DEPARTMENT of HEALTH and HUMAN SERVICES

Food and Drug Administration

FY 2012 Online Performance Appendix

Introduction

The FY 2012 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 the HHS agencies' FY 2012 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Summary of Performance and Financial Information (SPFI). These documents are available at http://www.hhs.gov/budget/.

The FY 2012 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2010 Annual Performance Report and FY 2012 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The HHS SPFI summarizes key past and planned performance and financial information.

MESSAGE FROM THE FDA COMMISSIONER

I am pleased to present the Fiscal Year 2012 Online Performance Appendix (OPA) for the Food and Drug Administration (FDA).

At FDA, we manage our programs to achieve measurable results and objectives that protect and advance the public health through a life-cycle approach to the safety of the products we regulate. We do this not only through our attention to the performance goals in our annual performance budget, but also through our FDA-TRACK initiative (www.fda.gov/fdatrack). This Performance Report reflects the goals and objectives in the Department of Health and Human Services Strategic Plan and the FDA Strategic Action Plan.

In FY 2010, FDA met or exceeded approximately 90% of our performance goals that have been reported on so far. In fact, each prior year since 2002, FDA has met or exceeded at least 90% of our performance goals for each year. This is an excellent record of achievement, and reflects well on the efforts and professionalism of FDA's employees.

In accordance with the requirements of the Reports Consolidation Act of 2000, I, as the Agency Head, assert that the performance information in this report is accurate, complete and reliable, based on available data in FDA's performance information systems. The FY 2010 Performance Report includes descriptions of the means by which HHS requires us to verify and validate performance data and related data issues, including the completeness and reliability of the data. Where required, the programs have included discussions of the actions planned and completed to improve the completeness and reliability of the data.

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

/s/ Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

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Summary of Targets and Results Table

The Summary of Targets and Results Table provides an overview of all targets established for each corresponding fiscal year.

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	51	51	100%	49	96%
2008	45	45	100%	41	90%
2009	47	46	98%	44	95%
2010	76	60	79%	54	89%
2011	80				
2012	80				

Priority Goal

Resources and Performance
(dollars in millions)

	FY 2010 Actuals	FY 2011 Continuing Resolution	FY 2012 President's Budget
Salmonella enteritidis Activities (CFSAN)	$2.4	$2.0	$2.0
Salmonella enteritidis Activities (ORA)	$11.3	$41.6	$33.6
Salmonella enteritidis Activities (Office of the Commissioner)	$0.1	$0.1	$0.1
Total	$13.8	$43.7	$35.7

Foods

Performance Measure	**FY 2009 Result**	**FY 2010 Target**[1]	**FY 2011 Target**[1]	**FY 2012 Target**[1]
Decrease the rate of *Salmonella enteritidis* (SE) illness in the population (cases per 100,000)	2.6 cases/ 100,000 (Historical Actual: average rate of SE illness from 2007 to 2009)	NA	2.3 cases/ 100,000	2.2 cases/ 100,000

[1] CDC's FoodNet system reports pathogen-specific illness data based on the calendar year, not the fiscal year. Therefore, achievement of the annual targets reported here is evaluated based on the calendar year data, not fiscal year data.

A regulation to reduce illnesses from *Salmonella enteritidis* (SE) has recently been promulgated by the Food and Drug Administration (FDA). FDA's final egg rule, "Prevention of *Salmonella enteritidis* in Shell Eggs During Production, Storage and Transportation", was published on July 9, 2009. This rule requires shell egg producers to implement controls to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. The regulation also requires egg producers to maintain records concerning their compliance with the egg rule and to register with FDA. The final rule is expected to reduce SE-associated illnesses and deaths by reducing the likelihood that shell eggs are contaminated with SE. The compliance date is July 9, 2010 for egg producers with 50,000 or more laying hens, and July 9, 2012 for producers with fewer than 50,000 but at least 3,000 laying hens. For persons who must comply with the refrigeration requirements, the compliance date is July 9, 2010. FDA will implement the new regulation by:

- Developing guidance to provide the regulated community with specific information about how to comply with the rule;
- Training investigators so they have the information they need to enforce the regulation;
- Conducting inspections to ensure compliance with the regulation; and
- Using State Contracts to extend the reach of FDA investigators to ensure compliance.

An increase of illnesses from *Salmonella enteritidis* in shell eggs was detected by CDC in spring of 2010. Investigation revealed that many of these illnesses could be traced back to shell eggs. The impact of this increased rate of illnesses in 2010 on the ability to meet the goal in 2011 is unknown.

Foods Performance Detail

Long Term Objective: Advance Food Safety and Nutrition

Measure	FY	Target	Result
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. *(Output)*	*2012*	90%	October, 2013
	2011	80%	October, 2012
	2010	70%	October, 2011
	2009	60%	100% (Target Exceeded)
	2008	60%	100% (Target Exceeded)
	2007	50%	100% (Target Exceeded)

Measure	Data Source	Data Validation
213301	CFSAN's electronic workflow system	The Food Application Regulatory Management (FARM) System is a comprehensive image-based electronic document management, workflow, and reporting automation system. FARM supports electronic processing, review, maintenance, and reporting for food ingredient submissions, including management of food and color additive petitions, Food Contact Notifications (FCNs) (until FY 2008), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations. FARM expedites the ingredient review process and subsequent safety decisions. It also helps FDA perform associated activities such as responding and managing correspondence and Freedom of Information requests. FARM also supports industry electronic submission of food ingredient submissions and correspondence in a standard electronic format, further improving efficiencies for industry and FDA. The CFSAN electronic workflow module 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.

Measure	FY	Target	Result
214101: 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. *(Outcome)*	*2012*	423 enrolled	December, 2012
	2011	398 enrolled	December, 2011
	2010	347 enrolled	388 enrolled (Target Exceeded)
	2009	332 enrolled	333 enrolled (Target Exceeded)
	2008	317 enrolled	320 enrolled (Target Exceeded)
	2007	240 enrolled	302 enrolled (Target Exceeded)

Measure	Data Source	Data Validation
214101	Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm121796.htm.	A listing of jurisdictions enrolled in the Voluntary National Retail Food Regulatory Program Standards can be found on the CFSAN web page at: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm121796.htm. This listing identifies regulatory agencies that have enrolled in the Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments, and to develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff that compiles the information and maintains the listing.

Measure	FY	Target	Result
214306: The average number of days to serotype priority pathogens in food (Screening Only). *(Output)*	*2012*	4 working days	December, 2012
	2011	7 working days	December, 2011
	2010	N/A	10 working days (Historical Actual)
	2009	N/A	14 working days (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
214306	Bioplex and ibis Biosensor systems	CFSAN scientists are developing the means to evaluate and adapt commercially available instruments to develop and validate more rapid, accurate, and transportable tests to stop the spread of food borne illness and cases of chemical contamination. CFSAN scientists are using one such system, known as Bioplex, to rapidly serotype pathogens such as *Salmonella*. The Bioplex system can serotype 48 different samples in 3 to 4 hours, vastly improving response time in food borne illness outbreaks. CFSAN scientists also are using the ibis Biosensor system to speed the identification of *Salmonella*, *E. coli*, and other pathogens, toxins, and chemical contaminants. When fully deployed, this technology holds the promise of reducing the time to conduct these analyses from 10-14 days to 1-2 days.

Measure	FY	Target	Result
214207: The number of assessments/questionnaires to completed to initiate the process of establishing comparability of foreign country food	*2012*	9	December, 2012
	2011	5	December, 2011
	2010	N/A	N/A

Measure	FY	Target	Result
safety systems to that of the U.S. relative to public health outcomes. *(Output)*	*2009*	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
214207	FDA Surveillance Systems (e.g., FoodNet, PulseNet, eLEXNET)	FDA will conduct administrative assessments of regulatory food safety systems in developed and developing countries to measure their performance against FDA program standards. These assessments will include reviews of inspections, investigations, sample collections and analyses, and enforcement, response, recovery, and outreach activities. The data generated by these assessments will be linked to FDA food safety monitoring activities, and the data will be recorded and analyzed so that the results can be used to enhance the safety of the U.S. food supply.

Measure	FY	Target	Result
214208: Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. *(Outcome)*	*2012*	+10% over baseline	December, 2012
	2011	Set Baseline	December, 2011
	2010	N/A	N/A
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
214208	Consumer Focus Group	FDA will use data collected from focus group research to develop FY 2011 baseline. FDA will increase consumer awareness by 10% through research-based and targeted education and outreach campaigns followed by repeat survey/focus groups to determine increase in awareness of FDA's Adverse Event Reporting System for Cosmetics.

Measure	FY	Target	Result
214201: Number of prior notice import security reviews. *(Output)*	*2012*	80,000	December, 2012
	2011	80,000	December, 2011
	2010	80,000	81,618 (Target Exceeded)
	2009	80,000	81,157 (Target Exceeded)
	2008	80,000	80,543 (Target Exceeded)
	2007	60,000	84,088 (Target Exceeded)

Measure	FY	Target	Result
214202: Number of import food field exams. *(Output)*	*2012*	160,000	December, 2012
	2011	160,000	December, 2011
	2010	140,000	170,392 (Target Exceeded)
	2009	120,000	138,916 (Target Exceeded)
	2008	85,000	100,718 (Target Exceeded)
	2007	71,000	94,743 (Target Exceeded)
214203: Number of Filer Evaluations. *(Output)*	*2012*	1,000	December, 2012
	2011	1,000	December, 2011
	2010	1,000	1,277 (Target Exceeded)
	2009	1,000	1,208 (Target Exceeded)
	2008	1,000	1,356 (Target Exceeded)
	2007	1,000	1,355 (Target Exceeded)
214204: Number of examinations of FDA refused entries. *(Output)*	*2012*	7,000	December, 2012
	2011	7,000	December, 2011
	2010	7,000	8,658 (Target Exceeded)
	2009	5,000	7,201 (Target Exceeded)
	2008	4,000	5,926 (Target Exceeded)
	2007	3,000	5,510 (Target Exceeded)
214205: Number of high risk food inspections. *(Output)*	*2012*	8,850	December, 2012
	2011	7,800	December, 2011
	2010	6,750	6,926 (Target Exceeded)
	2009	6,100	6,182 (Target Exceeded)
	2008	5,700	6,230 (Target Exceeded)
	2007	5,625	6,421 (Target Exceeded)
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from	*2012*	5 data exchange additions/conversions	December, 2012
	2011	5 data exchange additions/conversions	December, 2011

Measure	FY	Target	Result
existing manual data streams to automated data exchange. *(Outcome)*	*2010*	5 data exchange additions/conversions	5 data entry labs (Target Met)
	2009	5 data exchange additions/conversions	5 data entry labs (Target Met)
	2008	5 data entry labs	11 data entry labs (Target Exceeded)
214206: Maintain accreditation for ORA labs. *(Outcome)*	*2012*	13 labs	December, 2012
	2011	13 labs	December, 2011
	2010	13 labs	13 labs (Target Met)
	2009	13 labs	13 labs (Target Met)
	2008	13 labs	13 labs (Target Met)
	2007	13 labs	13 labs (Target Met)
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	*2012*	2,500 rad & 2,100 chem	December, 2012
	2011	2,500 rad & 2,100 chem	December, 2011
	2010	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem (Target Met)
	2009	2,500 rad & 1,650 chem	2,500 rad & 1,650 chem (Target Met)
	2008	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem (Target Met)
	2007	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem (Target Met)

Measure	Data Source	Data Validation
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.

Measure	FY	Target	Result
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. *(Outcome)*	*2012*	11.9 cases/100,000	March, 2014
	2011	12.3 cases/100,000 (New Baselines)*	March, 2013
	2010	12.3 cases/100,000	March, 2012

Measure	FY	Target	Result
	2009	N/A	March, 2011
	2008	N/A	12.8 cases/100,000 (Historical Actual)
	2007	N/A	12.8 cases/100,000 (Historical Actual)
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. *(Outcome)*	*2012*	1.08 cases/100,000	March, 2014
	2011	1.14 cases/100,000 (New Baselines)*	March, 2013
	2010	1.0 cases/100,000	March, 2012
	2009	N/A	March, 2011
	2008	N/A	1.1 cases/100,000 (Historical Actual)
	2007	N/A	1.2 cases/100,000 (Historical Actual)
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. *(Outcome)*	*2012*	.28 cases/100,000	March, 2014
	2011	.29 cases/100,000 (New Baselines)*	March, 2013
	2010	.24 cases/100,000	March, 2012
	2009	N/A	March, 2011
	2008	N/A	.29 cases/100,000 (Historical Actual)
	2007	N/A	.27 cases/100,000 (Historical Actual)
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. *(Outcome)*	*2012*	14.4 cases/100,000	March, 2014
	2011	14.8 cases/100,000 (New Baselines)*	March, 2013
	2010	6.8 cases/100,000	March, 2012
	2009	N/A	March, 2011
	2008	N/A	16.2 cases/100,000 (Historical Actual)
	2007	N/A	14.9 cases/100,000 (Historical Actual)

* The FY 2010 targets for reducing the incidence of infection caused by *Campylobacter* species, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species were set in the year 2000 as part of the **Healthy People 2010 Initiative**. The targets for FY 2010 were all calculated as 50% reductions from 1997 baseline incidence levels for these food borne pathogens. The targets for 2010 have not yet been achieved for any of the pathogens included in this objective (though *Campylobacter* species, *E. coli* O157:H7 and *Listeria monocytogenes* are very close, with 48%, 47% and 38% reductions, respectively, as of the 2008 data). Further investigation is needed to identify sources for emerging *Salmonella* serotypes, since that rate of infection has increased in the past decade.
The FY 2011 targets start the next decade of targets as part of the **Healthy People 2020 Initiative**, and are therefore not comparable to the FY 2010 targets. In order to align the new targets for future reductions with more recent data, the baseline data for the FY 2011 targets are from FoodNet data collected from FY 2006 – FY 2008. Consequently, the FY 2011 targets show an increase over the Healthy People 2010 targets due to the new baseline. The Health and Human Services Office of Disease Prevention and Health Promotion (ODPHP) has recently given guidance to the Healthy People work groups on target setting for **Healthy People 2020**, recommending improvement targets of 10% over the 10-year period.

Measure	Data Source	Data Validation
212404 212405 212406 212407	FoodNet	The proactive use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods is a significant focus of FDA. FDA collects data from the FoodNet Data Base to assess and communicate the specific risks associated with specific food products to American consumers and to industry on a routine basis as well as during food borne illness outbreaks to reduce the incidence of infection with key food borne pathogens. CDC's FoodNet system reports pathogen-specific illness data based on the calendar year, not the fiscal year. Therefore, achievement of the annual targets reported here is evaluated based on the calendar year data, not fiscal year data.

Measure	FY	Target	Result
212409: Decrease the rate of *Salmonella enteritidis* (SE) illness in the population (cases per 100,000). (*Outcome*)	*2012*	2.2 cases/100,000	July, 2013
	2011	2.3 cases/100,000	July, 2012
	2010	N/A	July, 2011
	2009	N/A	2.6 cases/100,000 (Historical Actual: average rate of SE illness from 2007 to 2009)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
212409	CDC/ FoodNet	The modeled rates, which are calculated using an approach based on the approach used in FoodNet's annual MMWR article to assess changes in rates over time, adjust for the changes in the FoodNet surveillance area over time and for the different baseline disease incidence rates in the various surveillance areas. The modeled rates, therefore, provide a more consistent and accurate framework within which to assess changes in disease rates over time than crude rates. CDC's FoodNet system reports pathogen-specific illness data based on the calendar year, not the fiscal year. Therefore, achievement of the annual targets reported here is evaluated based on the calendar year data, not fiscal year data.

Measure	FY	Target	Result
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. *(Outcome)*	*2012*	+5% over baseline	December, 2012
	2011	Set Baseline	December, 2011
	2010	N/A	N/A
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
212408	NHANES	In FY 2011 FDA will use data from NHANES to obtain a baseline assessment of consumer awareness of dietary factors associated with disease risk and their knowledge of and ability to use the nutrition and ingredient information on the food label. FDA will increase consumer awareness through research-based, targeted education and outreach campaigns. FDA will use repeat survey/focus groups to determine increase in awareness and NHANES and USDA data to track changes in food intake patterns and biological responses.

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

Context: The likely number of submissions to the food and color additives premarket review program was uncertain for FY 2007 and FY 2008 as a result of statutory triggers in section 409(h) of the FD&C Act that might have dramatically increased the number of submissions to this program. The factors impacting the uncertainty in submission numbers have lessened and performance has stabilized. The FY 2011 target has been increased to 80%, and the FY 2012 target to 90%.

Performance: All petitions filed in FY 2010 were completed before the end of FY 2011, exceeding the target for this measure by 40%. This program has consistently exceeded its performance goal each of the last four years. One reason goals have continued to be met is that the actual number of submissions has decreased over that period.

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*. (214101)

Context: Strong and effective regulatory programs at the state, local and tribal level are needed to prevent food borne illness and reduce the occurrence of food borne 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 food borne illness. The success of the FDA National Retail Food Team in increasing enrollment and use of the Standards reflects continued recognition that the Standards help programs improve food safety in food service 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. The FY 2010 Targets shown in the table above are based on an expectation that additional local jurisdictions will enroll in FY 2010 and make progress toward meeting the Standards as the result, in part, of FY 2009 efforts by FDA to make funds available to jurisdictions who agree to provide FDA with written reports on their progress. With the additional funds that FDA made available to this program in FY 2009, FDA has increased the FY 2011 target to enrolling fifty-one additional jurisdictions to the program. The FY 2012 target has been increased to a total of 423 jurisdictions enrolled. 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.

Performance: FDA exceeded its FY 2010 target by increasing the number of states, local, and tribal retail food inspection programs enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards by 55 new jurisdictions. This raised the total number of enrolled jurisdictions to 388. FDA has consistently exceeded its targets for this measure for the past 3 years.

3. The average number of days to serotype priority pathogens in food (Screening Only). (214306)

Context: FDA Foods Program scientists are evaluating commercially available instrumentation that can be adapted to support the FDA regulatory mission. CFSAN has advanced two of these technology platforms to Field laboratories, the Bioplex and the ibis Biosensor systems. The instrumentation is laboratory-based and provides broad-range and strain-specific identification of infectious organisms for multiple applications (clinical and environmental). The application does not require any prior knowledge of the sample identity and can simultaneously identify and characterize bacterial, viral, fungal, and other infectious organisms. The technology is extremely high throughput and can analyze thousands of samples a week. CFSAN has a contract with the developer that has advanced to allow detection of multiple pathogens down to the species level (Escherichia coli O157:H7 may also be determined), CFSAN researchers have field-tested 400 tomato samples to determine the microbiome associated with this commodity. Further research will evaluate the ability to detect Salmonella genus and sero/subtyping specifics through the next year. This year, CFSAN will purchase at least two of the systems for placement in other laboratories. CFSAN researchers will then begin coordinated testing and refinement of the technology for FDA's needs. The FY 2011 target for this goal is seven working days and the FY 2012 target is four working days.

