DEPARTMENT of HEALTH and HUMAN SERVICES

Food and Drug Administration

FY 2008 Annual Performance Report

Introduction

This FY 2008 Annual Performance Report provides information on FDA's actual performance and progress in achieving the goals established in the FY 2008 Annual Performance Plan which was published in February 2007.

The goals and objectives contained within this document support the Department of Health and Human Services' Strategic Plan (available at http://aspe.hhs.gov/hhsplan/2007/).

MESSAGE FROM THE FDA COMMISSIONER

I am pleased to present the FY 2008 Performance Report for Food and Drug Administration (FDA).

At FDA, we manage our programs to achieve measurable results and objectives that protect and advance the public health through a life-cycle approach to the safety of the products we regulate. This Performance Report reflects the goals and objectives in the Department of Health and Human Services Strategic Plan and the FDA Strategic Action Plans.

In FY 2008, FDA has met and/or exceeded 97% of its performance goals that have been reported on so far. FDA has met and/or exceeded 98% of its performance goals for the previous two years. In fact, since 2002, FDA has met and/or exceeded at least 92% of its performance goals. This is an excellent record of achievement over the years, and reflects well on the effort and professionalism of FDA's employees.

In accordance with the requirements of the Reports Consolidation Act of 2000, I, as the Agency Head, assert that the performance information in this report is accurate, complete and reliable, based on available data in FDA's performance information systems. The FY 2008 Performance Report includes descriptions of the means by which HHS requires us to verify and validate performance data and related data issues, including the completeness and reliability of the data. Where required, the programs have included discussions of the actions planned and completed to improve the completeness and reliability of the data.

At FDA, we pledge to continue to speed innovations that make our food and cosmetics supply safer and make medical products effective, safer, and more affordable for both human and animal consumption. We also pledge to continue to ensure that the public receives accurate and timely science-based information so they can use medical products and foods to improve their health. We will continue to be good stewards of the resources that Congress provides and build a healthier America for generations to come.

/Andrew C. von Eschenbach, M.D./
Andrew C. von Eschenbach, M.D.

Table of Contents

Summary of Performance Targets and Results

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2005	45	45	100%	42	93%
2006	46	46	100%	45	98%
2007	51	47	92%	46	98%
2008	47	34	72%	33	97%
2009	48				

Foods Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Increase access to safe and nutritious new food products.								
1	Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. (213301) (output)	100% of 7	87% of 7	50%	100% of 7	60%	10/09	60%
Long-Term Objective 2: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.								
2.1	Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards (214101) (outcome)	185 enrolled	259 enrolled	240 enrolled	302 enrolled	317 enrolled	320 enrolled	332 enrolled
2.2	Percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214102) (outcome)	NA	24%	26%	32%	32%	32%	32%
Long-Term Objective 3: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.								
3.1	Increase consumer understanding of diet-disease relationships (dietary fats and CHD) Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. (212401)	32%	NA	45%	1/09	NA	NA	NA
3.2	Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. (212402)	74%	NA	81%	1/09	NA	NA	NA
3.3	Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease. (212403)	31%	NA	34%	1/09	NA	NA	NA

Long-Term Objective 4: Detect safety problems earlier and better target interventions to prevent harm to consumers.								
4	Number of prior notice import security reviews. (214201) (output)	86,187	89,034	60,000	84,088	80,000	80,543	80,000
5	Number of import food field exams. (214202) (output)	84,997	94,545	71,000	94,743	85,000	100,718	104,440
6	Number of Filer Evaluations. (214203) (output)	1,407	1,441	1,000	1,355	1,000	1,356	1,000
7	Number of examinations of FDA refused entries. (214204) (output)	5,655	5,846	3,000	5,510	4,000	5,926	5,000
8	Number of high risk food inspections. (214205) (output)	7,568	6,795	5,625	6,421	5,700	6,230	6,100
9	Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome)	NA	NA	NA	NA	5 data entry labs	11 data entry labs	5 data exchange labs
10	Maintain accreditation for ORA labs. (214206) (outcome)	6 labs	13 labs	13 labs	13 labs	13 labs	13 labs	13 labs
11	Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305) (outcome)	0	1,200 chem	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem	2,500 rad & 1,650 chem

Other Outcome Indicators Measured in the HHS Strategic Plan

Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 3: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.							
Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species.	12.7 cases/ 100,000	12.7 cases/ 100,000	TBD	09/08*	TBD		TBD
Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7.	1.1 cases/ 100,000	1.3 cases/ 100,000	TBD	09/08*	TBD		TBD
Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*.	0.30 cases/ 100,000	0.31 cases/ 100,000	TBD	09/08*	TBD		TBD
Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species.	14.5 cases/ 100,000	14.7 cases/ 100,000	TBD	09/08*	TBD		TBD

* CDC has not published the final FY 2007 FoodNet data, although it was expected to be published this fall.

1. Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. (213301)

Context: The likely number of submissions to the food and color additives premarket review program has been uncertain for FY 2007 and FY 2008 because of statutory triggers in section 409(h) of the FD&C Act that might have dramatically increased the number of submissions to this program. Our performance target for FY 2009 is based on our current level of certainty that program submissions will not dramatically increase during FY 2009.

Performance: Because of the 360 day review time associated with this goal, the FY 2008 actual data will not be available until October 2009. FDA recently reported the FY 2007 results and exceeded the target of 60%. However, although this program has reached or exceeded its performance goal each of the last three years, program resources have been reduced. One reason goals have continued to be met is that the actual number of submissions has fallen off over that time period. An increase in the number or complexity of incoming submissions could reduce performance.

2. Number of 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. (214101 and 214102)

Context: Strong and effective regulatory programs at the state, local and tribal level are needed to prevent foodborne illness and reduce the occurrence of foodborne illness risk factors in retail and foodservice operations. The voluntary use of the Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing foodborne illness. The success that FDA's National Retail Food Team has had in increasing enrollment and use of the Standards reflects continued recognition that the Standards help programs improve food safety in foodservice and retail food establishments. Effective use of the Standards is assured by having enrolled complete program self-assessments to identify program strengths and areas for improvement.

Performance: FDA exceeded its FY 2008 target by enrolling 18 additional states, local and tribal retail food inspection programs enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards. This raised the total number of enrolled jurisdictions to 320. 102 of these 320, or 32%, of the enrolled jurisdictions reported meeting at least 2 of the 9 Program Standards, based on their own self assessments. The FY 2009 targets in the Outputs Table are based on an expectation of enrolling fifteen additional enrolled jurisdictions. These targeted increases are more modest than previous year's enrollments in recognition that, in addition to enrolling new jurisdictions, ORA personnel must devote time and resources to assisting the growing number of enrollees with Program Standards implementation. In fact, the target for FY 2009 is to maintain the current percentage of those enrolled jurisdictions that meet 2 or more of the Standards at 32%.

3. Increase consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease (CHD). (212401, 212402, 212403)

Context: Coronary Heart Disease (CHD) is the leading cause of death among Americans, accounting for more than 1 in 5 deaths annually. CHD is also the leading cause of premature,

permanent disability in the labor force. Dietary factors, especially consumption of some fats, play a significant role in CHD risk. One modifiable factor that is important for reducing mortality and morbidity associated with heart disease is consumer understanding of the consequences of dietary choices with respect to CHD. Increased understanding will strengthen motivation to adopt and maintain recommended healthy dietary behavior and to make informed dietary choices. The target is directly in line with several of the Department's priorities and strategic goals. First, improving the American diet through informed choice about fats that increase or reduce the risk of heart disease is one of several important steps toward reducing the enormous morbidity and mortality burden of CHD. This burden is borne disproportionately by minority populations, including African-Americans, Hispanics, and Native Americans. As the leading cause of death and a significant cause of illness and disability, CHD also imposes substantial costs on the U.S. health care system.

Performance: The baseline data for FY 2005 has been developed. Although the target year for accomplishment was FY 2007, the Health and Diet Survey is currently in the field and data is expected to be available for analysis in early January 2009.

4. Number of prior notice import security reviews. (214201)

Context: FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

Performance: During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

5. Number of import food field exams on products with suspect histories. (214202)

Context: The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than

18.7 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA will use additional FY 2008 Supplemental resources to increase the number of import food field exams by 19,440 exams which brings the FY 2009 Target to 104,440 exams.

Performance: In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

6. Number of Filer Evaluations of import filers. (214203)

Context: The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices.

Performance: In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

7. Number of examinations of FDA refused entries. (214204)

Context: FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and

Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target has been increased to 5,000 examinations to better reflect the recent historical actuals for this goal.

Performance: In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many examinations of refused entries will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal. However, FDA has adjusted future targets upward based on actual performance data for the last several years. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

8. Number of high risk food inspections. (214205)

Context: High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on a firm's compliance history. The FY 2009 target has been increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal.

Performance: In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 inspections of high-risk domestic food establishments.

9. Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214301)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2008, 151 laboratories representing multiple

government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

Performance: In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. Explanation of why this goal was significantly exceeded: This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

10. Maintain accreditation for ORA labs. (214206)

Context: FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena.

Performance: In FY 2008, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

11. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305)

Context: A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing Federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as

soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year.

Performance: In FY 2008, FDA met this performance goal surge capacity target of 2,500 radiological samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 radiological samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which will increase the surge capacity in FY 2009 to 1,650 chemical samples per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of State, local, and tribal regulatory bodies.

Human Drugs Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.								
1.1	Percentage of Standard NDAs/BLAs within 10 months. (223201) (Output)	99% of 73	95% of 90	90%	88% of 84	90%	11/09	90%
1.2	Percentage of Priority NDAs/BLAs within 6 months (223202) (Output)	88% of 32	97% of 29	90%	90% of 21	90%	11/09	90%
2	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. (223101) (Output)	12/14	18/12	7/7	30/13	8/8	5/19	5/7
3	The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205) (Output)	1496	1456	NA	1779	1780	1934	1900
4	Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. (223206) (Output)	100%/17	100%/8	100%/5	100%/9	100%/5	100%/9	100%/5
5	Reduction in FDA approval time for the 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. (223207) (Outcome)	2/09	2/10	514 Days	2/11	NA	NA	NA
6	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 3-year submission cohort for FY 2005-2007. (223208) (Outcome)	17.8 months[1]	5/09	16.4 months	5/10	NA	NA	NA
7	Number of medical countermeasures in which there has been coordination and facilitation in development (223102) (Output)	11	6	4	4	5	6	4
Long-Term Objective 2: Improve information systems for problem detection and public communication about product safety.								
8	Improve the Safe Use of Drugs in Patients and Consumers (222301) (Output)	Reviewed and provided comments on 100% of RiskMAPs for NMEs or products FDA or	Stand-ardized communi-cation processes.	Imple-ment safety issue tracking system.	Imple-mented.	Conduct pilot and act upon 50% of issues within timelines	Conducte d pilot and acted upon 50% of issues within timelines	Act upon 50% of issues within timelines

[1] The reported results represent a three year average calculated using cohort data from the reported year and the two prior years.

