FDA's FY 2009 Congressional Justifications
Online Performance Appendix

January 30, 2008

Introduction

The Online Performance Appendix is one of several documents that fulfill the Department of Health and Human Services' (HHS') performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through HHS agencies' FY 2009 Congressional Justifications and Online Performance Appendices, the Agency Financial Report and the HHS Performance Highlights. These documents can be found at: http://www.hhs.gov/budget/docbudget.htm and http://www.hhs.gov/afr/.

The Performance Highlights briefly summarizes key past and planned performance and financial information. The Agency Financial Report provides fiscal and high-level performance results. The FY 2009 Department's Congressional Justifications fully integrate HHS' FY 2007 Annual Performance Report and FY 2009 Annual Performance Plan into its various volumes. The Congressional Justifications are complemented by the Online Performance Appendices, which consolidates all of the FDA performance information into a single location.

The ***FDA*** Congressional Justification and Online Performance Appendix can be found at (http://www.fda.gov/oc/oms/ofm/budget/documentation.htm.)

Summary of Measures and Results Table

FY	Total Measures in Plan	Results Reported		Targets			
		Number	%		Not Met		
				Met	Total	Improved	% Met
2002	69	69	100%	66	3	3	95%
2003	70	70	100%	65	5	5	92%
2004	53	53	100%	52	1	1	98%
2005	45	45	100%	42	3	1	93%
2006	47	46	98%	45	1	0	98%
2007	53	32	60%	32	0	0	100%
2008	49						
2009	49						

Foods 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 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)	89% of 9	100% of 7	70%	87% of 7	50%	10/08	60%[1]	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)	120 enrolled	185 enrolled	NA	259 enrolled	240 enrolled	302 enrolled	317[2] enrolled	332 enrolled
2.2	Percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214102) (outcome)	NA	NA	NA	24%	26%	32%	32%[3]	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	NA	NA	45%	1/09	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	NA	NA	81%	1/09	NA	NA
3.3	Improve by 10 percent the percentage of American consumers who correctly	31%	NA	NA	NA	34%	1/09	NA	NA

[1] FY 2008 target increased from 50%.
[2] FY 2008 target increased from 255 enrolled because enrollment was better than expected.
[3] FY 2008 target increased from 26% meet 2 standards because enrollment was better than expected.

	identify that omega-3 fat is a possible factor in reducing the risk of heart disease. (212403)								
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)	33,111	86,187	45,000	89,034	60,000	84,088	80,000[4]	80,000
5	Number of import food field exams. (214202) (output)	70,926	84,997	73,376	94,545	71,000	94,743	85,000[5]	105,000
6	Number of Filer Evaluations. (214203) (output)	1,745	1,407	1,000	1,441	1,000	1,355	1,000	1,000
7	Number of examinations of FDA refused entries. (214204) (output)	4,905	5,655	3,000	5,846	3,000	5,510	4,000[6]	4,000
8	Number of high risk food inspections. (214205) (output)	7,597	7,568	5,963	6,795	5,625	6,421	5,700	6,100
9	Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome)	NA	NA	NA	NA	NA	NA	5 data entry labs	5 data entry labs
10	Establish and maintain accreditation for ORA labs. (214206) (outcome)	1 lab	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)	NA	0	1,200 chem	1,200 chem	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem	2,500 rad & 1,200 chem[7]	2,500 rad & 1,200 chem

Other Outcome Indicators Measured in the HHS Strategic Plan

Key	FY 2004	FY 2005	FY 2006		FY 2007		FY 2008	FY 2009
Outcomes/Outputs	**Actual**	**Actual**	**Target**	**Actual**	**Target**	**Actual**	**Target**	**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.	12.8 cases/ 100,000	12.7 cases/ 100,000	NA	12.7 cases/ 100,000	TBD	09/08	TBD	TBD
Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli*	0.9 cases/ 100,000	1.1 cases/ 100,000	NA	1.3 cases/ 100,000	TBD	09/08	TBD	TBD

[4] FY 2008 target increased to 80,000 to better align with recent historical actual data.
[5] FY 2008 target increased to 85,000 to better align with recent historical actual data.
[6] FY 2008 target increased to 4,000 to better align with recent historical actual data.
[7] The FY 2008 target was reduced to 1,200 chemical samples per week because the FY 2007 RCR funding level did not fund the three new Chemical Labs.

O157:H7.								
Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*.	0.27 cases/ 100,000	0.30 cases/ 100,000	NA	0.31 cases/ 100,000	TBD	09/08	TBD	TBD
Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species.	14.6 cases/ 100,000	14.5 cases/ 100,000	NA	14.7 cases/ 100,000	TBD	09/08	TBD	TBD

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 targets for FY 2008 and FY 2009 are based on our current level of certainty that program submissions will not dramatically increase during FY 2008 or FY 2009.

Performance: In FY 2008 and FY 2009, FDA hopes to maintain performance close to or at the FY 2007 level. However, although this program has reached or exceeded its performance goal each of the last three years, program resources have continued to shrink. One reason goals have continued to be met is that the actual number of submissions has fallen off over that time period. Even a slight increase in the number or complexity of incoming submissions could dramatically reduce performance. This goal is based in part on the assumption that the FCN program will be funded adequately in FY 2008 and FY 2009.

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 FY07 target by enrolling 43 additional state, 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 302. 97 of these 302, or 32%, of the enrolled jurisdictions reported meeting at least 2 of the 9 Program Standards,

based on their own self assessments. The FY 2008 and FY 2009 targets in the Outputs Table are based on an expectation of enrolling fifteen additional enrolled jurisdictions each year. 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 FY08 and FY09 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 protocol for implementing the Health and Diet Survey is under review.

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. The FY 2008 and FY 2009 targets have been increased to 80,000 security reviews to better reflect recent historical actuals for this goal. However, they are still lower than the FY 2007 actuals since it is unknown how many entries will be flagged for review as a potential security or public health risk in a given year. 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: In FY 2007, FDA exceeded this goal of 60,000 by conducting 84,088 import security reviews. The FDA Prior Notice Center collaborated with Customs and Border Protection to direct field personnel to hold and examine five (5) suspect shipments of imported foods; refused 390 lines of imported food for prior notice violations; conducted 333 informed compliance calls, responded to 29,490 phone and e-mail inquiries; and conducted the 84,088 intensive security reviews of the 9,804,001 Prior Notice submissions received in order to detect and intercept contaminated products before they enter the food supply. Explanation of why this goal was significantly exceeded: This goal is a difficult goal to set targets for because it is not known in advance how many food/feed entry lines will require an import security review, but FDA is required to review all of them. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal even if the number of lines requiring an import security review in a given year decreases from historical averages. FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years. The change in target should have minimal impact on FDA's ability to identify and prevent imported food and feed products that may be intentionally contaminated with biological, chemical or radiological agents, or which may pose a significant health risk to the American Public from entering the US.

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 9.3 million line entries of imported food out of an estimated 15.9 million lines of FDA regulated products in FY 2007. In FY 2009, FDA expects approximately 10.4 million line entries of imported food within a total of more than 18.2 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. The FY 2008 target is lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in the next year. In FY 2009, FDA will use additional Food Protection resources to increase the number of import food field exams by 20,000 exams.

Performance: In FY 2007, FDA exceeded this goal of 71,000 by completing 94,743 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 must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed 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. The FY 2009 target is being maintained even though it is lower than the FY 2007 actuals because the historical accomplishments for this goal have decreased every year.

Performance: In FY 2007, FDA exceeded this goal of 1,000 by performing 1,355 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 2008 and FY 2009 targets have been increased to 4,000 examinations to better reflect the recent historical actuals for this goal.

Performance: In FY 2007, FDA exceeded this goal of 3,000 by performing 5,510 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. 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 2008 and FY 2009 targets have been increased over the FY 2007 target but are lower than the FY 2007 actuals because the available inventory of firms for this goal is highly variable. Also, the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in subsequent years.

