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The FDA FY2009 Budget

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The FDA FY2009 Budget

Summary

The Administration's FY2009 budget request of $2.676 billion for the Food and Drug Administration (FDA) would provide a 17.9% increase ($406 million) over FY2008. User fees would make up 23.5% of the total amount requested and would account for 19.8% of the proposed increase. These figures reflect the Administration's amended request, issued in June 2008, which added $275 million to the amount originally requested by the Administration in February 2008. Based on the initial request, cost-of-living pay increases, rather than new program activities, would have accounted for about half of the total increase over FY2008. With the amended request, such pay increases would use only 7.7%.

The amended FY2009 request, 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 user fee request includes $609 million in currently authorized fees and $21 million for generic human and animal drug review. The budget justification documents include an additional $27 million in proposed fees for reinspections and food and animal feed certification.

The Senate Committee on Appropriations, in S. 3289, recommended an FY2009 total of $2.646 billion for FDA. It did not include the generic drug user fees, the proposed reinspection and certification fees, or the authorized fees for the advisory review of direct-to-consumer television prescription drug advertising. Updates to this report will track legislative activity as the House Committee on Appropriations and the full Senate and House consider FY2009 appropriations.

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The FDA FY2009 Budget

Budget Overview

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 appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, and is handled by the corresponding appropriations subcommittees in the House and Senate. For historical information on the 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*, by Judith A. Johnson, Donna V. Porter, Susan Thaul, and Erin D. Williams.

The Administration's FY2009 budget request for FDA (FY2009 request) is $2.676 billion, an increase of $406 million (17.9%) over FY2008.[2] (See **Table 1** at the end of this report.) The FY2009 request is composed of budget authority (also called direct appropriations) of $2.046 billion and user fees of $630 million. The budget authority amount is a $326 million (18.9%) increase over FY2008. Of this requested amount, $25 million would cover cost-of-living pay increases. The requested user fee amounts include $609 million in currently authorized fees and $21 million for proposed new user fees for generic human and animal drugs for which new authority was needed.[3] The amount for currently authorized fees represents a $59 million (10.8%) increase over FY2008 and includes $14 million in new fees for the advisory review of direct-to-consumer (DTC) television advertisements, a

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

[2] 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; and the Senate Committee on Appropriations recommendations as reported in S. 3289 and S.Rept. 110-426, July 21, 2008.

[3] 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. The fees would cover $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.)

program authorized in the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).[4] 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.[5]

The Administration submitted its FY2009 request in February 2008. Within the following months, two respected sources of expertise expressed continuing concern that the FDA budget was inadequate to meet the challenges the agency faces. 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.[6] In May 2008, FDA Commissioner Andrew von Eschenbach released a Professional Judgment Budget that noted resource needs of $275 million to supplement the FY2008 budget.[7] The President 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. The Senate Committee on Appropriations recommended FY2009 direct appropriations for FDA that essentially matched the Administration's amended request. It did not follow the agency's request for user fees: the Senate committee recommendations did not include revenue from the proposed human or animal generic drug user fee programs, or from the FDAAA-authorized program to collect user fees for the advisory review of DTC television advertisements of prescription drugs. Furthermore, S.Rept. 110-426 does not include those fees in its representation of the Administration's request.

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 in separate sections of this report. The sixth, Toxicological Research, is non-regulatory and conducts or coordinates 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.

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[4] See CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul, and CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

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

[6] *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].

[7] The Commissioner's Professional Judgment Budget is available at [http://www.fdanews.com/ext/files/Drug_Industry_Daily/vonEschenbachSpector.pdf].

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 but does not include a separate request. The requested resources are assigned to each FDA regulatory program and included in those program budgets, which show considerable variation in the use of Field activity. For FY2009, summing across the program areas, FDA requested $716 million for Field Activities/ORA. This represents 26.8% of the agency's total request (35% of the requested budget authority) and includes a $161 million (29.2%) increase over the ORA FY2008 budget.

The 110th Congress has been addressing 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.[8] 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 budget requests for each of FDA's regulatory program areas. **Table 1** displays FDA's budget items by budget authority, user fees, and total program levels, for FY2007, FY2008, and the FY2009 request.

