Summary of Full Costs

(Dollars in Millions)

Performance Program Area	FY 2006	FY 2007	FY 2008
Foods	$547	$568	$601
Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (11001) (Output)	$50	$45	$47
Number of eligible state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (11010) (Outcome)	$106	$104	$117
Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk. (11040) (Output)	$10	$11	$12
Perform import food field exams on products with suspect histories. (11036) (Output)	$68	$67	$78
Perform Filer Evaluations of import filers. (19015) (Output)	$24	$22	$25
Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. (19016) (Output)	$24	$22	$25
Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (Output)	$168	$187	$196
Expand federal/ state/ local involvement in FDA's eLEXNET system by having laboratories submit data in the system; and, beginning in FY 2007, expand the capability of the system to detect and provide notification of potential events; and, beginning in FY 2008, convert 5 data entry labs to automated data exchange. (19013) (outcome)	$2	$2	$2
Establish and maintain a quality system in the ORA Field laboratories which meets the requirements of ISSO 17025 (American Society for Crime Laboratory Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation.) (11041) (Outcome)	$135	$146	$146
Human Drugs	$594	$665	$689
Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. (12001) (Output)	$251	$273	$286
Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. (12026) (Output)	$12	$15	$14

Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. (12003) (Outcome)	$65	$71	$83
Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available. (12048) (Output)	$24	$24	$21
Enhance the protection of the American public against the effects of terrorist agents by facilitating the development of and access to medical countermeasures, providing follow-up assessments on therapies, and engaging in emergency preparedness and response activities. (12045) (Output)	$19	$20	$21
Improve the Safe Use of Drugs in Patients and Consumers (12007) (Output)	$69	$80	$88
Increase the efficiency of the Adverse Event Reporting Process by reducing the average cost associated with turning a submitted Adverse Event Report into a verified record in the database. (Efficiency goal)	$9	$8	$14
Increase risk-based compliance and enforcement activities to ensure drug product quality. (12020) (Output)	$94	$99	$103
Biologics	$224	$245	$252
Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months; and review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (13001) (Output)	$67	$75	$76
Complete review and action on standard PDUFA efficacy supplements within 10 months; and review and act on priority PDUFA efficacy supplements within 6 months of receipt (13002) (Output)	$61	$66	$68
Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date. (13005) (Output)	$36	$24	$24
Increase manufacturing diversity and capacity for pandemic influenza vaccine production through interacting with vaccine researchers and developers and issuing guidance and other documents and through global vaccine response coordination to facilitate the development and expedite the evaluation of cell-based technologies and dose-sparing approaches, such as the use of adjuvants. (13030) (Output)	$23	$40	$41
Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) (Output)	$29	$32	$34

Animal Drugs and Feeds	$125	$135	$140
Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (14020) (Output)	$46	$51	$55
Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) (Output)	$65	$70	$70
Medical Devices and Radiological Health	$329	$329	$363
Percentage of Expedited PMAs reviewed and decided upon within 300 days; Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1 (15033) (Outcome)	$41	$44	$48
Percentage of 180 day PMA supplements reviewed and decided upon within 180 days./1 (15031) (Outcome)	$21	$22	$25
Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days./1 (15032) (Outcome)	$79	$74	$82
Percentage of an estimated 9,100 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (15007) (Outcome)	$33	$32	$36
Expand actively participating sites in MedSun Network. (15012) (Outcome)	$33	$37	$40
Focus inspectional coverage on the device research enterprise to assure the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. (15025) (Output)	$13	$14	$16
Focus inspectional coverage on device firms to ensure consumers are protected and that the public health is advanced. (15005) (Output)	$79	$76	$86
National Center for Toxicological Research	$43	$37	$39
Use new technologies (toxicoinformatics, proteomics, metabolomics, and genomics) to study the risk associated with how an FDA-regulated compound or product interacts with the human body. (16014) (Output)	$19	$14	$15
Develop computer-based models and infrastructure to predict the health risk of biologically active products. (16003) (Output)	$7	$12	$12
Develop risk assessment methods and build biological dose-response models in support of Food Security. (16007) (Output)	$9	$7	$8
Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. (16012) (Output)	$9	$4	$5
Additional Program Management Performance Goals			
Increase the number of Commercial Activities that will be reviewed for competitive sourcing. (19003) (Efficiency)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		

Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack. (19008) (Output)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		
Full Cost Total	$1,863	$1,979	$2,085

* Full cost data for the measures under each performance program area are shown as non-adds. The sum of full costs of performance measures may not equal the full cost of the performance program area, to the extent the program has elements for which there are no current measures. However, each program in FDA has performance goals that account for 90-95% of its full costs when you include the relevant "Field Activities" for each program.