Performance: In FY 2007, FDA exceeded this goal of 5,625 by performing 6,421 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. To date, 135 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: FDA exceeded the previous FY 2007 goal by creating informational reports on 8 specific analytes and 5 select agents. eLEXNET automatically sends recurring reports regarding 8 analytes including salmonella in peanut butter, colors in all products, pesticide residue in all products, elemental analysis in all products, antibiotic residues in all products, E. coli in spinach, Shigella in all products, and results of FDA's protein surveillance assignments. eLEXNET also routinely sends reports to FERN laboratories on 5 select agents including Bacillus anthracis, clostridium botulinum, clostridium perfringens, aflatoxin, and ricin. The FY 2008 target reflects the new goal to convert manual data entry to automated for which accomplishment data will not be available until the end of FY 2008.

10. Establish and 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 2007, 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. Philadelphia District Lab underwent a renewal assessment in November 2007.
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 2007, FDA met this performance goal when the 2 State Radiological Laboratories funded in FY 2006 were provided equipment and training to support their analytical surge capacity of 1,000 radiological samples per week. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. Also in FY 2007, FDA awarded Cooperative Agreements to 3 State Radiological Laboratories to increase the capacity to respond

to radiological attacks on the food supply. These 3 laboratories are the basis for the increase of 1,500 radiological samples per week in the FY 2008 surge capacity goal.

Human Drugs 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.									
1.1	Percentage of Standard NDAs/BLAs within 10 months. (223201) (Output)	97% of 94	99% of 73	90%	95% of 90	90%	11/08	90%	90%
1.2	Percentage of Priority NDAs/BLAs within 6 months (223202) (Output)	96% of 28	88% of 32	90%	97% of 29	90%	11/08	90%	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)	NA	12/14	8/8	18/12	7/7	30/13	8/8	7/7
3	The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205) (Output)	1361	1496	NA	1456	NA	1779	1780[8]	1900
4	Percentage of Rx-to-OTC Switch applications within 10 months receipt in which there was a complete review action. (223206) (Output)	100%/8	100%/17	100%/6	100%8	100%/5	100%/9	100%/5	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)	2/08	2/09	NA	2/10	514 Days	2/11	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)	16.0 months	17.8 months[9]	NA	5/09	16.4 months	5/10	NA	NA
Long-Term Objective 2: 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.									
7	Number of medical countermeasures in which there	NA	11	5	6	4	4	5	4

[8] New measure for FY 2008 to better reflect FDA's current program management challenge to increase throughput and productivity to address the higher workload while maintaining standards of quality and safety.

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

	has been coordination and facilitation in development (223102) (Output)								
Long-Term Objective 3: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
8	Improve the Safe Use of Drugs in Patients and Consumers (222301) (Output)	NA	Reviewed and provided comments on 100% of RiskMAPs for NMEs or products FDA or sponsor initiated discussions	Stand-ardize Agency processes and criteria for commun-icating risk inform-ation.	Stand-ardized communi-cation processes.	Imple-ment safety issue tracking system.	Imple-mented.	Conduct [10] pilot and act upon 50% of issues within timelines	Act upon 60% of issues within timelines
9	Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201) (efficiency goal)	$19.30 per report	$17.35 per report	NA	$16.47 per report	$15 per report	2/08	$13/per report	$13/per report
10	Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202) (Outcome)	4.4%	9.4%	NA	13.2%	12.5%	8/08	NA	NA
11	Number of foreign and domestic high-risk human drug inspections. (224201) (output)	481	600	483	510	500	583	500	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

[10] FY 2008 target revised. CDER has standardized communication processes. FDAAA gives FDA substantial new resources for medical product safety so CDER is increasing its staff resources for tracking, managing, and monitoring safety issues.

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 2007 submission cohort until November 2008. The latest information on CDER's performance toward the targets for this performance goal is from FY 2006. In FY 2006, CDER met or exceeded all of the PDUFA review performance goals, including exceeding the goals for reviewing priority and standard NMEs and new BLAs.

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.

Performance: The target for FY 2007 performance was to issue at least 7 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 7 drugs that receive pediatric exclusivity. CDER issued 30 Written Requests to sponsors: 28 for on-patent drugs and 2 for drugs on NIH's annual Priority List, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committee meetings on adverse events for 13 drugs that received pediatric exclusivity.

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, we hope to remain near the FY 2007 performance level with a target of 1780 actions. During this time, OGD will move to the FDA White Oak campus, which is expected to cause a disruption in productivity. Also, OGD operated under a Continuing Resolution during the first quarter of FY 2008, which has also caused a delay in hiring and training new staff for the program. In FY 2009, the target is 1900 actions, an increase of almost 7%. 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, as well as the estimated increase in performance due to increased staffing levels proposed for FY 2009. At the time this budget was developed, FDA and industry are in discussions about the terms of a generic drug user fee program that could begin in FY 2009.

4. Percentage of Rx-to-OTC Switch applications within 10 months receipt in which there was a complete review action. (223206)

Context: OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients and the 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). In the next 5 years, FDA plans to complete the initial review of OTC monographs for 29 categories of drug products, thereby eliminating all unsafe and ineffective products from the OTC market. The ability to reach these goals will depend on maintaining experienced staff in all facets of rulemaking development and improvement in the efficiency of the FDA document clearance process.

Performance: FDA exceeded its 2007 target by completing review and action on 100% of Rx-to-OTC switch and direct to OTC applications within 10 months of receipt and making significant progress on 9 OTC monographs: (1) Internal Analgesic, Antipyretic, and Antirheumatic Drug Products - Organ Specific Warnings (proposed rule published 12/06); (2) OTC Vaginal Contraceptive Products Containing N9 - Required Labeling; (3) Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products - Nasal; Decongestants, Phenylephrine (subject of Advisory Committee discussion 12/07); (4) Insect Repellant-Sunscreen Drug Products (request for data published 2/07); (5) Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products (final rule published 3/07); (6) Sunscreen Drug Products (proposed rule published 8/07); (7) Topical Antimicrobial Drug Products - Healthcare and Consumer Antiseptics; (8) Labeling for OTC Drug Product - Convenience Size Labeling Rule (proposed rule published 12/06); and (9) Laxative Drug Products, Granular Psyllium Warning (final rule published 3/07).

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. An update of progress on this goal for the FY 2004 submission cohort is not expected until January 2008.

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. Despite the exponential increase in receipts, new resources to manage the increased workload have increased only marginally.

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. For example, although gentamicin has not been FDA-approved for treatment of plague, it is widely recommended as a preferred therapy by experts. Human clinical trial data and animal efficacy data have been generated to determine the safety and efficacy of gentamicin for specific plague treatments. 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 all drugs that reside in the SNS for counterterrorism uses. FDA is also active in department and agency efforts to prepare for other emergencies, such as natural disasters and pandemics.

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

- **Cyanokit** (hydroxocobalamin) was approved as an antidote to cyanide poisoning. The kit contains the drug hydroxocobalamin, intravenous tubing, and a sterile spike for reconstituting the drug product with saline. Approval of this product improves the nation's ability to respond to emergencies, including potential terrorist attacks.
- A supplement for **Tamiflu** (oseltamivir phosphate) was approved to provide instructions for pharmacists for the preparation of a suspension using the contents of Tamiflu capsules in an emergency setting, when the commercially manufactured oral suspension is not available. CDER also approved Tamiflu 30 mg and 45 mg capsules for the treatment of influenza. Previously, Tamiflu was available in 75 mg capsules and in an oral suspension for pediatric patients. These supplements for the lower dosage strengths also provide for carton and container labeling for the marketed product, Department of Defense stockpiles, state stockpiles, and the Strategic National Stockpile.
- Updated Home Preparation Instructions for **doxycycline** have been finalized and will be available for use by emergency response planners and public health personnel. In a terrorism event, if pediatric dosage forms are not available, tablets or capsules can be crushed with food.
- Enrollment for the third and final year of the CDER/CDC collaboration on human trials of **gentamicin** in plague in Africa has been completed. Efforts continue with NIH/NIAID and USAMRIID on monkey studies of gentamicin, ciprofloxacin, levofloxacin, ceftriaxone, and doxycycline in pneumonic plague.