Performance: The improvements in sample throughput, along with the high degree of specificity built into this technology, will dramatically improve our response and traceback capabilities. When fully deployed, this technology holds the promise of reducing the time to conduct these analyses from 14 days to 1-2 days.

4. The number of assessments/questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the U.S. relative to public health outcomes. (214207)

Context: FDA allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Approximately 15-20% of all foods consumed in the U.S. originated from foreign sources: 80% of the seafood and 25-35% of the produce eaten by American consumers are imported. The FDA does not have the resources to inspect all products that reach U.S. border in any given year; however, it is the expectation of American consumers that these imported foods are as safe as foods produced domestically. In response to this concern, FDA will conduct administrative assessments of regulatory food safety systems in developed and developing countries to measure their performance against FDA program standards. These assessments will include reviews of inspections, investigations, sample collections and analyses, and enforcement, response, recovery, and outreach activities. The data generated by these assessments will be linked to FDA food safety monitoring activities, and the data will be recorded and analyzed so that the results can be used to enhance the safety of the U.S. food supply. In FY 2011, FDA will conduct five additional administrative assessments of foreign regulatory food safety systems, and four additional assessments in FY 2012.

Performance: Since this is a new goal, performance data for FY 2011 will not be available until December 2011.

5. Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (214208**)**

Context: There are an increasing number of produces marketed as cosmetics that contain drug or other "active" ingredients. These products are not well-characterized and may pose different and more significant safety issues than traditional cosmetic products. Internet sales are increasing, but the entire extent of this segment of the cosmetic market is not well characterized and problems in traceback to

remove unsafe products could be highly significant. Problems may not come immediately to FDA attention because of the significant under-reporting of adverse events associated with cosmetics. FDA feels that increasing consumer awareness of FDA's Adverse Event reporting System for cosmetics would be a major step in reducing this important public health risk.

Performance: Baseline data will be developed in FY 2011 through focus group research. FDA will conduct research-based and targeted education and outreach campaigns followed by repeat survey/focus groups to determine increase in awareness of FDA's Adverse Event Reporting System for Cosmetics.

6. 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, and/or to identify those that may pose a significant health risk to the American public and prevent them from entering into the U.S. food supply. FDA will continue to focus much of its PNC resources on intensive prior notice security reviews of imported food/feed shipments that pose the highest potential bioterrorism risks to the U.S. consumer. Every (100%) prior notice is electronically screened and targeted and all those identified as high risk receive an intensive security review. The total number of intensive prior notice security reviews conducted by the PNC is impacted by current intelligence factors, targeting priorities, and the number of high risk shipments being imported. Therefore, this total may increase or decrease in future years. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: During FY 2010, FDA received 10,039,557 prior notice submissions on which the PNC conducted 81,681 intensive prior notice security reviews of import security reviews(exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. A total of 1,340 shipments were the subject of PNC compliance actions for prior notice or food facility registration violations, which was more than 1.5 times the total number of PN related actions from the previous fiscal year. The PNC operations actively strengthen the U.S. food supply and provide early food security/defense driven targeting and risk assessments to detect food shipments that pose or may pose a potential terrorist threat. In addition, the PNC responded to more than 21,000 phone and e-mail inquiries, and conducted over 826 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

7. 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 9.8 million line entries of imported food out of an estimated 20.0 million lines of FDA regulated products in FY 2009. In FY 2010, FDA expects approximately 10.1 million line entries of imported food within a total of more than 23.2 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. In FY 2009 through FY 2011 FDA increased the target by 20,000 exams each year. In FY 2012, the target is being maintained at the FY 2011 level of 160,000 field exams.

Performance: In FY 2010, FDA exceeded the target of 140,000 by completing 170,392 imported food lines examined. Explanation of why this goal was significantly exceeded: With the increase in funding, FDA was able to bring on a significant number of new investigators. Field exams play a significant role in new investigator training which resulted in exceeding the goal. Since new investigators were using these for training purposes, more resources than would normally go toward this target were utilized. Once investigators are fully trained, they will have other duties in addition to examining imported food lines. In FY 2011, FDA will retain our projected target of 160,000 due to the implementation of new field exam risk targeting procedures. The field exams will be more involved as a result of the new procedures but will result in a more focused public health outcome.

8. 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 2012 target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this goal of 1,000 by performing 1,277 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.

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

Context: FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. In FY 2010, the target was again increased to 7,000 to better reflect actual accomplishments. The FY 2012 target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this goal of 7,000 by performing 8,658 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 includes activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program. Explanation of why this goal was significantly exceeded: Examinations of refused entries are a function of refusals each year. More refusals result in a larger amount of verifications. In FY 2010, there

was an increased number of refusals which caused the examinations to increase as well. In FY 2012, the performance target will continue to be maintained at the FY 2011 level because there is no way to predict the number of refusals in a given year.

10. 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 and the immunocompromised. The Field intends to inspect such establishments annually, or more frequently on a "for cause" basis. 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 or sample results. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target was increased to 6,750 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 1,050 inspections for a new target of 7,800 inspections. In FY 2012, the target is being increased to 8,850 inspections.

Performance: In FY 2010, FDA exceeded this goal of 6,750 by performing 6,926 high-risk foreign and domestic food inspections.

11. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. (214303)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2009, there are 224 total laboratories currently participating in eLEXNET overall. These labs include segments of a wide variety of food safety organizations on Federal, Military, State, and Local government levels. These labs also span the agricultural, environmental, public health, veterinary, and diagnostic disciplines as well. Of the 224 participating laboratories in all 50 states, 144 are actively entering or submitting data. There are 44 labs among them that are fully automated via Data Exchange and transfer their LIMS sample data on a regular, ongoing basis. The 100 other remaining laboratories enter data in eLEXNET through manual data entry. The overall goal of the FDA's eLEXNET program is to continue to integrate those labs participating in eLEXNET via Data Exchange and to identify new labs to expand our membership. Through continued expansion of our membership base and active data sources, the eLEXNET program will continue to serve as a key collaborative tool for food surveillance entities nationwide. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met its performance goal by fully automating electronic data exchange between five new labs and FDA's eLEXNET (electronic Laboratory Exchange Network). This makes the total number of automated data exchange participant labs to 44. The automated data transfer does not require any human intervention and is completely maintenance free unless there is a change in the lab environment.

12. 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. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

13. 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. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which increased the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA added three additional FERN chemical labs in FY 2009 which increased the surge capacity to 2,100 chemical samples per week. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met this performance goal surge capacity target of 2,100 chem samples per week. FDA also maintained the surge capacity for 2,500 rad samples per week. The FERN laboratories increasingly provide critical analytical surge capacity during food emergency events. An FDA assignment ("Surveillance, Inspection and Sample Collection and Analyses of Products Related to the Salmonella St. Paul Investigation" issued by ORA/CFSAN) directed samples to the FERN labs in the Salmonella outbreak in peppers, with 290 samples tested. FERN Chemistry laboratories participated in the #09-06 CFSAN Melamine Import Assignment (2008-2009), assisting FDA in the analysis of milk and protein samples, analyzing 340 samples. These FERN labs were a key factor in clearing an FDA sample backlog, which arose due to very high collection rates. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA’s capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

14. Reduce the incidence of infection caused by key pathogens commonly transmitted by food. (212404 – 212407)

Context: The Nation's challenges to food protection are increasing as consumers buy food from around the globe. FDA's Foods Program features a science and risk-based approach of prevention, intervention, and response to ensure the safety of domestic as well as imported foods. Federal, Tribal, and State partners use a combination of research, inspections, surveillance, regulation and guidance, standardization and education as strategies to improve food safety. The proactive use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods is a significant focus of FDA. FDA collects data from the FoodNet Data Base to assess and communicate the specific risks associated with specific food products to American consumers and to industry on a routine basis as well as during foodborne illness outbreaks to reduce the incidence of infection with key foodborne pathogens. Foodborne illness surveillance information is also used to determine what additional food safety strategies are needed and to measure the effectiveness of interventions over time.

Performance: The FY 2010 targets for reducing the incidence of infection caused by *Campylobacter* species*, Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species were set in the year 2000 as part of the Healthy People 2010 Initiative. The targets for FY 2010 were all calculated as 50% reductions from 1997 baseline incidence levels for these foodborne pathogens. The targets for 2010 have not yet been achieved for any of the pathogens included in this objective (though *Campylobacter* species, *E. coli* O157:H7 and *Listeria monocytogenes* are very close, with 48%, 47% and 38% reductions, respectively, as of the 2008 data). Further investigation is needed to identify sources for emerging Salmonella serotypes, since that rate of infection has increased in the past decade. The FY 2011 targets start the next decade of targets as part of the Healthy People 2020 Initiative, and are therefore not comparable to the FY 2010 targets. In order to align the new targets for future reductions with more recent data, the baseline data for the FY 2011 targets is from FoodNet data collected from FY 2006 – FY 2008. Consequently, the FY 2011 targets show an increase over the Healthy People 2010 targets due to the new baseline. The Health and Human Services Office of Disease Prevention and Health Promotion (ODPHP) has recently given guidance to the Healthy People work groups on target setting for Healthy People 2020, recommending improvement targets of 10% over the 10-year period.

15. Decrease the rate of *Salmonella enteritidis* (SE) illness in the population (cases per 100,000). (212409)

Context: A regulation to reduce illnesses from *Salmonella enteritidis* (SE) has recently been promulgated by the Food and Drug Administration (FDA). FDA's final egg rule, "Prevention of *Salmonella enteritidis* in Shell Eggs During Production, Storage and Transportation", was published on July 9, 2009. This rule requires shell egg producers to implement controls to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. The regulation also requires egg producers to maintain records concerning their compliance with the egg rule and to register with FDA. The final rule is expected to reduce SE-associated illnesses and deaths by reducing the likelihood that shell eggs are contaminated with SE. The compliance date is July 9, 2010 for egg producers with 50,000 or more laying hens, and July 9, 2012 for producers with fewer than 50,000 but at least 3,000 laying hens. For persons who must comply with the refrigeration requirements, the compliance date is July 9, 2010. FDA will implement the new regulation by:

- Developing guidance to provide the regulated community with specific information about how to comply with the rule;
- Training investigators so they have the information they need to enforce the regulation;
- Conducting inspections to ensure compliance with the regulation; and
- Using State Contracts to extend the reach of FDA investigators to ensure compliance.

An increase of illnesses from *Salmonella enteritidis* in shell eggs was detected by CDC in spring of 2010. Investigation revealed that many of these illnesses could be traced back to shell eggs. The impact of this increased rate of illnesses in 2010 on the ability to meet the goal in 2011 is unknown. The FY 2011 target is 2.3 cases/100,000 and the FY 2012 target is 2.2 cases/100,000.

Performance: Reducing the rate of food-borne illness is an important outcome goal. Preventing *Salmonella* illness depends not only on oversight actions by the regulatory agencies, but also on information gathered and decisions made throughout the entire farm-to-table process by industry and consumers. The rate of illness will also depend on actions taken by all these stakeholders to detect and respond to outbreaks when they do occur. In other words, if an outbreak is detected early and effectively responded to quickly, fewer people will get sick. The regulatory role is shared by local, state and federal agencies. In addition, state and local public health agencies and CDC play a critical role with their data collection and their ability to link public health impacts with specific food commodities. Clearly, the accomplishment of any food-borne disease reduction goal is dependent on efforts made by many stakeholders. CDC's FoodNet system reports pathogen-specific illness data based on the calendar year, not the fiscal year. Therefore, achievement of the annual targets reported is evaluated based on the calendar year data, not fiscal year data. CY 2010 data will be available in July 2011.

16. The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (212408)

Context: One of the most important strategies in assuring that citizens lead long, healthy lives and minimize the likelihood of chronic disease is the use of science-based nutrition information to make wise choices about the foods they consume. The costs to inform, educate, and motivate consumers to these dietary choices are small compared to the costs to society of dealing with the chronic illnesses whose prevalence is based on a poor diet. The public health focus of this initiative is to expand and enhance food-labeling programs, education, outreach, and research to enable American consumers to make more informed and healthful food choices, maintain health, and reduce the risk of chronic diseases such as type 2 diabetes, cardiovascular disease, and obesity.

Performance: CFSAN will develop effective dietary guidance messages, education, and outreach programs. This will support efforts to increase consumer recognition of dietary factors that are associated with chronic disease risk and the steps they can take to reduce risk. The target for this item was shifted forward a year due to the 2010 Census and OMB moratorium on survey/focus groups, etc. CFSAN will set the baseline in FY 2011.

Human Drugs Performance Detail

Long Term Objective: Advance Human Drug Safety and Effectiveness

Measure	FY	Target	Result
223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)*	*2012*	90%	Nov 30, 2013
	2011	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	92% (Target Exceeded)
	2008	90%	84% (Target Not Met)
	2007	90%	88% (Target Not Met)
223202: Percentage of Priority NDAs/BLAs within 6 months. *(Output)*	*2012*	90%	Nov 30, 2013
	2011	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	80% (Target Not Met)
	2008	90%	63% (Target Not Met)
	2007	90%	90% (Target Met)
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year. *(Output)*	*2012*	2000	Nov 30, 2012
	2011	2000	Nov 30, 2011
	2010	1900	2,079 (Target Exceeded)
	2009	1900	2,006 (Target Exceeded)
	2008	1780	1,934 (Target Exceeded)
	2007	N/A	1,779 (Historical Actual)

Measure	Data Source	Data Validation
223201 223202 223101 223205 223207	Review performance monitoring is being done in terms of cohorts, e.g., FY 2009 cohort includes applications received from October 1, 2008, through September 30, 2009. CDER uses the Document Archiving, Reporting, and Regulatory Tracking System (DARRTS). FDA has a quality control process in place to ensure the reliability of the performance data in DARRTS. The Pediatric Exclusivity Database tracks all data	The Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. DARRTS is the core database upon which most mission-critical applications are dependent. The type of information tracked in DARRTS includes status, type of document, review assignments, status for all assigned

Measure	Data Source	Data Validation
	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.	reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in DARRTS. 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 DARRTS. The task leader then validates that all data entered into DARRTS 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.

Measure	FY	Target	Result
222303: Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA. *(Output)*	*2012*	80%	Nov 30, 2012
	2011	80%	Nov 30, 2011
	2010	80%	94% (Target Met)
	2009	N/A	75% (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A
222201: The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. *(Efficiency)*	*2012*	$10 per report	Nov 30, 2012
	2011	$10 per report	Nov 30, 2011
	2010	$12 per report	$7.35 per report (Target Exceeded)
	2009	$12 per report	$10.79 per report (Target Exceeded)
	2008	$13 per report	$10.59 per report (Target Exceeded)
	2007	$15 per report	$13.64 per report (Target Exceeded)
222203: The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry. *(Outcome)*	*2012*	90%	Nov 30, 2012
	2011	90%	Nov 30, 2011
	2010	80%	87% (Target Met)
	2009	N/A	83% (Historical Actual)
	2008	N/A	N/A

	2007	N/A	N/A
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)*	*2012*	70 million	Oct 1, 2012
	2011	70 million	Oct 1, 2011
	2010	55 million	60 million (Target Exceeded)
	2009	N/A	35 million (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A
292203: Number of safety analyses that are conducted using Medicare and Medicaid SafeRx* pilot. *(Output)*	*2012*	13	Oct 1, 2012
	2011	13	Oct 1, 2011
	2010	10	15 (Target Exceeded)
	2009	N/A	7 (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
222201 222203	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
292202	Automated Healthcare databases from Federal Partners' Collaboration (i.e., CMS, DoD, VA) Mini-Sentinel Pilot contractor (i.e., Harvard Pilgrim Health Care) automated Healthcare data from private sources (non-government)	Data validation is based on a review of the access to both publicly and privately available automated healthcare data. Participating Federal Partners will verify patient population numbers that are accessible for evaluation of safety signals. Harvard Pilgrim Health Care will verify patient population numbers accessible for evaluation of safety signals, to include all distributed partners within the contract.
292203	FDA Principal Lead for FDA-CMS Interagency Agreement to analyze safety signals from automated healthcare databases	Data validation is based on a review of the past period's activities and verification by the CMS Contracting Officer's Technical Representative (COTR) that verifies workload on ongoing basis to monitor funding provided by FDA to CMS for this collaborative safety project. FDA provides guidance on which safety signals to investigate and collaboratively reviews the data.

Measure	FY	Target	Result
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	*2012*	750	December, 2012
	2011	750	December, 2011
	2010	700	705 (Target Exceeded)
	2009	600	687 (Target Exceeded)
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)

Measure	Data Source	Data Validation
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.

Measure	FY	Target	Result
222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)*	*2012*	30%	Dec 31, 2012
	2011	Submit draft guidance & establish baseline	Dec 31, 2011
	2010	Issue guidance & establish baseline	Guidance Drafted and Undergoing Review (Target Not Met)
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

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 (FDAAA) of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. A key determinant in knowing if CDER is effective and efficient is to measure the

time to "first action." The first action is the first regulatory action CDER takes (complete response, approvable, not approvable, or approval letter) at the end of the review of the original NDA/BLA submission (the first review cycle). The "first action time" refers to the time it takes to review and take an action on the original submission. This statistic is different from "total approval time" which is the time it takes from the original receipt of the application until it is approved, which may take more than one review cycle. "Total approval time" includes time spent reviewing an application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the complete response or approvable/not approvable letter(s) and to re-submit the application for review. CDER's featured targets under this performance goal are to measure time to first action for "priority" submissions and "standard" submissions. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. In FY 2012, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: CDER tracks performance to these review goals by fiscal year cohorts. If an application is submitted in September of 2009, it will be tracked in the FY 2009 cohort even though much of the review work associated with the application, and the goal action date, may occur in the following fiscal year. As such, the most recent available performance information is for the FY 2009 cohort. CDER exceeded the review performance goal for standard reviews for the FY 2009 cohort by reviewing 92% of standard NDAs/BLAs within 10 months. CDER did not meet the review performance goal for priority reviews for the FY 2009 cohort Longer CDER priority review times for FY 2009 reflect the impact of several factors. FDAAA reauthorized the Prescription Drug User Fee Act in FY 2008, and also added significant new authorities and requirements that have added or expanded tasks that must be performed within the process of human drug review. As CDER was undertaking an aggressive effort to hire new staff to handle the existing scope and level of review work, the Center has also been implementing new requirements to be addressed within the review process. This includes the increased use of advisory committees mandated under FDAAA—particularly for drugs receiving a priority review—coupled with a lengthier process to plan meetings using the more stringent advisory committee member screening process under FDAAA that allows significantly fewer waivers for conflicts of interest for otherwise qualified candidates. Similarly, FDAAA Title IX risk management provisions add steps to the review to determine whether a Risk Evaluation and Mitigation Strategy (REMS) will be required at the time of new drug approval. These additional FDAAA-related processes have expanded the work required within review time goals that were established ten years earlier, under the Food and Drug Administration Modernization Act (FDAMA) of 1997. To ensure a rapid and compliant process CDER is continuing to examine the expanded review process requirements, while training the significant number of newly-hired staff to enable them to achieve review expertise as rapidly as possible.

