Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
Center for Food Safety and Applied Nutrition				
11001	Complete review and action on the safety evaluation of 75% of food and color additive petitions within 360 days of receipt.	Revised	Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (Target: Complete review and action on the safety evaluation of 75% of food and color additive petitions within 360 days of receipt.)	New overall goal statement added; target the same
11025	Respond to 95% of notifications for dietary supplements containing "new dietary ingredients" within 75 days.	Dropped		This goal will be included in expanded premarket goal (11001) to better allocate full costs.
11010	Increase the percentage of the U.S. population that will live in states that have adopted the Food Code.	Revised	Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the nation's food supply. (Target: Increase the percentage of the U.S. population that will live in states that have adopted the Food Code.)	New overall goal statement added; target the same
Center for Drug Evaluation and Research				
12001	Ensure a safe and effective drug supply is available to the public. Review and approve upon 90% of original standard NDAs within 10 months of receipt. Review and approve upon 90% of original priority NDAs within 6 months of receipt.	Revised	Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. New FY 05 Target: Review and act upon 90% of original standard NDAs within 10 months of receipt. Review and act upon 90% of original priority NDAs within 6 months of receipt.	New overall goal statement added and revised wording of target
12003	Ensure safe and effective generic drugs are available to the public.	Revised	Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans.	New overall goal statement added
12007	Enhance postmarketing drug safety. Coordinate with agency to develop methodology and resources to determine baseline for number of adverse drug experiences (ADEs) related to medication dispensing and administration errors in US hospitals.	Revised	Improve the Safe Use of Drugs in Patients and Consumers. New FY 05 Target: Review and provide comments on 100% of Risk Minimization Action Plans (RiskMAPs) for NMEs and for those products for which the sponsor or FDA initiated discussions, in accordance with applicable PDUFA goal dates.	New overall goal statement added and revised target to make it more quantifiable

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
12026	Increase the number of drugs that are adequately labeled for children. Report on activities that are responsive to the Best Pharmaceuticals for Children Act and those that are triggered by the Pediatric Research Equity Act.	Revised	Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. New FY 05 Target: Issue at least 8 written requests for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for 7 drugs that receive pediatric exclusivity.	New overall goal statement added and revised target to make it more quantifiable
12045	Facilitate development and availability of medical countermeasures to limit the effects of the intentional use of biological, chemical, or radiologic/nuclear agents. Support research activities and the application of appropriate regulatory mechanisms to facilitate development and availability of medical countermeasures	Revised	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. New FY 05 Target: Coordinate and facilitate development for at least 5 medical countermeasures.	New overall goal statement added and revised target to make it more quantifiable
12048	Increase the number of drugs adequately labeled available for OTC use.	Revised	Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available.	New overall goal statement added
12051	Create state-of-the-art information management systems and practices to move to a paperless environment (e-Government).	Unchanged		
12052	Improve the capability and efficiency of pharmaceutical development and manufacturing. (formerly 12016)	Unchanged		
Center for Biologic Evaluation and Research				
13001	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	Unchanged		
13002	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.	Unchanged		

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
13005	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.	Unchanged	.	
Center for Veterinary Medicine				
14020	Complete review and action on 90% of original NADAs & reactivations of such applications received in FY 05 within 270 days.	Revised	Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. FY 05 Target: Complete review and action on 90% original NADAs and reactivation of such applications within 270 days.	The scope of this original premarket goal was broadened in order to reflect a comprehensive display of the Animal Drugs User Fee Act (ADUFA) goals. The previous FY 05 CJ goal is now changed to a target under this new goal.
Center for Devices and Radiological Health				
15007	Ensure at least 97% of an estimated 9,200 domestic mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems.	Revised	Ensure at least 97% of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems.	Revised to correctly report the number of domestic mammography facilities.
15012	Expand implementation of the MedSun System to a network of 250 facilities.	Revised	Expand implementation of the MedSun System to a network of 350 facilities.	Revised to reflect new facility target.
15027	Maintain inspection and product testing coverage of Radiological Health industry at 10% of an estimated 2000 electronic products.	Unchanged		
15031	Complete Review and Decision on 80% of 180 day PMA supplements within 180 days./1	Unchanged		
15032	Complete Review and Decision on 75% of 510(k)s (Premarket Notifications) within 90 days./1	Unchanged		
15033	Complete Review and Decision on 70% of Expedited PMAs within 300 days./1	Revised	Complete Review and Decision on 80% of Expedited PMAs within 300 days./1	Revised to reflect new expedited PMA target.
National Center for Toxicological Research				
16003	Develop computer-based models and infrastructure to predict the health risk of biologically active products	Revised	Develop at least one protocol (proof of concept) to aid in defining drug toxicity studies and studies into mechanistic age-associated degenerative disease.	Redefined to address research concepts that will evolve as a result of integrating NCTR systems toxicology functions into a unique systems biology research program that will effectively aid FDA in performing toxicity drug and chemical research studies.