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

Context: CDER is working toward a policy of more transparency to ensure that patients and physicians have the most up-to-date and complete information necessary to make their treatment decisions. The Food and Drug Amendments Act (FDAAA), sweeping new legislation signed by

the President in September 2007, for the first time 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 moving toward establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way that pre-market issues are tracked 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.

Performance: In FY 2007, CDER met its target of establishing a tracking system for postmarketing safety issues. The safety application functions to track postmarketing safety issues as well as archive reviews, forms, and correspondence pertaining to the tracked issues. The system also has a report generating function so that managers can monitor active issues. CDER will be focusing its efforts in FY 2008 on increasing its staff resources for tracking, managing, and monitoring safety issues. The Center will be conducting a pilot for prioritizing safety issues, developing action plans and timelines for those issues, and monitoring and managing progress toward those plans. During the first year of this new process, CDER is targeting acting upon at least 50 percent of the identified priority safety issues within an established timeframe.

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. FDA expects to achieve further improvements in efficiencies due to improved automation of the submission and validation processes, and outreach to improve adoption of electronic submissions. The proposed FY 2007 target of $15 per report represents almost a 32% reduction in cost per adverse event report compared to the FY 2003 level, not including inflationary impacts.

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.

The Secretary of Health and Human Services directed FDA to promulgate the bar coding regulation to reduce preventable errors from medical products. This rule is expected to enable the uptake and use of bar code scanners that will allow a health professional to compare the bar code on a human drug product to a specific patient's drug regimen and then verify that the right patient is receiving the right drug, at the right dose, via the right route, at the right time. 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) 2006 annual survey of pharmacy practice in hospital settings (dispensing and administration) were published in 2007. Over the last few years the adoption rate of bar code medication administration technology has grown each year, up to 13.2% overall in 2006, with a slightly higher rate of adoption in larger hospitals. The differentiation between small and large hospitals is becoming less each year.

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 2007 goal of 500 by inspecting 583 high-risk foreign and domestic drug manufacturers.

Biologics 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 infections diseases.									
1	Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. (233201) (Output)	100% of 6	100% of 3	90%	100% of 2	90%	11/08	90%	90%
2	Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (233202) (Output)	100% of 1	100% of 3	90%	100% of 3	90%	4/08	90%	90%
3	Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (233203) (Output)	100% of 7	100% of 10	90%	100% of 9	90%	11/08	90%	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 1	100% of 4	90%	100% of 2	90%	11/08	90%[11]	90%
5	Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (233206) (Output)	100% of 542	100% of 401	90%	100% of 326	90%	11/08	90%[12]	90%
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	NA	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.	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	NA	NA	870[13]	870
8	Number of highest priority human tissue establishment inspections. (234203) (output)	NA	NA	250	354	325	427	325	370

[11] FY 2008 target increased to 90% due to the revised FY 07 funding levels.
[12] FY 2008 target increased to 90% due to the revised FY 07 funding levels.
[13] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Biologics. While the overall number of inspections in this program are not decreasing, this goal guarantees that the riskiest establishments are inspected, better protecting the public health.

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. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year, and complete performance data is not available until the prescribed review time, i.e., 10 months after receipt, is expired, making the FY 2007 data unavailable until November of 2008. In FY 2006, CBER exceeded its goal by completing review and action on 100 percent of 2 standard applications within 10 months of receipt and has met or exceeded this performance goal since 1994.

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

Context: The Prescription Drug User Fee Act 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. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data is not available until the prescribed review time, i.e., 6 months after receipt, is expired, making the FY 2007 data unavailable until April of 2008. In FY 2006, CBER exceeded its goal by completing review and action on 100 percent of 3 priority applications within 6 months of receipt and has met or exceeded this performance goal since 1994.

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. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data is not available until the prescribed review time, i.e., 10

months after receipt, is expired, making the FY 2007 data unavailable until November of 2008. In FY 2006, CBER exceeded its goal by completing review and action on 100% of 9 standard PDUFA efficacy supplements within 10 months of receipt has met or exceeded most of these performance goals since 1994.

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

Context: In FY 2009 CBER will work to complete review and action on 90 percent of the complete blood bank and source plasma BLA submissions within 12 months. Since so few complete blood bank and source plasma submissions are received by FDA, the actual performance may be significantly different than the target. User fee resources are not available for blood bank and source plasma BLA supplements.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data is not available until the prescribed review time, i.e., 12 months after receipt, is expired, making the FY 2007 data unavailable until November of 2008. In FY 2006, CBER exceeded its goal by reviewing and acting on 100% of 2 submissions within 12 months of receipt.

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

Context: In FY 2009 CBER will work to complete review and action on 90 percent of the complete blood bank and source plasma BLA submissions within 12 months. FDA does not expect to exceed the target, as we have in past years, since user fees are not available for blood bank and source plasma BLA supplements.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data is not available until the prescribed review time, i.e., 12 months after receipt, is expired, making the FY 2007 data unavailable until November of 2008. In FY 2006, CBER exceeded its goal by reviewing and acting on 100% of 326 supplements within 12 months of receipt.

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 2007 the targets include: Issue one guidance or concept paper to facilitate development of non-egg-based influenza vaccines; evaluate the potency of monovalent influenza vaccines from at least three manufacturers by

using quality systems guidelines; demonstrate two new or improved methods for improved influenza vaccine manufacture; develop at least four influenza virus vaccine strains optimized for growth in non-egg culture systems by using quality systems guidelines. In FY 2008 the pandemic target is to: facilitate rapid development, evaluation and availability of at least one new pandemic influenza vaccine, and one new trivalent 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. The 2009 pandemic target is to begin to develop a pilot program that utilizes a national healthcare database to evaluate the safety of potential pandemic vaccines and participate in at least one international workshop or conference.

Performance: In FY 2006, CBER accomplished all of it targets for this goal. The targets included: developing a concept paper on clinical data needed to support license of new trivalent vaccines and of pandemic vaccines; draft a guidance on cell substrates to facilitate development on non-egg based influenza vaccines and co-sponsor two workshops with WHO an pandemic vaccines. In FY 2007, CBER met all of its pandemic targets. This included: issuing the guidance "Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines" to facilitate development of non-egg-based influenza vaccines; evaluated the potency of five influenza vaccines (four inactivated and one live) using quality systems guidelines; demonstrated four methods for improved influenza manufacture and develop four influenza virus vaccine strains optimized for growth in non-egg culture systems by using reverse genetics and recombination on the backbone of A/Puerto Rico/8/34 virus.

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. There are currently an estimated 2,450 establishments in the Biologics program inventory covered under the cGMP regulation. 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 2007, FDA exceeded the previous statutory inspection goal of 1,138 by inspecting 1,256 blood banks, source plasma and biologics manufacturing establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

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 45 additional tissue inspections in order to cover more of the firms that registered as a result of the new regulations. However, the FY 2008 and 2009 targets are lower than the FY 2007 actuals because the FY 2007 actuals reflect a one-time Agency blitz of US companies to look for problems related to tissue recovery issues uncovered in FY 2006.

Performance: In FY 2007, FDA exceeded the human tissue goal of 325 by conducting 427 inspections under new regulations.

Animal Drugs and Feeds Program 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 3.1: 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%	100%	90% w/in 230 days	100%	90% w/in 200 days	01/09	90% w/in 180 days	90% w/in 180 days
Long-Term Objective 4.2: 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	NA	NA	233[14]	233
3	Number of targeted prohibited material BSE inspections (244203) (output)	647	588	516	516	490	523	490	490

1. Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (243201)

Context: The FY 2008 goal and target reflects one of the ADUFA user fee goals and the Center's move toward completion of 90% of specified new animal drug submission reviews within statutorily mandated time frames over a five-year period under the initial implementation of ADUFA in FY 2004. The FY 2009 goal assumes reauthorization of ADUFA and continued achievement of statutory review timeframe(s).

