Disposition of FY 2007 Performance Goals

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
Foods				
11001	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 50% of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt.	Unchanged		
11010	Percentage of the approximately 3,000 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* by October 1, 2007 and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards by October 1, 2007. Target: 9% (270)/ 26%	Revised	New target: 240 enrolled / 26% meet 2 standards	The Program has reduced this performance target to more realistically reflect the redeployment of resources to address rent and rent related activities.
	Increase consumer understanding of diet-disease relationships (dietary fats and CHD) Target: 45%	Unchanged		
11040	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. Target: 60,000	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
11036	Perform import food field exams on products with suspect histories. Target: 71,000	Unchanged		
19015	Perform Filer Evaluations of import filers. Target: 1,000	Unchanged		
19016	Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. Target: 3,000	Unchanged		
11020	Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. Target: 5,700	Revised	New Target: 5625	The Program has reduced this performance target to more realistically reflect the redeployment of resources to address rent and rent related activities.
19013	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 provide automated notification of potential events. FY 2007 Measure: The number of analytes and select agents routinely tested and evaluated by eLEXNET pattern-detection algorithms such that departures from normal trends of detection trigger notifications to FDA food safety and security officials. Target: 5 analytes and 5 select agents	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
11041	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.) Target: Maintain accreditation for 13 labs	Unchanged		
	Increase laboratory surge capacity in the event of terrorist attack on the food supply.	Revised	Add capacity for 1,000 radiological samples per week (2 Radiological CAP Labs) & maintain 1,200 chemical samples (known analyte) per week	This goal was a PART Long Term Outcome Goal whose targets were still under development last year.
Human Drugs				
12001	Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. Measure 1A: Percentage of Standard NDAs within 10 Months. Target: 90% Measure 1B: Percentage of Priority NDAs within 6 Months. Target: 90%	Unchanged		
12026	Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. Measure: Number of written requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. Target: 7/7	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
12003	Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. Measure: Number of months of the average FDA time to approval or tentative approval for the fastest 25% of original generic drugs application. Target: Fastest 25% by .5 mos	Revised	Complete review and action upon 60% of fileable original generic drug applications within 6 months after submission date, excluding first cycle approvals.	CDER reverted back to the FY 2005 format for measuring performance within the generic drug program. With the significant increase in workload in the program, CDER is concerned about meeting its statutory obligations. Targets for FY 2007 and FY 2008 reflect the target performance toward the statutory requirement given the new workload, planned resources for FY 2007, and proposed resources for FY 2008. Applications which can be approved within 180 days are not included.
12048	Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available. Measure: Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was complete review and action. Number of OTC monographs in which there was significant progress on completion. Target: 100%/5	Unchanged		
	Reduce time to marketing approval for new drugs and biologics. Measure: Reduction in FDA approval time for the fastest 50 percent of priority New Molecular Entities/ Biologics Licensing Applications approved, using the 3-year submission cohort for FY 2005-2007. Target: 514 days	Revised	Measure: Reduction in FDA approval time for fastest 50 percent of standard New Molecular Entities/ Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007.	The goal statement was corrected to identify the proper type of NDA review for this goal. This is one of FDA's PART Long Term Outcome Goals, and it features Standard NDA/BLA Applications, not Priority NDA/BLA Applications.

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
	Reduce the time to marketing approval or tentative approval for safe and effective new generic drugs. Measure: Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the three year submission cohort for FY 2005 - 2007. Target: 16.4 months	Unchanged		
12045	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. Measure: Number of medical countermeasures in which there has been coordination and facilitation in development. Target: 5	Revised	New Target: 4	Due to competing priorities, CDER is focusing its resources on drug safety and generic drug issues which results in fewer resources available to apply to the medical countermeasure target.
12007	Improve the Safe Use of Drugs in Patients and Consumers Target: Evaluate new processes for communicating risk information and establish timeliness measures for time between identification of safety issues and action on those issues; Collaborate with the Centers for Medicare and Medicaid Services (CMS) on at least one study of a high priority safety issue in the Medicare population	Revised	New Target: Evaluate new processes for communicating risk information and establish timeliness measures for time between identification of safety issues and action on those issues; Collaborate with the Centers for Medicare and Medicaid Services (CMS), including training FDA staff on the content and use for drug safety research of CMS Medicare and Medicaid databases and completing at least one pilot study of a safety issue in the Medicare population	Center wanted to target study completion and include FDA staff training.

