FDA FY2009 Appropriations

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Summary

Food and Drug Administration (FDA) funding for the first five months of FY2009 is provided in the Continuing Appropriations Resolution, 2009 (the CR), which is Division A of the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329). It allows most agencies to continue at the same rate of spending as set by the FY2008 appropriations. For FDA, the base includes the mid-year FY2008 supplemental. The CR carries through March 6, 2009. If Congress chooses to continue at that rate for the remainder of FY2009, FDA would receive $2.42 billion, 10.6% ($256 million) less than the Administration's FY2009 amended budget request of $2.676 billion.

The Administration FY2009 request (as amended), according to budget documents, would provide for expanded activities to ensure the safety of foods and drugs, enhance workforce development and recruitment, and accelerate the availability of new medical products. The request included $609 million in currently authorized user fees (including $14 million for the advisory review of direct-to-consumer [DTC] television prescription drug advertising) and $21 million in proposed user fees for the review of generic human and animal drugs. It described another $27 million in proposed fees for reinspections and food and animal feed certification, but did not include them in the budget request totals.

The Senate Committee on Appropriations, in S. 3289, recommended an FY2009 total of $2.646 billion for FDA. It did not include the requested user fees for generic drug review, reinspection and certification, or DTC advertising review. The full Senate did not consider S. 3289. There was no FY2009 agriculture appropriations action in the House committee.

Updates to this report will track legislative activity as the fiscal year continues.

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The Food and Drug Administration (FDA) regulates more than $1 trillion worth of products annually.[1] It regulates the safety of foods (including animal feeds) and cosmetics, and the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices. FDA's annual funding is provided in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, and is handled by the corresponding appropriations subcommittees in the House and Senate. FDA's program level, the total amount that FDA can spend, is composed of direct appropriations (which FDA calls budget authority) and other funds, which are mostly user fees.[2]

The standard appropriations procedure involves congressional passage of 12 annual regular appropriations acts, of which agriculture (including FDA) is one.[3] Not having completed the normal appropriations process, 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). Many refer to the Act's Division A, the Continuing Appropriations Resolution, 2009, as the Continuing Resolution or the CR. It provided agencies with continuing appropriations to allow spending, until March 6, 2009, at the rate of their FY2008 appropriations. The annualized amount at this rate would provide FDA with $2.42 billion in total program level for all of FY2009. Congress could, however, alter its appropriations decisions later in the year.[4] **Table 1** provides a timeline of the various Administration requests, congressional actions, and enacted laws relating to FDA appropriations for FY2009.

Table 1. FDA Appropriations Timeline for FY2009

Date	Action
February 4, 2008	President's FY2009 request submitted
June 9, 2008	President's amended FY2009 request submitted—*the FY2009 request*
June 30, 2008	FY2008 supplemental appropriations enacted
	[P.L. 110-252, Supplemental Appropriations Act, 2008]
July 21, 2008	Senate Committee on Appropriations FY2009 recommendation reported
	[S. 3289 and S.Rept. 110-426]
September 30, 2008	Continuing appropriations enacted—*the CR*
	[P.L. 110-329, Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009; Division A is the Continuing Appropriations Resolution (CR)]

[1] FDA, "Frequently Asked Questions," at http://www.fda.gov/opacom/faqs/faqs.html.

[2] 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).

[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).

[4] CRS Report RL34711, *Consolidated Appropriations Act for FY2009 (P.L. 110-329): An Overview*, by (name redacted), provides a summary and legislative history of the act.

The FY2009 Request

The Administration's FY2009 budget request for FDA (FY2009 request) was $2.676 billion, an increase of $256 million (10.6%) over FY2008.[5] (See **Table 2**.) The FY2009 request is composed of budget authority of $2.046 billion and user fees of $630 million. The budget authority amount is a $176 million (9.4%) increase over FY2008. Of this requested amount, $25 million was for cost-of-living pay increases. The requested user fee amounts included $609 million in currently authorized fees. This included $14 million in new fees for the advisory review of direct-to-consumer (DTC) television advertisements, a program authorized in the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).[6] The amount for currently authorized fees represented a $59 million (10.8%) increase over FY2008. FDA indicated that the additional FY2009 funding would support, among other things, activities included in FDAAA, the agency's Food Protection Plan, and the government-wide Action Plan for Import Safety.[7]

In addition to the authorized fees, the FY2009 request included $21 million in proposed new user fees for generic human and animal drugs, pending authorizing legislation.[8] It described another $27 million in proposed fees for reinspections and food and animal feed certification, but did not include them in the budget request totals.

