appropriations for the start of FY2009 as part of the larger Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329, signed on September 30, 2008). In March 2009, Congress passed an omnibus appropriations bill that included FDA (P.L. 111-8).

[1] For historical information on FDA's budget and statutory authorities, and descriptions of the responsibilities of FDA program areas, see CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by (name redacted), and CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*, by (name redacted).

[2] For FY2010, Congress will likely include a new major program—Tobacco Products, following the enactment of P.L. 111-31, the Family Smoking Prevention and Tobacco Control Act.

[3] "Congress has developed certain rules and practices for the consideration of appropriations measures, referred to as the congressional appropriations process.... Regular appropriations bills provide most of the funding that is provided in all appropriations measures for a fiscal year, and must be enacted by October 1 of each year. If regular bills are not enacted by the deadline, Congress adopts continuing resolutions to continue funding generally until regular bills are enacted" (CRS Report 97-684, *The Congressional Appropriations Process: An Introduction*, by (name redacted)).

Table 1. Action on FY2010 Appropriations Regarding FDA

Group	Document	Action and Date
The Administration	*FDA Justification of Estimates for Appropriations Committees, FY2010*	Released, May 7, 2009
House Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies	Chairman's mark (DeLauro)	Marked up, June 11, 2009
House Committee on Appropriations	H.R. 2997 and H.Rept. 111-181	Reported, June 23, 2009
Senate Committee on Appropriations	Chairman's mark (Kohl): S. 1406 and S.Rept. 111-39	Reported, July 7, 2009
House	H.R. 2997, amended	Passed, July 9, 2009
Senate	Amendment 1908 to H.R. 2997, amended	Passed, August 4, 2009
Conference Committee	H.Rept. 111-279 (conference agreement), to accompany H.R. 2997	Submitted, September 30, 2009
House	Conference Report	Agreed to, October 7, 2009
Senate	Conference Report	Agreed to, October 8, 2009
President	P.L. 111-80	Signed, October 21, 2009

Table 2. Legislative Vehicle for Final FDA Appropriations, FY1999-FY2010

Fiscal Year	Final Appropriations Bill	Public Law and Date Enacted
2010	*"Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2010, and for other purposes."*	P.L. 111-80, October 21, 2009
2009	Omnibus Appropriations Act, 2009	P.L. 111-8, March 11, 2009
2008	Consolidated Appropriations Act, 2008	P.L. 110-161, December 26, 2007
2007	Revised Continuing Appropriations Resolution, 2007	P.L. 110-5, February 15, 2007
2006	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006*	P.L. 109-97, November 10, 2005
2005	Consolidated Appropriations Act, 2005	P.L. 108-447, December 8, 2004
2004	Consolidated Appropriations Act, 2004	P.L. 108-199, January 23, 2004
2003	Consolidated Appropriations Resolution, 2003	P.L. 108-7, February 20, 2003
2002	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2002*	P.L. 107-76, November 28, 2001
2001	*"making appropriations for agriculture, rural development, food and drug administration, and related agencies programs for the fiscal year ending September 30, 2001, and for other purposes"*	P.L. 106-387, October 28, 2000
2000	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2000*	P.L. 106-78, October 22, 1999
1999	Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999	P.L. 105-277, October 21, 1998

Notes: Cells in italics indicate "regular" agriculture appropriations bill, rather than a consolidated or omnibus bill. None of these bills were enacted before the beginning of the fiscal year to which they applied.

FDA Budget and the President's Request for FY2010

In February of each year (except for when a new President has taken office the month before), the President presents a budget request to Congress. The annual *Food and Drug Administration Justification of Estimates for Appropriations Committees* contains program-level details of the President's request, while also highlighting successes, needs, and special initiatives (e.g., drug safety, imports, bioterror countermeasures, inspections). Because the topics selected for discussion vary over the years, analysts cannot use this information to track exact changes over time. The program-level detail, however, provides a window into the priorities and activities of the agency.

The FY2010 request—$3.178 billion—is 19% higher than FY2009-enacted appropriations. It includes increased funding for food and medical product safety activities and cost-of-living expenses. Data column 4 of **Table 3** displays the President's FY2010 request by major program area. This follows columns for FY2008-enacted appropriations, FY2008 actual appropriations (as of April 2009), and FY2009-enacted appropriations.