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
16007	Develop risk assessment methods and build biological dose-response models in support of the Food Safety Initiative.	Unchanged		
16012	Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment	Unchanged		
16014	Use new technologies (toxicoinformatics, imaging, proteomics, metabonomics, and microarray) to study the risk associated with how an FDA-regulated compound or product interacts with the human body.	Unchanged		
Field Activities				
Foods Field Activities				
11040		New	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.	This goal is a critical new measure and will eventually replace the Import Field Exams as the primary measure for import security.
11036	Perform 97,000 import field exams and conduct sample analyses on products with suspect histories.	Revised	Perform 60,000 import field exams and conduct sample analyses on products with suspect histories.	Changed to accurately reflect the performance that is attainable with current resources.
11020	Inspect 95% of estimated 7,200 high-risk domestic food establishments once every year.	Revised	Conduct postmarketing monitoring, food surveillance, inspection, and enforcement activities with the objective of reducing the health risks associated with food, cosmetics and dietary supplements products. (Target: Inspect 95% of estimated 6,800 high-risk domestic food establishments once every year.)	New overall goal statement added; target the same. In addition, the current estimate of the FY 2005 high risk inventory has been reduced.
19013	Expand federal/state/local involvement in FDA's eLEXNET system by having 104 laboratories participate in the system by the end of FY 05.	Revised	Expand federal/state/local involvement in FDA's eLEXNET system by having 95 laboratories participate in the system.	Changed to accurately reflect the performance that is attainable with current resources.
19015	Perform at least 1,000 Filer Evaluations under new procedures.	Unchanged		
19016	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.	Unchanged		

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
11041		New	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 (American Association for Laboratory Accreditation). FY 05: Achieve and maintain accreditation for 6 laboratories	New goal added to highlight the importance of Field laboratory activities.
11020	Inspect 95% of estimated 7,200 high-risk domestic food establishments once every year.	Revised	Conduct postmarketing monitoring, food surveillance, inspection, and enforcement activities with the objective of reducing the health risks associated with food, cosmetics and dietary supplements products. (Target: Inspect 95% of estimated 6,800 high-risk domestic food establishments once every year.)	New overall goal statement added; target the same. In addition, the current estimate of the FY 2005 high risk inventory has been reduced.
19013	Expand federal/state/local involvement in FDA's eLEXNET system by having 104 laboratories participate in the system by the end of FY 05.	Revised	Expand federal/state/local involvement in FDA's eLEXNET system by having 95 laboratories participate in the system.	Changed to accurately reflect the performance that is attainable with current resources.
Human Drug Field Activities				
12020	Inspect 55% of registered high-risk human drug manufacturers.	Revised	Increase risk-based compliance and enforcement activities to ensure product quality. Target: Inspect 55% of registered high-risk human drug manufacturers.	New overall goal statement added
Biologics Field Activities				
13012	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.	Unchanged		

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
Animal Drugs and Feeds Field Activities				
14006	Conduct targeted BSE inspections of 100% of all known renderers and feed mills processing products containing prohibited material.	Revised	(See 14009 below.)	This FY 05 CJ goal/target was changed to a target under the new postmarket goal. (See 14009 below.)
14009	Maintain biennial inspection coverage by inspecting 50% of 1,440 registered animal drug and feed establishments.	Revised	Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. FY 05 Target(s): Maintain biennial inspection coverage by inspecting 50% of 1,390 registered animal drug and feed establishments; Conduct targeted BSE inspections of 100% of all known renderers and feed mills processing products containing prohibited material.	Two previous goals, the BSE goal and the biennial goal, are now targets under a new postmarket goal broadened in order to reflect a comprehensive display of the performance and cost of the CVM field surveillance and compliance work. The previous FY 05 CJ biennial inspection goal is now a target under this new revised goal.
Device and Radiological Health Field Activities				
15005.01	Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers at 20% of estimated 5,550.	Revised	Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers at 20% of estimated 5,540.	Revised to correctly report the number of firms
15005.02	Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 9% of estimated 2,500.	Revised	Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 7% of estimated 2,500.	Changed to accurately reflect the performance that is attainable with current resources.
15025	Conduct 295 domestic and foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.	Unchanged		
Other Activities				
19002	Implement 'shared services' concept and consolidate selected functions in the agency	Dropped		
19003	Increase the number of Commercial Activities that will be reviewed for competitive sourcing.	Unchanged		
19006	Increase percentage of contract dollars allocated to performance based contracts	Unchanged		

Disposition of FY 2005 Performance Goals

Goal ID	Original Goal Statement as stated in FY 05 Congressional Justification	Disposition	Revised FY 2005 Targets	Explanation
19017	Implement Financial Enterprise Solutions, FDA's version of UFMS	Unchanged		
19008	Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack.	Unchanged		