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

Context: Generics play an important and increasing role in providing safe, effective, and affordable drugs to the American public and thereby in controlling health care expenditures. The number of generic applications submitted to CDER's generic drug program has grown considerably over the past decade – nearly three-fold since 2001 – outpacing the growth in program personnel. In order to manage the increasing workload CDER has launched initiatives to streamline and modernize the generic review program. The growing capacity of the program is measured in total actions taken on generic drug applications. An action is defined as any approval, tentative approval, not approvable, and approvable decision taken on a generic drug application. The target for FY 2009 and FY 2010 was 1,900 actions; the FY 2011 target is 2,000 actions, the FY 2012 target is to maintain 2,000 actions.

Performance: In FY 2010 CDER's generic program took 2,079 actions – exceeding the target measure by 179 actions.

3. Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA. (222303)

Context: CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. The FDA Amendments Act of 2007 (FDAAA) recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way CDER tracks pre-market issues according to PDUFA requirements. Consequently, CDER has determined that the previous measure (identifying priority postmarketing safety reviews and acting upon those reviews within an established timeframe) does not reflect current risk management practices following implementation of new authorities regarding postmarket safety of drugs with the 2007 enactment of FDAAA, particularly new authorities related to safety labeling changes. CDER has determined a more meaningful measure is the number of safety labeling change supplements reviewed within the timeframes established by FDAAA. This measure draws a direct connection to the safe use of drugs by Safe Use patients and health care providers by ensuring that the most up-to-date safety information is available in a timely manner as specified in FDAAA.

Performance: In FY 2010, CDER reviewed 94% of safety labeling change supplements within the timeframe specified by FDAAA.

4. 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. The targets for FY 2012 and FY 2011 have been reduced to $10 per report.

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 2008, the actual cost per report was $10.59 per report. In FY 2009 the cost per report rose slightly to $10.79 per report but was still below the target of $12 per report.

In FY 2010, the cost per report was reduced to $7.35. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports. In the absence of electronic submissions, the program costs for manual data entry would be nearly double what they are today.

5. The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry. (222202)

Context: Drug manufacturers are required to submit to FDA reports of adverse events they receive related to their products. These reports provide crucial information to help enable CDER to monitor the post-market safety of drug products in use. Currently, manufacturers may submit these reports to CDER by mail, fax, or electronically through CDER's MedWatch portal. As electronic reporting streamlines CDER processes, saves time and money, and ensures quicker reporting, CDER is committed to increasing the proportion of reports submitted electronically. FDA is currently developing an improved web-interface reporting system to be called MedWatch Plus. The MedWatch Plus portal will include a rational questionnaire which will help facilitate improved communication, ease of reporting, and enable more complete and higher quality reporting. This timelier and higher quality reporting will positively affect public heath by enabling improved scientific analysis of adverse event reporting and more timely and accurate detection of safety signals. CDER's target for FY 2010 of 80% of all manufacturing reports submitted electronically was exceeded by 7%. The FY 2011 and FY 2012 targets are set at 90%.

Performance: The percentage of all reports submitted electronically (not limited to industry reports) grew from 33% in FY 2006 to 87% in FY 2010.

6. Number of people for whom FDA is able to evaluate product safety through multiple miniature Sentinel pilots. (292202)

Context: The goal of the ***Sentinel Initiative*** is to create a national, integrated, electronic system (the Sentinel System) for monitoring medical product safety. The Initiative, which will be developed and implemented in stages, will ultimately enable FDA to leverage the capabilities of multiple, large databases (e.g., electronic health record systems, medical claims databases) to augment the Agency's existing safety monitoring capability. As currently envisioned, Sentinel will facilitate targeted queries, within the bounds of established privacy and security safeguards, across large remote data systems and be scalable to enable small or large queries using broad or narrowly focused data. Sentinel, ultimately, will expand and strengthen FDA's ability to monitor the performance of a product throughout its entire life cycle and facilitate data mining and other research-related activities.

Performance: In FY 2010, miniature Sentinel pilots enabled FDA to reach 60 million patients. With the addition of a collaborative project with Federal partners, expectations are to be able to reach 70 million people by late FY 2011, and maintain that level of access in FY 2012.

7. Number of safety analyses that are conducted using Medicare and Medicaid data through the SafeRx Project. (292203)

Context: Several projects are under way using Medicare and Medicaid data that are testing the ability to analyze safety on FDA-regulated products. The SafeRx project is using Medicare and Medicaid data to perform in-depth safety analyses. Analyses involve many types of active surveillance and epidemiology methodologies, which may last many months. Each analysis enables experts to test and evaluate tools necessary to perform almost real-time surveillance and also more thorough epidemiology studies.

Performance: In FY 2010, 15 safety analyses were conducted through the SafeRx pilot.

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 2010. 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. For FY 2010, the target was increased to 700 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 50 inspections for a new target of 750 inspections. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: FDA exceeded the FY 2010 goal of 700 by inspecting 705 high-risk foreign and domestic drug manufacturers.

9. Percentage of television advertisements requiring submission reviewed within 45 days. (222302)

Context: Under the Food and Drug Amendments Act of 2007 (FDAAA) FDA gained authority to require submission of television advertising for review 45 days before dissemination in order to protect the well-being of consumers and ensure advertising information remains consistent with prescribing information for the product under review. FDA is developing a risk-based set of standards to leverage limited resources in a manner that best protects the public health by assuring that TV ads accurately and effectively communicate key information about the product, including its major risks and its indications. These standards will focus reviews on products with particularly serious risks or at times when feedback on the risk and indication communication is critical, such as when a drug is first advertised on TV and after a drug has received significant safety labeling updates. The FY 2010 target of issuing draft guidance and establishing the baseline was not met as the draft guidance is still undergoing review. The target for FY 2011 is to issue the draft guidance to industry on the program and receive submissions for pre-review. The FY 2012 target is 30% of reviews of TV ads completed within 45 days for advertising identified as meeting the high-risk criteria.

Performance: As this is a new authority, prior performance data does not exist.

Biologics Performance Detail

Long Term Objective: Advance Biologics Safety and Effectiveness

Measure	FY	Target	Result
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	*2012*	90%	Nov 30, 2013
	2011	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	100% (Target Exceeded)
	2008	90%	100% (Target Exceeded)
	2007	90%	100% (Target Exceeded)
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	*2012*	90%	Apr 30, 2013
	2011	90%	Apr 30, 2012
	2010	90%	Apr 30, 2011
	2009	90%	75% (Target Not Met)
	2008	90%	100% (Target Exceeded)
	2007	90%	100% (Target Exceeded)
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	*2012*	90%	Nov 30, 2013
	2011	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	100% (Target Exceeded)
	2008	90%	100% (Target Exceeded)
	2007	90%	100% (Target Exceeded)
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	*2012*	90%	Nov 30, 2013
	2011	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	100% (Target Exceeded)
	2008	90%	100% (Target Exceeded)
	2007	90%	100% (Target Exceeded)
233206: Complete review and action on	*2012*	90%	Nov 30, 2013

Measure	FY	Target	Result
complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)*	*2011*	90%	Nov 30, 2012
	2010	90%	Nov 30, 2011
	2009	90%	99% (Target Exceeded)
	2008	90%	100% (Target Exceeded)
	2007	90%	99% (Target Exceeded)

Measure	Data Source	Data Validation
233201 233202 233203 233205 233206	CBER's regulatory management 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). RMS-BLA is CBER's VAX-based (Virtual Address eXtension), Oracle database 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 used to track all Investigational New Drug (IND) Applications, 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 the Document Control Center, the application review offices, RIMS, and several mechanisms are built into BIMS. The Blood Logging and Tracking System (BLT) records and tracks various applications reviewed by the Office of Blood Research and Review (OBRR). OBRR also has a New Drug Application (NDA) tracking system. Data retrieved from these systems are reviewed and validated by 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 Report (BPDR) (previously called error and accident report) enables CBER to evaluate and monitor establishments, provide field staff and establishments with trend analyses of the reported deviations and unexpected events, and assist CBER in responding appropriately to reported biological product deviations.

Measure	FY	Target	Result
234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production. *(Output)*	*2012*	Evaluate and compare new methods to determine the potency of influenza vaccines	Nov. 30, 2012

Measure	FY	Target	Result
	2011	Apply novel technologies including mass spectrometry, an analytical technique for the determination of the elemental composition of a molecule, to quantify the absolute amount of hemagglutinin, a substance that causes red blood cells to aggluntinate, in the reference standards that are used to determine influenza vaccine potency.	Nov 30, 2011
	2010	Completed and evaluated the pilot vaccine adverse-effects program and participated in an international workshop on alternative methods to reduce, refine, and replace the use of animals in vaccine potency and safety testing.	All targets met.
	2009	Started a pilot program to develop and evaluate new methods to detect possible adverse effects, both pre-specified and non-pre-specified, of newly licensed vaccines, including pandemic influenza vaccines, in large population databases. Participated in at least one international workshop or conference.	All targets met.
	2008	Facilitated development and evaluation of one new pandemic influenza vaccine and one new trivalent vaccine; demonstrated an improved method for evaluating the safety, potency or immunogenicity of influenza vaccines; and participated in one international workshop.	All targets met
	2007	Issued guidance on	All targets met

Measure	FY	Target	Result
		clinical data to support licensure of pandemic influenza vaccines; evaluated potency of five influenza vaccines; demonstrated methods for improved influenza manufacture.	

Measure	Data Source	Data Validation
234101	CBER's Office of Vaccines Research and Review; and CBER's Medical Director for Emerging and Pandemic Threat Preparedness	The data are validated by the appropriate CBER offices and officials.

Measure	FY	Target	Result
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	*2012*	1,000	December, 2012
	2011	1,000	December, 2011
	2010	1,000	1,073 (Target Exceeded)
	2009	870	1,001 (Target Exceeded)
	2008	870	1,014 (Target Exceeded)
234203: Number of human tissue establishment inspections. *(Output)*	*2012*	533	December, 2012
	2011	533	December, 2011
	2010	518	564 (Target Exceeded)
	2009	380	434 (Target Exceeded)
	2008	325	383 (Target Exceeded)
	2007	325	427 (Target Exceeded)

Measure	Data Source	Data Validation
234202 234203	Field Data Systems	ORA use the following two main information technology systems to track and verify field performance goal activities: Field Accomplishments and Compliance Tracking System (FACTS) and Operational and Administrative System Import Support (OASIS). FACTS include 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.

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 to shorten the time needed for these products to reach the market. Standard original BLAs are license applications for biological products, not intended as therapies for serious or life-threatening diseases. In FY 2012, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2009, CBER exceeded its goal by completing review and action on 100 percent of 8 standard applications within 10 months of receipt and has met or exceeded this performance goal since 1994. The FY 2010 performance data for this goal will not be available until November 2011.

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

Context: PDUFA authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. A BLA will receive priority review if the product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. In FY 2012, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 6 months after receipt, is expired. In FY 2009, CBER did not achieve its goal by completing review and action on 75 percent of 4 priority applications within 6 months of receipt. The goal for one application was missed because critical new data were submitted by the sponsor near the PDUFA review deadline. CBER decided to continue the review and to not issue a Complete Response letter to meet the PDUFA review deadline because of the public health importance of the vaccine. The FY 2010 performance data for this goal will not be available until April 2011.

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

Context: PDUFA authorizes the FDA to collect fees from the prescription drug and biologic industries to expedite the review of human drugs and biologics to shorten the time needed for these products to reach the market. An efficacy supplement is a change to an approved licensed product to modify the "approved effectiveness" of a product, such as, a new indication which normally requires clinical data. In FY 2012, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2009, CBER exceeded its goal by completing review and action on 100 percent of 16 standard PDUFA efficacy supplements within 10 months of receipt. CBER has met or exceeded most of these performance goals since 1994. The FY 2010 performance data for this goal will not be available until November 2011.

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

Context: For FY 2012, CBER maintains the goal of reviewing and acting upon complete blood bank and source plasma BLA submissions at 90% within 12 months after submission. Since CBER receives only a few complete blood bank and source plasma submissions, the actual performance may be significantly different than the target.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 12 months after receipt, is expired. In FY 2009, CBER exceeded its goal by reviewing and acting on 100 percent of 2 submissions within 12 months of receipt. The FY 2010 performance data for this goal will not be available until November 2011.

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

Context: In FY 2012, CBER maintains the goal of reviewing and acting upon complete blood bank and source plasma BLA supplement submissions within 12 months after submission. User fee resources are not available for blood bank and source plasma application review.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 12 months after receipt, is expired. In FY 2009, CBER exceeded its goal by reviewing and acting on 99 percent of 346 supplements within 12 months of receipt. The FY 2010 performance data for this goal will not be available until November 2011.

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

Context: 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 or H1N1 influenza, can rapidly change. Vaccines will need to be produced for pandemic influenza strains on a short notice; therefore, 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. The FY 2012 pandemic preparedness target will be to evaluate and compare new influenza-vaccine potency methods.

Performance: In FY 2010, CBER accomplished its targets for this goal.

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

Context: FDA will enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers of biological products, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. Inspections for this performance goal are conducted to ensure compliance with current Good Manufacturing Practices (cGMPs) requirements and applicable standards, and to ensure the safety, purity and potency of biological products. The biologics inventory includes blood establishments, plasma derivative manufacturing establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target was increased to 1,000 inspections to reflect historical accomplishments. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this high risk inspection goal of 1,000 by inspecting 1,073 blood banks and biologics manufacturing establishments.

8. Number of foreign and domestic 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 increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 15 inspections for a new target of 533 inspections. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded the human tissue goal of 518 by conducting 564 inspections under new regulations.

Animal Drugs and Feeds Performance Detail

Long Term Objective: Advance Animal Drug Safety and Effectiveness

Measure	FY	Target	Result
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	*2012*	55%	January 2013
	2011	22%	January 2012
	2010	50%	22% (Target Not Met)
	2009	N/A	34% (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	*2012*	90% w/in 180 days	January 2014
	2011	90% w/in 180 days	January 2013
	2010	90% w/in 180 days	January 2012
	2009	90% w/in 180 days	100% of 5 w/in 180 days (Target Exceeded)
	2008	90% w/in 180 days	100% of 4 w/in 180 days (Target Exceeded)
	2007	90% w/in 200 days	100% of 7 w/in 200 days (Target Exceeded)
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	*2012*	90% w/in 380 days	January 2015
	2011	90% w/in 500 days	January 2014
	2010	90% w/in 680 days	January 2013
	2009	90% w/in 700 days	January 2012
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
242201	Adverse Drug Experiences (ADE) database	CVM utilizes and maintains an Adverse Drug Experiences (ADE) database to provide an early warning or signaling system to the Center for adverse effects not detected during pre-market testing of FDA-approved animal drugs and for monitoring the performance of drugs not approved for use in animals.
243201 243202	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.

Measure	FY	Target	Result
244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)*	*2012*	250	December, 2012
	2011	250	December, 2011
	2010	250	279 (Target Exceeded)
	2009	233	262 (Target Exceeded)
	2008	233	244 (Target Exceeded)
244203: Number of targeted prohibited material BSE inspections. *(Output)*	*2012*	500	December, 2012
	2011	490	December, 2011
	2010	490	567 (Target Met)
	2009	490	526 (Target Exceeded)
	2008	490	555 (Target Exceeded)
	2007	490	523 (Target Exceeded)
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting the firms to identified deviations in order to become compliant. *(Output)*	*2012*	50% w/in 15 working days	January 2013
	2011	50% w/in 15 working days	January 2012
	2010	80% w/in 15 working days	25% w/in 15 working days (Target Not Met)
	2009	N/A	38% w/in 15 working days (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A
244301: The total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. (*Outcome*)	*2012*	11	January 2013
	2011	9	January 2012
	2010	2	9 (Target Exceeded)
	2009	N/A	0 (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
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, FACTS and OASIS, and will also include additional functionality.
244204	Compliance Management System (CMS)	An electronic case submission system used to process all violation letters.
244301	CVM	Data validated by the appropriate CVM program office.

1. Review adverse experience reports to detect animal product hazards early. (242201)

Context: Protecting the public health includes monitoring marketed animal drugs, pet food, and veterinary devices to assure their safety and effectiveness. FDA relies on information from adverse event reporting to ensure the safety of animal drugs, pet food, and devices. All information and insight learned from the adverse event program is used to proactively identify drug safety signals and effectiveness issues of concern. For example, pet owners may be exposed to potent hormones, cancer drugs and other potentially toxic drugs. Inappropriate use of animal drugs in food producing species may also result in drug residues involving milk and meat. Also, pets receiving multiple medications may become ill from unknown drug interactions (they are not on the label) when these products are prescribed by their veterinarians. FDA works with the drug manufacturers, so this information can then be expeditiously communicated to veterinarians and consumers to prevent and mitigate risks associated with the use of these products. More timely and effective communication of adverse event issues to practitioners and the public will help prevent harm to animals and humans and may reduce product liability issues for drug manufacturers as well. Also, this adverse event program data and information benefits the FDA pre-approval process as it identifies safety and effectiveness issues that should be addressed as similar or related products are being developed by drug manufacturers

Performance: FY 2009 baseline data reflects the Center for Veterinary Medicine (CVM) reviewed 34% of the AERs received. CVM reviewed 22% of the AERs received in FY 2010. Performance was impacted by insufficient program staffing, software complications and information technology (IT) deficiencies associated with the new electronic submissions system. CVM anticipates FY 2010 level of performance to continue into FY 2011. Review performance of AERs is expected to rise to 55% in FY 2012 due to the increase request, as well as IT support improvements.

