Food and Drug Administration
FY 2012 Congressional Budget Request
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Executive Summary

Statement of FDA Mission

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

FY 2012 Budget Overview

The fiscal year (FY) 2012 President's Budget request for FDA is $4,360,281,000. This represents a total program level increase of $1,076,215,000 above the amount enacted into law for FY 2010. The FDA total program level includes new budget authority, current law user fees, and new proposed user fees.

The FY 2012 increase for user fees is $694,036,000, including $59,568,000 in proposed new user fees. The FY 2012 increase in budget authority is $382,179,000, of which $4,896,000 is for the cost of living pay increase.

The following information summarizes the FDA budgets for fiscal years 2010, 2011, and 2012.

FY 2012 Overview Table Food and Drug Administration (Dollars in thousands)						
Program[1]	FY 2010 Enacted[2]	FY 2010 Adjusted Enacted	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 PB request	+/- FY 2010 Adjusted Enacted
Budget Authority	$2,363,786	$2,361,786	$2,369,396	$2,361,786	$2,743,965	$382,179
User Fees	$922,280	$922,280	$748,265	$1,011,175	$1,616,316	$694,036
Total	$3,286,066	$3,284,066	$3,117,661	$3,372,961	$4,360,281	$1,076,215
FTE	12,335	12,335	12,381	12,381	14,436	2,101

[1] FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include $1.3 million for CRADA.

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

FDA FY 2012 Budget Request

The initiatives and resources for FY 2012 will allow FDA to achieve fundamental public health priorities in the following areas:

A. Transforming Food Safety and Nutrition +$218,424,000 / 435 FTE

The Transforming Food Safety and Nutrition Initiative allows FDA to implement the landmark Food Safety Modernization Act. FDA will establish a prevention-focused food safety system and leverage the valuable work of FDA's state and local food safety partners. The resources in this initiative will also empower Americans to make more healthful food choices through nutrition labeling for menu and vending machine items.

The FY 2012 budget does not include any legislative proposals for new food safety user fees. However, FDA plans to work with Congress during FY 2013 to enact additional food safety fees to support the full implementation of the FDA Food Safety Modernization Act.

B. Advancing Medical Countermeasures +$70,000,000 / 165 FTE

The Advancing MCM Initiative strengthens FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear threats, and to respond to naturally emerging diseases such as pandemic

influenza. With this initiative, FDA will enhance the review of MCMs and develop new tools and standards to speed the development of MCMs. To improve public health response, FDA will also strengthen the legal, regulatory and policy framework that governs MCM development and availability. These efforts will accelerate development of MCM products for pressing public health and national security needs.

C. Protecting Patients
+$56,323,000 / 118 FTE

The Protecting Patients Initiative allows FDA to develop a pathway for approving biosimilars. Establishing a pathway for biosimilars offers the potential of significant savings for government and private sector health care systems that provide care to millions of Americans. This initiative also strengthens FDA efforts to modernize and improve safety throughout the foreign and domestic supply chain of medical products and includes other measures to assure the safety of medical products.

D. FDA Regulatory Science and Facilities
+$48,675,000 / 50 FTE

The FY 2012 budget will allow FDA to strengthen its core regulatory scientific capacities. The Regulatory Science and Facilities Initiative will help FDA review and approve products that rely on new and emerging technologies and that offer promising new opportunities to diagnose, treat, cure and prevent disease. This initiative also contains resources for FDA to outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex to ensure that the facilities are operational and ready for occupancy in FY 2014.

E. Contract and Administrative Savings
-$29,723,000 / -46 FTE

During FY 2012, FDA will achieve contract and administrative savings by increasing competition, using FDA-wide contracts to combine resources and reduce cost, replacing traditional classroom training with online training, achieving savings on information technology procurement, and reducing administrative support FTE.