Foods Program

The Foods Program is responsible for ensuring that most foods for humans are safe, sanitary, wholesome, and accurately labeled,[9] 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 is $661 million, a $151 million increase (29.6%) over FY2008, all from budget authority. The Senate committee recommended the same amount. More than two-thirds of the Foods Program budget

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[8] 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).

[9] 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.

is devoted to Field Activities. The primary focus of the request is the Protecting America's Food Supply Initiative, including implementing the goals of FDA's Food Protection Plan, released in November 2007.[10] 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. It executes its regulatory responsibilities in three areas: new drug safety and effectiveness, generic drug review, and postmarket safety and surveillance. The program is administered by FDA's Center for Drug Evaluation and Research (CDER). It is funded through both budget authority and user fees authorized by the Prescription Drug User Fee Act (PDUFA).[11]

The FY2009 request for the Human Drugs Program is $789 million ($407 million in budget authority and $381 million in user fees), a $108 million (15.9%) increase over FY2008. The requested amount for user fees includes 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 program 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).[12]

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

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

[12] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History,* (continued...)

The FY2009 request for the Biologics Program is $268 million ($181 million in budget authority and $87 million in user fees), a $32 million (13.6%) 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, the Bush Administration is seeking new statutory authority that will allow FDA to approve abbreviated applications for follow-on biologics.[13] The Administration would like the legislative proposal to 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 Administration's position.

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.[14] 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).[15]

The FY2009 request for the Animal Drugs and Feeds Program is $132 million, a $23.5 million (21.7%) increase over FY2008. The total requested amount consists of $114 million in budget authority, $14 million in authority for ADUFA, and $4 million for a proposed Animal Generic Drug User Act (AGDUFA).[16] More than $7 million of the requested increase would be used to support the Protecting America's

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[12] (...continued)
Reauthorization in 2007, and Effect on FDA, by Susan Thaul, and CRS Report RL33981, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, by Erin D. Williams.

[13] 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 Judith A. Johnson.

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

[15] See CRS Report RL34459, *Animal Drug User Fee Programs*, by Sarah A. Lister.

[16] 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.

Food Supply Initiative, including the development of processing and ingredient standards for animal foods as required by FDAAA.[17] 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 is $326 million ($277 million in budget authority and $49 million in user fees), a $42.6 million (15%) increase over FY2008. Most of the increase would cover a cost-of-living pay increase. A smaller portion would be used 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 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.

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[17] For more information, see CRS Report RS22779, *Food Safety: Provisions in the Food and Drug Administration Amendments Act of 2007*, by Donna V. Porter.

Table 1. FDA Appropriations: FY2008 Enacted, FY2009 President's Request, and FY2009 Senate Committee on Apppropriations Recommendation

(dollars in millions)

Program Area	Funds	FY2008 Enacted	FY2009 President's Request[a]	FY2009 Senate Committee[b]
Foods	BA	510	661	661
(no user fees)	Total	510	661	661
Human drugs	BA	353	407	410
	Fees	327	381	354
	Total	680	789	763
Biologics	BA	155	181	182
	Fees	81	87	86
	Total	236	268	268
Animal drugs and feeds	BA	97	114	114
	Fees	12	18	14
	Total	109	132	128
Devices and radiological health	BA	238	277	278
	Fees	46	49	49
	Total	284	326	327
Toxicological research	BA	44	52	52
(no user fees)	Total	44	52	52
Headquarters and Office of the Commissioner	BA	97	122	123
	Fees	36	40	39
	Total	133	162	161
GSA rent	BA	131	131	131
	Fees	29	25	21
	Total	159	155	151
Other rent and rent-related (including White Oak consolidation)	BA	89	89	89
	Fees	10	20	23
	Total	99	119	112
Export and color certification funds	Fees	10	10	10
(user fees only)	Total	10	10	10
Subtotal, Salaries & Expenses	BA	1,714	2,034	2,039
	Fees	549	630	595
	Total	2,264	2,664	2,633
Buildings & Facilities	BA	6	12	12
(no user fees)	Total	6	12	12
Total, FDA Budget Authority	BA	1,720	2,046	2,051
Total, FDA User Fees	Fees	549	630	595
TOTAL, FDA PROGRAM LEVEL	Total	2,270	2,676	2,646

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]; 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; and S. 3289 and S.Rept. 110-426, July 21, 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. 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. Does not include user fees for DTC advertisement review, GDUFA, or AGDUFA