		sponsor initiated discussions						
9	Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201) (efficiency goal)	$17.35 per report	$16.47 per report	$15 per report	$13.64 per report	$13/per report	$10.59 per report	$12 per report
10	Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202) (Outcome)	9.4%	13.2%	12.5%	19.6%	NA	NA	NA
11	Number of foreign and domestic high-risk human drug inspections. (224201) (output)	600	510	500	583	500	534	600

1. Percentage of Standard NDAs/BLAs and Priority NDAs/BLAs within 10 months. (223201 and 223202)

Context: This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes new drug and biologics licensing applications. Central to that focus is FDA's commitment to meeting PDUFA goals and requirements. The Food and Drug Administration Amendments Act of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. A key determinant in knowing if CDER is effective and efficient is to measure the time to "first action." The first action is the first regulatory action CDER takes (complete response, approvable, not approvable, or approval letter) at the end of the review of the original NDA/BLA submission (the first review cycle). The "first action time" refers to the time it takes to review and take an action on the original submission. This statistic is different from "total approval time" which is the time it takes from the original receipt of the application until it is approved, which may take more than one review cycle. "Total approval time" includes time spent reviewing an application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the complete response or approvable/not approvable letter(s) and to re-submit the application for review. CDER's featured targets under this performance goal are to measure time to first action for "priority" submissions and "standard" submissions. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: CDER will not have the final performance numbers for the FY 2008 submission cohort until November 2009. The latest information on CDER's performance toward the targets for this performance goal is from FY 2007. In FY 2007, CDER met the PDUFA review performance goals for reviewing priority NDAs and BLAs, including meeting the goal for reviewing priority NMEs and new BLAs, but did not meet the PDUFA review performance goals for reviewing standard NDAs and BLAs, including not meeting the goal for reviewing standard NMEs and new BLAs. CDER met its FY 2007 performance target for priority reviews. However, it narrowly missed its target of 90% review of standard applications. CDER's 88% performance on standard applications represents early indications of the impact of a shift in Center policy to put equal emphasis on post-market safety review decisions as on pre-market review decisions. CDER stretched its existing resources to implement the new policy.

2. 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. (223101)

Context: The context of the Pediatric Program's performance goal in CDER covers the activities and requirements of the various laws passed to ensure safe and effective drug products are available for children, including the Best Pharmaceuticals for Children Act (BPCA), which provides incentives to manufacturers who conduct studies in children including a 6-month extension of marketing exclusivity for conducting pediatric studies requested by FDA, and the Pediatric Research Equity Act (PREA) which provides FDA the authority to require pediatrics studies for certain new and already marketed drug and biological products. In FY 2009, the targets are five written requests and seven drugs reported to the pediatric advisory committee.

Performance: The target for FY 2008 performance was to issue at least 8 written requests to drug sponsors for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for 8 drugs that receive pediatric exclusivity. CDER issued 5 Written Requests to sponsors for on-patent drugs, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committee meetings on adverse events for 19 drugs that received pediatric exclusivity. CDER's 5 Written Requests (WRs) issued for drugs and 19 drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity represents early indications of the impact of a shift in Center policy. CDER stretched its existing resources to implement the new policy requiring safety assessments to be submitted with application and post marketing requirements for safety monitoring.

3. The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205)

Context: The Office of Generic Drugs (OGD) has experienced a dramatic increase in workload, with the number of generic drug applications almost doubling over the past 4 years at a time when staffing levels have increased less than 20%. Consequently, the previous measure (the percentage of new applications for which first action is taken within 180 days) no longer reflects FDA's current program management challenge to increase throughput and productivity to address the higher workload while maintaining standards of quality and safety. Therefore, FDA has determined that a more meaningful performance goal for the generic drug program is the number of total actions taken on abbreviated new drug applications. The total number of actions includes approvals, tentative approvals, not approvable, and approvable actions on applications.

Performance: In FY 2008, the Office of Generic Drugs exceeded its goal by more than 150 actions, while also exceeding the number of actions in FY 2007. In FY 2009, the target is 1900 actions, an increase of almost 7% over the FY 2008 target. This reflects both the estimated increase in performance as new staff that are expected to be hired in FY 2008 are trained and achieve full performance levels.

4. Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. (223206)

Context: OTC drug products can be legally marketed in the United States under an approved new drug application (NDA) or pursuant to an OTC drug monograph. OTC drugs can be approved under an NDA through an Rx-to-OTC switch or by direct to OTC. OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients, dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet the same, uniform criteria. Final monographs (agency final rules) need to be completed for a number of large product categories (e.g., external analgesics, internal analgesics, antimicrobials, oral health care products, laxatives). FDA is working to review OTC monographs for 29 categories of drug products to eliminate unsafe and ineffective products from the OTC market. The ability to reach these goals is contingent upon the addition of experienced staff in all facets of rulemaking development as well as improvement in the efficiency of the FDA document clearance process.

Performance: FDA exceeded its 2008 target by completing review and action on 100% of Rx-to-OTC switch and direct to OTC applications within 10 months of receipt. All Rx-to-OTC switch applications received in FY2008 with action goal dates in FY2008 were acted on within 10 months of receipt. There were 4 approval actions encompassing a total 7 switch products.

FDA made significant progress on the following 9 monographs: (1) Internal Analgesic, Antipyretic, and Antirheumatic Drug Products - Organ Specific Warnings, Final Rule (proposed rule published 12/06); (2) Pediatric Dosing for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products - Amendment of the Final Rule (Advisory Committee meeting held 10/18/07 ; Part 15 Hearing held 10/2/08) ; (3) UVA Testing and Labeling for OTC Sunscreen Drug Products, Final Rule (proposed rule published 8/07); (4) OTC Topical Acne Drug Products Containing Benzoyl Peroxide, Final Rule; (5) Vaginal Contraceptive Drug Products – Proposed Amendment to the Proposed Rule ; (6) Laxative Professional Labeling, Proposed Rule; (7) Topical Antimicrobial Drug Products - Consumer Antiseptics; (8) Labeling for OTC Drug Product - Convenience Size Labeling Rule (proposed rule published 12/06); and (9) Cold Cough Allergy, Bronchodilator and Antiasthmatic Drug Products – Labeling for Bronchodilators to Treat Asthma (Ephedrine Single Ingredient) Final Rule.

5. Reduction in FDA approval time for the 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. (223207)

Context: Reducing unnecessary delays in the approval time for safe and effective drugs that truly represent new therapies [i.e., new molecular entities (NMEs) and biologics] means earlier patient access for these medicines. Reducing unnecessary delays in drug approval also helps to both control the cost of new drug development, cited as a factor affecting the cost to consumers, and supports market competition among innovators. This is both good for the drug industry and

good for consumers. New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition both from new drugs with therapeutic value – but not blockbuster potential, and new innovators that don't have access to the capital available to more established pharmaceutical companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated, helping speed patient access to new drugs, and reducing the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty. The targeted reductions in this FDA outcome goal represent approximately 10.5 percent reductions in total FDA review times for priority and standard NMEs and BLAs. Using Tufts estimates of potential cost reductions by phase of drug development, a 10 percent reduction in regulatory review time yields a 1.6 percent reduction in total capital costs, now estimated at $802 million, translating to a savings of $12.8 million per NME approved.

Performance: The FDA approval time for the fastest 50 percent of standard NME and biologics licensing applications (BLAs) approved in CDER and CBER for the FY 2001-2003 cohort is 523 days as compared to 575 days for the baseline FY 1999-2001 submission cohort. This is a reduction of 52 days versus the FY 2005-2007 target of a reduction of 61 days. Performance for the FY 2004 submission cohort was 547 days.

6. 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 3-year submission cohort for FY 2005-2007. (223208)

Context: FDA achievement of this goal will create earlier access to lower cost drug alternatives for patients. The high cost of drugs limits patient access to treatment. The lower income and uninsured populations are particularly affected. Research has shown that 42 percent of the uninsured do not fill prescriptions because of financial reasons. The Center for Medicaid and Medicare Services has stated that the new Medicaid prescription drug coverage has come in under budget and points to the availability of more generic products as a factor in this outcome. Increasing the availability of generic drugs will make many important treatments more affordable to the poor and the elderly and significantly improve access to treatment. Optimal access and use of generic drugs will enable policy decision makers to contain costs in both the Medicare and Medicaid programs. This will only become more important as more of the top selling brand name drugs go off patent over the next few years.

Performance: The FDA approval time for the fastest 70 percent of original generic drug applications approved for the FY 2003-2005 cohort is 17.8 months as compared to 17.9 months for the baseline FY 1998-2000 submission cohort. This is an increase from the FY 2002-2004 cohort of 16.0 months. In the last several years, submissions of abbreviated new drug applications have increased exponentially.

7. Number of medical countermeasures in which there has been coordination and facilitation in development. (223102)

Context: In the Federal Government's response to a biological, chemical, or radiological/nuclear attack or to a natural disaster, drugs will be mobilized from the CDC's

Strategic National Stockpile (SNS). However, not all drugs in the SNS are FDA-approved as countermeasures against threat agents or emerging infections. FDA has been taking an aggressive and proactive approach to identify and facilitate development of new therapeutic options as well as to obtain information on existing approved drugs that may be used for an unapproved indication. Identification of gaps in the therapeutic armamentarium and development of a plan to address these gaps will move the FDA closer to a goal of labeling medical countermeasures that reside in the SNS. For example, although ciprofloxacin and doxycycline are FDA approved for post-exposure prophylaxis of anthrax, these drugs are not recommended for use in children and pregnant women unless no other drug is available. Amoxicillin may be recommended as an alternative for these special populations, but it is not FDA approved and the optimal dose and dosing frequency are unknown. Hollow fiber studies with amoxicillin may provide data to develop appropriate dosing regimens. FDA is also active in department and agency efforts to prepare for other emergencies, such as natural disasters and pandemics. In FY 2009, the target remains at 4 countermeasures.

Performance: In FY 2008, CDER facilitated the development of and access to medical countermeasures for counterterrorism and emerging infections through these actions:

- FDA extended the expiry of **Tamiflu (oseltamivir)** capsules from 5 years to 7 years.
- FDA assisted the HHS/PHEMCE Radiological/Nuclear Integrated Program Team (R/N IPT) in preparing a White Paper for the Enterprise Executive Committee: "**Neupogen** in the Strategic National Stockpile to Address Neutropenia Associated with Acute Radiation Syndrome -- Issues Regarding Potential Use in an Emergency."
- FDA provided comments to the Department of Health and Human Services (HHS) regarding a plan for anticipated information needs to support submission of an NDA for approval of a "**home MedKit**" containing antiviral drugs as a mitigation strategy for a potential influenza pandemic.
- **Levaquin (levofloxacin)** tablets, injection, and oral solution were approved for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis* in pediatric patients. The drug previously was approved to treat adults after exposure to inhaled anthrax.
- To prepare the American population for an anthrax attack, FDA posted on its internet site revised home preparation instructions for **doxycycline** dosing for children and adults who are not able to swallow pills, at: http://www.fda.gov/cder/drug/infopage/penG_doxy/home_prep.htm.
- FDA awarded a contract for hollow fiber studies and mathematical modeling to determine the optimal dosing regimen for **amoxicillin** for anthrax post-exposure prophylaxis for pregnant women and children.