2. Complete review and action on original NADAs and reactivations of such applications received during the fiscal year. (243201)

Context: The FY 2009, FY 2010, FY 2011 and FY 2012 goal and targets reflect the reauthorization of ADUFA and continued achievement of statutory review timeframe(s) over a five-year period (FY 2009-

FY 2013). The goal and targets reflect one of the ADUFA user fee goals and CVM's ability to maintain FY 2008 review time frames for specified new animal drug application reviews.

Performance: Based on the final performance update for FY 2008, FDA exceeded all ADUFA performance goals. FDA reviewed and acted on all four original NADAs and reactivations of such applications received during FY 2008 within 180 days. As of September 30, 2010, the final performance assessment of FY 2009 data indicates FDA exceeded all ADUFA goal(s), including submissions under the end-review amendment (ERA) process. For FY 2010, FY 2011, and FY 2012, CVM plans to review and act on all original NADAs and reactivations of such applications received within 180 days.

3. Complete review and action on Non-administrative original ANADAs and reactivations of such applications received during the fiscal year. (243202)

Context: This new measure reflects the FY 2008 authorization of the new Animal Generic Drug User Fee Act (AGDUFA). The FY 2009, FY 2010, FY 2011, and FY 2012 goal and targets reflect one of the AGDUFA user fee goals to complete the review of 90% of specified abbreviated applications for the approval of generic new animal drugs within incrementally decreasing time frames over a five-year period (FY 2009-FY 2013).

Performance: AGDUFA is a new performance goal and target as of FY 2009. For FY 2009, FY 2010, FY 2011, and FY 2012, CVM plans to review and act on all non-administrative original ANADAs and reactivations of such applications received within 700 days, 680 days, 500 days, and 380 days, respectively.

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

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based current Good Manufacturing Practices (cGMP) inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which FDA had no historical experience, and was unsure how the new site-selection methodology would evolve. In FY 2010, the target was slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this inspection goal of 250 by inspecting 279 high risk animal drug and feed establishments.

5. 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. In FY 2012, FDA will continue to conduct inspections of 100% of the firms known to be processing with prohibited materials.

Performance: In FY 2010, FDA completed the inspection of all 567 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

6. Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. (244204)

Context: Issuing warning letters is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act) for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected. FDA sends warning letters to individuals or firms, advising them of specific noted violations and requesting a written response as to the steps which will be taken to correct the violation.

Performance: As part of the FDA Enhanced Enforcement Strategy, FDA will: 1) streamline the warning letter process by only having the letter reviewed by the relevant offices; 2) prioritize follow-up on warning letters and other enforcement actions quickly to assess and follow-up on corrective action taken by industry after a warning letter is issued or a major product recall occurs; and 3) determine a firm has fully corrected violations raised in a warning letter, issue an official "close-out" notice and post this information on the FDA website, motivating manufacturers to take corrective actions promptly. FY 2009 baseline data reflects CVM completed review and action on 38% of the warning letters received within 15 working days. In FY 2010, CVM completed 25% of the warning letters received within 15 working days. In FY 2010, staff were deferred from work on the increasing load of warning letters to work on the increased number of injunctions, which have a higher priority. In addition, staff time had to be shared with the development and implementation of new regulations and training related to the Food and Drug Administration Amendments Act (FDAAA) and the Food Safety Modernization Act (FSMA). CVM anticipates the FY 2010 workload will continue into FY 2011 and FY 2012 but plans to have complete review and action on 50% of warning letters within 15 days of Center receipt.

7. The total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. (244301)

Context: The lack of coordination between federal and state veterinary diagnostic laboratories to respond to high priority chemical and microbial feed contamination events by examining animal tissues for infectious agents/toxins, puts animals at risk to both inadvertent and intentional introduction of contaminants. FDA will improve emergency response by developing a network of state and federal laboratories that integrate resources and expertise for timely and accurate reporting, identification, and analysis of animal feed contamination events through examination of animal tissues for infectious agents, toxins, and other causes of disease. The network will enhance the ability to conduct root cause analysis and develop the data, information, and protective measures needed to help prevent future outbreaks.

Performance: The network will coordinate the facilities, equipment and professional expertise of U.S. and federal veterinary diagnostic laboratories to provide the means for quick identification of reports of animal injury associated with animal feed contamination, and protocols for immediate diagnostic reporting to FDA. In FY 2010, CVM collaborated with ORA and USDA to fund 9 diagnostic laboratories. In FY 2011, CVM is implementing a grant review process to support 9 laboratories in FY 2011 and 11 laboratories in FY 2012.

Medical Devices and Radiological Health Performance Detail

Long Term Objective: Advance Medical Device Safety and Effectiveness

Measure	FY	Target	Result
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. *(Outcome)*	*2012*	50% in 180 days and 60% in 295 days	Jan 31, 2014
	2011	50% in 180 days and 70% in 295 days	Jan 31, 2013
	2010	60% in 180 days and 90% in 295 days	Jan 31, 2012
	2009	60% in 180 days and 90% in 295 days	86% of 28 in 180 days and 93% of 28 in 295 days (Target Exceeded)
	2008	60% in 180 days and 90% in 295 days	68% of 33 in 180 days and 89% of 33 in 295 days (Target Not Met)
	2007	90% in 320 days	96% of 33 (Target Exceeded)
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. *(Outcome)*	*2012*	75% in 180 days and 85% in 210 days	Jan 31, 2014
	2011	80% in 180 days and 90% in 210 days	Jan 31, 2013
	2010	85% in 180 days and 95% in 210 days	Jan 31, 2012
	2009	85% in 180 days and 95% in 210 days	93% of 153 in 180 days and 97% of 153 in 210 days (Target Exceeded)
	2008	85% in 180 days and 95% in 210 days	91% of 170 in 180 days and 96% of 170 in 210 days (Target Exceeded)
	2007	90% in 180 days	97% of 132 (Target Exceeded)
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. *(Outcome)*	*2012*	75% in 90 days and 80% in 150 days	Jan 31, 2014
	2011	85% in 90 days and 93% in 150 days	Jan 31, 2013
	2010	90% in 90 days and 98% in 150 days	Jan 31, 2012
	2009	90% in 90 days and 98% in 150 days	91% of 3,324 in 90 days and 98% of 3,324 in 150 days (Target Exceeded)
	2008	90% in 90 days and 98% in 150 days	94% of 3,255 in 90 days and 99% of 3,255 in 150 days (Target Exceeded)

Measure	FY	Target	Result
	2007	80% in 90 days	92% of 3,531 (Target Exceeded)
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	*2012*	300	December, 2012
	2011	300	December, 2011
	2010	300	392 (Target Exceeded)
	2009	300	305 (Target Exceeded)
	2008	300	301 (Target Exceeded)
	2007	295	323 (Target Exceeded)

MDUFMA, and MDUFMA as amended review goals (Goals 253203, 253204, and 153205) 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.

Measure	Data Source	Data Validation
253203 253204 253205 253201	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.

Measure	FY	Target	Result
252201: The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit. *(Outcome)*	*2012*	3	December 31, 2012
	2011	3	December 31, 2011
	2010	3	3 (Target Met)
	2009	Ensure the active participation of 95% of MedSun facilities in FY 2009 (at least 1 report)	1 Report Minimum by 98% of Sites (Target Exceeded)

Measure	FY	Target	Result
	2008	Ensure the active participation of 95% of MedSun facilities in FY 2009 (at least 1 report)	1 Report Minimum by 98% of Sites (Target Exceeded)
	2007	Ensure the active participation of 90% of MedSun facilities in FY 2009 (at least 1 report)	1 Report Minimum by 90% of Sites (Target Met)
252202: By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. *(Outcome)*	*2012*	73%	December 2012
	2011	67%	December 2011
	2010	40%	47% (Target Exceeded)
	2009	N/A	25% (Historical Actual)
	2008	N/A	13% (Historical Actual)
	2007	N/A	N/A

Measure	Data Source	Data Validation
252201 252202	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.

Measure	FY	Target	Result
254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. *(Output)*	*2012*	75%	December 2012
	2011	75%	December 2011
	2010	90%	66% (Target Not Met)
	2009	N/A	68% (Historical Actual)
	2008	N/A	53% (Historical Actual)
	2007	N/A	N/A
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	*2012*	1,515	December, 2012
	2011	1,445	December, 2011
	2010	1,365	1,659 (Target Exceeded)
	2009	1,340	1,471 (Target Exceeded)
	2008	1,270	1,431 (Target Exceeded)

Measure	FY	Target	Result
	2007	1,195	1,468 (Target Exceeded)
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	*2012*	97%	December 31, 2012
	2011	97%	December 31, 2011
	2010	97%	97% (Target Met)
	2009	97%	97% (Target Met)
	2008	97%	97% (Target Met)
	2007	97%	97% (Target Met)

Measure	Data Source	Data Validation
254202	Center Tracking System and Mission Accomplishment and Regulatory Compliance Services (MARCS) system.	CDRH uses the Center Tracking System and the Mission Accomplishment and Regulatory Compliance Services (MARCS) system to track GMP Warning Letters and timeframes.
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.
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.

Measure	FY	Target	Result
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	*2012*	125	December 31, 2012
	2011	125	December 31, 2011
	2010	125	127 (Target Exceeded)
	2009	N/A	110 (Historical Actual)
	2008	N/A	70 (Historical Actual)
	2007	N/A	N/A
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	*2012*	1,175	December 31, 2012
	2011	1,175	December 31, 2011
	2010	1,175	1,429 (Target Exceeded)
	2009	N/A	1,128 (Historical Actual)
	2008	N/A	956 (Historical Actual)
	2007	N/A	N/A

Measure	Data Source	Data Validation
252101 253207	CDRH E-Consults and Office of Science and Engineering Laboratories Productivity database.	Technical Analysis and Reviews are tracked and verified through the CDRH E-Consults and Office of Science and Engineering Laboratories databases.

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

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. PMAs involve potentially high-risk devices with the highest likelihood of significantly improving the treatment of patients. The steps taken in MDUFMA and MDUFA II to reduce approval times for PMA applications are expected to reduce approval times for all filed applications. However, some applications may not ultimately meet FDA's standards for safety and effectiveness, and performance measures based on all applications will take more time to observe. MDUFA II performance targets for Original PMA applications will be to arrive at a decision on 60% of Original PMA applications within 180 days and 90% within 295 days.

Performance: CDRH is currently exceeding performance for tier 1 of the FY 2009 target by making decisions on 86% of 28 Original PMA applications in 180 days and 93% of 33 Original PMA applications in 295 days. The current baseline for FDA decision time for standard PMAs is 295 days. The cohort remains open. The FY 2010 performance data for this goal will not be available until January 2012. If the number of reviewers remains constant, CDRH expects performance levels to decrease due to the increasing complexity of PMAs.

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

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

Performance: CDRH is currently exceeding performance for the FY 2009 target by making decisions on 93% of 153 PMA Supplements applications in 180 days and 97% of 153 PMA Supplements applications in 210 days. The cohort remains open. The FY 2010 performance data for this goal will not be available until January 2012. If the number of reviewers remains constant, CDRH expects performance levels to decrease due to the increasing complexity of PMAs.

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

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: substantially equivalent or not substantially equivalent. This goal for review and decision on 510(k)s within 90 days addresses the statutory requirement to review a 510(k) within 90 days**.** Due to the renegotiation of MDUFMA, the Performance targets for 510(k)s will be to arrive at a decision on 90% of applications within 90 days and 98% within 150 days.

Performance: CDRH is currently exceeding performance for tier 1 of this FY 2009 target by making decisions on 91% of 3,324 510(k)s in 90 days and met performance for tier 2 of the FY 2009 target by making decisions on 98% of 3,324 510(k)s in 150 days. The cohort remains open. The FY 2010 performance data for this goal will not be available until January 2012. If the number of reviewers remains constant, CDRH expects performance levels to decrease.

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 2012, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2012. In FY 2012, the target is maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this goal of 300 by conducting 392 medical device related Bioresearch Monitoring inspections. Reason why this goal was exceeded: Bioresearch Monitoring Inspections are conducting based on the submission of PMA applications to FDA each year. There will be no change to the goal in year to come because the increase in FY 2010 was an anomaly rather than a trend of what is to come. Historically, Bioresearch Monitoring inspections as a result of PMA applications align with the target of 300.

5. The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit. (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: For FY 2010, the target for minimum number of reports per year was 3. This target was reached. CDRH will keep the target for minimum number of reports at 3 for FY 2011 and FY 2012.

6. By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. (252202)

Context: Improving electronic reporting of adverse events will help the FDA maintain its safety surveillance of FDA-regulated products. Information obtained from these reports may prompt a modification in use or design of the product, improves the safety profile of devices, and leads to increased patient safety. eMDR allows FDA to receive medical device adverse event reports electronically. eMDR will improve the agency's ability to detect important postmarket medical device issues and will reduce the reporting burden for both large and small volume medical device adverse event reporters.

Performance: In FY 2010, CDRH enrolled 47% of the top 15 MDR reporters into the eMDR program, exceeding the target of 40%. CDRH is on track to meet the FY 2011 goal of enrolling at least 67% of the top 15 MDR reporters.

7. Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. (254202)

Context: FDA's practice is to give industry an opportunity to take voluntary prompt action to correct violations. A Warning Letter is issued for violations of significant regulatory significance which may lead to enforcement actions if not promptly and adequately corrected. FDA inspectors issue Establishment Inspection Reports and other documents explaining the nature of observed violations. Timely Compliance Officer review is a key element in issuing Warning Letters in a timely manner.

Performance: CDRH did not expect to meet the 90% target in FY 2010 due to the lag time it takes for new hires to be able to reach a level of proficiency that will allow the staff to operate at optimal performance. In FY 2010, CDRH was able to meet the 45 working day target for device warning letters 66% of the time. Based on the current staff, the targets for FY 2011 and FY 2012 have been revised and set at 75%.

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

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. For FY 2010, the target was increased to 1,365 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 80 inspections for a new target of 1,445 inspections. In FY 2012, the target is being increased by 70 inspections for a new target of 1,515 inspections.

Performance: FDA exceeded the FY 2010 medical device performance goal of 1,365 by inspecting 1,659 foreign and domestic high-risk Class II and Class III medical device manufacturers.

9. Percentage of an estimated 8,700 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% of inspections. Inspectors perform science-based inspections to determine the radiation dose, to assess phantom image quality, and to empirically evaluate the quality of the facility's film processing. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. FDA also employs an extensive outreach program to inform mammography facilities and the public about MQSA requirements. These include: an Internet website, collaboration with NIH to provide a list of MQSA-certified facilities, and a toll-free facility hot line.

Performance: FDA met this goal in FY 2010 by ensuring that 97% of an estimated 8,700 mammography facilities met inspection standards with less than 3% level I (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.

10. Number of technical analyses of postmarket device problems and performance. (252101)

Context: Postmarket device problems and performance issues constitute one of the Center's primary public health priorities. Typically, the appearance of such problems begins with many ambiguities and gaps in understanding exactly what happened in the reported incident(s) and, more importantly, why. The Center's technical analysis of these problems illuminates each of these two questions, and points the way to an optimal science-based regulatory response involving the Center as a whole.

Performance: In FY 2010, CDRH completed 127 technical analyses of device problems. This baseline encompasses work by CDRH laboratory staff on Health Hazard Evaluations, PMI Action Teams, formal enforcement cases, Postmarket Surveillance Studies, development of inspectional guidances, field inspections, and regulatory sample analyses. The reports for which involve laboratory staff activities are typically selected because of the unusually difficult engineering questions that are posed. The technical analyses provided by CDRH's laboratory staff are used to assess the priority and hazards, determine the adequacy of proposed corrective actions, determine appropriate test methods, and develop case strategies for reported problems.

11. Number of technical reviews of new applications and data supporting requests for premarket approvals. (253207)

Context: The most challenging premarket device regulatory issues faced by CDRH typically involve (1) novel technologies in which the relevant technical questions are not obvious; (2) submissions in which there is a need for independent data to verify manufacturers' claims; or (3) new products for which there are no well validated test methods. Technical reviews by CDRH engineers and scientists bring specialized expertise to the process, frequently enabling the Center to address these challenges in a science-based decision process.

Performance: In FY 2010, CDRH completed 1,429 technical reviews of new applications. The number or technical reviews of new applications and data supporting requests for premarket approvals was greater than expected for FY 2010 due to an influx of applications for MRI compatible medical devices. It is anticipated that the number of technical reviews will return to the baseline in FY 2011. These reviews by CDRH's laboratory staff are associated with the submissions having the most novel, difficult, and complex engineering analyses and issues.

National Center for Toxicological Research Performance Detail

Long Term Objective: Advance Regulatory Science and Innovation

Measure	FY	Target	Result
262401: Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. *(Output)*	*2012*	1) Develop analytical methods to assess drug-induced heart damage 2) Identify target genes for obesity and the consequent development of metabolic syndrome diseases and heart disease	December 2012
	2011	Identify target genes that can predict potential for obesity and type 2 diabetes to provide individually tailored therapeutic treatment and dietary guidelines for use in improving health	December 2011
	2010	Identify patterns in serum biomarkers to use in monitoring dietary intervention protocols to reduce obesity	Patterns were identified from analysis of 2009 CBPR data and preliminary analysis of 2010 CBPR data in serum biomarkers that can be used to monitor dietary intervention protocols to reduce obesity. (Target Met)
	2009	N/A	Incorporated the linkage between physical responses to a healthier diet and genetic analyses via the Community Based Participatory Research (CBPR) project resulting in 45 blood samples and approximately 660,000 genotypes (genetic makeup) identified for each participant (Historical Baseline)
	2008	N/A	Examined the effects of better nutrition on serum levels of certain vitamins and metabolites in children via the CBPR project. (Historical Baseline)
	2007	N/A	N/A

Measure	Data Source	Data Validation
262401	NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board (SAB) 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	NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and

Measure	Data Source	Data Validation
	reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals.	consumer organizations, and subject matter experts representing all of the FDA product centers—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 high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the Good Laboratory Practices (GLP) guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences.