F. FDA Current Law User Fees
+$634,468,000 / +1,229 FTE

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, and medical devices and reviews of other FDA-regulated products. Fees also allow FDA programs to achieve enhanced premarket review performance. Other FDA user fees support the regulation of tobacco products, the inspection of mammography facilities, the certification

services for color additives, and the certification of FDA-regulated products exported from the United States. Finally, new user fees enacted by the FDA Food Safety Modernization Act support food recalls, food reinspections, and the voluntary qualified importers program. The budget request includes inflationary increases for FDA user fee programs authorized by law.

Details of the FDA FY 2012 Initiatives

The FDA Congressional Budget Justification contains business case papers justifying the funding increases described above. Within each business case paper, FDA identifies the need for the FY 2012 funding, the activities that FDA will conduct, and the performance that FDA will achieve.

OVERVIEW OF PERFORMANCE

Background

This Performance Budget details the resources FDA needs and the performance commitments FDA is making to address public health challenges in FY 2012. In an increasingly global economy, and facing revolutionary advances in science and technology, FDA recognizes the need to modernize and transform our operations to address the emerging needs of the 21st century. For more than a century, FDA demonstrated a dedication to principles that have made it the world's "gold standard" for regulating food and medical products. These principles are:

- dedication to assuring the safety of the products that we regulate
- dedication to protecting Americans against persistent and emerging public health threats
- commitment to advancing the public health by empowering consumers to make safe and healthy choices about medicine and nutrition
- commitment to accelerating the development and availability of promising new medical therapies and technologies that will extend and improve lives
- commitment to transparency and accountability by sharing information about how we make decisions and how well we are performing our critical mission activities.

FDA has changed the format of this Performance Budget to make it more useful and to focus on our commitment to achieving improved public health outcomes

and performance results at the subprogram level. This change in format mirrors a more fundamental change in how FDA will be measuring and reporting on our performance in the future, moving beyond measures of activities and outputs, to focus greater attention on the key program results and public health outcomes valued by the American public. Developing the right measures for each subprogram is an important and challenging endeavor requiring continual improvement over time.

FDA Summary of Targets and Results Table

The Summary of Targets and Results Table provides an overview of all targets established for each corresponding fiscal year.

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	51	51	100%	49	96%
2008	45	45	100%	41	90%
2009	47	46	98%	44	95%
2010	76	60	79%	54	89%
2011	80				
2012	80				

FDA Linkages to HHS Strategic Plan

The table below shows the alignment of FDA's strategic goals with HHS Strategic Plan goals.

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
1 Transform Health Care					
1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured					
1.B Improve health care quality and patient safety			X		

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
1.C Emphasize primary and preventive care linked with community prevention services					
1.D Reduce the growth of health care costs while promoting high-value, effective care					
1.E Ensure access to quality, culturally competent care for vulnerable populations					
1.F Promote the adoption of health information technology					
2 Advance Scientific Knowledge and Innovation					
2.A Accelerate the process of scientific discovery to improve patient care					
2.B Foster innovation at HHS to create shared solutions					
2.C Invest in the regulatory sciences to improve food and medical product safety	X				
2.D Increase our understanding of what works in public health and human service practice					
3 Advance the Health, Safety and Well-Being of the American People					
3.A Ensure the safety, well-being, and healthy development of children and youth					
3.B Promote economic and social well-being for individuals, families and communities					
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults					
3.D Promote prevention and wellness		X		X	
3.E Reduce the occurrence of infectious diseases		X			

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies		X	X		
4 Increase Efficiency, Transparency, and Accountability of HHS Programs					
4.A Ensure program integrity and responsible stewardship of resources					X
4.B Fight fraud and work to eliminate improper payments					
4.C Use HHS data to improve the health and well-being of the American people					
4.D Improve HHS environmental, energy, and economic performance to promote sustainability					X
5 Strengthen the Nation's Health and Human Service Infrastructure and Workforce					
5.A Invest in the HHS workforce to meet America's health and human services needs today and tomorrow					X
5.B Ensure that the Nation's health care workforce can meet increased demands					
5.C Enhance the ability of the public health workforce to improve public health at home and abroad					
5.D Strengthen the Nation's human services workforce					
5.E Improve national, state, and local surveillance and epidemiology capacity		X			