8. Improve the Safe Use of Drugs in Patients and Consumers. (222301)

Context: CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. The FDA Amendments Act of 2007 (FDAAA) recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and

authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way CDER tracks pre-market issues according to PDUFA requirements. Activities in FY 2006 and FY 2007 to standardize communications policies and procedures and to develop a tracking system to capture information about known and emerging safety issues established a foundation upon which CDER can now begin to build the capacity and capability to more effectively manage safety issues in a timely fashion. In FY 2009 the target is to act on 50% of the issues within timelines.

Performance: In FY 2008, CDER met its target of acting upon at least 50 percent of the identified priority postmarket safety issues within an established timeframe. During the first year of this new process, CDER focused its efforts on increasing its staff resources for tracking, managing, and monitoring postmarket safety issues. CDER conducted a pilot for prioritizing postmarket safety issues, developing action plans and timelines for those issues, and monitoring and managing progress toward those plans.

9. Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201)

Context: The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product to identify unexpected safety risks associated with the use of a human drug that could not have been predicted by clinical trials and biostatistical analysis. Reports of these unexpected safety problems, called adverse events, are captured in the Adverse Event Reporting System (AERS), a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. Information captured in AERS allows FDA scientists and statisticians to search for patterns that may indicate an emerging safety hazard, which is the first step in analyzing the potential causes and formulating an effective risk management response. FDA is working to make AERS more efficient by improving the data entry work processes and reengineering the system to increase the percentage of electronic submissions, to reduce the amount of manual re-keying, along with other efficiencies. These system improvements will allow the FDA to reduce the average cost and time associated with turning a submitted Adverse Event Report into a verified record in the database. This improvement in efficiency will allow scientists and statisticians to access safety information sooner, and will free up resources that can be redirected to risk analysis activities that directly improve our ability to recognize and respond to drug safety problems.

Performance: The average cost associated with turning a submitted Adverse Event Report into a verified record in the database has been decreasing since FY 2003 due to FDA efforts to streamline its business processes and improve the information systems that are used to process records. In FY 2003, the cost per report was $21.91/per report. In FY 2004, the cost per report was $19.30/per report. In FY 2005, the cost per report was $17.35/per report. In FY 2006, the

cost per report was $16.47/per report. In FY 2007, the cost per report was $13.64/per report. In FY 2008, the actual cost per report was $10.59/per report. The proposed FY 2009 target of $12 per report is an increase over the FY 2008 value due to the expected addition of periodic reports that have not been previously entered in the past. The cost decrease for the FY 2008 actual of $10.59 per report as compared to the target value of $13 per report is due mainly to the high volume of electronic submissions, thereby offsetting the cost per report. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports. In the absence of electronic submissions, the program costs for manual data entry would be nearly double what they are today.

10. Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202)

Context: In November 1999, the Institute of Medicine released a report estimating that as many as 98,000 patients die from medical errors in hospitals alone. Many of these deaths, as well as additional non-fatal illnesses, are associated with errors involving FDA regulated medical products, especially medications. A significant percentage of drug related mortality and morbidity results from errors that are preventable. In addition to their human cost, these errors impose significant economic costs on the U.S. health care system. The total cost of preventable adverse events has been estimated at $17 Billion. Preventing some of the adverse drug events related to medication errors in U.S. hospitals will significantly reduce related morbidity, mortality and health care costs. Research to date has demonstrated the ability of bar code scanners at the point of care to intercept errors in dispensing and administration of medications and thereby prevent related adverse events. Consequently, this measure tracks the adoption rate of bar code medication administration technology in hospitals, with the expectation that increased adoption rates will be directly related to decreased medication error-related adverse events.

Performance: The results of the American Society of Health-System Pharmacists (ASHP) national survey of pharmacy practice in hospital settings: prescribing and transcribing-2007 were published in 2008. Over the last few years the adoption rate of bar code medication administration technology has grown each year, up to 19.6% overall in 2007.

11. Number of foreign and domestic high-risk human drug inspections. (224201)

Context: FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2009. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 high-risk foreign and domestic drug manufacturers.

Biologics Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infections diseases.								
1	Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. (233201) (Output)	100% of 3	100% of 2	90%	100% of 9	90%	11/09	90%
2	Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (233202) (Output)	100% of 3	100% of 3	90%	100% of 6	90%	4/09	90%
3	Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (233203) (Output)	100% of 10	100% of 9	90%	100% of 9	90%	11/09	90%
4	Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (233205) (Output)	100% of 4	100% of 2	90%	100% of 5	90%	11/09	75%
5	Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (233206) (Output)	100% of 401	100% of 326	90%	99% of 371	90%	11/09	80%
Long-Term Objective 2: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.								
6	Increase manufacturing diversity and capacity for pandemic influenza vaccine production. (234101) (Output)	NA	Accom-plished targets. See goal-by goal section, below.	See goal-by goal section, below.	Accom-plished targets. See goal-by-goal section, below.	See goal-by goal section, below.	Accom-plished targets. See goal-by-goal section below.	See goal-by-goal section below.
Long-Term Objective 3: Detect safety problems earlier and better target interventions to prevent harm to consumers.								
7	Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202) (output)	NA	NA	NA	NA	870	1,014	870
8	Number of highest priority human tissue establishment inspections. (234203) (output)	NA	354	325	427	325	383	380

1. Complete review and action on standard original PDUFA NDA and BLA submissions within 10 months of receipt. (233201)

Context: The Prescription Drug User Fee Act (PDUFA) authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. Standard original BLAs are license applications for biological products, not intended as therapies for serious or life-threatening diseases.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year, and complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 9 standard applications within 10 months of receipt, and has met or exceeded this performance goal since 1994. The FY 2008 performance data for this goal will not be available until November 2009.

2. Complete review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (233202)

Context: The PDUFA authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. A BLA will receive priority review if the product, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 6 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 6 priority applications within 6 months of receipt, and has met or exceeded this performance goal since 1994. The FY 2008 performance data for this goal will not be available until April 2009.

3. Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (233203)

Context: The PDUFA authorizes the FDA to collect fees from the prescription drug and biologic industries to expedite the review of human drugs and biologics so they can reach the market more quickly. An efficacy supplement is a change to an approved licensed product to modify the "approved effectiveness" of a product such as a new indication, and normally requires clinical data.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 9 standard PDUFA efficacy supplements within 10 months of receipt has met or exceeded most of these performance goals since 1994. The FY 2008 performance data for this goal will not be available until November 2009.

4. Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (233205)

Context: CBER has established the performance goal of reviewing and acting upon complete blood bank and source plasma BLA submissions within 12 months after submission.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 12 months after receipt, is expired. In FY 2007, CBER exceeded its goal by reviewing and acting on 100 percent of 5 submissions within 12 months of receipt. The FY 2008 performance data for this goal will not be available until November 2009.

5. Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (233206)

Context: CBER has established the performance goal of reviewing and acting upon complete blood bank and source plasma BLA supplement submissions within 12 months after submission.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 12 months after receipt. In FY 2007, CBER exceeded its goal by reviewing and acting on 99 percent of 371 supplements within 12 months of receipt. The FY 2008 performance data for this goal will not be available until November 2009.

6. Increase manufacturing diversity and capacity for pandemic influenza vaccine production. (234101)

Context: The Biologics Program has received appropriated funding to establish the infrastructure and surge capability to react to a potential disease pandemic. Influenza pandemics are explosive global events in which most, if not all, persons worldwide are at risk for infection and illness. Pandemic influenza strains, such as avian influenza, can rapidly change and current vaccines will not provide protection. Industry will need to produce vaccines for pandemic influenza on a short notice, and FDA needs to provide new and accelerated pathways to facilitate their rapid production and evaluation. This goal changes on a yearly basis to ensure continued progress in preparation for a pandemic outbreak. In FY 2008, the pandemic target was to: facilitate rapid development, evaluation and availability of at least one new pandemic influenza vaccine and one new trivalent (seasonal influenza) vaccine; demonstrate one improved method for evaluating the safety, potency or immunogenicity of influenza vaccines; and establish international regulatory cooperation, harmonization and information sharing in vaccine evaluation and safety activities by participating in one international workshop or conference.

Performance: In FY 2008, CBER accomplished all of it targets for this goal. CBER received a BLA to market a seasonal influenza (trivalent) vaccine in the United States, however, the data did not support licensure, and a Complete Response action was taken on August 29, 2008. All six influenza vaccine manufacturers for the 2008-2009 influenza season were licensed before the season began. CBER facilitated the development of a new pandemic influenza vaccine by:

- Completed production of an H5 reassortant, "Influenza A virus reassortant A/Duck/Laos/3295/2006 (H5N1), DUCK/LAOS-PR8/CBER-RG1 reference strain" and has been distributed to the recipients including the National Institute for Biological Standards and Control (NIBSC) in the UK and Taiwan-CDC in China; Characterization of attenuated reassortant of A/duck/Laos/3295/06 with modified internal gene is ongoing.

- Completed collaborative calibration (with National Biological Standards Board-UK) for A/Anhui/2/2005
- Engaged in pre-BLA discussions with GlaxoSmithKline to provide advice for their pandemic vaccine BLA which is projected to be submitted in 2009.

CBER posted guidelines on the WHO website of The WHO Guidelines on regulatory preparedness for pandemic influenza vaccines. The guidelines, co-authored by WHO, FDA and Health Canada, resulted from three technical workshops that were convened with representation of national regulatory authorities (NRAs) from a broad range of countries. The goal of these workshops was to build a global network of key regulatory authorities engaged in and responsible for pandemic influenza vaccine regulation and to develop regulatory guidelines for preparedness of human pandemic influenza vaccines. The guidelines are intended to provide, both NRAs and vaccine manufacturers, state of-the art advice concerning regulatory pathways for human pandemic influenza vaccines; regulatory considerations to take into account in evaluating the quality, safety and efficacy of vaccine candidates; and requirements for effective postmarketing surveillance of human pandemic influenza vaccines.

7. Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202)

Context: FDA will increase risk-based compliance and enforcement activities by inspecting the highest priority registered manufacturers of biological products. The highest priority firms will be those whose operations are determined to be the highest risk, new product types in need of an inspectional history to evaluate and stratify risk, and, emergency response situations. Inspections for the goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure, as appropriate, the safety, purity and potency of biological products. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines.

Performance: In FY 2008, FDA exceeded this high risk inspection goal of 870 by inspecting 1,014 blood banks and biologics manufacturing establishments. The FY 2008 target was exceeded due to an increase in the number of reinspected firms from FY 2007. Although normally blood banks and biologics manufacturers are inspected every other year, in FY 2008 there were more reinspections than usual because the American Red Cross Consent Decree Committee requested specific ARC blood banks be reinspected and the Center requested selected vaccine and flu manufactures to start being inspected annually.

8. Number of highest priority human tissue establishment inspections. (234203)

Context: Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance

with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA will increase this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations.

Performance: In FY 2008, FDA exceeded the human tissue goal of 325 by conducting 383 inspections under new regulations.