Measure	FY	Target	Result
263101: 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. *(Output)*	*2012*	1) Establish an imaging consortium of scientific experts from NCTR, CDER, and from other government agencies, industry, and academia to refine the imaging tools 2) Build a knowledge base to annotate existing drug-risk factor associations of immune-related drug reactions 3) Determine pathways of toxicity and preventive strategies for pediatric anesthetics using a high-speed, high-volume method (zebrafish)	December 2012
	2011	1) Implement the Voluntary Exploratory Data Submission (VXDS) tool, called VISIONS (VXDS/ Interdisciplinary Pharmacogenomics Review Group (IPRG) Status and Information ON-line System) to accelerate the regulatory review process	December 2011

Measure	FY	Target	Result
		2) Present preliminary data on markers that indicate nervous system damage from pediatric anesthetic use at national scientific meetings which may lead to improved guidelines	
	2010	1) Create a demonstrable tool to use in the drug-review process based upon the liver toxicity knowledge base 2) Develop translatable biomarkers for studying pediatric products (e.g. ketamine, methylphenidate, etc.)	1) Developed drug selection criteria for the Liver Toxicity Knowledge Base, collected data, performed high-content assays, and developed a systematic approach to characterize the potential risk of liver injury of these drugs. Tool is being piloted. (Target Met) 2) Established zebrafish facility for toxicity assessments and have eliminated some potential candidates, narrowing search and evaluating data to identify translatable biomarkers. (Target Met)
	2009	Analyze imaging data by application of pattern-recognition algorithms to other tissues and diseases	1) Reviewed novel methods to normalize the spectra generated from various magnetic resonance imaging (MRI) scanners, an approach that will translate across tissues (Target Met) 2) Improved pattern recognition algorithms to interpret complex Magnetic Resonance Spectroscopy (MRS) scans to an accuracy rate of over 96% for nine types of tissues (Target Met)
	2008	1) Identify omics data in the review process 2) Determine limitations of the algorithms (e.g. staging disease)	1) Reviewed seven VXDS submissions using omics tools (Target Met) 2) Developed algorithm to classify four disease categories (Target Met)
	2007	1) Test systems biology in drug review process to assess value in drug review and approval 2) Develop proof-of-principle that pattern recognition can supplement MRS brain scan interpretation	1) Developed urinary biomarkers for kidney failure (Target Met) 2) Identified azidothymidine (AZT) effects on mitochondria (Target Met) 3) Successfully developed prototype algorithm from 30 MRS brain scans (Target Met)
263102: Develop computer-	*2012*	Develop 3D/4D Quantitative	December 2012

Measure	FY	Target	Result
based models and infrastructure to predict the health risk of biologically active products. *(Output)*		Spectrometric Data-activity Relationship (QSDAR) models for predicting endocrine disruptor activity	
	2011	Deliver the alpha version of the FDA SNPTrack to support the FDA review of pharmacogenetics (how genetic variations affect individual responses to drugs) data and provide more personalized treatment options	December 2011
	2010	Develop molecular signature and biomarker modules in ArrayTrack™ to support VXDS	Molecular signature and biomarker functions developed in ArrayTrack™ to support VXDS (Target Met)
	2009	Expand ArrayTrack™ to include two new libraries and classification methods for model building and predictions on clinical, nonclinical, and toxicological microarray data	Developed ArrayTrack™ Version 3.5.0 (Target Met)
	2008	Create bioinformatics data package	Developed SNPTrack Version 1 (Target Met)
	2007	Increase the utility of ArrayTrack™ and training for reviewers	1) Completed JMP® and ArrayTrack™ integration (Target Met) 2) Offer regulatory training on ArrayTrack™ to reviewers (Target Met)

Measure	Data Source	Data Validation
263101 263102	NCTR Project Management System; peer-review through FDA/NCTR SAB 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.	NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—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 high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected.

Measure	Data Source	Data Validation
		Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences.

Measure	FY	Target	Result
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)*	*2012*	Develop new characterization methods for nano-based zinc oxide within FDA-regulated products	December 2012
	2011	Validate FDA standard operating procedures (SOPs) for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/Arkansas Regional Laboratory (ORA/ARL)	December 2011
	2010	Establish and implement SOPs in research protocols for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/ARL	Established and implemented three SOPs for research protocols to detect nanoscale materials in FDA-regulated products in collaboration with ORA/ARL. (Target Met)
	2009	Establish an operational joint NCTR/ORA Nanotechnology Core Facility to provide analytical support, materials characterizations, and electron microscopy support for nanomaterial studies	Established and operationalized the NCTR/ORA Nanotechnology Core Facility (Target Met)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
263201	NCTR Project Management System; peer-review through FDA/NCTR SAB 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	NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts

Measure	Data Source	Data Validation
	publication in peer-reviewed journals.	representing all of the FDA product centers—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 high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences.

Measure	FY	Target	Result
264101: Develop risk assessment methods and build biological dose-response models in support of food protection. *(Output)*	*2012*	Expand Rapid B system to include new pathogen-specific (PS) assays (tests)	December 2012
	2011	1) Develop base guidelines to assess extent of kidney toxicity caused by the combination of melamine and cyanuric acid and ultimately improve diagnosis and treatment 2) Develop and initiate protocols (research/study design, approach, and methods) for RAPID-B tests for viruses and toxins to aid FDA in protecting public health from viruses and toxin contamination	December 2011
	2010	1) Rapidly detect toolkits for foodborne pathogens applicable to fresh produce; evaluate in field situations 2) Develop and initiate approved protocols for Bisphenol A (BPA), a component in baby bottles and formula containers	1) Developed and validating field-rugged technologies for rapid screening of samples to rule in, or rule out, contamination with select foodborne pathogens applicable to fresh produce (Target Met) 2) Research completed on Bisphenol A (BPA) resulting in the publication of data to improve the prediction of internal

Measure	FY	Target	Result
			exposures of target tissues in human infants and fetuses. (Target Met)
	2009	1) Detect rapid pathogen 2) Identify antibiotic resistance markers	1) Validated RAPID-B detection of *E. coli* in nine food types (Target Met) 2) Identified 775 antimicrobial resistance genes in *Salmonella* (Target Met)
	2008	Develop ricin screening assay	Developed cell-based assay and polymerase chain reaction (PCR)-based biochemical assay (Target Met)
	2007	Develop flow cytometry technology	1) Developed test kits and methods for pathogens (Target Met) 2) Developed additional *Salmonella* biochip (Target Met)

Measure	Data Source	Data Validation
264101	NCTR Project Management System; peer-review through FDA/NCTR SAB 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.	NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—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 high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences.

1. Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. (262401)

Context: NCTR's goal is to define the correlations between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. This research will provide baseline data that supports the FDA goal of providing consumers clear and timely information to help promote personalized nutrition and health. Identifying biomarkers of health, susceptibility to chronic disease, and gene-micronutrient interactions is essential to gaining a more complete scientific understanding of health. NCTR is implementing a novel research program for personalized nutrition and health that relies on the "challenge homeostasis" concept for identifying markers of health and susceptibility. This approach implements a safe, but acute, challenge to the body's ability to regulate and maintain balance. NCTR will use its current omics capabilities, in conjunction with its expanded genomic analyses capabilities, to conduct this research. The intervention design proposed by NCTR establishes a model that may be used by the emerging International Micronutrient Genomics Project that will compare gene-micronutrient interactions across populations and cultures.

Performance: NCTR's Division of Personalized Nutrition and Medicine (DPNM) expanded its research into identifying correlations between an individual's nutrition, genetic profiles, and health. Since 2008, FDA/NCTR and USDA/ARS have had an ongoing partnership with a community development center in the Mississippi Delta region of Arkansas to conduct community-based participatory research (CBPR) that studies the effects of dietary intake and its influence on the development of obesity-associated diseases. This ongoing collaboration analyzes dietary intake patterns, micronutrient levels in the blood samples of children and adults, and calories expended. In 2010, scientists from NCTR analyzed data from the 2009 CBPR study using standard statistical approaches and novel methods to assess individual responses. The result of the analyses identified patterns in serum biomarkers that could be used to monitor dietary intervention protocols to reduce obesity. In FY 2011, NCTR plans to analyze the DNA sequence of 400 candidate genes from the CBPR participants to identify target genes that can predict potential for obesity and type 2 diabetes. For FY 2012, NCTR will continue to identify target genes for obesity and the consequent development of metabolic syndrome diseases and heart disease. In addition, NCTR will develop analytical methods to assess drug-induced heart damage to provide data on the mechanisms underlying heart damage caused by therapeutic drug treatment. New methods that lead to earlier detection may reduce the rate of severe heart failure and improve therapeutic patient treatment.

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

Context: With the advent of new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, and the expanding capabilities of noninvasive imaging technologies, FDA has the necessary tools to detect disease at an earlier stage and to better understand how an FDA-regulated compound or product interacts with the human body. The accelerated rate at which technological advances are being made in the marketplace dictates that FDA accelerate its rate of innovation in the regulatory-research arena. Combining genomic knowledge with microPET imaging (Positron Emission Tomography imaging for small animals) is expected to facilitate the search for genetic predictors of drug response. Devices such as microPET that reveal clinical and pharmacogenomic information will serve to individualize medicine both for the diagnosis and treatment of disease, and allow for monitoring the efficacy of treatment regimens. The enormous amount of data generated by these technologies also requires the development of new tools to allow researchers and reviewers to use the data to evaluate potential risks related to use of an FDA-regulated compound or product.

Performance: In the spring of FY 2010, NCTR established a zebrafish facility that has already yielded data on translatable biomarkers to assess pediatric products such as ketamine and methylphenidate. These research findings will help the medical community understand the relationship between the amount, type, duration, and frequency of pediatric anesthetic use and its adverse effects on children in order to provide rapid screening tests and understand pathways of toxicity and prevention of pediatric anesthetics. In addition, in FY2010 NCTR developed a set of criteria to select drugs for the Liver Toxicity Knowledge Base (LTKB) project, collected risk factors and mechanistic data for them from literature, and developed a systematic approach to characterize the potential risk of liver injury of these drugs. The development of a knowledge base for liver toxicity will be useful as a hypothesis-generating tool for designing liver toxicity-related experiments and as a reference tool in the FDA drug approval process.

In FY 2011, NCTR will implement a VXDS data submission tool, called VISIONS that will accelerate the regulatory-review process. In addition, researchers will present preliminary data on markers that indicate nervous system damage from pediatric anesthetic use at national scientific meetings which may lead to improved product-use guidelines. For FY 2012, NCTR will continue its research in pediatric anesthetics by discovering pathways of toxicity and preventive strategies using a high-through, high-volume method. In addition, NCTR will utilize scientific expertise from across government and academia to refine the imaging tools and plans to build a database that will contain information on known drug-risk factor associations of immune-related drug reactions.

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

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

Performance: In FY 2010, NCTR enhanced the ArrayTrack™ tool by adding a protein and metabolite panel and a Gene Ontology for Functional Analysis (GOFFA) library, as well as a Support Vector Machine for outcome prediction and data mining. ArrayTrack™ allows for the addition of new capabilities to handle priorities and evolving technologies and now includes a Microbial Library and new data processing and visualization tools. NCTR's goal in FY 2011 is to deliver the alpha version of the FDA SNPTrack to support the FDA review of pharmacogenetics data and provide more personalized treatment options. In FY 2012, NCTR's goal is to develop a 3-D/4-D Quantitative Spectral Data Activity Relationships (QSDAR) model that will predict endocrine disruptor activities.

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

Context: NCTR's goal to develop a science base to support the FDA regulatory review of new and emerging technologies by establishing a joint NCTR/ORA Nanotechnology Core Facility will strengthen the FDA's ability to prevent potential health-endangering products from entering the marketplace. It is anticipated that NCTR's nanotechnology research program will expand as the number of nanoscale

products that the regulated community seeks to market increases. The FDA has already reviewed and approved some nanotechnology-based products, and expects a significant increase in the use of nanoscale materials in drugs, devices, biologics, cosmetics, and food. Improved understanding of nanomaterials, their transport, and their toxicity will provide a framework for regulatory guidelines for safe and effective use of nanomaterials in FDA-regulated foods, cosmetics, and medical products and provide early recognition of potential safety issues before they become adverse events in the patient population.

Performance: To strengthen FDA's nanotechnology product evaluation capability, in FY 2010 the NCTR/ORA Nanotechnology Core Facility was opened, equipped, and staffed with a Senior Electron Microscopy Technician and a Staff Fellow with expertise in nanotechnology. The Nano Facility is providing support to FDA through materials characterization – external techniques to probe into the internal structure and properties of a material – analytical support, and electron microscopy support for a broad range of nanomaterial studies. In FY2010, Standard Operating Procedures were established for 1) Transmission Electron Microscope (TEM), 2) tissue preparation for TEM, and 3) particle-size determination with more SOP development in progress. The Nano Facility is supporting various collaborative studies with FDA/ORA, NIEHS/NTP, NCI/NCL, and USAF on quantification and migration of nanosilver, particle-size determination of nanosilver, and the toxicity of nanomaterials on cultured brain cells and on cells used in genotoxicity assays. Research on nanomaterials in food-packaging, cosmetics, and sunscreen has started producing some findings. For example, the results of a study on nano- and submicron-particles of titanium dioxide in sunscreens which suggests that their use does not result in internal exposure to the nano- and submicron-particles of titanium dioxide was published in *Toxicological Sciences,* 2010. For FY 2011, NCTR's goal is to validate the SOPs at the agency-level. With the SOPs validated, NCTR can pursue its FY 2012 goal to develop new characterization methods for nano-based zinc oxide within FDA-regulated products.

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

Context: To address research needs and build the FDA's capability to assess and reduce food-related health threats, NCTR researchers evaluate key regulatory issues of food safety, conduct multidisciplinary studies to develop risk-assessment methods, and develop biological dose-response models vital to food security. Identifying the prevalence of antibiotic-resistant genes and the genetic fingerprinting of these genes will help identify similar strains isolated from different samples. Another food-related health threat, especially for infants and children, is the presence of BPA, an endocrine disruptor that can mimic hormones and a compound used in a wide variety of household items including baby bottles, drinking bottles, and liners for canned food. NCTR will be initiating studies in collaboration with the National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program to address the health concerns associated with exposures to low doses of BPA during critical periods of perinatal development. Effects reported include alterations in the central nervous system (CNS) anatomy, lesions in prostate and mammary glands, urinary tract abnormalities, and the early onset of puberty.

Performance: NCTR scientists discovered in FY 2010, a new and potentially patentable technique called Direct Impact Corona Ionization (DICI) mass spectrometry. This technique enables plasma vaporization of whole-cell bacteria to produce information-rich spectral fingerprints that can accurately identify bacteria and could prove invaluable to rapid detection methods. Also in FY 2010, NCTR conducted research in partnership with the National Institutes of Health to determine if BPA administered to a pregnant nonhuman primate crosses the placenta and exposes the fetus to measurable levels of BPA *in utero*. As a result of this research, FDA will gain an improved understanding of the pharmacokinetic profile of BPA and the associated risk of exposure to BPA in various stages of development. NCTR has aggressive goals for FY 2011 in the area of risk assessment with plans to: 1) develop base guidelines to assess extent of kidney toxicity caused by the combination of melamine and cyanuric acid and ultimately

improve diagnosis and treatment; 2) conduct a successful FERN Level 4 validation for the RAPID-B *E. coli* O157 test method so it can be approved for use in regulatory reviews or food emergency situations; and 3) develop and initiate protocols for RAPID-B tests for viruses and toxins to aid FDA in protecting public health from viruses and toxin contamination. In FY 2012, NCTR will expand the RAPID-B system to include new pathogen specific assays (tests).

Office of Regulatory Affairs Performance Detail

Long Term Objective: Advance Food Safety and Nutrition

Measure	FY	Target	Result
214201: Number of prior notice import security reviews. *(Output)*	*2012*	80,000	December, 2012
	2011	80,000	December, 2011
	2010	80,000	81,618 (Target Exceeded)
	2009	80,000	81,157 (Target Exceeded)
	2008	80,000	80,543 (Target Exceeded)
	2007	60,000	84,088 (Target Exceeded)
214202: Number of import food field exams. *(Output)*	*2012*	160,000	December, 2012
	2011	160,000	December, 2011
	2010	140,000	170,392 (Target Exceeded)
	2009	120,000	138,916 (Target Exceeded)
	2008	85,000	100,718 (Target Exceeded)
	2007	71,000	94,743 (Target Exceeded)
214203: Number of Filer Evaluations. *(Output)*	*2012*	1,000	December, 2012
	2011	1,000	December, 2011
	2010	1,000	1,277 (Target Exceeded)
	2009	1,000	1,208 (Target Exceeded)
	2008	1,000	1,356 (Target Exceeded)
	2007	1,000	1,355 (Target Exceeded)
214204: Number of examinations of FDA refused entries. *(Output)*	*2012*	7,000	December, 2012
	2011	7,000	December, 2011
	2010	7,000	8,658 (Target Exceeded)
	2009	5,000	7,201 (Target Exceeded)
	2008	4,000	5,926 (Target Exceeded)
	2007	3,000	5,510 (Target Exceeded)

Measure	FY	Target	Result
214205: Number of high risk food inspections. *(Output)*	*2012*	8,850	December, 2012
	2011	7,800	December, 2011
	2010	6,750	6,926 (Target Exceeded)
	2009	6,100	6,182 (Target Exceeded)
	2008	5,700	6,230 (Target Exceeded)
	2007	5,625	6,421 (Target Exceeded)
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	*2012*	5 data exchange additions/conversions	December, 2012
	2011	5 data exchange additions/conversions	December, 2011
	2010	5 data exchange additions/conversions	5 data entry labs (Target Met)
	2009	5 data exchange additions/conversions	5 data entry labs (Target Met)
	2008	5 data entry labs	11 data entry labs (Target Exceeded)
214206: Maintain accreditation for ORA labs. *(Outcome)*	*2012*	13 labs	December, 2012
	2011	13 labs	December, 2011
	2010	13 labs	13 labs (Target Met)
	2009	13 labs	13 labs (Target Met)
	2008	13 labs	13 labs (Target Met)
	2007	13 labs	13 labs (Target Met)
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	*2012*	2,500 rad & 2,100 chem	December, 2012
	2011	2,500 rad & 2,100 chem	December, 2011
	2010	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem (Target Met)
	2009	2,500 rad & 1,650 chem	2,500 rad & 1,650 chem (Target Met)
	2008	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem (Target Met)
	2007	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem (Target Met)

Long Term Objective: Advance Human Drug Safety and Effectiveness

Measure	FY	Target	Result
224201: Number of foreign and	*2012*	750	December, 2012

Measure	FY	Target	Result
domestic high-risk human drug inspections. *(Output)*	*2011*	750	December, 2011
	2010	700	705 (Target Exceeded)
	2009	600	687 (Target Exceeded)
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)

Long Term Objective: Advance Biologics Safety and Effectiveness

Measure	FY	Target	Result
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	*2012*	1,000	December, 2012
	2011	1,000	December, 2011
	2010	1,000	1,073 (Target Exceeded)
	2009	870	1,001 (Target Exceeded)
	2008	870	1,014 (Target Exceeded)
234203: Number of human tissue establishment inspections. *(Output)*	*2012*	533	December, 2012
	2011	533	December, 2011
	2010	518	564 (Target Exceeded)
	2009	380	434 (Target Exceeded)
	2008	325	383 (Target Exceeded)
	2007	325	427 (Target Exceeded)

Long Term Objective: Advance Animal Drug Safety and Effectiveness

Measure	FY	Target	Result
244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)*	*2012*	250	December, 2012
	2011	250	December, 2011
	2010	250	279 (Target Exceeded)
	2009	233	262 (Target Exceeded)
	2008	233	244 (Target Exceeded)
244203: Number of targeted	*2012*	500	December, 2012

Measure	FY	Target	Result
prohibited material BSE inspections. *(Output)*	*2011*	490	December, 2011
	2010	490	567 (Target Met)
	2009	490	526 (Target Exceeded)
	2008	490	555 (Target Exceeded)
	2007	490	523 (Target Exceeded)

Long Term Objective: Advance Medical Device Safety and Effectiveness

Measure	FY	Target	Result
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	*2012*	300	December, 2012
	2011	300	December, 2011
	2010	300	392 (Target Exceeded)
	2009	300	305 (Target Exceeded)
	2008	300	301 (Target Exceeded)
	2007	295	323 (Target Exceeded)
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	*2012*	1,515	December, 2012
	2011	1,445	December, 2011
	2010	1,365	1,659 (Target Exceeded)
	2009	1,340	1,471 (Target Exceeded)
	2008	1,270	1,431 (Target Exceeded)
	2007	1,195	1,468 (Target Exceeded)

Measure	Data Source	Data Validation
253201	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

Measure	Data Source	Data Validation
		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.

