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The FDA FY2009 Budget Request

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Summary

The Administration's FY2009 budget request of $2.4 billion for the Food and Drug Administration (FDA) would provide a 5.7% increase ($130 million) over FY2008. User fees would make up about 26% of the total amount requested and would account for 61% of the proposed increase. Within the five programs that administer FDA's regulatory responsibilities, proposed increases range from 2.5% for Devices and Radiological Health to 9.9% for Animal Drugs and Feeds. Budget documents indicate that the additional funding would provide for expanded activities to ensure the safety of foods and drugs, as well as to accelerate the availability of new medical products. About half of the requested increase would be used for cost-of-living pay increases, as opposed to new program activities.

Budget Overview.[1] FDA regulates more than $1 trillion worth of products annually.[2] 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 subcommittees in the House and Senate.

The Administration's FY2009 budget request for FDA is $2.4 billion, an increase of $130 million, or 5.7%, over FY2008.[3] (See **Table 1** at the end of this report.) The FY2009 proposal is composed of budget authority (also called direct appropriations) of $1.771 billion and user fees of $628 million. The budget authority amount is a $51 million (3%) increase over FY2008. Of this requested amount, $25 million would cover

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[1] 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.

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

[3] 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].

cost-of-living pay increases. The requested user fee amounts include $607 million in currently authorized fees and $21 million for proposed new user fees for generic human and animal drugs for which new authority would be needed.[4] The amount for currently authorized fees represents a $58 million (11%) increase over FY2008 and includes $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).[5] 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.[6] Some believe that the Administration's FY2009 FDA request is inadequate, given the challenges the agency faces.[7] These challenges include ensuring the safety of a growing number of imported products and monitoring the safety of drugs, devices, and biologics after they are approved.

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.

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 requests $608 million for Field Activities/ORA. This represents 25% of the agency's total request and includes a $32.4 million (6%) increase over the ORA FY2008 budget.

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[4] 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.)

[5] 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.

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

[7] *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, submitted at the request of Representatives Dingell, Waxman, Stupak, and Pallone, at [http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.Estimated Resources.pdf]; Congress is considering a supplemental FDA appropriation for FY2008, which reflects a Professional Judgement Budget prepared by Commissioner von Eschenbach, at [http://www.fdanews.com/ext/files/Drug_Industry_Daily/vonEschenbachSpector.pdf].

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 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.

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 budget request for the Foods Program is $543 million, a $33 million increase (6.4%) over FY2008, all from budget authority. Nearly two-thirds of the Foods Program budget 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

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[8] The requirement is at 521 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.

[10] 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).[11]

The FY2009 budget request for the Human Drugs Program is $739 million ($358 million in budget authority and $381 million in user fees), a $58 million (8.6%) increase over FY2008. Almost all of the proposed increase would come from currently authorized or proposed new user fees, rather than from budget authority. 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 ($15 million). 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]

The FY2009 budget request for the Biologics Program is $245 million ($158 million in budget authority and $87 million in user fees), a $9.5 million (4%) 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). 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. 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

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[11] See CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization*, by Susan Thaul.

[12] See CRS Report RL33914, as above, and CRS Report RL33981, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, by Erin D. Williams.

[13] For more information, 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.

safety of the food supply, largely through its activities to ensure the safety of drugs and feeds used for food-producing animals. The program is funded through both budget authority and user fees authorized by the Animal Drug User Fee Act (ADUFA).[15]

The FY2009 budget request for the Animal Drugs and Feeds Program is $119 million, a $10.8 million (9.9%) increase over FY2008. The total requested amount consists of almost $104 million in budget authority, almost $12 million in authority for the animal drug user fee program, and $4 million for a proposed generic animal drug user fee program.[16] About half 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,[17] and expansion of existing activities. Most of the rest of the requested increase would be for the user fee programs. 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 budget request for the Devices and Radiological Health Program is $291 million ($242 million in budget authority and $49 million in user fees), a $7.1 million (2.5%) 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. 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 devices.

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[15] See CRS Report RL34459, *Reauthorization of the Animal Drug User Fee Act (ADUFA)*, by Sarah A. Lister.

[16] Authority for the current animal drug user fee program sunsets at the beginning of FY2009. Unless it is reauthorized, this authority would not be current for the purposes of FY2009 appropriations. The requested user fee program for generic animal drugs would require new authority.

[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. Food and Drug Administration

(dollars in millions)

Program area	Funds	FY2007 Actual	FY2008 Enacted	FY2009 Request[a]	% Change FY08 to FY09
Foods	BA	457	510	543	6.4%
(no user fees)	Total	457	510	543	6.4%
Human drugs	BA	315	353	358	1.3%
	Fees	228	327	381	16.4%
	Total	544	680	739	8.6%
Biologics	BA	146	155	158	1.9%
	Fees	56	81	87	8.2%
	Total	202	236	245	4.0%
Animal drugs and feeds	BA	95	97	104	6.7%
	Fees	11	12	16	37.0%
	Total	106	109	119	9.9%
Devices and radiological health	BA	231	238	242	1.6%
	Fees	37	46	49	7.1%
	Total	268	284	291	2.5%
Toxicological research	BA	42	44	46	4.1%
(no user fees)	Total	42	44	46	4.1%
Headquarters and Office of the Commissioner	BA	92	97	99	2.0%
	Fees	20	36	40	10.8%
	Total	111	133	139	4.3%
GSA rent	BA	127	131	131	0.0%
	Fees	12	29	25	-11.4%
	Total	139	159	156	-2.0%
Other rent and rent-related (including White Oak consolidation)	BA	68	89	89	0.0%
	Fees	18	10	20	92.9%
	Total	86	99	109	9.8%
Export and color certification funds	Fees	10	10	10	8.4%
(user fees only)	Total	10	10	10	8.4%
Subtotal, Salaries & Expenses	BA	1,572	1,714	1,769	3.2%
	Fees	391	549	628	14.4%
	Total	1,964	2,264	2,397	5.9%
Buildings & Facilities	BA	10	6	2	-60.5%
(no user fees)	Total	10	6	2	-60.5%
Total, FDA Budget Authority	BA	1,583	1,720	1,771	2.9%
Total, FDA User Fees	Fees	391	549	628	14.4%
TOTAL, FDA Program Level	Total	1,974	2,270	2,400	5.7%

Source: Adapted by CRS from the FDA, *Fiscal Year 2009 Justification of Estimates for Appropriations Committees*, February 2008, at [http://www.fda.gov/oc/oms/ofm/budget/documentation.htm].

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 authorized direct-to-consumer television advertisement advisory review ($14.0 million), proposed generic drug user fees ($16.6 million), and proposed animal generic drug user fees ($4.8 million).