Performance: Based on the final performance update for FY 2006, FDA exceeded all ADUFA performance goal(s). FDA reviewed and acted on all seven (7) original NADAs and reactivations of such applications received during FY 2006 within 230 days. Final performance numbers for FY 2007 will not be available until January 2009. However, as of September 30, 2007, the preliminary performance assessment for FY 2007 data indicates FDA has exceeded the ADUFA goal(s). Additional information is forthcoming in the FY 2007 ADUFA Performance Report.

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 will be 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 will focus on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed

[14] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Animal Drugs and Feeds. This new goal guarantees that the riskiest establishments are inspected, thus better protecting the public health.

manufacturing facilities that will utilize 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 2007, FDA exceeded the previous registered animal drugs and feed establishments' statutory inspection goal of 620 by inspecting 671 registered establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

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. The FY 2008 target is being maintained into FY 2009 because this goal is a 100% accomplishment goal; therefore, the target is set to the number of known manufacturers at the beginning of the fiscal year.

Performance: In FY 2007, FDA completed the inspection of all 523 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 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.									
1.1	Percentage of Expedited PMAs reviewed and decided upon within 180 and 280 days. (253202) (Outcome)	NA	83% of 6	80% in 300 days	1/09	90% in 300 days	1/10	50% in 180 days and 90% in 280 days[15]	50% in 180 days and 90% in 280 days
1.2	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	NA	80% in 320 days	95% of 51	90% in 320 days	9/08	60% in 180 days and 90% in 295 days[16]	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)	NA	95% of 101	80%	95% of 131	90%	1/09	85% in 180 days and 95% in 210 days[17]	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)	NA	92% of 3,376	75% in 90 days	93% of 3,549	80% in 90 days	9/08	90% in 90 days and 98% in 150 days[18]	90% in 90 days and 98% in 150 days
4	Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201) (output)	354	335	295	336	295	323	300[19]	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)	492 days	2/08	NA	2/09	290 days	2/10	NA	NA
Long-Term Objective 2: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
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% of 9,100	97%	97%	97%	97%	97%	97%

[15] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[16] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[17] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[18] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[19] FY 2008 target increased to 300 to better align with recent historical actual data.

#	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
7	Number of domestic and foreign Class II and Class III device inspections. (254201) (output)	1,709	1495	1,234	1,506	1,195	1,468	1,270	1,300
Long-Term Objective 3: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
8	Participation rate of facilities in the MedSun Network. (252201)	NA	NA	NA	NA	90%	90%	95%	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 Expedited PMAs reviewed and decided upon within 180 and 280 days and Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253202 and 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.

The MDUFMA, as amended expedited review performance goals will apply only when the number of submissions granted expedited review equals 10 or more in any one fiscal year. If in any one fiscal year, the number of submissions granted expedited review is less than 10, then it is acceptable to combine the submissions for the following year(s) in order to form a cohort of 10 submissions upon which FDA will be held to the performance goals.

Performance: CDRH has exceeded performance for this goal in FY 2005 and is currently on pace to exceed agreed upon performance in FYs 2006 and FY 2007. The current baseline for FDA decision time for standard PMAs is 320 days.

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.

Performance: CDRH has exceeded performance for this goal in FYs 2005 and FY 2006 and is currently on pace to exceed agreed upon performance for this goal in FY 2007.

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**.**

Performance: CDRH has exceeded performance for this goal in FYs 2005 and FY 2006 and is currently on pace to exceed agreed upon performance for this goal in FY 2007.

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. The FY 2008 and FY 2009 targets have been increased slightly to 300 inspections to better reflect recent actuals. However, they are slightly lower than the FY 2007 actuals because the number of applications under review that may require BIMO inspections can only be estimated.

Performance: In FY 2007, FDA exceeded this goal of 295 by conducting 323 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 Expedited PMAs approved for the FY 2002-2004 cohort is 320 days compared to 360 days for the baseline FY 1999-2001 submission cohort. *This is a reduction of 40 days versus the FY 2005-2007 target reduction of 30 days.* CDRH initially calculated the baseline data for this goal, time to approval for the fastest fifty percent of expedited PMAs, for the time period of FYs 1999 – 2001.

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. In FY 2009, FDA will ensure at least 97% of an estimated 8,800 domestic mammography facilities meet inspection standards.

Performance: FDA met this goal in FY 2007 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 inventory of Class II and Class III foreign and domestic firms is approximately 10,900 firms. 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 2008 and FY 2009 targets have been increased over the FY 2007 target to better reflect recent actuals. However, they are lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that cannot be estimated in advance.

Performance: FDA exceeded the FY 2007 medical device performance goal of 1,195 by inspecting 1,468 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.

Performance: In FY 2007, FDA expanded actively participating sites in MedSun Network to 90% and maintained a cohort of 350 facilities.

NCTR 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.									
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)	Skin tumor induction	1) Biomarkers of liver toxicity 2) PPAR effects on liver gene expression 3) Age-related changes in gene expression	Novel technologies to assess changes in genes	Hepatotoxicity of Type II diabetes drugs	1) Systems biology in drug review 2) Proof of principle that pattern recognition can supplement MRS brain scan interpretation	1) Urinary biomarkers for kidney failure 2) AZT effects on mitochondria 3) Prototype algorithm was successfully developed from 30 MRS brain scans	1) "Omics" data in the review process 2) Determine limitations of the algorithms (e.g. staging disease)	Analyze imaging data by application of pattern recognition algorithms to other tissues and diseases
2	Develop computer-based models and infrastructure to predict the health risk of biologically active products. (263102) (output)	Genotoxicity of liver and lung carcinogens	ArrayTrack implemented	Interpret DNA study using ArrayTrack	Microarray studies on nutritional supplements comfrey and aristolochic acid.	Utility of ArrayTrack and training for reviewers	1) JMP® and ArrayTrack™ integration 2) Regulatory training on ArrayTrack™	Bioinformatics data package	Expand ArrayTrack
Long-Term Objective 2: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.									
3	Develop risk assessment methods and build biological dose-response models in support of Food Security. (264101) (output)	1) White paper with CFSAN/CVM on Nutrition Research 2)Surrogate microbes	*Salmonella* biochip	Oligonucleotide microarray method	Method to screen 131 antibiotic resistance markers	Flow cytometry technology	1) Test kits and methods for pathogens 2) Additional *Salmonella* biochip	Ricin screening assay	1) Rapid pathogen detection 2) Antibiotic resistance markers
Long-Term Objective 3: Detect safety problems earlier and better target interventions to prevent harm to consumers.									

#	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
4	Develop standard biomarkers to establish risk measures for FDA-regulated products. (264201) (output)	Study Ketamine using Micro-PET Imaging – BSL3 lab	1) Neuro-imaging in non-human primates 2) Data from PET technology	Neuro-pathology and behavioral risk as predictor	1) Behavioral effects of acrylamide 2) Concurrent neuropathological analysis	Carbon nano-materials methods and ketamine research	1) Ketamine induced neuro-toxicity in primate model 2) Synthesis methods for nano-tubes	Micro-array data standards	Biological effects of manganese nano-particles

1. Use new technologies (toxicoinformatics, proteomics, metabolomics and genomics to study the risk associated with how an FDA-regulated compound or product interacts with the human body. (263101)

Context: With the advent of new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, and the expansion of existing technologies such as imaging and nanotechnology, the 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 the FDA also accelerates its rate of innovation in the regulatory research arena, which is why this NCTR goal is also featured as a goal in the Department of Health and Human Services (DHHS) Strategic Plan. FDA's goal to determine the feasibility of using systems biology in the drug review process and the development of a test case with a collaborative partner is a step toward the development of safer and more effective therapies that replace one-size-fits-all drugs. Treatments that focus on specific population needs will help provide personalized nutrition and medicine to the American public.