Animal Drugs and Feeds Program Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new medical products available to patients.								
1	Complete review and action on original NADAs & reactivations of such applications received during FY 2009. (243201) (output)	100% of 4 w/in 270 days	100% of 7 w/in 230 days	90% w/in 200 days	100% of 7 w/in 200 days	90% w/in 180 days	1/10	90% w/in 180 days
Long-Term Objective 2: Detect safety problems earlier and better target interventions to prevent harm to consumers.								
2	Number of domestic and foreign high risk animal drug and feed inspections. (244202) (output)	NA	NA	NA	NA	233	244	233
3	Number of targeted prohibited material BSE inspections (244203) (output)	588	516	490	523	490	555	490

1. Complete review and action on original NADAs & reactivations of such applications received during FY 2009. (243201)

Context: The FY 2009 goal and target reflects reauthorization of ADUFA and continued achievement of statutory review timeframe(s) over a five-year period (FY 2009-FY 2013). The goal and target reflects one of the ADUFA user fee goals and the Center's ability to maintain FY 2008 review time frames for specified new animal drug application reviews.

Performance: Based on the final performance update for FY 2007, FDA exceeded all ADUFA performance goals. FDA reviewed and acted on all seven (7) original NADAs and reactivations of such applications received during FY 2007 within 200 days. As of September 30, 2008, the preliminary performance assessment for FY 2008 data indicates FDA has exceeded the ADUFA goal(s). Additional information is forthcoming in the FY 2008 ADUFA Performance Report to Congress.

2. Number of domestic and foreign high risk animal drug and feed inspections. (244202)

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target is being maintained into FY 2009 because this is a new, risk-based goal for which we have no historical experience, and are unsure how the new site-selection methodology will evolve.

Performance: In FY 2008, FDA exceeded this inspection goal of 233 by inspecting 244 high risk animal drug and feed establishments.

3. Number of targeted prohibited material BSE inspections (244203)

Context: FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc.

Performance: In FY 2008, FDA completed the inspection of all 555 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

Medical Devices and Radiological Health Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.								
1	Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253203) (Outcome)	NA	81% of 40	90% in 320 days	96% of 33	60% in 180 days and 90% in 295 days	1/10	60% in 180 days and 90% in 295 days
2	Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. (253204) (Outcome)	95% of 101	95% of 136	90%	97% of 132	85% in 180 days and 95% in 210 days	1/10	85% in 180 days and 95% in 210 days
3	Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. (253205) (Outcome)	91% of 3,382	91% of 3,530	80% in 90 days	92% of 3,531	90% in 90 days and 98% in 150 days	1/10	90% in 90 days and 98% in 150 days
4	Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201) (output)	335	336	295	323	300	301	300
5	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. (253206) (Outcome)	322	10/09	290 days	2/10	NA	NA	NA
Long-Term Objective 2: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.								
6	Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (254101) (Outcome)	97% of 9,100	97%	97%	97%	97%	97%	97%
7	Number of domestic and foreign Class II and Class III device inspections. (254201) (output)	1495	1,506	1,195	1,468	1,270	1,431	1,340
Long-Term Objective 3: Improve information systems for problem detection and public communication about product safety.								
8	Participation rate of facilities in the MedSun Network. (252201) (outcome)	NA	NA	90%	90%	95%	98%	95%

MDUFMA, and MDUFMA as amended review goals (Goals 1, 2, and 3) are based on FDA review time only, and do not include time that elapses when the sponsor is responding to questions or issues raised by FDA. This means that FDA cannot determine exactly when all the applications in a review cohort will be completed. The actual results reported for this goal are as of the times noted, and as the final applications in the cohort are resolved, small changes to previously reported results may occur.

1. Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253203)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. PMAs involve potentially high-risk devices with the most chance of significantly improving the treatment of patients. The steps taken in MDUFMA, and MDUFMA as amended, that will reduce approval times for PMA applications are expected to reduce approval times for all filed applications, while recognizing that some applications may not ultimately meet FDA's standards for safety and effectiveness and that performance measures based on all applications will take more time to observe. Due to the renegotiation of MDUFMA, the Performance targets for Original PMA applications will be to arrive at a decision on 60% of Original PMA applications within 180 days and 90% within 295 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by arriving at a decision on 96% of Original PMA applications within 320 days. The current baseline for FDA decision time for standard PMAs is 295 days. The FY 2008 performance data for this goal will not be available until January 2010.

2. Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. (253204)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: approval, approvable, approvable pending GMP inspection, not approvable, denial. PMAs involve potentially high-risk devices that have the highest likelihood of significantly improving the treatment of patients. Supplemental applications are generally submitted for changes in already approved products such as technology changes or the addition of a new indication. It is essential that FDA complete the review process for these products quickly and thoroughly. Due to the renegotiation of MDUFMA, the Performance targets for 180 day PMA Supplements will be to arrive at a decision on 85% of applications within 180 days and 95% within 210 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by reviewing and arriving at a decision on 97% of PMA Supplements applications. The FY 2008 performance data for this goal will not be available until January 2010.

3. Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. (253205)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: substantially equivalent or not substantially equivalent. This goal for review and decision on 510(k)s within 90 days addresses the statutory

requirement to review a 510(k) within 90 days**.** Due to the renegotiation of MDUFMA, the Performance targets for 510(k)s will be to arrive at a decision on 90% of applications within 90 days and 98% within 150 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by reviewing and arriving at a decision on 92% of 510(k)s. The FY 2008 performance data for this goal will not be available until January 2010.

4. Number of Medical Device Bioresearch Monitoring (BIMO) inspections. (253201)

Context: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach.

Performance: In FY 2008, FDA exceeded this goal of 300 by conducting 301 medical device related Bioresearch Monitoring inspections.

5. 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. (253206)

Context: MDUFMA commits FDA to significant improvements in device review performance. This is important to the entire device industry, which is expanding in size and technical complexity. The industry is relying on FDA to take a leadership role in regulating a rapidly emerging frontier of medical device technology with timeliness, quality, scientific consistency, and international harmonization. Most of the device industry is small and rapidly changing. Many small and new start-up firms rely heavily on FDA for guidance and outreach, and the reviews from these firms take extra FDA time and energy.

- About 25 percent of PMAs are for breakthrough technologies; and
- Over 25 percent of PMAs are from first-time submitters.

The area of expedited devices is particularly important because they are the most complex, raise new medical and scientific issues, and FDA often works with first time or small device sponsors. These devices are for uses that have not been approved yet, and could have great clinical impact. Our expedited program is the area where we have the most improvements to make.

Standard PMAs are also for the most complex (Class III) devices, and also have significant clinical impact. For example, a drug-eluting cardiac stent could, if used properly, reduce repeat angioplasty of bypass surgery by 15-30 percent.

Performance: The FDA approval time for the fastest 50 percent of Original PMAs approved for the FY 2003-2005 cohort is 322 days compared to 360 days for the baseline FY 1999-2001 submission cohort.

6. Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (254101)

Context: This goal will ensure that mammography facilities remain in compliance with established quality standards and improve the quality of mammography in the United States. Under the Mammography Quality Standards Act (MQSA), which was reauthorized in 2004, annual MQSA inspections are performed by trained inspectors with FDA, with State agencies under contract to FDA, and with States that are certifying agencies. State inspectors conduct approximately 90 percent of inspections. Inspectors perform science-based inspections to determine the radiation dose, to assess phantom image quality, and to empirically evaluate the quality of the facility's film processing. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. FDA also employs an extensive outreach program to inform mammography facilities and the public about MQSA requirements. These include: an Internet website, collaboration with NIH to provide a list of MQSA-certified facilities, and a toll-free facility hot line.

Performance: FDA met this goal in FY 2008 by ensuring that 97 percent of an estimated 8,800 mammography facilities met inspection standards with less than 3 percent level 1 (serious) problems. Inspection data continue to show facilities' compliance with the national standards for the quality of mammography images. Improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. FDA works cooperatively with the States to achieve this goal.

7. Number of domestic and foreign Class II and Class III device inspections. (254201)

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. The FY 2009 target is increased to 1,340 inspections due to FY 2008 Supplemental funding increases in the Field Devices Program.

Performance: FDA exceeded the FY 2008 medical device performance goal of 1,270 by inspecting 1,431 foreign and domestic high-risk Class II and Class III medical device manufacturers.

8. Participation rate of facilities in the MedSun Network. (252201)

Context: FDAMA gives FDA the mandate to replace universal user facility reporting with the Medical Product Surveillance Network (MedSun) that is composed of a network of user facilities that constitute a representative profile of user reports. MedSun is a critical component in

increasing the percent of the population covered by active surveillance, which will allow for more rapid identification and analysis of adverse events. FDA will ensure the active participation of 95% of Medsun facilities in FY 2009.

Performance: In FY 2008, FDA expanded actively participating sites in MedSun Network to 98% and maintained a cohort of 350 facilities.

NCTR Outcomes Table

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new medical products available to patients								
1	Use new 'omics' technologies and pattern recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. (263101) (output)	1) Biomarkers of liver toxicity 2) PPAR effects on liver gene expression 3) Age-related changes in gene expression	Hepatotoxicity of Type II diabetes drugs	1) Systems biology in drug review 2) Proof of principle that pattern recognition can supplement MRS brain scan interpret-tation	1) Urinary biomarkers for kidney failure 2)AZT effects on mitochondria 3) Prototype algorithm was success-fully developed from 30 MRS brain scans	1) Omics data in the review process 2) Determine limitations of the algorithms (e.g. staging disease)	1) 7 VXDS submissions reviewed using omics tools 2) Algorithm able to classify four disease categories	Analyze imaging data by application of pattern recogni-tion algorithms to other tissues and diseases
2	Develop standard biomarkers to establish risk measures for FDA-regulated products. (264201) (output)	1) Neuro-imaging in nonhuman primates 2) Data from PET technology	1) Behavioral effects of acrylamide 2) Concurrent neuropatho logical analysis	Carbon nanomateri als methods and ketamine research	1) Ketamine induced neuro-toxicity in primate model 2) Synthesis methods for nanotubes	Microarray Data Standards	MAQC-II results are in and 15 manuscripts on track for Mar 2009 submission	Biological effects of manganese nano-particles
Long-Term Objective 2: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science								
3	Develop computer-based models and infrastructure to predict the health risk of biologically active products. (263102) (output)	ArrayTrack ™ imple-mented	Microarray studies on nutritional supple-ments comfrey and aristo-lochic acid	Utility of Array Track™ and training for reviewers	1) JMP® and Array Track™ integration 2) Regulatory training on Array Track™	Bioinform-atics data package	SNPTrack Version 1 developed	Expand Array Track™
4	Develop science base for supporting FDA regulatory review of new and emerging technologies. (263201)	NA	NA	NA	NA	NA	NA	Opera-tional joint NTP/FDA Nanotech-nology Core Facility
Long-Term Objective 3: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.								