Measure	Data Source	Data Validation
214201 214202 214203 214204 214205 214303 224201 234202 234202 244202 244203 254201 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.

1. 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, and/or to identify those that may pose a significant health risk to the American public and prevent them from entering into the U.S. food supply. FDA will continue to focus much of its PNC resources on intensive prior notice security reviews of imported food/feed shipments that pose the highest potential bioterrorism risks to the U.S. consumer. Every (100%) prior notice is electronically screened and targeted and all those identified as high risk receive an intensive security review. The total number of intensive prior notice security reviews conducted by the PNC is impacted by current intelligence factors, targeting priorities, and the number of high risk shipments being imported. Therefore, this total may increase or decrease in future years. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: During FY 2010, FDA received 10,039,557 prior notice submissions on which the PNC conducted 81,681 intensive prior notice security reviews of import security reviews(exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. A total of 1,340 shipments were the subject of PNC compliance actions for prior notice or food facility registration violations, which was more than 1.5 times the total number of PN related actions from the previous fiscal year. The PNC operations actively strengthen the U.S. food supply and provide early food security/defense driven targeting and risk assessments to detect food shipments that pose or may pose a potential terrorist threat. In addition, the PNC responded to more than 21,000 phone and e-mail inquiries, and conducted over 826 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

2. 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 9.8 million line entries of imported food out of an estimated 20.0 million lines of FDA regulated products in FY 2009. In FY 2010, FDA expects approximately 10.1 million line entries of imported food within a total of more than 23.2 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. In FY 2009 through FY 2011 FDA increased the target by 20,000 exams each year. In FY 2012, the target is being maintained at the FY 2011 level of 160,000 field exams.

Performance: In FY 2010, FDA exceeded the target of 140,000 by completing 170,392 imported food lines examined. Explanation of why this goal was significantly exceeded: With the increase in funding, FDA was able to bring on a significant number of new investigators. Field exams play a significant role in new investigator training which resulted in exceeding the goal. Since new investigators were using these for training purposes, more resources than would normally go toward this target were utilized. Once investigators are fully trained, they will have other duties in addition to examining imported food lines. In FY 2011, FDA will retain our projected target of 160,000 due to the implementation of new field exam risk targeting procedures. The field exams will be more involved as a result of the new procedures but will result in a more focused public health outcome.

3. 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 2012 target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this goal of 1,000 by performing 1,277 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.

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

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

of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. In FY 2010, the target was again increased to 7,000 to better reflect actual accomplishments. The FY 2012 target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this goal of 7,000 by performing 8,658 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 includes activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program. Explanation of why this goal was significantly exceeded: Examinations of refused entries are a function of refusals each year. More refusals result in a larger amount of verifications. In FY 2010, there was an increased number of refusals which caused the examinations to increase as well. In FY 2012, the performance target will continue to be maintained at the FY 2011 level because there is no way to predict the number of refusals in a given year.

5. 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 and the immunocompromised. The Field intends to inspect such establishments annually, or more frequently on a "for cause" basis. 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 or sample results. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target was increased to 6,750 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 1,050 inspections for a new target of 7,800 inspections. In FY 2012, the target is being increased to 8,850 inspections.

Performance: In FY 2010, FDA exceeded this goal of 6,750 by performing 6,926 high-risk foreign and domestic food inspections.

6. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. (214303)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2009, there are 224 total laboratories currently participating in eLEXNET overall. These labs include segments of a wide variety of food safety organizations on Federal, Military, State, and Local government levels. These labs also span the agricultural, environmental, public health, veterinary, and diagnostic disciplines as well. Of the 224 participating laboratories in all 50 states, 144 are actively entering or submitting data. There are 44 labs among them that are fully automated via Data Exchange and transfer

their LIMS sample data on a regular, ongoing basis. The 100 other remaining laboratories enter data in eLEXNET through manual data entry. The overall goal of the FDA's eLEXNET program is to continue to integrate those labs participating in eLEXNET via Data Exchange and to identify new labs to expand our membership. Through continued expansion of our membership base and active data sources, the eLEXNET program will continue to serve as a key collaborative tool for food surveillance entities nationwide. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met its performance goal by fully automating electronic data exchange between five new labs and FDA's eLEXNET (electronic Laboratory Exchange Network). This makes the total number of automated data exchange participant labs to 44. The automated data transfer does not require any human intervention and is completely maintenance free unless there is a change in the lab environment.

7. 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. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

8. 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. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which increased the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA added three additional FERN chemical labs in FY 2009 which

increased the surge capacity to 2,100 chemical samples per week. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA met this performance goal surge capacity target of 2,100 chem samples per week. FDA also maintained the surge capacity for 2,500 rad samples per week. The FERN laboratories increasingly provide critical analytical surge capacity during food emergency events. An FDA assignment ("Surveillance, Inspection and Sample Collection and Analyses of Products Related to the Salmonella St. Paul Investigation" issued by ORA/CFSAN) directed samples to the FERN labs in the Salmonella outbreak in peppers, with 290 samples tested. FERN Chemistry laboratories participated in the #09-06 CFSAN Melamine Import Assignment (2008-2009), assisting FDA in the analysis of milk and protein samples, analyzing 340 samples. These FERN labs were a key factor in clearing an FDA sample backlog, which arose due to very high collection rates. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

9. 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 2010. 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. For FY 2010, the target was increased to 700 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 50 inspections for a new target of 750 inspections. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: FDA exceeded the FY 2010 goal of 700 by inspecting 705 high-risk foreign and domestic drug manufacturers.

10. Number of registered domestic blood bank and biologics manufacturing inspections. (234202)

Context: FDA will enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers of biological products, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. Inspections for this performance goal are conducted to ensure compliance with current Good Manufacturing Practices (cGMPs) requirements and applicable standards, and to ensure the safety, purity and potency of biological products. The biologics inventory includes blood establishments, plasma derivative manufacturing establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target was increased to 1,000 inspections to reflect historical accomplishments. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this high risk inspection goal of 1,000 by inspecting 1,073 blood banks and biologics manufacturing establishments.

11. Number of foreign and domestic 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 increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 15 inspections for a new target of 533 inspections. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded the human tissue goal of 518 by conducting 564 inspections under new regulations.

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

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based current Good Manufacturing Practices (cGMP) inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which FDA had no historical experience, and were unsure how the new site-selection methodology would evolve. In FY 2010, the target was slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues. In FY 2012, the target is being maintained at the FY 2011 level.

Performance: In FY 2010, FDA exceeded this inspection goal of 250 by inspecting 279 high risk animal drug and feed establishments.

13. 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. In FY 2012, FDA will continue to conduct inspections of 100% of the firms known to be processing with prohibited materials.

Performance: In FY 2010, FDA completed the inspection of all 567 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

14. 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 2012, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2012.

Performance: In FY 2010, FDA exceeded this goal of 300 by conducting 392 medical device related Bioresearch Monitoring inspections. Explanation of why this goal was significantly exceeded: Bioresearch Monitoring Inspections are conducting based on the submission of PMA applications to FDA each year. There will be no change to the goal in year to come because the increase in FY 2010 was an anomaly rather than a trend of what is to come. Historically, Bioresearch Monitoring inspections as a result of PMA applications align with the target of 300.

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

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. For FY 2010, the target was increased to 1,365 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 80 inspections for a new target of 1,445 inspections. In FY 2012, the target is being increased by 70 inspections for a new target of 1,515 inspections.

Performance: FDA exceeded the FY 2010 medical device performance goal of 1,365 by inspecting 1,659 foreign and domestic high-risk Class II and Class III medical device manufacturers.

Tobacco Performance Detail

Long Term Objective: Establish an Effective Tobacco Regulation, Prevention, and Control Program

Measure	FY	Target	Result
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)*	*2012*	Conduct research on how to assess the public health impact of modified risk products, and continue to evaluate the impact of tobacco regulations on the public health. Issue regulations to protect the public health.	January 2013
	2011	Select initial set of data and calculate baseline for long term assessment of public health impact of tobacco regulation and associated FDA programs. Issue regulations to protect the public health.	January 2012
	2010	Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products.	Issued regulations protecting the public health from the harmful effects of tobacco use including: prohibiting misleading descriptors, requiring new warning labels on smokeless tobacco products, and the "Reissued 1996 Rule." (Target Met) Initiated or conducted research on the impact of tobacco control regulations. (Target Met)
	2009	NA	FDA has issued a ban on flavored cigarettes (Historical Actual)
	2008	NA	NA
	2007	NA	NA

Measure	Data Source	Data Validation
280001	CTP's Office of Science	The data will be validated by the appropriate CTP offices and officials.

Measure	FY	Target	Result
280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. *(Output)*	*2012*	Establish a list of harmful and potentially harmful ingredients and constituents in tobacco products and tobacco smoke. TPSAC to issue a report on dissolvable tobacco products. Issue a proposed rule or draft guidance that establishes requirements or contains recommendations regarding the scientific evidence required for assessment and ongoing review of modified risk products.	January 2013
	2011	Select initial set of harmful ingredients and establish adequate testing methods	January 2012
	2010	Identify potential set of harmful ingredients; establish criteria for evaluating testing methods	Held 6 TPSAC meetings focusing on the public health impact of menthol in cigarettes and establishing a list of harmful/potentially harmful constituents in tobacco products and smoke. (Target Met)
	2009	NA	N/A
	2008	NA	NA
	2007	NA	NA

Measure	Data Source	Data Validation
280002	CTP's Office of Science	The data are validated by the appropriate CTP offices and officials.

Measure	FY	Target	Result
280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children	*2012*	95%	January 2013
	2011	75%	January 2012
	2010	25%	27% (Target Met)
	2009	NA	0% (Historical Actual)
	2008	NA	NA

Measure	FY	Target	Result
and Adolescent (formally known as the Re-Issued 1996 Rule) to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. *(Outcome)*	*2007*	NA	NA

Measure	Data Source	Data Validation
280003	CTP's Office of Regulations and Compliance	The data are validated by the appropriate CTP offices and officials.

Measure	FY	Target	Result
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	*2012*	Continue to implement and improve programs designed to educate the public and industry.	January 2013
	2011	Implement and refine education program directed to retailers and the general public, especially youth.	January 2012
	2010	Develop education program directed to retailers and the general public, especially youth.	Announced the Stakeholder Discussion Series (Target Met) Launched the "Break the Chain of Tobacco Addiction" campaign to educate retailers and the public about new tobacco regulations (Target Met)
	2009	NA	NA
	2008	NA	NA
	2007	NA	NA

Measure	Data Source	Data Validation
280004	CTP's Office of Public Education and External Relations	The data are validated by the appropriate CTP offices and officials.

1. Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. (280001**)**

Context: A major goal of the tobacco program will be implementing policies and issuing regulations to protect the public health by reducing morbidity and mortality related to the use of tobacco products. FDA needs to conduct research and evaluation studies to better understand how marketing and advertising of tobacco products influences use of tobacco products by various sectors of the public; to evaluate the early impact of the tobacco regulations issued in 2009 and 2010; and to develop baseline measures to better assess the impact of later provisions in the statute. This may include research on the behavioral effects of industry marketing methods, the impact of governmental and other tobacco-use risk educational

programs, and the impact of minors' access to tobacco products, tobacco marketing restrictions, and smokeless warning labels. These studies may be funded through contracts, grants, interagency agreements, or contracts, grants, or cooperative agreements with other entities such as universities or private foundations.

Performance: The Tobacco Control Act requires regulations to be issued pursuant to certain timetables. FDA met all of the statutory deadlines required by the Tobacco Control Act for FY 2009 and 2010. FDA successfully issued "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." FDA also issued regulations prohibiting the use of misleading descriptors, such as "light," "low," and "mild" without FDA approval, and issued regulations requiring new warning labels to be place on smokeless tobacco products. FDA will continue in to enforce these regulations in FY 2011. In FY 2011, FDA will continue to issue regulations to protect the public health from the harmful effects of tobacco use in accordance with the timelines set forth in the Tobacco Control Act. FDA has issued a proposed rule requiring new graphic health warning labels to be placed on cigarette packs and cigarette advertisements. FDA also conducted an 18,000 person consumer research study on the 36 images intended to demonstrate the negative health consequence of smoking contained in the proposed rule and published the study in the Federal Register for public comment. The final regulations will be issued in June 2011. Also, in FY 2011, FDA will also issue regulations to implement the exemptions from requirements to demonstrate substantial equivalence, and will issue regulations concerning the sale and distribution of tobacco products through means other than a face-to-face transaction. In FY 2012, FDA will issue regulations or guidance regarding:

- The promotion/marketing of tobacco products through means other than a direct exchange;
- The scientific evidence required for assessment and ongoing review of modified risk tobacco products; and
- Regulations that permit the filing of a single application for a new tobacco product that is to be marketed as a modified risk tobacco product.

2. Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. (280002**)**

Context: FDA is authorized to conduct research in support of its regulation of tobacco products. This effort is supported by one of the requirements of the Tobacco Control Act, which beginning in FY 2010, requires regulated industry to submit information to FDA on all ingredients used in cigarettes and some other tobacco products. In order to begin the ongoing review of the population health effects of those ingredients and their impact on tobacco usage, FDA will need a substantial capacity to conduct laboratory research. In addition scientific information developed by FDA will be applied in developing ongoing controls for marketed products, such as Good Manufacturing Practices and inspection and testing procedures, and Tobacco Product Standards. FDA will also need scientific capacity to provide support for the future processes of reviewing applications for new tobacco products and products claimed to reduce the risks of tobacco use. While FDA may be able to provide some laboratory and research capability within the agency at the National Center for Toxicological Research and at some field laboratories (ORA), it is expected that a much larger capacity will be needed. Other public health agencies such as CDC and NIH clearly have the expertise and potential laboratory capacity to conduct research in many areas related to tobacco, and FDA is considering the possibility of utilizing the expertise of these Federal agencies as well as other expert scientific resources. FDA will implement research efforts using a potential combination of contracts, cooperative agreements, and inter-agency agreements, all funded from tobacco program funds. This work will inform future substantial equivalent tobacco product review activities, among other requirements of the Tobacco Control Act.

Performance: In FY 2010, FDA established the Tobacco Products Scientific Advisory Committee (TPSAC). During the year, TPSAC considered the public health impact of menthol in cigarettes and the framework for establishing a list of harmful/potentially harmful constituents in tobacco products and smoke. FDA held six meetings of TPSAC in FY 2010 on these two topics. TPSAC has met three times in FY 2011 to consider menthol-related issues, and will continue to consider the public health impact of menthol in cigarettes as it prepared to issue its report on menthol in cigarettes to the Secretary of Health and Human Services in March 2011. FDA will also issue regulations and guidance to industry regarding substantial equivalence, and review substantial equivalence applications submitted by industry. In FY 2012, FDA will establish a list of harmful and potentially harmful ingredients and constituents in tobacco products and tobacco smoke. FDA will also evaluate the report on dissolvable tobacco products that will be issued by TPSAC, and continue to build the scientific base for tobacco products regulation based on a population health standard.

3. **Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18.** (280003)

Context: The Tobacco Control Act requires FDA to reissue a rule by March 2010 that incorporates specific portions of the 1996 rules on tobacco aimed at limiting access by youths under age 18 to purchase tobacco products, and also limiting marketing practices and advertising aimed at youths. This rule will take effect in June 2010. A key element in deterring youth access to tobacco, as it was under the 1996 rule, will be contracts with U.S. States and Territories to conduct compliance checks to assure that retailers refuse sales of tobacco to adolescents under the age of 18. There are civil money penalties for illegally selling cigarettes or smokeless tobacco to minors. Ultimately, by reducing the sale, access, and allure of tobacco products to minors, this rule and its enforcement, as well as education and other efforts, will constitute a critical component of FDA's contributions to the overall HHS goals of reducing disease and deaths caused by tobacco products.

Performance: In order to enforce the requirements of the Tobacco Control Act and subsequent regulations, FDA began contracting with U.S. States for the purpose of conducting retail inspections. FDA contracted with 15 states in FY 2010. Those states were: Alabama, Arizona, Arkansas, Colorado, Idaho, Illinois, Kansas, Maine, Maryland, Massachusetts, Mississippi, Missouri, Pennsylvania, Tennessee, and Washington. These 15 states constitute 27 percent of U.S. States and Territories. This exceeds FDA's FY 2010 goal of contracting with 25 percent of U.S. States and Territories. In FY 2011, FDA will continue to contract with U.S. States and Territories. FDA's goal for FY 2011 is to have enforcement contracts with 75 percent of all U.S. States and Territories, and to have enforcement contracts with 95 percent of U.S. States and Territories in FY 2012.