Performance: In FY 2007, NCTR conducted two studies analyzing metabolites in urine samples to identify biomarkers for adverse reactions and susceptibility to toxicity, and also conducted research on the side-effects of anti-HIV drugs. In collaboration with the University of Arkansas for Medical Sciences (UAMS) and the University of Cincinnati, NCTR analyzed samples from children during and after cardiac surgery. This resulted in the detection of a mechanistic biomarker at 4 and 12 hours after cardiac surgery for patients who, two or three days after the surgery, developed acute kidney failure. In a separate study, in collaboration with CDER, NCTR analyzed urine samples to investigate age-related differences in susceptibility to toxicity, especially in the pediatric population. The results from the study with CDER showed that an increase in urinary glucose is a biomarker of liver toxicity and that hydroxyproline (an amino acid) and glucose are biomarkers in antibiotic-induced renal toxicity. Additionally in FY 2007, NCTR studied the effects of anti-HIV drugs (AZT) on mitochondrial function. Drug-induced toxic effects on mitochondria were investigated in the liver and the skeletal muscle of infant mice exposed to AZT just before and after birth. The knowledge gained by using these genomic

approaches in research can potentially improve treatment strategies for cardiac and HIV-infected patients, and particularly the pediatric patients.

2. 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 scientist that allows for the management, analysis, and interpretation of vast amounts of omics date. The FY 2007 goal to demonstrate the utility of ArrayTrack™ in the regulatory environment, continue training of reviewers, and initiate testing of an additional ArrayTrack™ module is an important step towards the American public benefiting from the vast amount of bioinformatic data being generated from the new technologies. The expanded use of Arraytrack™ and other bioinformatic tools allows the FDA to support the rapid translation of scientific research into reliable and safer treatments by improving the management of available data**.**

Performance: The widely used JMP® Genomics software has been integrated with the FDA genomic tool, ArrayTrack™, under a Cooperative Research and Development Agreement (CRADA) between NCTR and SAS. The newly integrated module allows reviewers and scientists to toggle between the two software platforms to access the analysis functions available from both genomic tools. Additionally, NCTR has continued to provide regulatory training to FDA reviewers on the use of ArrayTrack™. NCTR also has developed several new functions in ArrayTrack™ to support the Voluntary Genomic Data Submission (VGDS) program, the CommonPathway tool and the Significance Analysis of Microarray (SAM) Data method. The CommonPathway allows for integrated analysis of multiple "omics" data in the VGDS review. The SAM Data method enhances the ability to identify genes from differently treated groups, which will allow for more accurate results in the genomic-data review process.

3. Develop risk assessment methods and build biological dose-response models in support of Food Security. (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 doses-response models vital to food security. NCTR's FY 2007 goals to incorporate flow cytometry technology into regulatory procedures to rapidly identify terror agents and continue development of additional *Salmonella* biochips will help in the development and validation of new technologies for rapid identification of contaminants and intervention strategies to reduce threats to human health.

Performance: In FY 2007, NCTR developed flow cytometry methods and associated kits that could be used as detection tools. Assays for three foodborne pathogens (*Salmonella* spp., *Listeria* spp., and *E. coli* general) also were developed and are now beginning Association of Official Analytical Chemists validation. The methods are being expanded to detect more hazardous foodborne pathogens like *E. coli O157* and the bacteria that causes botulism, as well as in clinical areas like the detection of tuberculosis and multiple antibiotic-resistant staph. Additionally in FY 2007, NCTR developed a *Salmonella* biochip to characterize multiple antibiotic-resistant *Salmonella* strains. This research and other Food Protection research activities at NCTR will allow the 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.

4. Develop standards biomarkers to establish risk for FDA-regulated products. (264201)

Context: NCTR's research to develop tools, methods, and standard biomarkers to manage or assess risk associated with the products regulated by FDA helps prevent potential health-endangering products to remain in and continue 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. 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.

Performance: In FY 2007, NCTR conducted research on the behavioral changes associated with long-term exposure to the pediatric anesthetic, ketamine, and other related compounds. Gene changes associated with acute exposure to ketamine during the peak of the brain growth spurt and ketamine-induced neuronal cell death were examined. NCTR is conducting animal studies with ketamine to determine the level of safety during all stages of pregnancy and early childhood; the relationship of dose-level and anesthesia duration to cell death; and the permanency of damage to brain cells. The results from these studies are not only providing fundamental insight into normal developmental processes, but are also providing important data to guide pre- and post-market regulatory decisions and guidance for future preclinical and clinical studies. Also, in FY 2007, NCTR via an outside collaboration developed synthesis methods for carbon nanofibers, multi-wall carbon nanotubes, and double-wall carbon nanotubes. Among the accomplishments resulting from this collaboration is a novel method for preparing high quality delivery devices used in medical products.

ORA Outputs / Outcomes Table

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

#	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: 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)	354	335	295	336	295	323	300[20]	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)	33,111	86,187	45,000	89,034	60,000	84,088	80,000[21]	80,000
3	Number of import food field exams. (214202) (output)	70,926	84,997	73,376	94,545	71,000	94,743	85,000[22]	105,000
4	Number of Filer Evaluations. (214203) (output)	1,745	1,407	1,000	1,441	1,000	1,355	1,000	1,000
5	Number of examinations of FDA refused entries. (214204) (output)	4,905	5,655	3,000	5,846	3,000	5,510	4,000[23]	4,000
6	Number of high risk food inspections. (214205) (output)	7,597	7,568	5,963	6,795	5,625	6,421	5,700	6,100
7	Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome)	NA	NA	NA	NA	NA	NA	5 data entry labs	5 data entry labs
8	Number of foreign and domestic high-risk human drug inspections. (224201) (output)	481	600	483	510	500	583	500	600
9	Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202) (output)	NA	NA	NA	NA	NA	NA	870[24]	870
10	Number of highest priority human tissue establishment inspections. (234203) (output)	NA	NA	250	354	325	427	325	370
11	Number of domestic and foreign high risk animal drug and feed inspections. (244202) (output)	NA	NA	NA	NA	NA	NA	233[25]	233
12	Number of targeted prohibited material BSE inspections (244203)	647	588	516	516	490	523	490	490

[20] FY 2008 target increased to 300 to better align with recent historical actual data.
[21] FY 2008 target increased to 80,000 to better align with recent historical actual data.
[22] FY 2008 target increased to 85,000 to better align with recent historical actual data.
[23] FY 2008 target increased to 4,000 to better align with recent historical actual data.
[24] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Biologics. While the overall number of inspections in this program are not decreasing, this goal guarantees that the riskiest establishments are inspected, better protecting the public health.
[25] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Animal Drugs and Feeds. This new goal guarantees that the riskiest establishments are inspected, thus better protecting the public health.

#	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
	(output)								
13	Number of domestic and foreign Class II and Class III device inspections. (254201) (output)	1,709	1495	1,234	1,506	1,195	1,468	1,270	1,300
14	Establish and maintain accreditation for ORA labs. (214206) (outcome)	1 lab	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)	NA	0	1,200 chem	1,200 chem	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem	2,500 rad & 1,200 chem[26]	2,500 rad & 1,200 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. The FY 2008 and FY 2009 targets have been increased slightly to 300 inspections to better reflect recent actuals. However, they are slightly lower than the FY 2007 actuals because the number of applications under review that may require BIMO inspections can only be estimated.

Performance: In FY 2007, FDA exceeded this goal of 295 by conducting 323 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. The FY 2008 and FY 2009 targets have been increased to 80,000 security reviews to better reflect recent historical actuals for this goal. However, they are still lower than the FY 2007 actuals since it is unknown how many entries will be flagged for review as a potential security or public health risk in a given year. 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,

[26] The FY 2008 target was reduced to 1,200 chemical samples per week because the FY 2007 RCR funding level did not fund the three new Chemical Labs.

the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

Performance: In FY 2007, FDA exceeded this goal of 60,000 by conducting 84,088 import security reviews. The FDA Prior Notice Center collaborated with Customs and Border Protection to direct field personnel to hold and examine five (5) suspect shipments of imported foods; refused 390 lines of imported food for prior notice violations; conducted 333 informed compliance calls, responded to 29,490 phone and e-mail inquiries; and conducted the 84,088 intensive security reviews of the 9,804,001 Prior Notice submissions received in order to detect and intercept contaminated products before they enter the food supply. Explanation of why this goal was significantly exceeded: This goal is a difficult goal to set targets for because it is not known in advance how many food/feed entry lines will require an import security review, but FDA is required to review all of them. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal even if the number of lines requiring an import security review in a given year decreases from historical averages. FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years. The change in target should have minimal impact on FDA's ability to identify and prevent imported food and feed products that may be intentionally contaminated with biological, chemical or radiological agents, or which may pose a significant health risk to the American Public from entering the US.