Congressional Action on Appropriations

The appropriations committees in the House and the Senate each have subcommittees that parallel the 12 annual appropriations bills. The subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies consider FDA appropriations.[4] The textbook order of activity is as follows:

- In each chamber, the subcommittee considers the issues, perhaps holds hearings, and marks up a bill for the full committee's consideration.
- In each chamber, the full committee considers the subcommittee-marked bill or a version that the full committee chair presents, and reports a bill, perhaps with committee amendments, to the full House or the full Senate for consideration.
- The full House considers the House Committee on Appropriations-reported bill, perhaps amending it on the floor, and passes the bill; the full Senate considers the Senate Committee on Appropriations-reported bill, perhaps amending it on the floor, and passes the bill.
- If the House-passed and Senate-passed bills are not identical, each chamber assigns Members to meet in conference to work out one acceptable bill. Each chamber must vote to approve the conference bill; the second chamber that passes the conference bill sends it to the President for signing.

[4] For coverage of the entire agriculture appropriations bills for FY2009 and FY2010, see CRS Report R40000, *Agriculture and Related Agencies: FY2009 Appropriations*, coordinated by (name redacted), and CRS Report R40721, *Agriculture and Related Agencies: FY2010 Appropriations*, coordinated by (name redacted).

House

Committee-Reported Bill

On June 23, 2009, the full Committee on Appropriations reported H.R. 2997, which the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies had marked up on June 11, 2009. The bill matched the President's request but did not include the proposed new user fees. Data column 5 of **Table 3** shows the committee-reported amounts. As it had in previous years, the committee included in the bill a provision to preclude FDA's closing or relocating its Division of Pharmaceutical Analysis outside the St. Louis, MO, area.[5]

In H.Rept. 111-181, which accompanied H.R. 2997, the committee highlighted the increased support for food and medical product safety that would cover, for example, more foreign and domestic inspections. The committee also noted that the increase would fund research in biomarkers; collection and analysis of data on foodborne illnesses; research on screening tests for bloodborne diseases; efforts to understand adverse events related to medical devices used in pediatric hospitals; evaluations of drug Risk Evaluation and Mitigation Strategies; and investment in information technology. The report also noted funding for congressionally directed spending items.

In its report, the committee stated its intention to authorize FDA to collect and spend tobacco product user fee revenue once the tobacco legislation was signed into law.[6] The committee also encouraged FDA to prioritize its review of products that would address neuroblastoma; to issue a final rule on over-the-counter sunscreen testing and labeling; to devise targeted communications strategies to allow consumers to use the findings of the upcoming Dietary Guidelines Advisory Committee report; and to remind honey manufacturers about the law's misbranding and adulteration provisions and to respond to a pending citizen petition proposing a standard of identity for honey.

House-Passed Bill

The House-passed bill included an anticipated amendment to allow the collection and spending of newly authorized tobacco product user fees. It would allocate most of the $235 million to a new Center for Tobacco Products and related field activities of the Office of Regulatory Affairs, reserving a small part for rent and rent related activities, GSA rent, and other activities, including the Office of the Commissioner. Data column 7 of **Table 3** shows the House-passed amounts.

[5] This provision has been included in appropriations acts since at least FY1999 (the earliest year readily available online in the LIS Appropriations Status tables).

[6] After the appropriations committees reported the Agriculture appropriations bill for FY2010, Congress passed P.L. 111-31, the Family Smoking Prevention and Tobacco Control Act, which authorizes FDA to regulate aspects of tobacco sales and authorizes FDA to collect user fees from manufacturers to fund these activities.

Senate

Committee-Reported Bill

On July 7, 2009, the Committee on Appropriations reported S. 1406, although the subcommittee had not voted on and referred a bill. The budget authority and user fee amounts matched both the House committee-reported and the President's request amounts; it also included the St. Louis, MO, provision. Data column 6 of **Table 3** shows the committee-reported amounts.

The accompanying report, S.Rept. 111-39, highlighted the increase related to food and medical product safety, which would allow additional inspections. The Senate committee also mentioned laboratory capacity; screening test development; adverse event data collection and analysis; research on bioequivalence standards of generic products; enforcement against fraudulent products; noninvasive techniques to better understand the risks of anesthetic use in children; and information technology systems.