5	Develop risk assessment methods and build biological dose-response models in support of Food Protection. (264101) (output)	*Salmonella* biochip	Method to screen 131 antibiotic resistance markers	Flow cytometry technology	1) Test kits and methods for pathogens 2) Additional *Salmonella* biochip	Ricin screening assay	Cell-based assay and PCR-based biochemical assay developed	1) Rapid pathogen detection 2) Antibiotic resistance markers

1. Use new 'omics' technologies and pattern recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. (263101)

Context: With the advent of new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, and the expanding capabilities of noninvasive imaging technologies, FDA has the necessary tools to detect disease at an earlier stage and to better understand how an FDA-regulated compound or product interacts with the human body. The accelerated rate at which technological advances are being made in the marketplace dictates that FDA also accelerate its rate of innovation in the regulatory research arena. The challenge for clinicians to utilize emerging and typically high-dollar medical technologies for the detection and staging of disease is to have equally powerful and automated interpretive aids. Combining genomic knowledge with new imaging technologies is expected to facilitate the search for biomarkers of disease and genetic predictors of drug response.

Performance: In FY 2008, the NCTR-developed omics tool, Arraytrack™, was used in seven Voluntary eXploratory Data Submissions (VXDS) reviews. This integration of a bioinformatics infrastructure within FDA is essential to the incorporation of omics data into regulatory processes. Also in FY 2008, NCTR scientists expanded a pattern-recognition algorithm that was developed to increase the ease and accuracy of interpreting complex magnetic resonance spectroscopy (MRS) scans from more than 30 brain scans to include a set of more than 130 brain scans which provided confirmation that the approach can provide enough information to classify and grade tumors at more than an 85% accuracy rate. In FY 2009 the goal is to develop and apply pattern-recognition algorithms to identify early biomarkers of brain disease and to use algorithms to analyze imaging data of other tissues and diseases such as breast and prostate cancer.

2. Develop standard biomarkers to establish risk measures for FDA-regulated products. (264201)

Context: NCTR's research to develop standard biomarkers to establish risk measures for FDA-regulated products prevents potential health-endangering products from remaining in and continuing to enter the marketplace. NCTR's research increases the number of safe and effective medical products available to the public by integrating new automated tools and standards into the review and evaluation of FDA-regulated products at all stages of the product lifecycle. As more array-based data is included with industry's voluntary exploratory data submissions, it is important for FDA and the research community to have established microarray data standards.

In addition, by increasing the understanding of the biological effects and toxicity of nanomaterials, FDA will be able to identify biomarkers of toxicity thus providing early recognition of potential safety issues before they become adverse events in the general population. These regulatory guidelines will assist industry in identifying the most promising uses of this technology resulting in more cost-effective product development.

Performance: In FY 2008, NCTR organized and led the eighth Microarray Quality Control (MAQC) meeting, as part of the second phase of the MAQC project which is focused on the reproducibility of gene expression experiments and the standardization of microarray data analysis. Six microarray data sets were identified and distributed to 30 organizations to develop predictive models for clinical and preclinical applications. Currently, 15 manuscripts are being prepared that outline the MAQC-II results and "best practices" in the development and validation of microarray-based predictive models and are on track to be submitted for publication in Mar 2009. The FDA guidance document produced as a result of the MAQC project will provide the research and regulatory communities with a foundation to confidently use microarrays in clinical practice and regulatory decision-making. The FY 2009 goal to study the biological effects of manganese nanoparticles will help FDA to understand the toxicological consequences of exposure to nanomaterials.

3. Develop computer-based models and infrastructure to predict the health risk of biologically active products. (263102)

Context: To effectively support large datasets generated using new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, NCTR scientists develop and enhance scientific analytical software in collaboration with colleagues from government, academia, and industry to advance the incorporation of this data analysis into the regulatory process. NCTR's key objective is to develop computer-based models and infrastructure to predict the health risk of biologically active products. ArrayTrack™ is software invented by NCTR scientists that allows for the management, analysis, and interpretation of omics data, and is an important tool for the American public to benefit from the vast amount of bioinformatic data being generated from the new technologies. The expanded use of Arraytrack™ and other bioinformatic tools allows FDA to support the rapid translation of scientific research into reliable and safer treatments, regimen, and risk evaluations by improving the analysis and management of available data**.**

Performance: In FY 2008, NCTR developed a bioinformatics infrastructure, SNPTrack Version 1, for genotyping data management, analysis, and interpretation which has been used in VXDS reviews. The FY 2009 goal to expand ArrayTrack™ to accommodate the analysis of other omics data such as proteomics will even further simplify and enhance FDA's data analysis and review process. Another important accomplishment in FY 2008 is the selection of ArrayTrack™ by Eli Lilly for their clinical gene-expression data storage and baseline analysis. ArrayTrack™ was chosen as Eli Lilly's data management and analysis tool because of its architectural structure, quality, security, and the its ability to support their gene-expression studies.

4. Develop science base for supporting FDA regulatory review of new and emerging technologies. (263201)

Context: NCTR's goal to develop a science base to support the FDA regulatory review of new and emerging technologies by establishing a joint NTP/FDA Nanotechnology Core Facility will strengthen the FDA's ability to prevent potential health-endangering products from entering the marketplace. By increasing the understanding of the biological effects and toxicity of nanomaterials, FDA will be able to identify biomarkers of toxicity thus providing early recognition of potential safety issues before they become adverse events in the general population. In addition, the regulatory guidelines will assist industry in identifying the most promising uses of this technology resulting in more cost effective product development. It is anticipated that NCTR's nanotechnology research program will expand as the number of nanoscale products the regulated community seeks to market increases. FDA has already reviewed and approved some nanotechnology-based products, and expects a significant increase in the use of nanoscale materials in drugs, devices, biologics, cosmetics, and food.

Performance: In FY 2008, NCTR identified collaborations, funding, and resource requirements to facilitate the establishment of the Jefferson Laboratories Nanotechnology Core Facility. NCTR is currently conducting, and will continue to conduct studies to understand the toxicological and biological impact of animal exposure to nanomaterials. It is important for FDA to understand the toxicological consequences of the administration of nanoscale drugs, intentional exposure to nanoscale devices, and unintended exposure to nanoscale materials. Improved understanding of nanomaterials, their transport, and their toxicity will provide a framework for regulatory guidelines for safe and effective use of nanomaterials in FDA-regulated foods, cosmetics, and medical products and provide early recognition of potential safety issues before they become adverse events in the patient population.

5. Develop risk assessment methods and build biological dose-response models in support of Food Protection. (264101)

Context: To address research needs and build the capability to assess and reduce food-related health threats, NCTR researchers evaluate key regulatory issues of food safety, conduct multidisciplinary studies to develop risk assessment methods, and develop biological dose-response models vital to food security. NCTR is expanding the FDA's capability to rapidly respond to food-related health threats by developing new methods and risk-based techniques to identify naturally occurring and intentional contamination of the food supply or the environment. Identifying the prevalence of antibiotic-resistant genes and the genetic fingerprinting of these genes will help identify similar strains isolated from different samples.

Performance: NCTR will support the implementation of the Food Protection Plan by hiring five researchers and providing equipment to develop test systems for neurotoxins (including Class B select agents) and develop tests to rapidly identify and characterize strains of the foodborne microbial pathogen, *Salmonella*. In addition, NCTR will work toward the development of rapid detection methods for foodborne pathogens that can be used in the field. NCTR's development of a ricin-screening assay and a PCR-based biochemical assay resulted in three manuscripts that

are in preparation and five presentations given at national meetings, including the annual Society of Toxicology meeting in March 2008. Both assay systems developed at NCTR will be applied in FY 2009 to validate new technologies for rapid identification of contaminants and intervention strategies to reduce threats to human health. These goals and the goal to identify antibiotic-resistant markers will allow FDA to reduce the spread of foodborne outbreaks and enable the development of intervention strategies to reduce the frequency of multi-drug resistant pathogens in the U.S. food supply.

ORA Outcomes Table

(These goals are repeated here to give a cohesive look at ORA)

#	Key Outcomes/Outputs	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.								
1	Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201) (output)	335	336	295	323	300	301	300
Long-Term Objective 2: Detect safety problems earlier and better target interventions to prevent harm to consumers.								
2	Number of prior notice import security reviews. (214201) (output)	86,187	89,034	60,000	84,088	80,000	80,543	80,000
3	Number of import food field exams. (214202) (output)	84,997	94,545	71,000	94,743	85,000	100,718	104,440
4	Number of Filer Evaluations. (214203) (output)	1,407	1,441	1,000	1,355	1,000	1,356	1,000
5	Number of examinations of FDA refused entries. (214204) (output)	5,655	5,846	3,000	5,510	4,000	5,926	5,000
6	Number of high risk food inspections. (214205) (output)	7,568	6,795	5,625	6,421	5,700	6,230	6,100
7	Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome)	NA	NA	NA	NA	5 data entry labs	11 data entry labs	5 data exchange labs
8	Number of foreign and domestic high-risk human drug inspections. (224201) (output)	600	510	500	583	500	534	600
9	Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202) (output)	NA	NA	NA	NA	870	1,014	870
10	Number of highest priority human tissue establishment inspections. (234203) (output)	NA	354	325	427	325	383	380
11	Number of domestic and foreign high risk animal drug and feed inspections. (244202) (output)	NA	NA	NA	NA	233	244	233
12	Number of targeted prohibited material BSE inspections (244203) (output)	588	516	490	523	490	555	490
13	Number of domestic and foreign Class II and Class III device inspections. (254201) (output)	1495	1,506	1,195	1,468	1,270	1,431	1,340
14	Maintain accreditation for ORA labs. (214206) (outcome)	6 labs	13 labs	13 labs	13 labs	13 labs	13 labs	13 labs
15	Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305) (outcome)	0	1,200 chem	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem	2,500 rad & 1,650 chem

1. Number of Medical Device Bioresearch Monitoring (BIMO) inspections. (253201)

Context: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach.

Performance: In FY 2008, FDA exceeded this goal of 300 by conducting 301 medical device related Bioresearch Monitoring inspections.

2. Number of prior notice import security reviews. (214201)

Context: FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

Performance: During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

3. Number of import food field exams on products with suspect histories. (214202)

Context: The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than 18.7 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety

and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA will use additional FY 2008 Supplemental resources to increase the number of import food field exams by 19,440 exams which brings the FY 2009 Target to 104,440 exams.

Performance: In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

4. Number of Filer Evaluations of import filers. (214203)

Context: The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices.

Performance: In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

5. Number of examinations of FDA refused entries. (214204)

Context: FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP

that the refused products have been destroyed or exported. The FY 2009 target has been increased to 5,000 examinations to better reflect the recent historical actuals for this goal.

Performance: In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many examinations of refused entries will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal. However, FDA has adjusted future targets upward based on actual performance data for the last several years. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

6. Number of high risk food inspections. (214205)

Context: High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on a firm's compliance history. The FY 2009 target has been increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal.

Performance: In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 inspections of high-risk domestic food establishments.

7. Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214301)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2008, 151 laboratories representing multiple government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing

data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

Performance: In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. Explanation of why this goal was significantly exceeded: This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

8. Number of foreign and domestic high-risk human drug inspections. (224201)

Context: FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2009. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 high-risk foreign and domestic drug manufacturers.

9. Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202)

Context: FDA will increase risk-based compliance and enforcement activities by inspecting the highest priority registered manufacturers of biological products. The highest priority firms will be those whose operations are determined to be the highest risk, new product types in need of an inspectional history to evaluate and stratify risk, and, emergency response situations. Inspections for the goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure, as appropriate, the safety, purity and potency of biological products. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines.