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 9.3 million line entries of imported food out of an estimated 15.9 million lines of FDA regulated products in FY 2007. In FY 2009, FDA expects approximately 10.4 million line entries of imported food within a total of more than 18.2 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. The FY 2008 target is lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in the next year. In FY 2009, FDA will use additional Food Protection resources to increase the number of import food field exams by 20,000 exams.

Performance: In FY 2007, FDA exceeded this goal of 71,000 by completing 94,743 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 must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed 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. The FY 2009 target is being maintained even though it is lower than the FY 2007 actuals because the historical accomplishments for this goal have decreased every year.

Performance: In FY 2007, FDA exceeded this goal of 1,000 by performing 1,355 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 2008 and FY 2009 targets have been increased to 4,000 examinations to better reflect the recent historical actuals for this goal.

Performance: In FY 2007, FDA exceeded this goal of 3,000 by performing 5,510 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. 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 2008 and FY 2009 targets have been increased over the FY 2007 target but are lower than the FY 2007 actuals because the available inventory of firms for this goal is highly variable. Also, the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in subsequent years.

Performance: In FY 2007, FDA exceeded this goal of 5,625 by performing 6,421 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. To date, 135 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: FDA exceeded the previous FY 2007 goal by creating informational reports on 8 specific analytes and 5 select agents. eLEXNET automatically sends recurring reports regarding 8 analytes including salmonella in peanut butter, colors in all products, pesticide residue in all products, elemental analysis in all products, antibiotic residues in all products, E. coli in spinach, Shigella in all products, and results of FDA's protein surveillance assignments. eLEXNET also routinely sends reports to FERN laboratories on 5 select agents including Bacillus anthracis,

clostridium botulinum, clostridium perfringens, aflatoxin, and ricin. The FY 2008 target reflects the new goal to convert manual data entry to automated for which accomplishment data will not be available until the end of FY 2008.

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 2007 goal of 500 by inspecting 583 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. There are currently an estimated 2,450 establishments in the Biologics program inventory covered under the cGMP regulation. 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 2007, FDA exceeded the previous statutory inspection goal of 1,138 by inspecting 1,256 blood banks, source plasma and biologics manufacturing establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

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 45 additional tissue inspections in order to cover more of the firms that registered as a result of the new regulations. However, the FY 2008 and 2009 targets are lower than the FY 2007 actuals because the FY 2007 actuals reflect a one-time Agency blitz of US companies to look for problems related to tissue recovery issues uncovered in FY 2006.

Performance: In FY 2007, FDA exceeded the human tissue goal of 325 by conducting 427 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 will be 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 will focus on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that will utilize 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 2007, FDA exceeded the previous registered animal drugs and feed establishments' statutory inspection goal of 620 by inspecting 671 registered establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

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. The FY 2008 target is being maintained into FY 2009 because this goal is a 100% accomplishment goal; therefore, the target is set to the number of known manufacturers at the beginning of the fiscal year.

Performance: In FY 2007, FDA completed the inspection of all 523 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 inventory of Class II and Class III foreign and domestic firms is approximately 10,900 firms. 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 2008 and FY 2009 targets have been increased over the FY 2007 target to better reflect recent actuals. However, they are lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that cannot be estimated in advance.

Performance: FDA exceeded the FY 2007 medical device performance goal of 1,195 by inspecting 1,468 foreign and domestic high-risk Class II and Class III medical device manufacturers.

14. Establish and 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 2007, 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. Philadelphia District Lab underwent a renewal assessment in November 2007.
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 2007, FDA met this performance goal when the 2 State Radiological Laboratories funded in FY 2006 were provided equipment and training to support their analytical surge capacity of 1,000 radiological samples per week. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. Also in FY 2007, FDA awarded Cooperative Agreements to 3 State Radiological Laboratories to increase the capacity to respond to radiological attacks on the food supply. These 3 laboratories are the basis for the increase of 1,500 radiological samples per week in the FY 2008 surge capacity goal.

Headquarters and the Office of the Commissioner 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: 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 Conduct Clerical Study	350 FTE (combined with FY 2004)	154 FTE	Study cancelled in February 2007 with the approval of the CSO.	308 by Sept 15	354 FTE by 9/15/07	154 FTE by Sept 15	154 FTE by Sept 15
2	FDA's implementation of HHS's Unified Financial Management System (UFMS). (291402) (Efficiency)	Began development of FDA's unique interfaces and test global interfaces	Implemented the General Ledger and the Payroll interface	Pilot activity-based costing application for PDUFA FDA's legacy core financial system decommissioned	Goal accomplished through various activities discussed under Performance text.	Finalize decision on an activity-based costing application and make it operational for its user fee programs.	01/08	Stabilize UFMS environment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials[27]	Begin migration to the latest version 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)	Developed Crisis Management Plan for CT and Agency Emergency Operations Network	EON IMS version 2.2 implemented in March 2005 and used during the April 2005 TOPOFF 3 Exercise	Enhance functionality and continue deployment of the EON IMS through out the Agency (HQ, Centers, Field offices)	EON IMS Version 2.4 August 06. deployed to OCM/ OEO located in FDA field offices and used to prep and respond to emergencies	Continue Enhancement EON IMS Coordinate FDA's participation in exercises, including TOPOFF 4 Develop an FDA emergency response plan for pandemic	EON IMS version 3.2.1 implemented December 2007 and used in the preparation and response to natural disasters and crises and emergencies. FDA emergency response	Continued enhancement of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participation	Continued enhancement of EON IMS and GIS capabilities. Coordinate FDA's participation in exercises and work-groups, including TOPOFF 5.

[27] This goal had originally been dropped in the FY 2008 CJ because FDA had implemented and was maintaining the UFMS system. However, FDA remains involved in the continued rollout of UFMS to other OPDIVs, and is planning to move to a later version of ORACLE Federal Financials.

#	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
						influenza.	plan for pandemic influenza developed Sept 2007.	in other exercises and workgroup.	

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. For FY 2007, the FDA announced 308 commercial FTE positions by September 15.

Performance: FDA exceeded its FY 2007 Competitive Sourcing goal by 15% by announcing 354 positions divided into thirteen individual streamlined studies. Eight of these studies have been completed, resulting in in-house wins. The remaining five studies are nearly complete with decisions expected by January 31, 2008. The eight studies completed in FY 2007 resulted in a total projected annual savings of $2,163,879. Combined with the seven in-house wins resulting from FY 2002-2005 studies, the total projected annual savings for the FDA now exceeds $7.6 million. FDA was also recently identified as a critical component to the DHHS receiving a Government wide Presidential Quality Award for Competitive Sourcing.

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, FDA will begin migration to the latest version of ORACLE

Federal Financials. This version of Federal Financials will do away with multiple manual processes and will enhance reporting capabilities.

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).

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."

Performance: In FY 2007, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.2.1 and plans to release version 3.3 in June 2008. 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 2007 hurricane season, response activities related to outbreaks involving peanut butter, and illnesses caused by pet food manufactured with contaminated ingredients imported from foreign sources. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners. OCM completed the FDA emergency response plan for pandemic influenza in September 2007 and participated in the TOPOFF4 exercise in October 2007.

Discussion of Agency's Strategic Plan

FDA Strategic Action Plan

FDA's strategic vision for transforming FDA operations responds to emerging scientific, technological, and economic trends affecting our regulatory mission. FDA presents this vision in a new Strategic Action Plan published in September 2007, which describes the priorities, goals, objectives, and strategies that FDA will use over the next five years to advance our vision of improved public health through world-class, science-based regulatory operations in the 21st century.