The committee specifically encouraged FDA to develop a program for increasing the inspection of imported shrimp for banned antibiotics; to issue guidance regarding antibiotic development and to work with others to promote development and appropriate use of antibacterial drugs for humans; and to continue its activities regarding antimicrobial resistance. The committee recommended a $2 million increase (approximately a 25% increase) to the cosmetics program. It directed the agency to use $18 million for its critical path initiative, with one-third going to partnerships, and to use at least $2 million of the critical path partnership funding to support research in treatment or rapid diagnosis of tropical diseases. The committee directed FDA to report quarterly on critical path spending.

The committee also directed the agency to clarify the relationship of dietary supplements to a definition of food; recommended $3 million for demonstration grants for improving pediatric device availability; directed FDA to report on planned research involving bioequivalent anti-epileptic drugs; recommended $93 million for the generic drugs program, increasing the Office of Generic Drugs by $10 million; directed the Department of Health and Human Services (HHS) and FDA to resolve problems with the Rockville Human Resources Center and to report to the Committee;[7] directed FDA to submit a report regarding infant formula products introduced in the past decade; recommended that $5 million in appropriated funds, as well as the $19 million in user fees, be used for Mammography Quality Standards Act activities; urged FDA to stimulate the development of products that could address orphan tropical diseases; and recommended $6 million for the Office of Women's Health. It also directed FDA to consider the need for regulations on the safe handling and processing of packaged ice; to continue priority attention to products for neuroblastoma; to work with states to more aggressively combat fraud in the seafood industry; to respond to a proposed standard of identity to prevent the misbranding and adulteration of honey. The committee instructed FDA to report quarterly on its use of appropriated funds in its implementation of the new tobacco program, and noted its intention to authorize the collection and use of fees.

[7] HHS's Rockville Human Resources Center authority to hire individuals from outside the government was suspended due to performance problems. FDA, despite paying HHS, has been outsourcing human resources activities to the Office of Personnel Management.

Senate-Passed Bill

The Senate-passed bill included an anticipated amendment to allow the collection and spending of newly authorized tobacco product user fees. It also authorized the FDA commissioner to conduct and report on a study regarding addiction to certain types of food and addiction to classic drugs of abuse. Data column 8 of **Table 3** shows the Senate-passed amounts.

Another amendment authorized the commissioner to establish two review groups to recommend activities regarding products to prevent, diagnose, and treat rare diseases and neglected diseases of the developing world, and directed the commissioner to report to Congress on those recommendations and to develop review standards based on those recommendations. The Senate-passed bill also directed the commissioner to report (with the administrator of the National Oceanic and Atmospheric Administration) to Congress on the technical challenges associated with inspecting imported seafood, and to study the labeling of FDA-regulated personal care products for which organic content claims are made.

Conference Report

A conference committee, with members appointed by each chamber, submitted a conference report, H.Rept. 111-279, on September 30, 2009, concerning H.R. 2997, the agriculture appropriations bill for FY2010. **Table 3** displays the FDA-relevant amounts in data column 9.

Bill Language

The conference agreement would provide FDA with a total program level of $3.279 billion. The two components of the total are $2.357 in direct appropriations (budget authority) and $922 million in user fees. The total, which includes $235 million in newly authorized user fees to support a new Center for Tobacco Products (and related activities of the agency-wide Office of Regulatory Affairs), would be 22.9% higher than FY2009 appropriations for FDA. Excluding the new tobacco program, to provide a comparison of similar program responsibilities, FY2010 appropriations would be 14.1% higher than FY2009 appropriations.

The conference agreement would increase the budget authority to the human drugs program by $7 million and specifies that at least $52 million be made available to the Office of Generic Drugs. It also specifies $4 million for a grant to the National Center for Natural Products Research.

Accepting a provision in the Senate and House bills, the conference agreement would prohibit the use of appropriated funds to close or relocate the FDA Division of Pharmaceutical Analysis in St. Louis, MO. The conference agreement includes a provision, based on one in the Senate-passed bill, to require the FDA commissioner to establish two review groups to recommend activities regarding products to prevent, diagnose, and treat rare diseases and neglected diseases of the developing world, and directed the commissioner to report to Congress on those recommendations and to develop guidance and internal review standards based on those recommendations.