4. **Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. (**280004**)**

Context: FDA's new authority to regulate tobacco products brings new transparency for the public about the ingredients, constituents, manufacturing and research processes for tobacco products, as well as about the risks associated with tobacco use. These new FDA authorities also mean new compliance requirements for those involved with the manufacture, distribution, marketing and sales of tobacco products. FDA's new Center of Tobacco Products (CTP) will develop a comprehensive educational program that will help improve understanding and awareness among the industry, importers, retailers, health professionals, tobacco control groups, and the general public about the new regulations that FDA is implementing (and for the regulated industry, information on how to comply with these new requirements). FDA also plans to develop a broad program of tobacco control and prevention education

and communications programs designed to reach the public with specific attention paid to as many racial, ethnic, cultural, and social elements of the population as possible. One of the primary ways to reduce the risks associated with tobacco use among youth is to increase educational efforts regarding the hazards of tobacco use, and specifically, to convey new information about tobacco product constituents, resulting from the information submitted to FDA by the industry and from the results of FDA's research activities. In FY 2011, FDA will continue its Stakeholder Discussion Series to fully explore ideas and options for overarching principles for the implementation of the Tobacco Control Act and the establishment of more effective communications mechanisms between and among FDA and various stakeholder groups.

Performance: FDA began the "Break the Chain of Tobacco Addiction" campaign in FY 2010 in an effort to educate retailers and the general public about new tobacco product regulations aimed at restricting youth access to tobacco products. This campaign has used traditional, web, phone, and social media outreach methods to reach retailers, industry, and the general public. In FY 2011, FDA will continue the "Break the Chain" campaign, and continually evaluate and refine the campaign in order to reach stakeholders and the general public in the most effective manner. FDA announced the Stakeholder Listening Series in FY 2010. This series will allow FDA to engage with various Stakeholders, and take advantage of the knowledge, ideas, feedback, and suggestions from all stakeholders affected by tobacco product regulation. This series will allow FDA to more effectively implement the Tobacco Control Act. As of December 2010, FDA had held two listening sessions and has another five scheduled in FY 2011. In FY 2012 FDA will continue to implement and improve programs that will educate industry, retailers, and the general public about new tobacco regulations, and the harmful effects of tobacco product use.

Headquarters and Office of the Commissioner Performance Detail

Long Term Objective: Manage for Organizational Excellence and Accountability

Office: Office of the Commissioner/ Office of International Programs

Measure	FY	Target	Result
291301: The number of FDA foreign posts to increase collaboration with foreign counterparts. *(Outcome)*	*2012*	16	October, 2012
	2011	14	October, 2011
	2010	15	12 foreign posts (Target Not Met)
	2009	N/A	11 foreign posts (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A
291302: The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization. *(Outcome)*	*2012*	16	October, 2012
	2011	14	October, 2011
	2010	12	12 (Target Met)
	2009	N/A	10 (Historical Actual)
	2008	N/A	6 (Historical Actual)
	2007	N/A	N/A

Measure	Data Source	Data Validation
291301	Internal Tracking, "Foreign Offices Approval Status" chart, which tracks the progress of steps involved in the approval process.	Foreign posts are considered established upon approval of the National Security Decision Directive (NSDD) 38.
291302	Regulatory Forums are invitation only events. An internal tracking system is used to record and monitor a list of invitees.	The meeting host records the names of attendees and reports this information as a part of the summary meeting report.

Office: Office of the Commissioner/ Office of the Chief Scientist

Measure	FY	Target	Result
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	*2012*	Implement changes to achieve target identified in the 2011 review	October, 2012
	2011	Set target based on data from pilot evaluation	October, 2011
	2010	Develop pilot evaluation of program	Pilot evaluation of the Fellowship program

			developed (Target Met)
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A
293206: Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)*	*2012*	Continue regulatory science studies on evaluating nanomaterials from 2011.	December, 2012
	2011	Initiate multi-year studies on safety issues (1) for evaluating nanoparticles that cross multiple product areas and (2) surrounding use of nanoparticles in cosmetic products.	December, 2011
	2010	N/A	N/A
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
291101	FDA will develop an Internal Tracking System to track number of offers made to Fellows and number of Fellows that are hired.	FDA will utilize existing HR systems to validate the number of actual hires.
293206	FDA Nanotechnology Task Force; National Nanotechnology Initiative (NNI); Science Board to the FDA; FDA staff presentations at public meetings; and manuscripts and other written materials for publication in peer-reviewed journals and other communication forums.	FDA will validate its efforts in promoting innovation and predictability in the development of safe and effective nanotechnology-based products by assessing outcomes and other progress in five areas related to nanotechnology including science, research, policy, communication, and planning. Information from several data sources and relevant FDA activities will provide measures in the five areas related to nanotechnology. Information will be gathered and documented from multiple data sources, which may include agency source data, agency guidance and other written materials, the NNI, cooperation and coordination with other regulatory agencies, public meetings, publications, and other areas.

Office: Office of the Commissioner/ Office of Orphan Product Development

Measure	FY	Target	Result
293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)*	*2012*	335	October, 2012
	2011	312	October, 2011
	2010	246	301 (Target Exceeded)
	2009	N/A	269 (Historical Actual)

Measure	FY	Target	Result
	2008	N/A	205 (Historical Actual)
	2007	N/A	201 (Historical Actual)
293202: The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program. *(Output)*	*2012*	100	October, 2012
	2011	90	October, 2011
	2010	1	80 (Target Exceeded)
	2009	N/A	N/A
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
293201	The data will be pulled from the OPD data base, which is updated daily.	Every decision has a written and signed document that is scanned into the data base; the original is filed and can be retrieved by hand.
293202	Each pediatric device consortia grantee submits a quarterly report that provides a description of the medical devices they are facilitating in development.	The OPD grant officers will monitor the grants and follow-up with the grantees to validate the information provided in the quarterly reports.

Office: Office of the Commissioner/ Office of Pediatric Therapeutics

Measure	FY	Target	Result
293203: Number of pediatric scientific and ethical product and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA and through collaboration with Latin America. *(Output)*	*2012*	36	October, 2012
	2011	36	October, 2011
	2010	10	62 (Target Exceeded)
	2009	N/A	10 (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
293203	Nvivo 8 Software, which is maintained by OPT, is used to track the monthly exchange of pediatric information between FDA and the European Medicine Agency (EMA). The information tracked includes the number of Pediatric Investigational Plans (PIPs) received from EMA, the number of PIPs for which OPT provided information to EMA and the number of PIPs and	Quality control of the Nvivo 8 Software is performed, which includes identification of duplicate reports, to assure reliability of the data.

	general topics discussed. Since Nvivo is text-based software, it also captures and stores FDA's and EMA's background information for each product discussed at the monthly exchanges. This background information is obtained from various FDA databases, such as DARRTS, and from EMA's Summary Reports. Following each monthly exchange, notes are written to capture the scientific and ethical issues discussed.	

Measure	*FY*	Target	Result
293204: Number of new medical products studied in children with labeling changes and safety reviews completed. *(Output)*	*2012*	30	October, 2012
	2011	30	October, 2011
	2010	25	36 (Target Exceeded)
	2009	N/A	21 (Historical actual)
	2008	N/A	12 (Historical Actual)
	2007	N/A	12 (Historical Actual)

Measure	Data Source	Data Validation
293204	Drug and Biologic Product labeling that relate to pediatrics are posted on the FDA OPT website http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM163159.pdf Listing of products with safety reporting to the Pediatric Advisory Committee (PAC) meetings is also updated on the OPT link http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm123229.htm	All FDA drug and biologic products that receive new Pediatric Labeling changes are tracked and listed by the date of labeling change. The list of labeling dates is reviewed by OPT personnel on a regular basis, 1-2 times a month, to track and determine the dates for mandated safety reviews to the PAC to occur within 2 years from date of labeling change. Full listing of products with safety reporting to the PAC is updated after each PAC on the website with links to the meetings and background materials.

Office: Office of the Commissioner/ Office of Combination Products

Measure	FY	Target	Result
293205: Percentage of requests for Designations processed within the 60 day statutory requirement. *(Output)*	*2012*	95%	October, 2012
	2011	95%	October, 2011
	2010	95%	100% (Target Exceeded)
	2009	N/A	100% (Historical Actual)
	2008	N/A	100% (Historical Actual)

Measure	FY	Target	Result
	2007	N/A	100% (Historical Actual)

Measure	Data Source	Data Validation
293205	OCP's internal tracking database	For every RFD submitted to OCP, the tracking database records the receipt date, the RFD filing and the date that the final decision is issued. Based on these dates, the tracking database calculates the number of days that OCP spent processing the RFD. The dates generated are compared against the 60 day statutory requirement of issuing a decision after filing. OCP's established administrative processes and procedures for RFDs ensure quality of the data. First, quality of the data is maintained through the issuance of dated letters to the submitter. When an RFD is filed, a letter is sent to the submitter informing them of the filing date. When a final decision is made, a designation letter is also sent to the submitter informing them of the final Agency's determination. As such, if there is any discrepancy on these dates, the submitter will contact OCP and inform us of the potential error. Second, OCP manually checks, upon filing, the dates generated by the tracking database to ensure that the dates have been calculated correctly. If appropriate, the office will take the necessary steps to correct any error to make sure that the information contained in the database is accurate.

Office: Office of the Commissioner/ Office of Special Health Issues

Measure	FY	Target	Result
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	*2012*	3	October, 2012
	2011	3	October, 2011
	2010	3	1 (Target Not Met)
	2009	N/A	1 (Historical Actual)
	2008	N/A	N/A
	2007	N/A	N/A

Measure	Data Source	Data Validation
292301	Office of Special Health Issues Strategic Planning Assessments	The number of new multi-faceted educational programs is measured through the OSHI annual strategic planning efforts, where completed and ongoing projects are reviewed and the upcoming year's projects are prioritized. OSHI determines if the multi-faceted educational programs are carried out by using a monthly internal staff survey to capture the separate components of the programs (i.e. webinars, CME programs, journal articles, etc.). This information is summarized and assessed on a quarterly basis as part of the FDA-TRACK program. Both the primary data source (OSHI strategic planning assessments), and

		the secondary data source (FDA-TRACK monthly surveys), are compared to validate the data.

Office: Office of the Commissioner/ Office of Women's Health

Measure	FY	Target	Result
294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. *(Output)*	*2012*	9	October, 2012
	2011	7	October, 2011
	2010	5	5 (Target Met)
	2009	N/A	4 (Historical Actual)
	2008	N/A	4 (Historical Actual)
	2007	N/A	N/A
291303: The number of collaborations and partnerships to maximize Outreach activities. *(Output)*	*2012*	400	October, 2012
	2011	350	October, 2011
	2010	300	300 (Target Met)
	2009	N/A	250 (Historical Actual)
	2008	N/A	250 (Historical Actual)
	2007	N/A	N/A

Measure	Data Source	Data Validation
294201	Office of Women's Health Internal ACCESS data base	Data is validated for these performance goals through the Unified Financial Management System (UFMS) and Gov Trip
291303	Office of Women's Health internal ACCESS data base	Data is validated from several sources for these performance goals including the Federal Procurement Data System (FPDS), the Unified Financial Management System (UFMS)

Office: Office of the Commissioner/ Office of Financial Management

Measure	FY	Target	Result
291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)*	*2012*	Continue to enhance training opportunities for all FDA stakeholders and continue to improve on Oracle Business Intelligence Enterprise Edition (OBIEE) reporting solution for management reports.	December, 2012
	2011	Expand FDA's reporting capabilities; define the TO-BE UFMS processes and a comprehensive training program.	December, 2011

Measure	FY	Target	Result
	2010	Continue OBI development, UFMS 2010 initiatives (to be defined), improve AS-IS UFMS processes to gain transparency, agility, and efficiency and in the process address deficiencies in the areas of SOD violations and other control deficiencies.	OBI Beta Implementation, UFMS 2010 initiatives (Target Met) - 1. Performance Assessment and Business Availability (Target Met). 2. OCI Tactical and Strategic Enhancements (Target Met). 3. Improve CAN Realignment (Target Met). 4. Improve YE CAN Management (Target Met). 5. e2e Process Documentation (Target Met). 6. Training Redesign Pilot Program (Target Met). 7. Transition to a Role Based Access in UFMS. (Target Met). 8. During FY2010 there were 4 Point Releases to deploy enhancements and bug fixes. (Target Met)
	2009	Begin migration to version 11-5-10 of ORACLE Federal Financials	UFMS was successfully upgraded to 11.5.10 for all Operating Divisions (OPDIVS). (Target Met)
	2008	Stabilize UFMS environment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials	All HHS OPDIVS are now in UFMS production. Stabilization for Indian Health Service (IHS) is underway (Target Met)
	2007	Finalize decision on an activity-based costing application and make it operational for its user fee programs	Finalized the decision on an activity-based costing application and made it operational for its user fee programs. (Target Met)

Measure	Data Source	Data Validation
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. OMB Circular A-123, Appendix A requires proper controls	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

	over financial reporting.	2001 FDA Workforce Restructuring Plan, monthly statements from bank card companies and the FDA Small Purchase System. FDA will ensure compliance within UFMS controls according to OMB Circular A-123, Appendix A over financial systems and reporting for 2011 and 2012 and ongoing.

Office: Office of the Commissioner/ Office of Information Management

Measure	FY	Target	Result
291404: Percentage of servers that are high efficiency energy star compliant. *(Output)*	*2012*	95%	October, 2012
	2011	95%	October, 2011
	2010	50%	89.2% (Target Exceeded)
	2009	N/A	25% (Historical Actual)
	2008	N/A	5% (Historical Actual)
	2007	N/A	0% (Historical Actual)
291405: Percentage of application availability during non-scheduled, emergency outages. *(Output)*	*2012*	99.9%	October 1, 2012
	2011	99.9%	October 1, 2011
	2010	98%	98.3% (Target Exceeded)
	2009	N/A	95% (Historical Actual)
	2008	N/A	95% (Historical Actual)
	2007	N/A	N/A

Measure	Data Source	Data Validation
291404	The FDA will use power consumption levels prior to and after migration to the new servers in addition to number of physical vs. virtual servers.	Due to the lack of power sub-metering in the agency's current primary Parklawn facility (decommissioning by 12/31/10), the agency will calculate current power consumption based on "faceplate" figures. Reduction in power will be validated with sub-metered power figures at the new facilities. Further validation will be provided via pre- and post-migration physical and virtual server count comparisons. Equipment purchased or leased under current contracts must be Energy Star compliant where applicable.
291405	Server utilization reports from automated data center server monitoring provide statistics regarding the availability of the servers that provide access to applications.	This is validated via outage reports provided by FDA users.

Office: Office of the Commissioner/ Office of Crisis Management

Measure	FY	Target	Result
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	*2012*	Enhance FDA's preparedness and planning capabilities by increasing participation in intra/interagency exercises by 25%. Emphasize evaluation of FDA responses to incidents and exercises by establishing a formal evaluation program which will include mandatory comprehensive lessons learned and after action reporting. Enhance interoperability of EON IMS with other systems including those administered by other agencies.	December, 2012
	2011	Implement electronic notifications of Reportable Food Registry Reports to Federal and State Counterparts. In addition OCM will conduct training for FDA staff on the implementation of the FDA Emergency Operations Plan and its incident specific annexes. Expand the geospatial capabilities of EON IMS to increase usage during incident response and recovery by 25%.	December, 2011
	2010	Pilot EON IMS data sharing with Federal and State counterparts. Enhance surveillance and detection capabilities within the Office of Emergency Operations. Revise and exercise FDA's Emergency Operations Plan and provide training on the plan and annexes. Coordinate participation in inter-agency work-groups, and implement an Agency-wide National Incident Management System (NIMS) plan	Piloted a mechanism to use EON IMS to share data with Federal and State counterparts. Enhanced surveillance and detection capabilities within the Office of Emergency Operations through the further expansion of GIS. Revised and exercised FDA's Emergency Operations Plan and designed and scheduled training on the plan and annexes. Coordinated participation in interagency work-groups, and implemented an Agency-wide National Incident Management System (NIMS) plan.(Target Met)
	2009	Continued enhancement of EON IMS and GIS capabilities.	EON IMS Version 3.3.4 implemented Aug 09.

		Coordinate FDA's participation in exercises and interagency work-groups, update remaining emergency response plans, and develop an Agency-wide National Incident Management System (NIMS) implementation plan.	Includes a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). OCM updated the FDA Emergency Response Plan, 3 incident-specific emergency response plans and created a draft FDA NIMS Implementation Plan and agency Incident Command System (ICS) structure. (Target Met)
	2008	Continued enhancement of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participation in other exercises and workgroup.	EON IMS Version 3.3 implemented Aug 08. Includes significant enhancements to further its knowledge mgmt and GIS capabilities. FDA-wide Incident Command System (ICS) training conducted for Headquarters and field offices. Finalized Pandemic Influenza Emergency Response Plan and began planning an FDA Pandemic Influenza Exercise for Oct 2008. (Target Met)
	2007	Continue Enhancement EON IMS Coordinate FDA's participation in exercises, including TOPOFF 4 Develop an FDA emergency response plan for pandemic influenza	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 plan for pandemic influenza developed Sept 2007. (Target Met)

Measure	Data Source	Data Validation
292201	Office of Crisis Management Emergency Operations Network Incident Management System (EON IMS) and Field Data Systems	Data validation is based on a review of the past period's activities and the Emergency Operations Network Incident Management System plan and schedule. The percentage increase over FY2010 baseline will be based on the number of maps created for use during incident response and recovery. Improved accuracy and completeness of complaint data entered into FACTS for OCM/OEO review and processing.

1. The number of FDA foreign posts to increase collaboration with foreign counterparts. (291301)

Context: The foreign posts will allow FDA to work more closely with its foreign counterparts to help ensure the safety and quality of FDA-regulated products. The activities of these offices include, gathering information on product manufacturing and transport, leveraging scientific and inspectional resources, working with third parties to assist in ensuring compliance, and providing technical assistance to increase the capacity of selected counterpart agencies.

Performance: In FY 2009, we established 11 FDA overseas posts and staffed nine of those posts in China (Beijing, Shanghai, and Guangzhou), India (New Delhi and Mumbai), Europe (Brussels and London), and Latin America (San Jose and Santiago). In FY 2010, we staffed the two posts established but not staffed in FY 2009 in Parma and Mexico City and establish one additional overseas post in the Middle East (Tunis, Tunisia). Due to refocusing of agency priorities the targeted posts changed effecting the processing of and subsequent approval of NSDD-38's for the total of four additional posts in FY 2010 as previously planned. In FY 2011, we plan to staff the one post established but not staffed in FY 2010, and establish two additional overseas posts, and in FY 2012 two additional posts are planned.