Performance: In FY 2008, FDA exceeded this high risk inspection goal of 870 by inspecting 1,014 blood banks and biologics manufacturing establishments. The FY 2008 target was exceeded due to an increase in the number of reinspected firms from FY 2007. Although normally blood banks and biologics manufacturers are inspected every other year, in FY 2008 there were more reinspections than usual because the American Red Cross Consent Decree Committee requested specific ARC blood banks be reinspected and the Center requested selected vaccine and flu manufactures to start being inspected annually.

10. Number of highest priority human tissue establishment inspections. (234203)

Context: Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA will increase this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations.

Performance: In FY 2008, FDA exceeded the human tissue goal of 325 by conducting 383 inspections under new regulations.

11. Number of domestic and foreign high risk animal drug and feed inspections. (244202)

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target is being maintained into FY 2009 because this is a new, risk-based goal for which we have no historical experience, and are unsure how the new site-selection methodology will evolve.

Performance: In FY 2008, FDA exceeded this inspection goal of 233 by inspecting 244 high risk animal drug and feed establishments.

12. Number of targeted prohibited material BSE inspections (244203)

Context: FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc.

Performance: In FY 2008, FDA completed the inspection of all 555 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

13. Number of domestic and foreign Class II and Class III device inspections. (254201)

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. The FY 2009 target is increased to 1,340 inspections due to FY 2008 Supplemental funding increases in the Field Devices Program.

Performance: FDA exceeded the FY 2008 medical device performance goal of 1,270 by inspecting 1,431 foreign and domestic high-risk Class II and Class III medical device manufacturers.

14. Maintain accreditation for ORA labs. (214206)

Context: FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena.

Performance: In FY 2008, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

15. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305)

Context: A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing Federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by

assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year.

Performance: In FY 2008, FDA met this performance goal surge capacity target of 2,500 radiological samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 radiological samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which will increase the surge capacity in FY 2009 to 1,650 chemical samples per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of State, local, and tribal regulatory bodies.

Headquarters and the Office of the Commissioner Outcomes Table

#	Key Outcomes	FY 2005 Actual	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2008 Actual	FY 2009 Target
Long-Term Objective 1: Strengthen FDA's base of operations.								
1	The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". (291401) (Efficiency)	350 FTE (combined with FY 2004)	Study cancelled in February 2007 with the approval of the CSO.	308 by Sept 15	354 FTE by 9/15/07	130 FTE by Sept 15 (target changed by HHS)	152 FTE by Sept 15	154 FTE by Sept 15
2	FDA's implement-ation of HHS's Unified Financial Management System (UFMS). (291402) (Efficiency)	Imple-mented the General Ledger and the Payroll interface	Goal accom-plished through various activities discussed under Perform-ance text.	Finalize decision on an activity-based costing application and make it operational for its user fee programs.	Finalized the decision on an activity-based costing application and made it operational for its user fee programs.	Stabilize UFMS environment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials	All HHS OPDIVS are now in UFMS production. Stabilization for IHS is underway.	Begin migration to version 11-5-10 of ORACLE Federal Financials
Long-Term Objective 2: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.								
3	Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (292201) (Output)	EON IMS version 2.2 imple-mented in March 2005 and used during the April 2005 TOP-OFF 3 Exercise	EON IMS Version 2.4 August 06. deployed to OCM/ OEO located in FDA field offices and used to prep and respond to emer-gencies	Continue Enhance-ment EON IMS Coordinate FDA's partici-pation in exercises, including TOPOFF 4 Develop an FDA emerg. response plan for pandemic influenza.	EON IMS version 3.2.1 imple-mented December 2007 and used in the preparation and response to natural disasters and crises and emer-gencies. FDA emergency response plan for pandemic influenza developed Sept 2007.	Continued enhance-ment of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participa-tion in other exercises and workgroup.	EON IMS Version 3.3 implement-ed Aug 08. Iincludes significant enhance-ments to further its knowledge mgmt and GIS capabilities. FDA-wide Incident Command System (ICS) training conducted for Head-quarters and field offices. Finalized Pandemic Influenza	Continued enhance-ment of EON IMS and GIS capabilities. Coordinate FDA's partici-pation in exercises and interagency work-groups, update remaining emergency response plans, and develop an Agency-wide National Incident Manage-

							Emergency Response Plan and began planning an FDA Pandemic Influenza Exercise for Oct 2008	ment System (NIMS) implement-ation plan.

1. The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". (291401)

Context: FDA plans to study at least 154 FTE per year based on the FAIR Act Inventory of 2003. To accomplish this, FDA conducts an intensive annual review of its FAIR inventory data from functional, organizational, geographic, and business perspectives. Once the review is completed, FDA evaluates all commercial positions that have not undergone a competitive sourcing study in order to identify a sufficient number of positions that will satisfy FDA's requirement in meeting the OMB and DHHS established goals. The commercial positions are presented to FDA senior management in the form of logical business units to determine what will be reviewed that year. The selected commercial business units are publicly announced and subjected to A-76 competitive sourcing competition either as one or more standard and/or streamline cost comparisons.

Performance: FY 2006 and FY 2007 studies were combined and as a result, FDA was required to announce 308 commercial FTE positions by September 15. FDA exceeded this goal by 15%, announcing 354 commercial FTE positions. A total of thirteen streamline studies were announced. All thirteen studies resulted in an in-house win for FDA, with a projected annual savings of $3,219,000. Due to exceeding the FY 2007 target, HHS officially reduced the target and required FDA to announce 130 commercial FTE positions. However, FDA exceeded this goal by 8.6 %, announcing 152 commercial FTE positions by September 15. For FY 2009, the target remains 154 FTE positions.

2. FDA's implementation of HHS's Unified Financial Management System (UFMS). (291402)

Context: The Department announced in FY 2001 that it intended to establish a unified financial management system to replace its operating division's individual financial management systems. The goal of the UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. FDA, CDC, NIH, and the Program Support Center (which covers the remaining components other than CMS and its contractors) began the design of the UFMS. Although this goal had originally been dropped after FDA had implemented UFMS, FDA has continued to be involved in the implementation of the UFMS system across the Department. A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009 the Department will migrate to Oracle Federal Financials

version 11-5-10 and also implement iProcurement and PRISM as the global solutions for requisitioning and acquisitions.

Performance: UFMS has been fully implemented in FDA. Because UFMS is an integrated system and all OPDIVs must share it, FDA remains involved and participates in all future phased implementations of other OPDIVs in the Department. As such, in FY 2006, we participated in the Program Support Center's phased implementation of UFMS and did so again in FY 2007 for Indian Health Services (which went live on October 1, 2007). In FY 2008, FDA is stabilizing the UFMS environment and exploring/analyzing the effects of moving to a later version of ORACLE Federal Financials.

3. Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (292201)

Context: FDA's Office of Crisis Management (OCM), which includes the Office of Emergency Operations and Office of Security Operations, is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents," HSPD-8, "National Preparedness," and HSPD-9, "Defense of United States Agriculture and Food." In FY 2009, FDA will continue to enhance the Emergency Operations Network Incident Management System (EON IMS) and Geographic Information System (GIS) capabilities and continue to coordinate FDA's participation in exercises and work-groups, including National Level Exercises (NLEs).

Performance: In FY 2008, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.3 and will release a version in 2009 to establish a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g.; melamine contaminated pet food, peanut butter contaminated with salmonella, and botulism in chili sauce. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2008 hurricane season, response activities related to outbreaks involving salmonella in imported produce, flooding in the mid-west, and wildfires and earthquakes in California. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners. OCM finalized the FDA Pandemic Influenza Emergency Response Plan during FY 2008 and conducted an FDA-wide Pandemic Influenza Exercise in October 2008. OCM will also update the FDA Emergency Response Plan, 3 incident-specific emergency response plans and develop an agency-wide National Incident Management System (NIMS) implementation plan in FY 2009.

FDA Strategic Goals Align with HHS Strategic Goals & Objectives

	FDA Strategic Goals			
	Strengthen FDA for Today and Tomorrow	**Improve Patient & Consumer Safety**	**Increase Access to New Medical and Food Products**	**Improve Quality and Safety of Manufactured Products and the Supply Chain**
HHS Strategic Goals				
1: Health Care Improve the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care.				
1.1 Broaden health insurance and long-term care coverage				
1.2 Increase health care service availability/ accessibility.			X	
1.3 Improve health care quality, safety, cost, value		X	X	X
1.4 Recruit, develop, and retain a competent health care workforce.	X			
2: Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental, and terrorist threats.				
2.1 Prevent the spread of infectious diseases.		X	X	X
2.2 Protect the public against injuries and environmental threats.		X		
2.3 Promote and encourage preventive health care, including mental health, lifelong healthy behaviors, and recovery.		X		
2.4 Prepare for & respond to natural & manmade disasters.		X	X	X
3: Human Services Promote the economic and social well-being of individuals, families, and communities.				
3.1 Promote economic independence and social well-being of individuals and families across the lifespan.				
3.2 Protect safety & foster well-being of children & youth.				
3.3 Encourage the development of strong, healthy, and supportive communities.				
3.4 Address the needs, strengths, and abilities of vulnerable populations.				
4: Scientific Research and Development Advance scientific and biomedical research and development related to health and human services.				
4.1 Strengthen the pool of qualified health and behavioral science researchers.	X			
4.2 Increase basic scientific knowledge to improve human health and human development.	X	X	X	X
4.3 Conduct and oversee applied research to improve health and well-being.	X	X	X	X
4.4 Communicate and transfer research results into clinical, public health, and human service practice.	X	X		

Findings and Recommendations for FDA Evaluations in the HHS Program Information Center and Completed in FY 2008

1. Food and Drug Administration (FDA) Condom Label Comprehension Study: Stage One Report of Findings

Purpose The study was designed to measure and compare consumer understanding of the labeling recommended for latex condoms under FDA's 1998 guidance document, "Latex Condoms for Men, Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions," which is found on currently marketed latex condoms, and the latex condom labeling proposed in the 2005 draft guidance document, "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex." The results of the study were used in FDA's final rulemaking process.

Findings The study found that readers with lower reading levels and those with less education (two variables not highly correlated) had lower comprehension scores than those with higher reading levels. However, there were no differences based on age, race, ethnicity, income, or the type of neighborhoods where the respondents resided.

The study also found that most participants understood the basic message in both the current and proposed labeling that latex condoms help protect against transmission of sexually transmitted infections (>80% correct responses). When comparing equivalent questions between the current and proposed latex condom labeling, for every comparison with a significant difference in rates of comprehension, the difference favored the current latex condom labeling over the proposed latex condom labeling. Most study participants did not understand the more complex messages about the relative degree of protection provided by condoms against different sexually transmitted infections (<30% correct responses). The study was not designed to determine the reasons for the differences in consumer comprehension of the two labeling versions.

Recommendations

No recommendations were presented in the study.