In the 2007 Strategic Action Plan, FDA developed a single, coherent framework of strategic goals and objectives that encompass our annual performance goals and measures, as well as near-term initiatives and action items. As we implement the new DHHS Performance Management Appraisal Program, FDA's annual performance goals and near-term action items will be assigned to individual performance plans systematically to ensure coordination and accountability for results. Table 1 shows how FDA's revised 2007 Strategic Action Plan aligns with FDA strategic goals published in the 2008 Congressional Justification.

Table 1: Crosswalk of FDA's Strategic Goals

Goals in 2008 Congressional Justification	Revised Strategic Goals
Enhance patient and consumer protection and empower them with better information about regulated products.	Improve Patient and Consumer Safety
Increase access to innovative products and technologies to improve health.	Increase Access to New Medical and Food Products
Improve product quality, safety, and availability through better manufacturing and product oversight.	Improve the Quality and Safety of Manufactured Products and the Supply Chain
Transform administrative systems and infrastructure to support FDA operations.	Collapsed into Objective 1.4, Strengthen FDA Base of Operations, under the new Goal, "Strengthen FDA for Today and Tomorrow"
Not Applicable	Strengthen FDA for Today and Tomorrow

Table 2 shows the alignment of FDA strategic goals with DHHS revised strategic goals and objectives.

Table 2: FDA Strategic Goals & Objectives Aligned by 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		

Summary of Full Cost

(Budgetary Resources in Millions)

	OPDIV		
HHS Strategic Goals and Objectives	**FY 2007**	**FY 2008**	**FY 2009**
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 and accessibility.	**$383**	**$431**	**$441**
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)	$52	$51	$49
Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. (233201)	$43	$52	$54
Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (233202)	$28	$34	$35
Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (233203)	$65	$77	$80
Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (233205)	$16	$19	$20
Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (233206)	$15	$18	$19
Percentage of Expedited PMAs reviewed and decided upon within 180 and 280 days. (253202)	$8	$9	$9
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)	$44	$49	$50
Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. (253204)	$20	$22	$22
Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. (253205)	$92	$101	$103
1.3 Improve health care quality, safety and cost/value.	**$718**	**$841**	**$905**
Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201)	$7	$16	$17
Percentage of Standard NDAs/BLAs within 10 months. (223201)	$207	$260	$281
Percentage of Priority NDAs/BLAs within 6 months (223202)	$76	$92	$100
The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205)	$66	$80	$95
Percentage of Rx-to-OTC Switch applications within 10 months receipt in which there was a complete review action. (223206)	$13	$16	$17
Complete review and action on original NADAs & reactivations of such applications received during FY 2009. (243201)	$53	$55	$61
Number of foreign and domestic high-risk human drug inspections. (224201)	$101	$108	$112
The number of high-risk registered domestic blood bank and biologics manufacturing inspections. (234202)	$22	$23	$23

The number of highest priority human tissue establishments to be inspected. (234203)	$10	$11	$11
Number of domestic and foreign high risk animal drug and feed inspections. (244202)	$27	$29	$32
Number of targeted prohibited material BSE inspections (244203)	$42	$43	$45
Number of domestic and foreign Class II and Class III device inspections. (254201)	$70	$75	$76
Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (254101)	$25	$33	$34
1.4 Recruit, develop, and retain a competent health care workforce.			
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.	**$150**	**$173**	**$204**
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)	$56	$59	$78
Percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214102)	$56	$59	$78
Number of import food field exams. (214202)	$46	$58	$68
Number of Filer Evaluations. (214203)	$22	$25	$28
Increase manufacturing diversity and capacity for pandemic influenza vaccine production. (234101)	$26	$30	$30
2.2 Protect the public against injuries and environmental threats.	**$381**	**$419**	**$437**
Number of high risk food inspections. (214205)	$184	$214	$227
Establish and maintain accreditation for ORA labs. (214206)	$145	$151	$153
Number of examinations of FDA refused entries. (214204)	$22	$25	$28
Participation rate of facilities in the MedSun Network. (252201)	$29	$29	$29
2.3 Promote and encourage preventive health care, including mental health, lifelong healthy behaviors and recovery.			
2.4 Prepare for and respond to natural and man-made disasters.	**$33**	**$32**	**$33**
Number of prior notice import security reviews. (214201)	$11	$13	$13
Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303)	$2	$3	$3
Number of medical countermeasures in which there has been coordination and facilitation in development (223102)	$20	$16	$17
3: Human Services Promote the economic and social well-being of individuals, families and communities.			
3.1 Promote the economic independence and social well-being of individuals and families across the lifespan.			
3.2 Protect the safety and foster the well being of children and youth.	**$7**	**$8**	**$9**
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)	$7	$8	$9

3.3 Encourage the development of strong, healthy and supportive communities.			
3.4 Address the needs, strengths and abilities of vulnerable populations.			
Strategic Goal 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.			
4.2 Increase basic scientific knowledge to improve human health and human development.	**$30**	**$37**	**$37**
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)	$18	$24	$23
Develop risk assessment methods and build biological dose-response models in support of Food Security. (264101)	$7	$7	$10
Develop standard biomarkers to establish risk measures for FDA-regulated products. (264201)	$5	$5	$4
4.3 Conduct and oversee applied research to improve health and well-being.	**$27**	**$25**	**$26**
Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201)	$12	$14	$14
Develop computer-based models and infrastructure to predict the health risk of biologically active products. (263102)	$15	$11	$12
4.4 Communicate and transfer research results into clinical, public health and human service practice.	**$85**	**$136**	**$164**
Improve the Safe Use of Drugs in Patients and Consumers (222301)	$85	$136	$164
Total	**$1,814**	**$2,101**	**$2,257**

Findings and Recommendations for FDA Evaluations in the HHS Program Information Center and Completed in FY 2007

1. Findings from Focus Groups Examining Pharmacist's Perceptions of FDA's Communications Regarding Emerging Drug Risks

Purpose Ascertain pharmacists' perceptions of how well FDA communicates emerging drug risks.

Findings The focus group participants generally agreed that it would be useful for them to have a single, credible source they could rely on for timely and accurate information about serious emerging drug risks. Relative to other messengers, FDA was judged by the pharmacists to be objective and credible; however, the participants acknowledged that they have not previously looked to FDA as the source for this information. Most remarked that during their very busy day, they do not have the time to search for information on the internet. Instead, they rely primarily on information sent to them by e-mail (including listservs) and fax.

Very few of the participants said they visit the FDA website, and expressed concern about how much navigation time and effort it might take for them to locate specific information about emerging drug risks on FDA's site. Most indicated that they found the "FDA Alert" and the specific recommendations contained in the sample provider and patient information sheets useful. They suggested that if FDA wants to make these information sheets available on-line, it should develop and maintain a separate web site that is dedicated solely to emerging drug risk information. They added that FDA should work with other credible intermediaries, such as state licensing boards and associations, to have links on their sites that will lead pharmacists to FDA's emerging drug risk information site.

Recommendations

- FDA needs to engage in targeted outreach to pharmacists to "brand" the Agency and its web site as the best source of information on serious emerging drug risks. This outreach can include direct marketing through e-mails, faxes, and a presence at regional and national meetings. It could also include indirect marketing through credible intermediaries such as state licensing boards, state associations, pharmacy schools, national pharmacy chains, professional journals/newsletters, and frequently-used subscription services such as Epocrates.
- FDA should look at the possibility of developing and maintaining both a dedicated web site and listserv for providing pharmacists with emerging drug risk information.

2. Findings from Six Focus Groups on Medical Device Safety Communications

Purpose This study examined the perception of FDA's communication of medical device safety using a series of six focus groups. Emphasis was placed on the group's reaction to various terms used when communicating information about medical device safety,

what should be included in safety reports, and how best to distribute such information.

Findings The term “recall” elicited many different emotions --- from "anxiety," "anger," and "distrust;" to the more benign feelings of "cautious" and "need more information." While most equated recall with “replace”, the term almost unanimously sent a message that patients would need to call their doctor or manufacturer to find out how they are affected. Finally, those who had non-implant devices and those who were well-informed about their implantable device (e.g. pacemakers) felt less anxiety about a potential recall.