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
12053	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. Measure: Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. Target: $14/report	Revised	New target: $15/report	The original FY07 target relied upon the approval and implementation of the eSADR rule requiring that adverse events reports be submitted electronically. The implementation has been delayed and so FDA continues to receive paper reports which cost more to process into AERS.
	Reduce medication errors in hospitals.	Revised	New Measure and Target: Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. Target: 12.5%	This goal was a PART Long Term Outcome Goal whose targets were still under development last year.
12020	Increase risk-based compliance and enforcement activities to ensure drug product quality. Measure: The number of inspections conducted of foreign and domestic establishments identified as high-risk human drug manufacturers. Target: 500	Unchanged		
Biologics				
13001	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. Measure 1A: Percentage of Standard Applications within 10 Months. Target 90% Measure 1B: Percentage of Priority Applications within 6 Months. Target 90%	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
13002	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. Measure 2A: Percentage of Standard Efficacy Supplements within 10 Months. Target: 90% Measure 2B: Percentage of Priority Efficacy Supplements within 6 Months: Target: 90%	Unchanged		
13005	Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date. Measure 3A: Percentage of BLA Submissions within 12 months. Target 50% Measure 3B: Percentage of BLA Supplements within 12 months. Target 75%	**Unchanged**		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
13030	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. Target: Issue one guidance or concept paper to facilitate development of non-egg-based influenza vaccines; evaluate the potency of monovalent influenza vaccines from at least three manufacturers by using quality system guidelines; demonstrate two new or improved methods for improved influenza vaccine manufacture; develop at least four influenza virus vaccine strains optimized for growth in non-egg culture systems by using quality systems guidelines.	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
13012	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. Measure 5A: The number of inspections conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments. Target: 1,175 Measure 5B: The number of human tissue inspections conducted to enforce the new regulations. Target: 325	Revised	Measure 5A: 1,138	The Program has reduced this performance target to more realistically reflect the redeployment of resources to address rent and rent related activities.
Animal Drugs and Feeds				
14020	Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. Measure: Complete review and action on original NADAs & reactivations of such applications received during FY 2007. Target: 90% within 200 days	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
14009	Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. Measure 2A: The number of inspections conducted of registered animal drug and feed establishments. Target: 651 Measure 2B: The number of targeted BSE inspections conducted of all known renderers, protein blenders, and feed mills processing products containing prohibited material. Target: 527	Revised	Measure 2A: 620 Measure 2B: 490	The targets for the animal drugs and feeds establishment and BSE inspection performance goals were reduced due to a reduction in firm inventory. ORA is still inspecting 50% and 100% of the inventories respectively.
Medical Devices				
15033	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. *Measure 1A*: Percentage of Expedited PMAs reviewed and decided upon within 300 days. Target: 90% *Measure 1B*: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days. Target: 90%	Unchanged		
15031	Percentage of 180 day PMA supplements reviewed and decided upon within 180 days Target: 90%	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
15032	Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days Target: 80%	Unchanged		
	Reduce the average time for marketing approval for safe and effective new devices. Measure: Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. Target: 290 days	Unchanged		
15007	Percentage of an estimated 9,100 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. Target: 97%	Unchanged		
15012	Expand actively participating sites in MedSun Network to 76%.	Revised	Expand actively participating sites in MedSun Network to 80%.	When the FY 2005 participation baseline data came in higher than expected, CDRH revised the FY 2007 target upwards. The Program then had to reduce this performance target to more realistically reflect the redeployment of resources to address rent and rent related
15025	Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. Target: 295	Revised	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. Target: 295	The goal statement was revised to reflect a more risk-based approach to the inspections.

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
15005	Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). Target: 1,300	Revised	Target: 1,195 inspections.	The Program has reduced this performance target to more realistically reflect the redeployment of resources to address rent and rent related activities. Changes were made to the goal context statements to reflect a more risk-based approach to inspections of medical
National Center for Toxicological Research				
16014	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. Target: Test systems biology in the drug review process to assess value in drug review and approval.	Revised	Determine the feasibility of using systems biology in the drug review process.	This target has been revised to more realistically reflect the redeployment of resources to address rent and rent related activities.
16003	Develop computer-based models and infrastructure to predict the health risk of biologically active products. Target: Demonstrate the utility of ArrayTrack in the regulatory environment	Unchanged		
16007	Develop risk assessment methods and build biological dose-response models in support of Food Security. Target: Through collaborative efforts, use flow cytometry to facilitate isolation of single bacteria from contaminated samples for rapid bacterial identification and for pyrolysis mass spectrometry.	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
16012	Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. Target: Develop a novel and efficient carbon nanomaterial research method in collaboration with outside entities for the synthesis and chemical modification of unusual materials (i.e., nanofibers used in explosive detectors).	Unchanged		
The Office of the Commissioner / Headquarters' Operations				
19003	Increase the number of Commercial Activities that will be reviewed for competitive sourcing Target: Review and Compete 154 FTE per "Green" Plan	Unchanged		
19017	FDA's implementation of HHS's Unified Financial Management System. Target: FDA will finalize its decision on an activity-based costing application and make it operational for its user fee programs.	Unchanged		

Goal ID	Original Goal Statement as stated in FY 2007 Congressional Justification	Disposition	Revised FY 2007 Targets	Explanation
19008	Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack. Target: Enhance functionality and continue deployment of the Emergency Operations Network Incident Management System throughout the Agency (HQ, Centers, Field offices). Coordinate FDA's participation in exercises, including Topoff 4 Conduct and participate in exercises and workgroups related to emergency preparedness and response and counterterrorism. Continue implementing the requirements of HSPD 12 by installing access control devices at FDA facilities including select agent laboratories.	Revised	Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products Target: Enhance functionality and continue deployment of the Emergency Operations Network Incident Management System throughout the Agency (HQ, Centers, Field offices). Coordinate FDA's participation in exercises, including TOPOFF 4. Conduct and participate in exercises and workgroups related to emergency preparedness and response, avian and pandemic influenza, and counterterrorism. Develop an FDA emergency response plan and exercise(s) for pandemic influenza.	Implementation of HSPD-12 requirements has been delayed due to reprioritization of funding.