2. Findings from Six Consumer Focus Groups on Indoor Tanning Equipment Warning Statement Label

Purpose The FDA retained Edge Research to conduct six consumer focus groups on indoor tanning equipment warning statement labeling. The purpose of this qualitative research was to better understand:

- Reactions to and perceptions of the current indoor tanning equipment warning statement label – overall, as well as the language, messaging, order and format of the statement
- Reactions to and perceptions of the proposed indoor tanning equipment warning statement label – overall, as well as the language, messaging, order and format of the statement
- Compare and contrast the two warning labels on: comprehension, likelihood to read, and impact on behavior
- Feedback on the location of the warning statement label on the tanning bed, including suggestions for location to increase its efficacy (notice and read)

Findings Participants in the focus groups represented a range of experiences with indoor tanning – from those who had just considered but never tried, to those who visit occasionally, to those who have a membership at a tanning salon and go on a regular basis, to those who stopped because of the risks. In most of the groups and without prompting, respondents mentioned some of the dangers associated with indoor tanning – specifically, damage to the skin and skin cancer. Those who "tan" on a regular basis said that while they are aware of these risks, they continue to go for beauty and relaxation.

Focus group respondents reviewed both the current and proposed warning statement labels, and discussed them in detail. When many saw the current label, their first reaction was that it looked like "legal mumbo jumbo" that they see on so many products these days, and have thus become "desensitized" to. Some of the wording, as well as the paragraph format and length, added to this perception. At the same time, there were some who found the information alarming, and thought it communicated a message to "proceed with caution."

Reactions to the proposed warning statement label were stronger across the board. The streamlined format and messaging made it more attention grabbing and easier to process, and made the range of messages stand out as important.

Respondents were asked to compare and contrast the two statements on several dimensions. Almost all (but three participants in one of the teen groups) said they would be more likely to read the proposed statement. The shorter length and bulleted format made it easer to focus on the risks and directives. When they saw the two statements on a picture of a life-size tanning bed, this preference was even stronger.

At the end of each focus group, participants were shown a life-size image of a tanning bed, with the warning statement label placed on the left side of the canopy (foot end), next to an exposure schedule and a statement with a warning regarding electrical hazards (in the center). Most agreed that the placement could be improved, and had a variety of recommendations.

Respondents had several other recommendations on how to call attention to the warning label – add color, a symbol, and/or make the font larger.

Recommendations

No recommendations were presented in the study.

3. Independent Evaluation of FDA's First Cycle Review Performance - Final Report

Purpose This study sought to identify and examine what factors contribute to and detract from FDA's ability to make an approval decision during the first-cycle review for products that are ultimately approved without major new data submissions. This evaluation contract was to determine the impact of FDA's initiatives to enhance first-cycle review performance during the five-year period of PDUFA III.

Findings The study found that:

- The Filing Review Notification, or 74-Day Letter, is an effective tool in communicating deficiencies to sponsors. Sixty-two percent of applications submitted during FY 2005 – FY 2007 had potential review issues that were listed in the 74-Day Letter resolved by the action date. Of those that resolved the potential review issues conveyed in the letter, 62% were approved in the first cycle, indicating that FDA successfully identified and communicated important review issues to the sponsor in the Filing Review Notification.

- Priority review designation, which is given to applications for products that offer major advances in treatment or provide a treatment where no adequate therapy exists, had the most significant impact on first-cycle approval rates. Applications with a Priority designation had a higher first-cycle approval rate (68%) than products with Standard review designation (36%).

- Applications were more likely to be approved in the first cycle if a major deficiency was identified pre-submission (40%) than if major deficiencies were identified during the review (19%). Applications for which no major deficiency was identified either pre-submission or during the review had a high first-cycle approval rate (92%).

- Products with a novel mechanism of action targeting life-threatening conditions had a greater first-cycle approval rate (62%) compared to that of products with non-novel mechanism of actions addressing non-life-threatening conditions (39%).

- Applications that complied with most or all of the assessed good review manufacturing procedures activities had the highest first-cycle approval rates. For applications assessed after the FY 2005 good review manufacturing procedures rollout, application reviews that complied with 80% of assessed good review manufacturing procedures activities and timeframes or more had a first-cycle approval rate of 71% compared to the first-cycle approval rate of

50% for those application reviews that complied with 20% of good review manufacturing procedures assessed activities.

Recommendations

- FDA should continue with good review manufacturing procedures implementation, ensuring adoption of both good review manufacturing procedures activities and timeframes.

- FDA should continue to use the 74-Day Letter to communicate application deficiencies early in the review process.

4. Independent Evaluation of FDA's Prescription Drug User Fee Act III -- Evaluations & Initiatives -- Task Order -- Post Marketing Commitments Study Report

Purpose The Food and Drug Administration (FDA) evaluates new drug and biological products prior to approval for marketing in the United States. In these instances, FDA may request that a sponsor seeking approval of a new drug or biological product conduct a postmarketing study to provide additional information about the safety, efficacy or optimal use of a drug or biological product that is important but not necessary for market approval. FDA commissioned this study to identify possible improvements to its existing postmarketing commitment (PMC) processes. The study retrospectively analyzed 743 unique PMCs agreed upon between FY 2002 and FY 2005.

Findings The study showed that PMCs were most often requested based on a need for additional data (21 percent) or analysis that did not significantly impact the overall assessment of safety and efficacy to warrant delaying approval. The next most common rationales were potential safety signals (13 percent), underrepresented subpopulations (12 percent) and drug-drug interaction concerns (10 percent).

The study found that sponsors generally agreed (86 percent) that the PMC program has a positive public health impact. More than half (51 percent) of fulfilled PMCs assessed in the study cohort resulted in a label change. The most common reasons for the label changes were validated safety and efficacy concerns (30 percent of fulfilled studies with a label change), validated drug-drug interaction concerns (18 percent), and expanded use in subpopulations (16 percent). However, 50 percent of sponsors questioned the value and/or rationale of specific PMCs. These sponsors noted that in some cases, the supporting studies were ongoing at the time of approval of the product, and the PMC was simply a mechanism to ensure the results were submitted to FDA. Others reported that they believed the PMC supported a reviewer's academic interests.

The study also found that the PMC milestones agreed on by FDA and the sponsor were not always met. Milestones for protocol submissions and final study reports were met by sponsors 76 percent and 60 percent of the time, respectively. FDA

reviewers met their goal dates for completing annual status report reviews (90days) 53 percent of the time, and final study report reviews (12 months or per PDUFA timelines) 61 percent of the time. The main reason for FDA failure to meet review goal dates was competing workload priorities.

Overall, the study found evidence that indicates PMCs positively impact public health, but need to be used judiciously to ensure that only commitments addressing important issues regarding safety, efficacy and optimal use are requested.

Recommendations

- FDA should make efforts to notify sponsors of issues that could lead to PMCs earlier in the review process. This could be achieved through informal communication after the preliminary discipline review is conducted, but before it is finalized. Notification would not guarantee that a PMC request was forthcoming, but rather grant the sponsor additional time to understand the concern, develop a feasible study to propose, or provide evidence demonstrating that the study is not necessary. Providing earlier notification would likely result in fewer PMCs and better study design for those that are ultimately agreed upon.

- FDA should reflect renegotiated timelines in their internal databases and PMC website when tracking and reporting the current status of PMCs. In many instances, new PMC schedules had been renegotiated and agreed upon by both sponsor and FDA, because the original schedule proved to be infeasible for reasons unrelated to the sponsor's level of effort to conduct the study. However, as required by regulations, these commitments were reported as delayed if they missed any milestone date in the original study schedule. This practice negatively impacts the perception of timeliness of the PMC pool by combining studies currently underway using a revised, agreed-upon timeline with those studies that are truly delayed. For situations where delays occurred due to circumstances beyond the control of the sponsor, a possible option for FDA to consider is to release and reissue commitments where FDA and the sponsor agree that the original study schedule cannot be met and a revised schedule is needed.

GAO High Risk Issue - Transforming Federal Oversight of Food Safety

Each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die. The fragmented US system of oversight has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.

Overall Goal: Reduce illnesses caused by contamination of the food supply.

Challenge: Prevent or deter intentional and unintentional contamination of food supply through risk-based, cost-effective allocation of resources.

FDA Actions:

- Fully implement the Salmonella Initiative Program to provide incentives for meat and poultry plants whose processes control foodborne pathogens.

Challenge: Early detection of contamination of the food supply.

FDA Actions:

- Build a quality public health infrastructure with data that is readily accessible to key decision-makers and front-line personnel.
- Improve Food and Drug Administration (FDA) detection systems and improve risk-based annual import activities.

Challenge: Protect human health and mitigate impact of food supply contamination by responding rapidly to food supply contamination through risk-based, cost effective allocation of resources.

FDA Actions:

- Enhancement of the Food Emergency Response Network (FERN) to ensure better geographic coverage.
- Implement Supply Chain Source Verification Requirements to accelerate both the response and the return to normalcy.
- Initiate the development of new Rapid Response Teams built on California Food Emergency Response Team (CalFERT) model.

More information about specific milestones the agency will accomplish to achieve this goal, including identification of the agency official responsible for each milestone can be found here (http://www.whitehouse.gov/omb/expectmore/issue_summary/issue_31.html) and here (http://www.whitehouse.gov/omb/expectmore/issue_summary/issueDetailedPlan_31.pdf)

Data Source and Validation Tables

Foods		
Measure Unique Identifier	**Data Source**	**Data Validation**
213301	CFSAN's electronic workflow system	The Food Additives Regulatory Management (FARM) Project's electronic information management system is designed to support electronic processing, review, maintenance, and reporting for food ingredient submissions. This includes management of food and color additive petitions, Food Contact Notifications (FCNs) (until FY 2008), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations, by providing modern electronic information management tools necessary for the food ingredient reviewers and managers to maximize their productivity. FARM allows reviewers to spend more time reviewing submissions, since they spend less time searching for, processing, and sharing information. FARM is currently able to support industry electronic submission of food ingredient submissions and correspondence in a consistent/standard electronic format further improving efficiencies for industry and FDA. Freedom of Information (FOI) requests and other communications disclosing information to industry and consumers are done electronically through the FARM System. CFSAN's electronic workflow system within FARM provides real-time tracking information on the progress, status, and timeliness of premarket submissions as well as the capability to generate ad-hoc reports including information and statistics on all significant events during the review process.
214101 214102 212401 212402 212403	Listing of Jurisdictions Enrolled in the draft Voluntary National Retail Food Regulatory Program Standards: http://www.cfsan.fda.gov/~dms/ret-jur.html. This listing identifies regulatory agencies that have enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments; and develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff who compile the information and maintain the listing.	Food Code adoption is tracked through the contract with the Association of Food and Drug Officials (AFDO) and measured as a percent of the U.S. Population. A listing of jurisdictions enrolled in the draft voluntary national retail food regulatory program standards can be found on the CFSAN web page at http://www.cfsan.fda.gov/~dms/ret-jur.html. This listing identifies regulatory agencies that have enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments; and develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff who compile the information and maintain the listing.
214201 214202 214203 214204 214205 214303 214206 214305	Field Data Systems.	ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as