While the Administration and Congress were looking to FY2009 funding, more immediate questions continued about FDA's FY2008 budget. The requests and actions regarding the two fiscal years overlapped in time. Following submission of the Administration's initial FY2009 request in February 2008, some expressed concern that the FDA budget was inadequate to meet continuing and upcoming challenges. The FDA Science Board, in response to congressional questions regarding its report, *FDA Science and Mission at Risk*, recommended a $375 million increase in the "appropriated (non-user fee) budget" in FY2009.[9] In May 2008, FDA Commissioner Andrew von Eschenbach released a Professional Judgment Budget that noted additional resource needs of $275 million to supplement the FY2008 budget.[10] The President

[5] Budget amounts and program details in this report are from *FDA, Fiscal Year 2009 Justification of Estimates for Appropriations Committees*, February 2008, at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm; letter from the President to the House Speaker amending the FY2009 request for the Department of Health and Human Services, June 9, 2008, at http://www.whitehouse.gov/omb/budget/amendments/amendment2_6_9_08.pdf; additional detail of the amended request provided to CRS by the FDA Office of Financial Management (amended budget authority table and telephone conversations), August 2008; the Senate Committee on Appropriations recommendations as reported in S. 3289 and S.Rept. 110-426, July 21, 2008; and the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329), September 30, 2008.

[6] For detailed descriptions of FDAAA, see CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by (name redacted) and (name redacted), and CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by (name redacted).

[7] See "FDA Key Initiatives" at http://www.fda.gov/oc/initiatives/advance/.

[8] The Animal Drug User Fee Amendments of 2008 (P.L. 110-316) in August 2008 authorized the animal generic drug user fee program. FDA's FY2009 budget justification also includes proposals for two user fees that would reimburse FDA for activities currently funded through budget authority: $23.3 million for reinspections of FDA-regulated facilities and $3.7 million for issuing food and animal feed export certificates. (The fees are listed as "non-add" items in the budget request tables.)

[9] *FDA Science and Mission at Risk: Report of the FDA Science Board's Subcommittee on Science and Technology—Estimated Resources Required for Implementation*, February 25, 2008, in response to the request of Representatives Dingell, Waxman, Stupak, and Pallone, at http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf.

[10] The Commissioner's Professional Judgment Budget is available at http://www.fdanews.com/ext/files/
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submitted an amended FY2009 request in June 2008, which included an additional $275 million for FDA activities involving food protection, enhanced inspection of imported products, and monitoring the safety of drugs, devices, and biologics after they are approved. (Note: Subsequent mentions in this report to the Administration's FY2009 request refer to the amended request.)

Congressional Actions

Congress passed an FY2008 supplemental appropriations bill at the end of June 2008 that provided an additional $150 million in budget authority for FDA; it made this funding available through the end of FY2009.

In July, the Senate Committee on Appropriations reported, in S. 3289 and S.Rept. 110-426, its recommended FY2009 direct appropriations for FDA that essentially matched the Administration's amended request (FY2009 request). The committee did not follow the agency's request for user fees: the Senate committee recommendations did not include the proposed human or animal generic drug user fee programs, or the FDAAA-authorized program to collect user fees for the advisory review of DTC television advertisements of prescription drugs. Furthermore, its report did not include those fees in its representation of the FY2009 request.

As the end of FY2008 approached, the full Senate had not considered the bill and the House had not introduced a comparable bill. The Continuing Appropriations Resolution allowed agencies to spend, until March 6, 2009, at the rate of their FY2008 appropriations. It specified that, for FDA, this base would include the $150 million from the FY2008 supplemental.

Impact on FDA

FDA's budget funds both agency-wide activities and specific program areas. Agency-wide activities include Headquarters and the Office of the Commissioner (which provides program direction and administrative services), rents, and buildings and facilities. The agency supports six program areas. Five of these administer FDA's regulatory responsibilities for products and are discussed later in this report. The sixth, Toxicological Research, is non-regulatory and involves activities (including scientific research, technical advice, and training) to inform FDA's regulatory decisions. For each of the five regulatory programs, FDA's congressional budget justification provides funding information divided into Center Activities and Field Activities.

