Summary of Full Costs

(Dollars in Millions)

Performance Program Area	FY 2004	FY 2005	FY 2006
Center for Food Safety and Applied Nutrition	$187	$192	$198
Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (11001)	$50	$46	$43
Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the nation's food supply. (11010)	$85	$84	$80
Center for Drug Evaluation and Research	$435	$491	$493
Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. (12001)	$245	$269	$271
Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. (12026)	$8	$9	$9
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)	$44	$48	$49
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)	$14	$16	$16
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 respon	$31	$34	$34
Improve the Safe Use of Drugs in Patients and Consumers (12007)	$68	$74	$75
Center for Biologic Evaluation and Research	$160	$162	$170
Complete review and action on 90% of standard original PDUFA NDA/BLA submissions within 10 months; and review and act on 90% of priority original PDUFA NDA/BLA submissions within 6 months of receipt. (13001)	$45	$45	$47
Complete review and action on 90% of standard PDUFA efficacy supplements within 10 months; and review and act on 90% of priority PDUFA efficacy supplements within 6 months of receipt. (13002)	$45	$45	$47
Complete review and action on 90% of complete blood bank and source plasma BLA submissions, and 90% of BLA supplements within 12 months after submission date. (13005)	$54	$55	$58

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Center for Veterinary Medicine	$73	$81	$84
Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals.	$38	$42	$43
Center for Devices and Radiological Health	$196	$223	$249
Complete Review and Decision on 80% of Expedited PMAs within 300 days./1 (15033)	$30	$33	$36
Complete Review and Decision on 80% of 180 day PMA supplements within 180 days./1 (15031)	$16	$18	$20
Complete Review and Decision on 75% of 510(k)s (Premarket Notifications) within 90 days./1 (15032)	$59	$66	$73
Maintain inspection and product testing coverage of Radiological Health industry at 10% of an estimated 2000 electronic products. (15027)	$22	$24	$27
Ensure at least 97% of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems. (15007)	$32	$36	$40
Expand implementation of MedSun to a network of 300-350 facilities. (15012)	$32	$36	$40
National Center for Toxicological Research	$43	$43	$45
Use new technologies (toxicoinformatics, proteomics, metabonomics, and genomics) to study the risk associated with how an FDA-regulated compound or product interacts with the human body. (16014)	$21	$21	$22
Develop computer-based models and infrastructure to predict the health risk of biologically active products. (16003)	$6	$6	$6
Develop risk assessment methods and build biological dose-response models in support of Food Security. (16007)	$8	$8	$8
Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. (16012)	$8	$8	$8
Field Activities	$585	$608	$642
Foods Field Activities	$331	$346	$372
Perform prior notice import security reviews on 38,000 food and animal feed line entries considered to be at high risk for bioterrorism and/or present the potential of a significant health risk.	NA	$7	$7
Perform 60,000 import field exams and conduct sample analyses on products with suspect histories.	$68	$69	$74
Perform at least 1,000 Filer Evaluations under new procedures. (19015)	$11	$12	$13
Conduct 2,000 examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. (19016)	$11	$12	$13

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Conduct postmarketing monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020)	$150	$163	$173
Expand federal/state/local involvement in FDA's eLEXNET system by having 105 laboratories participate in the system. (19013)	$6	$6	$8
Establish and maintain a quality system in the ORA Field Labs which meets the requirements of ISO 17025 (American Society for Crime Lab Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body	NA	$139	$147
Human Drugs Field Activities	$109	$107	$109
Increase risk-based compliance and enforcement activities to ensure product quality (12020)	$83	$91	$91
Biologics Field Activities	$35	$36	$37
Meet the biennial inspection statutory requirement by inspecting 50% of the approximately 2,700 registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination. (13012)	$33	$34	$35
Animal Drugs and Feeds Field Activities	$37	$43	$43
Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009)	$70	$79	$82
Device and Radiological Health Field Activities	$74	$77	$82
Conduct 295 domestic and foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. (15025)	$16	$18	$20
Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers at 20% of an estimated 5,540 firms. (15005.01)	$46	$51	$56
Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 7% of an estimated 2,500 firms. (15005.02)	$8	$9	$10
Additional Program Management Performance Goals			
Increase percentage of contract dollars allocated to performance based contracts (19006)	The full cost of this goal is included in the Program Management Allocation amount that has been spread over the Agency's programs.		

Summary of Full Costs

FDA's implementation of HHS's Unified Financial Management System. (19017)	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 respond in the event of a terrorist attack. (19008)	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	$1,679	$1,801	$1,881

* 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.