		where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Human Drugs		
Measure Unique Identifier	**Data Source**	**Data Validation**
223201 223202 223101 223205 223206 223207 223208	Review performance monitoring is being done in terms of cohorts, e.g., FY 2003 cohort includes applications received from October 1, 2002, through September 30, 2003. CDER uses the Center-wide Oracle Management Information System (COMIS) and New Drug Evaluation/Management Information System (NDE/MIS). FDA has a quality control process in place to ensure the reliability of the performance data in COMIS. The Pediatric Exclusivity Database tracks all data regarding pediatric exclusivity as mandated by FDAMA and reauthorized by BCPA. Specifically, this database tracks the number of WRs issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made. The Pediatric Page database captures all information regarding waivers, deferrals, and completed studies for applications that are subject to the Pediatric Research Equity Act. Published monographs that establish acceptable ingredients, doses, formulations, and consumer labeling for OTC drugs.	The Center-wide ORACLE Management Information System (COMIS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. COMIS is the core database upon which most mission-critical applications are dependent. The type of information tracked in COMIS includes status, type of document, review assignments, status for all assigned reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in COMIS. Document room task leaders conduct one hundred percent daily quality control of all incoming data done by their IND and NDA technicians. Senior task leaders then conduct a random quality control check of the entered data in COMIS. The task leader then validates that all data entered into COMIS are correct and crosschecks the information with the original document. CDER uses the Pediatric Exclusivity database and the Pediatric Research Equity Act Tracking System (PREATS) to track information such as number of written requests issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made as well as information related to the PREA legislation.
223102	FDA websites: CDER Drug and Biologic Approval Reports (http://www.fda.gov/cder/rdmt/default.htm) ; Guidance Documents (http://www.fda.gov/cder/guidance/index.htm); FDA Approves Treatment for Nerve-Poisoning Agents for Use by Trained Emergency Medical Services Personnel (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01473.html); FDA Approves First Generic Ciprofloxacin Injection, USP (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01438.html); Questions and Answers about Unapproved Drugs and FDA's Enforcement Action Against Carbinoxamine Products (http://www.fda.gov/cder/drug/unapproved	CDER has instituted multiple layers of verification and validation for ensuring the accuracy of performance information. CDER relies on data extracted from information systems to support demonstrating performance toward most performance goals and targets. CDER has developed manuals of policies and procedures (MaPPs) or other standard operating procedures for using or entering data into information systems. There are quality controls built in to the information systems – controls that help ensure the integrity and accuracy of the data entered. CDER has a number of analysts who have expertise in extracting information from these systems. Their knowledge and experience working with the data, and their familiarity and experience with the business of the Center provide another layer of validation. Further, the Center requires a multi-level clearance process for verifying and validating the accuracy of the information provided in the

	_drugs/qa.pdf); Drugs Marketed in the United States That Do Not Have Required FDA Approval (http://www.fda.gov/cder/drug/unapproved_drugs/default.htm); Federal Register Notices; CDC/DHS Strategic National Stockpile (SNS) program. HHS website: HHS Awards BioShield Contract for Two Additional Medical Countermeasures for Radiological or Nuclear Incidents (http://www.hhs.gov/news/press/2006pres/20060213.html)	annual performance report.
222301	CDC/DHS Strategic National Stockpile (SNS) program, database from Department of Energy/REAC/TS (Oakridge), published guidance for Industry, published Federal Register Notices, CDER internet site http://www.fda.gov/cder/drugprepare/default.htm.	
222201 222202	Drug Quality Reporting System (DQRS), Adverse Event Reporting System (AERS), OMB Form 300 on Drug Safety, UFMS cost data and published FDA CDER/CBER guidance for Industry, internet site http://www.fda.gov/cber/gdlns/barcode.htm.	AERS, UFMS, and OCIO quality control processes
224201	Field Data Systems.	ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Biologics		
Measure Unique Identifier	**Data Source**	**Data Validation**

233201 233202 233203 233204 233205 233206 234101 234202 234203	CBER's Regulatory Management System and Field Data Systems	The Center for Biologics Evaluation and Research (CBER) uses various databases to manage its diverse programs and to assess performance. The principal CBER database is the Regulatory Management System-Biologics License Application (RMS-BLA). The RMS-BLA is CBER's new VAX-based, Oracle database that is used to track all biologics license applications, and supplement submissions; provide information to facilitate the review process (product, application status, milestone tracking, facility, review committee, industry contacts, and other information); and produce a wide variety of management reports. The Regulatory Information Management Staff (RIMS) monitors and is responsible for maintaining data quality and integrity in RMS-BLA. The Biologics Investigational New Drug Management System (BIMS) is CBER's VAX-based, Oracle database that is used to track all Investigational New Drug Applications (IND), Investigational Device Exemption (IDE), and Master Files (MF) submissions; provide product, application status, and other information to facilitate the review process; and produce a wide variety of management reports. There are numerous mechanisms established for quality control in Document Control Center, the application review offices, the Regulatory Information Management Staff, and several built into BIMS itself. The Blood Logging and Tracking System (BLT) records and tracks the various applications reviewed by the Office of Blood Research and Review. The Office also has an NDA tracking system. The data retrieved from these systems are reviewed and validated by the RIMS and the application review offices. If errors are detected, they are corrected. Federal regulations (21 CFR, Part 600.14 and 606.171) require reporting of deviations in the manufacture of biological products that affect the safety, purity, or potency of the product. The Biological Product Deviation Reports (BPDRs) (previously called error and accident reports) enable the Agency to evaluate and monitor establishments, to provide field staff and establishments with trend analyses of the reported deviations and unexpected events, and to respond appropriately to reported biological product deviations to protect the pubic health The Biologics Program relies in the Office of Regulatory Affairs' Field Accomplishments and Tracking System (FACTS) to register and record biologics manufacturing establishment inspection and compliance data. FACTS versions 1 and 2 together will replace the several dozen applications that comprise the current Field Information System (FIS).

Animal Drugs and Feeds		
Measure Unique Identifier	**Data Source**	**Data Validation**
243201	Submission Tracking and Reporting System (STARS).	STARS tracks submissions, reflects the Center's target submission processing times and monitors submissions during the developmental or investigational stages and the resulting application for marketing of the product.
244202 244203	Field Data Systems.	ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments

		and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.

Medical Devices and Radiological Health		
Measure Unique Identifier	**Data Source**	**Data Validation**
253201 253202 253203 253204 253205 253206	CDRH Premarket Tracking System and Receipt Cohorts and Field Data Systems.	To help ensure Agency consistency in tracking and reporting Premarket activities, CDRH utilizes the Premarket Tracking System, which contains various types of data taken directly from the Premarket submissions. FDA employs certain conventions for monitoring and reporting performance; among these are groupings of Premarket submissions into decision and receipt cohorts. Decision cohorts are groupings of submissions upon which a decision was made within a specified time frame, while receipt cohorts are groupings of submissions that were received within a specified time frame. The Premarket performance goals are based on receipt cohorts. Final data for receipt cohorts are usually not available at the end of the submission year. Because the review of an application received on the last day of the submission year, e.g., a PMA with 180 day time frame, may not be completed for at least 6 months or longer, final data for the submission or goal year may not be available for up to a year or more after the end of the goal year.
254101	Mammography Program Reporting and Information System (MPRIS)	The Mammography Program Reporting and Information System (MPRIS) is a set of applications used to support all aspects of the FDA implementation of the Mammography Quality Standards Act of 1992. This includes the collection, processing and maintenance of data on mammography facility accreditation and certification, FDA inspections and compliance actions. MPRIS is envisioned as a centralized repository of information that supports FDA's mission to improve the quality of mammography and improves the overall quality, reliability, integrity, and accessibility of facility certification, inspection, and compliance data by eliminating multiple versions of the data while expanding and automating data edits, validation, and security of a single integrated database.
254201	Field Data Systems.	ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission

		Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality.
252201	CDRH Adverse Events Reports	FDA's adverse event reporting system's newest component is the Medical Device Surveillance Network (MedSun) program. MedSun is an initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events, medical errors and other problems to FDA and/or the manufacturer, and to ensure that new safety information is rapidly communicated to the medical community thereby improving patient care.

NCTR		
Measure Unique Identifier	**Data Source**	**Data Validation**
263101 263102 264101 264201	NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals.	The National Center for Toxicological Research, under the auspices of the Food and Drug Administration (FDA), provides peer-reviewed research that supports the regulatory function of the Agency. To accomplish this mission, it is incumbent upon the Center to solicit feedback from its stakeholders and partners, which include other FDA centers, other government agencies, industry and academia. The NCTR Science Advisory Board (SAB) is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure quality programs and overall applicability to FDA's regulatory needs. This board is composed of non-government scientists from industry, academia, and consumer organizations and further supplemented with subject matter experts and scientists representing all of the FDA product centers. Research proposals are monitored through partnerships with other scientific organizations. Scientific and monetary collaborations include interagency agreements with other government agencies, Cooperative Research and Development Agreements, technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the quality of its research and the accuracy of data collected in specific research studies. Study protocols are developed collaboratively by principal investigators and FDA product centers. Findings are recorded and verified by internal and external peer review. Statistical analyses and the analytic approach on each protocol are checked by members of the scientific staff and the Deputy Director for Research. The Project Management System utilized by the Planning and Resource Management staff at the Center tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors the experiments that fall within the Good Laboratory Practices (GLP) guidelines. NCTR's fiscal year research accomplishments, goals and publications are published in the NCTR Research Accomplishments and Plans document and on the Web for interested parties. Research findings are presented at national and international scientific

		meetings and published in peer-reviewed scientific journals. Many of the scientific meetings are sponsored or co-sponsored by NCTR scientists. On a recurring basis, NCTR scientists also make presentations and attend presentations in the local university communities; and many serve on international scientific advisory boards.

Other Activities		
Measure Unique Identifier	**Data Source**	**Data Validation**
291401	Fair Act Inventory, EASE, EHRP	Annual Fair Act Inventory Report & Competitive Sourcing (Green Plan) Report
291402	FDA Office of Management & Systems, 2001 FAIR Act Inventory. The agency will rely on the data from the Federal Procurement Data System (FPDS). The sources encompassed in the General Ledger & Federal Administrator, the Purchasing & Accounts Payable; and the Accounts Receivable. These sources are being prepared to transition to the Financial Business solutions systems.	FDA will ensure consistency in the tracking and reporting of the administrative management performance goals. In addition, FDA is taking steps to routinely monitor this data and take appropriate actions as needed. Data is from a variety of sources for these performance goals including the Annual Chief Financial Officer's Report, Civilian and Commission Corps personnel databases, monthly and annual full-time equivalent (FTE) reports and data-runs, the FDA FAIR Act Inventory and the FY 2001 FDA Workforce Restructuring Plan, monthly statements from bank card companies and the FDA Small Purchase System.
292201	Office of Crisis Management/Office of Emergency Operations.	Data validation is based on a review of the past period's activities and the Emergency Operations Network Incident Management System project plan and schedule.

Discontinued Outputs / Outcomes Table

#	Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.									
1	Complete review and action upon fileable original generic drug applications within 6 months after submission date, excluding first cycle approvals. (222304) (Output)	87% of 543	66% of 766	NA	NA	55% of 700 applic-ations	30%	NA	NA