Field Activities—which include inspection and laboratory testing for regulatory purposes, and enforcement activities—are administered by FDA's Office of Regulatory Affairs (ORA). The FDA's congressional budget justification describes the Field Activities/ORA. It then arrays those resources within each FDA regulatory program budget, showing considerable variation across program. For FY2009, summing across the program areas, FDA requested $716 million for Field Activities/ORA, representing 26.8% of the agency's total request (35% of the requested budget authority).

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Drug_Industry_Daily/vonEschenbachSpector.pdf.

The 110th Congress addressed the product inspection and standards enforcement functions of FDA in hearings and proposed legislation. Various committee Members have requested information on inspection staffing by program area. However, agency statements suggest that field inspectors may be redeployed to meet critical needs, such as foodborne outbreaks, rather than being permanently assigned to one program area. Some studies suggest that budget constraints have prevented FDA from making all of its required inspections. For example, a 2007 GAO report found that FDA had not inspected certain domestic medical device manufacturing establishments once every two years as required by law.[11] In addition, deaths associated with contaminated heparin (a blood-thinning drug) have added to concern about whether the FDA's field activities are adequate. Thus, field activity funding and management are among the key challenges FDA faces.

The remainder of this report provides brief program descriptions and synopses of the FY2009 request for each of FDA's regulatory program areas. **Table 2** displays FDA's budget items by budget authority, user fees, and total program levels, for FY2008 and FY2009 requests and congressional action.

Foods Program

The Foods Program is responsible for ensuring that most foods for humans are safe, sanitary, wholesome, and accurately labeled,[12] and for ensuring that cosmetic products are safe and properly labeled. The Foods Program addresses its regulatory responsibilities in four areas: food protection, improved nutrition, dietary supplement safety, and cosmetic safety. It is administered by FDA's Center for Food Safety and Applied Nutrition (CFSAN). The program is funded through budget authority and has no authorized user fees.

The FY2009 request for the Foods Program was an $84 million (14.5%) increase over FY2008. The Senate committee recommended the same amount. More than two-thirds of the Foods Program budget is devoted to Field Activities. The primary focus of the request was the Protecting America's Food Supply Initiative, including implementing the goals of FDA's Food Protection Plan, released in November 2007.[13] Key challenges for the program include whether the agency's resources are adequate to oversee the number and diversity of facilities in the food system, and whether the agency's approach to inspection is properly aligned toward food safety risks, especially for imports of produce and seafood.

Human Drugs Program

The Human Drugs Program is responsible for ensuring that prescription and nonprescription (over-the-counter) drugs, both branded and generic, are safe and effective. Its regulatory responsibilities include the review of marketing applications for new drugs for safety and effectiveness, similar reviews of generic drug applications, and postmarket safety and surveillance. The program is administered by FDA's Center for Drug Evaluation and Research

[11] The requirement is at 21 U.S.C. §360(h). Government Accountability Office, *Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations*, Report to Congress, GAO-07-157 (January 2007).

[12] This responsibility includes all domestic and imported food, with the exception of meat, poultry, and processed eggs, which are regulated by the U.S. Department of Agriculture.

[13] The plan is at http://www.fda.gov/oc/initiatives/advance/food/plan.html.

(CDER). It is funded through both budget authority and user fees authorized by the Prescription Drug User Fee Act (PDUFA).[14]

The FY2009 request for the Human Drugs Program was $789 million ($407 million in budget authority and $381 million in user fees), a $80 million (11.3%) increase over FY2008. The requested amount for user fees included increased revenues from PDUFA (up $26.5 million to $354 million), a new user fee for the advisory review of DTC television advertisements ($12 million), and a proposed new user fee program to support the review of generic drug applications (Generic Drug User Fee Act, GDUFA, $15 million). The Senate committee recommendation ($763 million total) matched the budget authority request, but did not include the requested fees for DTC advertisement review or the proposed GDUFA. Key challenges for the program include ensuring the safety of imported drugs and ingredients, and identifying and acting on emerging safety and effectiveness information about drugs once they are on the market.