Explanatory Statement

The Explanatory Statement, the part of the conference report with a narrative approach similar to the committee reports that accompany the bills in each chamber, included a few of the items from the Senate report.

The conference agreement states that at least $93 million is for the generic drugs program, of which $52 million is for the Office of Generic Drugs, noting that this is a $10 million increase from FY2009. Also included is a $2 million increase for cosmetics activities, $3 million for demonstration grants for improving pediatric device availability, $18 million for the critical path initiative, and $6 million for four congressionally directed projects.

The conference agreement requests FDA to report on adverse events and seizures associated with brand and generic anti-epileptic drugs, specifically the pharmacokinetic profiles of drugs that FDA rates as therapeutically equivalent, and to recommend changes to current bioequivalence testing. The conference agreement directs FDA to report on safety challenges associated with imported seafood. It also directs FDA to report regarding personal care products for which organic content claims are made, to include recommendations on the need for labeling standards and premarket approval of labeling.

Action

The House agreed to the conference report on October 7, 2009 (vote: 263-162). The Senate agreed to conference report on October 8, 2009 (vote: 76-22).

Table 3. FDA Appropriations

(dollars in millions)

Program area	Funds	FY2008 Enacted[a]	FY2008 Actual[b]	FY2009 Enacted[c]	FY2010 FY2010 Request	FY2010 House Committee-Reported	FY2010 Senate Committee-Reported	FY2010 House-Passed[i]	FY2010 Senate-Passed	FY2010 Enacted Conference Agreement[j]
Foods	BA	577	508	649	783	783	783	783	783	783
	Fees	—	—	—	63	0	0	0	0	0
	Total	577	508	649	846	783	783	783	783	783
Human drugs	BA	381	354	413	458	458	458	458	458	465
	Fees	327	327	364	450	415	415	415	415	415
	Total	708	681	777	908	873	873	873	873	880
Biologics	BA	168	155	183	206	206	206	206	206	206
	Fees	81	79	88	99	99	99	99	99	99
	Total	249	234	271	306	305	305	305	305	305
Animal drugs and feeds	BA	103	97	116	135	136	135	136	136	135
	Fees	12	12	18	36	20	20	20	20	20
	Total	115	110	134	171	156	156	156	156	156
Devices and radiological health[d]	BA	258	238	281	315	315	315	316	316	315
	Fees	46	38	49	56	53	53	53	53	53
	Total	304	275	330	371	368	368	369	369	368
Tobacco products	BA	—	—	—	—	—	—	—	—	0
	Fees	—	—	—	—	—	—	217	217	217
	Total	—	—	—	—	—	—	217	217	217
Toxicological research	BA	47	44	53	59	59	59	59	59	59
	Fees	—	—	—	—	—	—	—	—	—
	Total	47	44	53	59	59	59	59	59	59

Program area	Funds	FY2008 Enacted[a]	FY2008 Actual[b]	FY2009 Enacted[c]	FY2010 FY2010 Request	FY2010 House Committee-Reported	FY2010 Senate Committee-Reported	FY2010 House-Passed[i]	FY2010 Senate-Passed	FY2010 Enacted Conference Agreement[j]
Headquarters and Office of the Commissioner	BA	110	98	121	144	144	144	144	144	144
	Fees	36	26	40	61	42	42	56	56	56
	Total	146	123	160	205	186	186	200	200	200
GSA rent	BA	131	131	134	146	146	146	146	146	146
	Fees	29	15	21	27	23	23	26	26	26
	Total	159	145	155	173	169	169	172	172	172
Other rent and rent-related (including White Oak consolidation)	BA	89	89	89	91	91	91	91	91	91
	Fees	10	19	23	26	25	25	26	26	26
	Total	99	107	112	117	116	116	117	117	117
Export and color certification funds	BA	—	—	—	—	—	—	—	—	—
	Fees	10	10	10	10	10	10	10	10	10
	Total	10	10	10	10	10	10	10	10	10
Subtotal, Salaries & Expenses	BA	1,864	1,713	2,039	2,338	2,338	2,338	2,338	2,338	2,345
	Fees	549	524	613	828[e]	687[g]	687	922	922	922
	Total	2,414	2,237	2,652	3,166	3,025	3,025	3,260	3,260	3,267
Subtotal, Buildings & Facilities	BA	6	6	16	12	12	12	12	12	12
	Fees	—	—	—	—	—	—	—	—	—
	Total	6	6	16	12	12	12	12	12	12
Total, FDA Budget Authority	**BA**	**1,870**	**1,721**	**2,055**	**2,350**	**2,350**	**2,350**	**2,350**	**2,350**	**2,357**
Total, FDA User Fees[f]	**Fees**	**549**	**524**	**613**	**828[e]**	**687[g]**	**687**	**922**	**922**	**922**
Total, FDA Program Level	**Total**	**2,420**	**2,245**	**2,668**	**3,178**	**3,037[h]**	**3,037**	**3,272**	**3,272**	**3,279**