Participants agreed that the terms “Recall,” “Product Danger,” “Urgent Product Warning,” and “Urgent Public Safety Warning” all indicated the need to call the doctor or manufacturer immediately. Other terms such as “Safety Alert” and “Safety Advisory” indicated a less urgent message.

Participants most wanted information about the severity and potential health risks, device model numbers, symptoms, next steps, contact information, and potential costs.

Most participants said that information about a device recall would ideally be distributed through multiple channels -- the manufacturer, the doctor, and the media – so as to maximize the likelihood that the message would reach the affected audience.

Recommendations

No recommendations were presented in the study.

3. Premarket Medical Device Industry Perception Survey

Purpose This study aimed to survey the perception of industry regarding the premarket performance of the Center for Devices and Radiological Health (CDRH) during 2007 and compare results to responses given in 2006.

Findings Some of the perceptions held by respondents remained basically unchanged between 2006 and 2007, while some exhibited statistically significant differences. For example, approximately nine out of every ten survey respondents agreed that the CDRH Office of Device Evaluation (ODE) and Office of In Vitro Diagnostics (OIVD), reviewed and processed Premarket submissions in a timely manner in 2006 and 2007. The perceptions of OIVD stayed consistent in 2006 and 2007 with over 90% agreeing that review staff exhibited an appropriate level of scientific expertise in reviewing their submissions, and the respondents increased their perception of ODE timeliness of reviews from 80% to 87% for the same period. The perception that CDRH conducted premarket review meetings that were productive and met respondent needs improved significantly between 2006 and 2007, increasing from 30% to 49% in the ODE, and increasing from 42% to 56% in the OIVD.

Recommendations

- Guidance documents need updating, as they lag technology, are difficult to follow, or are not available.
- Reviewers should ask questions early on and address/resolve issues early to provide for quicker feedback.

4. Remote Usability Evaluation of the Center for Devices and Radiological Health (CDRH) Website with Industry Audience

Purpose This study sought to evaluate the usability of the CDRH website from the point of view of industry.

Findings Overall the site was found to be successful at meeting users' information needs only if users were willing to spend time and effort to navigate through it. Users new to the industry or the site had more difficult time locating information (48% success rate) compared to expert users (77% success rate). Neither group was particularly efficient in completing their tasks; only 13 tasks out of 106 were completed in less than two minutes. Specific recommendations for the site and for the database are listed below.

Recommendations for the Website

- Group similar items and use labels for the groups that make sense to users.
- Provide overviews with links to more detailed information.
- Make important information more visible: put it above the fold, reduce extraneous detail, and divide long pages into smaller "chunks" that cover one issue per page.

Recommendations for the Database

- Send users to the simple search version by default.
- Clearly indicate which database search version (simple vs. advanced) a user is currently on.
- Change the "Go To Simple/Advanced Search" from a button to a text link.

5. Report on User Card Sort of Content from the Center for Devices and Radiological Health (CDRH) Web Site

Purpose This study aimed to determine the best way to organize content on the CDRH website. Findings were based on the results of a focus group where participants from both industry and the public were asked to organize information the website using a card sorting exercise.

Findings The data indicated a moderately high level of agreement with the top-level categories. In general, participants tended to separate the contents into more groups than currently exist on the site, usually resulting from splitting some of the existing groups into two. In addition, participants had some difficulty sorting very general topics such as Databases, Standards, and Device Advice.

The study identified 16 phrases that caused confusion for participants. An additional 40 phrases were partly misunderstood, but may become clearer in the context of other information on the web site. Participants identified potential overlap among phrases used for contacting CDRH.

Overall, the study results indicate that current CDRH home page taxonomy better reflects healthcare and industry professionals' understanding of the medical device field than that of the general public.

Summary of Recommendations

Specific user recommendations are classified into three main categories:

1. P*resentation/Usability* Suggestions include providing clear descriptions of general topics and redundant links to material of strong interest to assist in orientation and navigation of the website.
2. *Organization/Structure* Suggestion address the logical and natural organization of the website structure, e.g. placing the most popular topics on the homepage in a prominent location for easy access, and arranging the site so that subtopics are placed under the relevant and properly-labeled section.
3. *Content* Suggestions focused on creating audience-specific areas (e.g. for non-industry audiences explaining how FDA regulates devices and device subcategories for health professionals) while at the same time emphasizing that separate navigation areas or content subscription options for specific audiences provide little benefit and are therefore not needed.

6. User Testing and Redesign Implementation Recommendations

Purpose The aim of this project was to gather feedback from Center for Devises and Radiological Health (CDRH) staff on how best to redesign the CDRH intranet website (CenterNet). Various types of data collection methods were employed, including audience research, discussions with CDRH project staff, interviews with employees, a staff-wide survey, and focus group sessions. Wire frame diagrams were constructed to reflect the proposed layout and general structure of the redesigned CenterNet.

Findings It was believed that the wire frames represented a significant improvement over the current CenterNet site. Office pages remained a popular way to organize content and direct specific user groups, and a unified template for office pages was also perceived as having high value. Express menus assisted users with finding information, and news relevant to CDRH and FDA were perceived as useful. Events and News do not need to be tied to specific offices within CDRH, as most events including training and staff announcements were of broader interest or not numerous enough to warrant that level of detail. Scientific information needs to be reviewed with experts within the Center to validate content and placement within the revised global navigation. Users preferred the layout of the new Employee Corner which introduced a number of

shortcuts to commonly used administrative tools and clear gateways too specific sections within the Employee Corner.

Summary of Recommendations

Recommendations focused on technology planning and implementation, content migration, governance, roles and responsibilities, and performance measurement.

7. Information Technology Training Needs Assessment: Summary of Findings

Purpose This study was intended to assess the information technology training needs of Center for Devices and Radiological Health (CDRH) staff in order to develop short and long-term goals for developing an effective training program.

Findings The results indicate that the largest skill gap and highest importance was for Image2000, followed by Center Tracking System, and Enhanced CDRH Information Retrieval System (eCIRS). Furthermore, when office specific and job family specific data were examined, gaps were evident between the desired skill level and current skill level for the major Information Technology systems in use for CDRH. Further evaluation and research is needed to identify specific training needs related to each system. The survey relied on self-assessed ratings of skill level for the various Information Technology systems. Validation of the survey results may be warranted if funds are available for a second round of data collection in the future.

Recommendations

The short-term recommendations were:

- Offer an overview class for all major CDRH Information Technology Systems.
- Develop a list of expert users who can be called upon as potential trainers and/or subject matter experts.
- Provide decision makers with a matrix describing major CDRH Information Technology applications with a description of subcomponents, target audience, and capabilities.

The long-term recommendations were:

- Plan, implement, and evaluate a phased training approach (Basic, Intermediate, Advanced) for the three CDRH Research specific Information Technology systems.
- The budget for new Information Technology systems should include allowances for training. Allocate resources for training as an integral part of any new system/application.

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: Detect safety problems earlier and better target interventions to prevent harm to consumers.									
1	Perform data analysis on laboratory results and create informational reports on specific analytes and select agents. (214302) (outcome)	NA	NA	NA	NA	5 analytes and 5 select agents	8 analytes and 5 select agents	NA	NA
2	Number of statutory CBER inspections. (234201) (output)	1,444	1,392	1,128	1,292	1,138	1,256	NA	NA
3	Number of statutory CVM inspections. (244201)	773	772	618	699	620	671	NA	NA
Long-Term Objective 2: 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.									
4.1	Number of months of the average FDA time to approval or tentative approval for the fastest 25% of original generic drugs application. (222303) (Output)	NA	NA	Fastest 25% by .5 mos	Fastest 25% by .3 mos	NA	NA	NA	NA
4.2	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	10/08	NA	NA
5	Complete review and action on priority PDUFA efficacy supplements within 6 months of receipt. (233204) (Output)	None Submitted	None Submitted	90%	None Submitted	90%	4/08	NA	NA

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.