Biologics Program

The Biologics Program is responsible for ensuring the safety, purity, potency, and effectiveness of biological products. The program carries out its regulatory responsibilities in three areas: blood and blood products; vaccines and allergenics; and cells, tissues, and gene therapies. It is administered by FDA's Center for Biologics Evaluation and Research (CBER) and operates with both budget authority and user fees authorized by PDUFA and the Medical Device User Fee Act (MDUFA).[15]

The FY2009 request for the Biologics Program was $268 million ($181 million in budget authority and $87 million in user fees), a $19 million (7.8%) increase over FY2008. The increase would provide additional budget authority to cover blood and tissue safety, and to help cover a cost-of-living pay increase for the entire program. The requested amount for user fees includes increased revenue from PDUFA (up $4.3 million to $74.4 million), MDUFA (up almost $1 million to $11.5 million), and the new fee for review of DTC advertisements ($1.4 million). The Senate committee recommendation ($268 million total) matched the budget authority request but did not include the requested fees for DTC advertisement review. For FY2009, Congress has been considering legislation that would allow FDA to approve abbreviated applications for follow-on biologics.[16] The Bush Administration requested that the legislation include, among other things, a public guidance process, prescribed data requirements, safety labeling related to interchangeability, intellectual property protections, and the implementation of new user fees to cover the associated costs. A key challenge will be negotiating a compromise among several existing legislative proposals and the position of the new Obama Administration.

[14] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by (name redacted).

[15] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by (name redacted), and CRS Report RL33987, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, by (name redacted).

[16] A follow-on biologic is similar but not identical to the brand-name, or innovator, biologic product, such as a drug or a vaccine, that is made from living organisms. See CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by (name redacted).

Animal Drugs and Feeds Program

The Animal Drugs and Feeds Program regulates animal drugs and devices to ensure their safety and effectiveness, and regulates the safety of animal feeds, including pet food.[17] The program is administered by FDA's Center for Veterinary Medicine (CVM). FDA claims that 70% of CVM's work is devoted to the safety of the food supply, largely through its activities to ensure the safety of drugs and feeds used for food-producing animals. In FY2008, the program was funded through both budget authority, and user fees for brand-name animal drugs authorized by the Animal Drug User Fee Act (ADUFA).[18]

The FY2009 request for the Animal Drugs and Feeds Program was $132 million, a $17 million (15.3%) increase over FY2008. The total requested amount consisted of $114 million in budget authority, $14 million in authority for ADUFA, and $4 million for a proposed Animal Generic Drug User Fee Act (AGDUFA).[19] More than $7 million of the requested increase would be used to support the Protecting America's Food Supply Initiative, including the development of processing and ingredient standards for animal foods as required by FDAAA.[20] The increase would also allow workforce development and the expansion of existing product safety and activities. In July 2008, the Senate committee recommended $128 million total. This matched the budget authority request and included the requested fees for ADUFA, contingent upon its reauthorization, but did not include the requested fees for AGDUFA, which had not yet been authorized. The Animal Drugs and Feeds Program faces challenges similar to those for comparable activities in the other programs. These challenges include evaluating drug approvals efficiently without compromising safety, monitoring drug safety after approval, and developing effective strategies to ensure the safety of imports.

Devices and Radiological Health Program

The Devices and Radiological Health Program is responsible for ensuring the safety and effectiveness of medical devices, and eliminating unnecessary exposure to radiation from medical and consumer products. The program divides its regulatory responsibilities into three areas: premarket device safety and effectiveness, postmarket safety and surveillance, and the Mammography Quality Standards Act (MQSA). The program is administered primarily by FDA's Center for Devices and Radiological Health (CDRH), and in part by CBER. It operates with both budget authority and user fees authorized by MDUFA and MQSA.

The FY2009 request for the Devices and Radiological Health Program was $326 million ($277 million in budget authority and $49 million in user fees), a $23 million (7.4%) increase over FY2008. Most of the increase was for a cost-of-living pay increase. A smaller portion was for the Modernizing Medical Product Safety and Development Initiative (MMPSDI) of the Administration's Import Safety Action Plan. The Senate committee recommendation ($327 million total) closely matched the FY2009 request. Ensuring the safety of imported devices is a

[17] Veterinary biologics are regulated by the U.S. Department of Agriculture.

[18] See CRS Report RL34459, *Animal Drug User Fee Programs*, by (name redacted).

[19] ADUFA authority was to sunset October 1, 2008, and the generic fee program was not authorized at the time of the budget request. P.L. 110-316, the Animal Drug User Fee Amendments of 2008, enacted in August 2008, reauthorized the brand-name animal drug user fee program, and authorized the new user fee program for generic animal drugs.