Sources: Adapted by CRS from FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2010 (Justification),* at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm; H.R. 2997 and the accompanying H.Rept. 111-181, as reported by the House Committee on Appropriations on June 23, 2009; S. 1406 and the accompanying S.Rept. 111-39, as reported by the Senate Committee on Appropriations on July 7, 2009; H.R. 2997 with amendments published in the *Congressional Record*, July 8, 2009, p. H7806, as passed by the House on July 9, 2009; H.R. 2997 with amendments, as passed by the Senate on August 4, 2009; and H.Rept. 111-279, Conference Report, September 30, 2009.

Notes: Because each cell value is rounded to the nearest million, some totals do not add exactly.
BA = budget authority, also referred to as direct appropriations. Fees = collected user fees. Total program level = budget authority plus user fees.

a. Includes P.L. 110-161 and the $150 million supplement to FDA in P.L. 110-252. The FDA FY2010 *Justification* labeled this as "Enacted."

b. The FDA FY2010 *Justification* labeled this as "Actual."

c. P.L. 111-8, Omnibus Appropriations Act, 2009.

d. Includes mammography user fees.

e. The FY2010 request includes a total of $141 million in proposed user fees: Generic Drug User Fee Act ($36 million), Food Export Certification ($4 million), Reinspection ($26 million), and Food Inspection and Facility Registration ($75 million).

f. Includes mammography, and color and export certification fees. For FY2010, these total $30 million.

g. The House Committee on Appropriations notes in H.Rept. 111-181 that "The Committee is aware of the proposals for user fees in the President's budget, but does not recommend establishing such fees in annual appropriations acts. The Committee will consider such fees if they are appropriated." This accounts for the $141 million difference between the Committee's recommendation and the President's request.

h. The House Committee on Appropriations notes in H.Rept. 111-181 that, while H.R. 2997 as reported on June 23, 2009 does not include costs of anticipated activities related to tobacco regulation (following congressional passage of H.R. 1256, it intends "that language to authorize the collection and spending of the tobacco fees for fiscal year 2010 will in included in the final appropriations bill for FDA for fiscal year 2010."

i. H.R. 2997, as amended, passed by the House of Representatives, July 9, 2009. The House-passed version differs from the House Committee-reported version in its addition of $235 million in tobacco product user fees to be allocated to a new Center for Tobacco Products and related activities of the Office of Regulatory Affairs, the Office of the Commissioner and other headquarter activities, GSA rent, and other rent and rent-related activities.

j. The House agreed to the conference report on October 7, 2009 (vote: 263-162); the Senate agreed on October 8, 2009 (vote: 76-22); and the President signed it into law on October 21, 2009 as P.L. 111-80.

Current Status

The FDA title of the agriculture appropriations bill as signed by the President on October 21, 2009, provides the agency with the budget authority and the authorized user fees that the President had requested, plus user fees that Congress enacted after the Administration had submitted its request. The conference agreement increased the budget authority by $7 million. The enacted appropriations provide FDA with a FY2010 total program level of $3.3 billion ($2.4 billion in budget authority and $922 million in user fees). This total does not include an additional $141 million in user fees that the Administration has proposed and included in its request (concerning generic drugs, food export certification, reinspection, and food inspection and facility registration).

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