[20] For more information, see CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by (name redacted).

key challenge for the program, as suggested by the request related to MMPSDI. A second challenge is ensuring the safety of medical devices already on the market. This may be complicated by the requirement that device user fees, which constitute an increasing proportion of the device budget, be spent only on activities related to the approval or clearance of new devices.

Table 2. FDA Appropriations: FY2008 Enacted, Administration's FY2009 Request, FY2009 Senate Committee on Appropriations Recommendation, and FY2009 Continuing Appropriations Resolution

(dollars in millions)

		FY2008			FY2009		
Program Area	Funds	Enacted	Suppl.	Total	Admin. Request[a]	Senate COA[b]	CR[c]
Foods	BA	510	67	577	661	661	577[c]
(no user fees)	Total	510		577	661	661	577[c]
Human drugs	BA	353	28	381	407	410	381[c]
	Fees	327		327	381	354	327[c]
	Total	680		708	789	763	708[c]
Biologics	BA	155	13	168	181	182	168[c]
	Fees	81		81	87	86	81[c]
	Total	236		249	268	268	249[c]
Animal drugs and feeds	BA	97	6	103	114	114	103[c]
	Fees	12		12	18	14	12[c]
	Total	109		115	132	128	115[c]
Devices and radiological health	BA	238	20	258	277	278	258[c]
	Fees	46		46	49	49	46[c]
	Total	284		304	326	327	304[c]
Toxicological research	BA	44	3	47	52	52	47[c]
(no user fees)	Total	44		47	52	52	47[c]
Headquarters and Office of the Commissioner	BA	97	13	110	122	123	110[c]
	Fees	36		36	40	39	36[c]
	Total	133		146	162	161	146[c]
GSA rent	BA	131		131	131	131	131[c]
	Fees	29		29	25	21	29[c]
	Total	159		159	155	151	159[c]
Other rent and rent-related (including White Oak consolidation)	BA	89		89	89	89	89[c]
	Fees	10		10	20	23	10[c]
	Total	99		99	119	112	99[c]
Export and color certification funds	Fees	10		10	10	10	10[c]
(user fees only)	Total	10		10	10	10	10[c]

Program Area		FY2008			FY2009		
	Funds	Enacted	Suppl.	Total	Admin. Request[a]	Senate COA[b]	CR[c]
Subtotal, Salaries & Expenses	BA	1,714	150	1,864	2,034	2,039	1,864[c]
	Fees	549		549	630	595	549[c]
	Total	2,264		2,414	2,664	2,633	2,414[c]
Buildings & Facilities	BA	6		6	12	12	6[c]
(no user fees)	Total	6		6	12	12	6[c]
Total, FDA Budget Authority	BA	1,720	150	1,870	2,046	2,051	1,870[c]
Total, FDA User Fees	Fees	549		549	630	595	549[c]
TOTAL, FDA PROGRAM LEVEL	Total	2,270		2,420	2,676	2,646	2,420[c]

Sources: Adapted by CRS from FDA, *Fiscal Year 2009 Justification of Estimates for Appropriations Committees*, February 2008, at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm; Supplemental Appropriations Act, 2008 (Suppl., P.L. 110-252), June 30, 2008; Administration's amended FY2009 request, at http://www.whitehouse.gov/omb/budget/amendments/amendment2_6_9_08.pdf; detail provided by the FDA Office of Financial Management, August 2008; S. 3289 and S.Rept. 110-426, July 21, 2008; and Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (CR, P.L. 110-329), September 30, 2008.

Notes: Totals and percentages may not compute exactly due to rounding.

BA = budget authority. Fees = user fees. Total (program level) = budget authority plus user fees.

a. Administration's FY2009 request includes, in addition to previously authorized user fees, $35.5 million in new user fees from DTC television advertisement advisory review ($14.0 million), authorized by P.L. 110-85 (FDAAA); animal generic drug user fees (AGDUFA, $4.8 million), authorized by P.L. 110-316 (ADUFA 2008); and proposed generic drug user fees (GDUFA, $16.6 million).

b. Senate Committee on Appropriation's recommendation does not include user fees for DTC ad review, GDUFA, or AGDUFA.

c. Continuing Appropriations Resolution, 2009 (CR, Div. A of P.L. 110-329) allows agencies to spend, until March 6, 2009, at the rate of their FY2008 appropriations, which for FDA includes the $150 million FY2008 supplemental funding.

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