2. The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization. (291302)

Context: FDA will work to increase the participation of counterpart agencies in the ICH Regulators Forum, which should hasten the implementation of the ICH-adopted harmonized guidelines for the regulation of drugs and biologics. These activities will increase consumer protection by improving the safety and quality of FDA-regulated products produced in other areas of the world.

Performance: In FY 2010 there were 6 additional agencies (outside the routine ICH partners from Europe, the US, Japan, Canada, Switzerland, and WHO) present at these meetings. In FY 2011 we plan to work to have 2 additional agencies present per meeting, for a total of 14 agencies present at these meetings. In FY 2012, we plan to add an additional 2 additional agencies present per meeting, for a total of 16 agencies.

3. Percentage of Fellows retained at FDA after completing the Fellowship program. (291101)

Context: The FDA Commissioner's Fellowship Program was initiated in the fall of 2008 and is a two-year program designed to train a cadre of highly accomplished scientists in FDA regulatory science across devices, drugs, biologics, foods, and cosmetics. The Commissioner's Fellowship Program brings highly motivated and promising individuals to FDA where they will contribute to and learn regulatory science and policy, enriching both their careers and FDA's capacity. They will learn about FDA's core mission, review processes, policies, and scientific and public health challenges, be supported in their professional development, and engage with a senior mentor in specific high priority projects directly related to FDA's public health mission. Depending on agency need and resources, many Fellows may remain at FDA after completing the program; others will carry an understanding of FDA with them in their future careers. In FY 2012, a target for the percentage of Fellows retained will be established based on a planned evaluation program that will be developed and executed in FY 2011.

Performance: The FDA Commissioner's Fellowship Program is new with 50 fellows who began the two-year Program in the fall of 2008 graduating in the fall of 2010. Fifty Fellows began the program in fall of 2009, and 45 Fellows began the program in the fall of 2010. In FY 2010, the performance target was met with a pilot evaluation of the entire program completed and a retention metric, based on the 2008 Fellows' retention, was identified. In FY 2011, a full formal evaluation of the program will be completed

with the identification of a hiring target. In FY 2012, changes to the program to meet the target will be implemented.

4. Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. (293206)

Context: For the FDA, a science-based regulatory agency whose mission is to protect and promote public health, nanotechnology poses regulatory challenges that are inherent in emerging technologies. Like many emerging technologies, there is the potential benefit that nanotechnology can bring to food, medicine, and other FDA-regulated product areas, but the risks to human and animal health are not yet completely identified or understood.

Performance: In FY 2010, FDA received notice of the first proposed FY 2011 funding for nanotechnology. In February 2010, the FDA Nanotechnology Task Force (Task Force) developed and published the agency's FY 2011 regulatory science research plan for nanotechnology that enables regulatory science studies relevant for the development of safe and effective nanotechnology-based products (http://www.nano.gov/NNI_2011_budget_supplement.pdf). The Task Force presented the agency's FY 2011 research plan to the Science Board to the FDA (Science Board) in a public forum in August 2010, and solicited comments from Science Board and the public. The Science Board concurred with FDA's FY 2011 research plan, including supporting studies such as those described above for the responsible development of nanotechnology. In FY 2011, FDA plans to implement its proposed regulatory science research plan for nanotechnology, including developing the CORES (Collaborative Opportunities for Research Excellence in Science) Program to support studies that can serve as a platform for the targets above, building laboratory capacity to assess nanotechnology products, and investing in training and staff development in the area of nanotechnology.

5. The total number of decisions on applications for promising orphan drug and humanitarian use device designations. (293201)

Context: FDA has a public health mission, as mandated by the Orphan Drug Act of 1983, and the Safe Medical Devices Act of 1990, to provide incentives for the development of promising new drugs and medical devices, respectively, for people with rare diseases and conditions, which is estimated to be more than 25 million people in the United States. This measure is an indication of the amount of progress by drug and medical device sponsors in getting an eventual market approval for these promising orphan products. OOPD does a significant amount of outreach to increase awareness of the statutory incentives and grants programs, and assists sponsors in moving promising products towards market approvals. The OOPD has a grant program to promote clinical research studies for promising orphan products (drugs, biologics, medical devices, and medical foods) and another grant program to promote the development of pediatric medical devices.

Performance: In FY 2009, OOPD made 248 decisions on orphan drug designation applications and 18 decisions on humanitarian device designation applications. In FY 2010, OOPD has made 273 decisions on orphan drug designation applications and 28 decisions on humanitarian device designation applications. This result exceeded the target partly as a result of new initiatives by OOPD in FY 2010 to stimulate designation application development. In FY 2011, OOPD expects to achieve the FY 2010 totals, and increase this amount by 4 percent. In FY 2012, OOPD expects to achieve the FY 2011 totals, and increase this amount by 7.5 percent.

6. The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program. (293202)

Context: The goal of the statutory Pediatric Device Consortia Grant Program is to promote pediatric device development, which has lagged far behind the development of device technology for adults. The Pediatric Device Consortia grants facilitate the development of needed medical devices for children. According to statute, the consortia will facilitate the development, production, and distribution of medical devices for children by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) Mentoring and managing pediatric device projects through the development process, from concept formation, to prototype development, to clinical development, to marketing; (3) Connecting innovators and physicians to existing Federal and non-Federal resources for funding of device development; (4) Assessing the scientific and technical merit of proposed pediatric device projects; and (5) Providing assistance as needed on business development, personnel training, prototype development, post-market and other activities.

Performance: So far, four Pediatric Device Consortia have been established under this program; collectively they have helped facilitate the early development of 80 potential medical devices for children." This result exceeded the stated target because the original target metric of having one device approved for marketing was replaced with number of devices under development. The four consortia are as follows:

- The Pediatric Cardiovascular Device Consortium, based out of Boston Children's Hospital,
- The UCSF Pediatric Device Consortium, based out of the University of California at San Francisco (http://www.pediatricdeviceconsortium.org/),
- The Michigan Pediatric Device (M-PED) Consortium, in partnership with the Pediatric Medical Devices Institute, of Roanoke, VA, based out of the University of Michigan (http://peddev.org/),
- The MISTRAL (Multidisciplinary Initiative for Surgical Technology Research Advanced Laboratory) Collaborative based out of SRI International in Stanford, California (http://mistralpediatric.org/).

In FY 2011, we anticipate the number of devices to increase to 90 devices under development, and in FY 2012, we anticipate the number of devices to increase to 100 devices under development.

7. Number of pediatric scientific and ethical product and product class issues identified through collaboration with the 27 European countries coordinated with the EMA and through collaboration with Latin America. (293203)

Context: The goal of our international collaborations is to prevent children from becoming a global commodity by conducting trials of the highest ethical and scientific rigor and decreasing their risk. This involves intense coordination of hundreds of protocols being submitted to the various agencies for identification of potential problems/issues. At present, OPT coordinates at least monthly teleconference exchanges between FDA (CDER and CBER) and the European Medicines Agency (EMA). Issues identified at each of these monthly teleconferences pertain to safety, clinical trial design, endpoints or ethics. These issues are ones that require additional collaboration. An example of an issue pertains to heart safety concerns with a product (Aplidin), which is under investigation to treat a specific cancer in children (neuroblastoma). OPT identified this issue and invited all involved parties to a discussion of this issue, which resulted in additional safety monitoring by EMA. In FY 2010, Japan and Canada joined the monthly pediatric teleconference exchanges as observers. Also, in FY 2010, the Health Science Administrator position for Latin America was filled. In FY 2011, the Medical Officer position for Latin America was filled. Both of these FTE positions for expansion to Latin America are being funded by the Office of International Programs (OIP) until FY 2012. In 2009, the monthly International Exchange changed to address only identified scientific, ethical, product and product class issues.

Performance: The exchange of scientific information between FDA and the European Medicines Agency began in September 2007 and through December 2010, information has been exchanged for over 450 products. Of these, 221 products have been discussed at monthly teleconferences as well as 18 general topics. Ten scientific/ethical issues requiring further discussion or oversight were identified in FY 2008 and in FY 2009. In FY 2010, 62 new or additional issues were identified. We project identification of 36 new or follow-up issues in FY 2011 and FY 2012. In FY 2010, the target was exceeded because it reflects the actual number of issues discussed per product as well as the number of general topic issues discussed during monthly teleconference.

8. Number of new medical products studied in children with labeling and safety reviews completed. (293204)

Context: The Office of Pediatric Therapeutics has been statutorily charged by Congress to report to the Pediatric Advisory Committee (PAC) all adverse events for products studied under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Originally, the mandate applied to drugs granted pediatric exclusivity under the Best Pharmaceuticals for Children Act (BPCA). FDAAA 2007 expanded the mandate to include drugs receiving a pediatric labeling change under BPCA, as well as drugs and biologicals under the Pediatric Research Equity Act (PREA) and pediatric devices that receive a Humanitarian Device Exemption (HDE). As a result, OPT has assumed greater responsibility and workload for safety reviews and public reporting and vetting of adverse events. In addition, OPT works with all involved FDA and external constituents to facilitate and enhance pediatric studies in order to obtain additional labeling information on efficacy, safety and dosing for children. OPT publicly posts summaries of safety reporting updates presented to the PAC as well as the PAC recommendations for products studied and labeled under FDAAA. In FY 2011, the target is 30, and in FY 2012, the target is 30 new medical products studied in children.

Performance: The number of new medical products studied in children, labeling changes and safety reviews completed under the Congressionally mandated pediatric legislation, BPCA and PREA, are: FY 2006: 12; FY 2007: 13; FY 2008: 12; FY 2009: 21; FY 2010: 36. The FY 2010 target was exceeded because FDAAA expanded the pediatric safety reporting requirement to include products receiving pediatric labeling under PREA for drugs and biologics as well as HDE pediatric devices. Further it reflects the growing number of pediatric labeling changes resulting from BPCA and/ or PREA studies.

9. Percentage of requests for Designations processed within the 60-day statutory requirement. (293205)

Context: By statute, OCP determines the classification and assignment of a drug, device, biological product and combination product. Under 21 CFR Part 3, an RFD (request for designation) is the regulatory vehicle used for that purpose. As technology advances, sometimes product classification and assignment is unclear. A company submits an RFD requesting a formal determination from OCP. The RFD determination made by OCP is a legally binding action that also identifies such things as the key governing regulations, the center/OCP contacts for next steps. In so doing, this should assist developers by decreasing uncertainty and allowing the firm to move directly to their next development steps. The FY 2010, 2011 and 2012 targets are set at 95% processed within the 60 days requirement.

Performance: In FY 2010, a total of 52 requests for designation were active. This includes 7 RFDs that were pending and not overdue at the beginning of 2010. Of these, 3 RFDs were withdrawn by the sponsor and 5 were remaining at the end of 2010 but not overdue. Of the remaining 44 requests that were eligible for determination, 44 (100%) were processed within the 60-day statutory requirement, which exceeded the target of 95% due to a commitment to make these decisions as quickly as possible. Over half (32 of 44) of product assignment requests were determined to be combination products. Of the 32

combination products; 23 were drug-device combinations, 4 were drug-biologic combinations, 3 were device-biologic combinations and 2 were drug-device-biologic combinations. Of the 12 designations that were not combination products, 7 were designated as drugs, 3 as biologic or tissues, and 2 as devices.

10. The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. (292301)

Context: Multi-faceted educational programs for patient advocates and health professionals are important ways for these groups to understand FDA's role and decision-making process on issues that are critical to them. Meetings and workshops allow FDA and participants to engage actively in dialogue, ask questions, and provide feedback on important aspects that might be unknown to each side. Web-based webinars, accredited continuing education modules, and written journal or newsletter articles allow patients and health professionals to more deeply explore and understand the far-reaching impact of the issues with which FDA grapples to protect the public health.

Performance: In FY 2009 FDA developed one educational program on opioid REMS which consisted of an educational workshop; a webinar; four educational meetings with patient advocates and health professionals; and an article published in a health professional newsletter. For FY 2010, OSHI developed one multi-faceted educational program on expanded access. The expanded access program, developed in conjunction with the American Society for Clinical Oncology consisted of a set of three online educational modules, including resources such as a glossary, an Expanded Access request checklist, and helpful templates for letters to manufacturers, consent forms, etc. OSHI had planned to produce another multifaceted educational program on REMS. We did not fully meet that target; however, we made significant steps to do so. For example, during FY 2010 we hosted a webinar for patient representatives on REMS. Additionally, substantial progress was made in developing an accredited, web-based continuing educational module for health professionals on REMS. Considerable staff time was devoted to writing, editing, and finalizing the script; however, the project was not completed. In FY 2011, OSHI will develop one additional multi-faceted educational program for patients. The program will consist of an online educational module for patients to learn about FDA issues, a newsletter, an annual meeting, an article for patients in the Drug Information Association publication, and a networking website where patients and patient advocates can exchange ideas. At the conclusion of FY 2011, OSHI plans to have a total of three multi-faceted educational programs. In FY 2012, the target is being maintained at the FY 2011 level.

11. Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. (294201)

Context: Site visits are an integral part of the FDA OWH Research & Development Program. They ensure that the research that investigators have proposed is being conducted as originally planned and to the highest scientific and ethical standards and that the funds received in this competitive scientific awards program are being appropriately used towards the intended scientific goal and that appropriate spending plans are in place.

Performance: In FY 2009, OWH made 4 site visits to facilities conducting OWH-funded laboratory-based research. In FY 2010, OWH met its target and successfully completed 5 site visits inspecting the locations and the progress of the funded studies. All site visits had positive results. OWH is increasing the target to 7 total site visits in FY 2011, and to 9 in FY 2012.

12. The number of collaborations and partnerships to maximize Outreach activities. (291303)

Context: Partnerships and collaborations are an integral part of the FDA OWH Outreach Program. OWH creates easy to read, concise, and credible consumer health materials about FDA regulated products such as medications, LASIK surgery, HPV vaccine, and mammography, among others. These materials are focus group tested, available in English and Spanish, and readily available for download from the FDA website. Through a variety of partnerships and collaborations, the penetration of the OWH publications in the community is expanded. These partnerships will help maximize the offices' collaboration efforts and educational program outcomes by reaching new audiences through these new partnerships through linking directly to the FDA OWH website and drive traffic from their websites to FDA OWH for consumer health information. Giving women health information empowers them to have discussions with their medical practitioner and enables them to make wise decisions for themselves and their families.

Performance: OWH developed 250 partnerships during Fiscal Years 2006 and 2007 maintaining these partnerships through FY 2008. OWH has met its FY 2010 target by increasing its existing partnerships from 250 in FY 2009 to 300 partnerships in FY 2010. OWH is increasing the target to 350 partnerships in FY 2011, and is planning 400 partnerships by the end of FY 2012.

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

Context: The Department announced in FY 2001 that it intended to establish a unified financial management system to replace its operating division's individual financial management systems. The goal of the UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. FDA, CDC, NIH, and the Program Support Center (which covers the remaining components other than CMS and its contractors) began the design of the UFMS. Although this goal had originally been dropped after FDA had implemented UFMS, FDA has continued to be involved in the implementation of the UFMS system across the Department. A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009 the Department will migrate to Oracle Federal Financials version 11-5-10 and also implement iProcurement and PRISM as the global solutions for requisitioning and acquisitions. For FY 2010 FDA will implement the Oracle Business Intelligence Enterprise Edition (OBIEE) Reporting Solution on a beta basis. Other FDA initiatives for FY2010 include documenting the AS-IS end-to-end (e2e) business processes, a training redesign pilot program and transitioning to a role based access to UFMS. In FY2011 FDA plans to expand the OBIEE Reporting Solution across the Agency (all Centers and OC), complete documenting the AS-IS Business Processes and start defining the TO-BE Business Processes and expand the training redesign program to a more comprehensive training program. In FY2012 FDA will continue the training initiative and complete its development of a comprehensive training program, continued expansion of the OBIEE Reporting Solution and continue the e2e Business Process improvement initiative.

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. In FY 2010, OFO successfully implemented a beta version of OBIEE for one of the Centers (CVM) and OFM. Completed deployment of the UFMS Supplier Management Automation Program and other UFMS 2010 initiatives (Performance Assessment and Business Availability (met the target of implementing to 10 solutions); Oracle Compuserve Interface (OCI) Tactical and Strategic Enhancements (met target of identifying all OCI related gaps); Improvement of CAN Realignment and Improve Year End CAN Management (met target by implementing Change Requests agreed to by all OpDivs); and, Continue the documentation and improvements of the e2e AS-IS UFMS processes to gain transparency, agility, and efficiency (completed documenting all the 12 Procure-to-Pay transactions and significant head-way in documenting the Collections-to-Budget transactions). Met

significant milestones in the role based definition initiative of granting UFMS access based on roles. Subsequently, this will address deficiencies in the areas of Segregation of Duties (SOD) violations and other control deficiencies. Also met significant milestones in the development of the Training Redesign Pilot Program Courses by identifying and developing three pilot courses based on the training assessment results to be evaluated using best practice methodologies. Also during FY 2010 there were 4 UFMS Point Releases to deploy enhancements and bug fixes. In FY 2011, FDA will continue to be compliant with OMB Circular A-123, Appendix A for internal controls over financial reporting. In FY 2011 FDA will continue to improve business processes and improve training capabilities including the use of OBIEE reporting tools for management. In FY 2012 FDA will continue to expand management financial reporting capabilities along with expanding training curriculum and opportunities for financial managers.

14. Percentage of servers that are high efficiency energy star compliant. (291404)

Context: FDA's server environment is outdated. FDA will replace current outdated data center servers with high efficiency energy star compliant servers for applications supporting the regulatory mission of the FDA. This will give the FDA the ability to collect, store, and analyze large volumes of regulatory, scientific, and risk based information from multiple internal and external sources promoting pro-active decisions and timely responses to issues impacting the Public Health.

Performance: The FDA began purchasing high efficiency energy star compliant servers in 2008 and replaced approximately 5% of the server environment by the end of FY 2008 with the high efficiency energy star compliant servers. By the end of FY 2009, 25% of the server environment was replaced with high efficiency energy star compliant servers. FDA exceeded the FY 2010 target by utilizing a highly virtualized and consolidated environment and achieved an 89.2% virtualization rate. This resulted in a significantly lower number of physical resources thus lowering energy use. By the end of FY 2011, 95% of the environment will be high efficiency energy star compliant servers. For FY 2012, the target is being maintained at the FY 2011 level.

15. Percentage of application availability during non-scheduled, emergency outages. (291405)

Context: OIM must ensure that critical systems (i.e., Prior Notice, drug registry, etc.) are available 24x7 in order to carry out the mission of the FDA; reducing the risk of adulterated, misbranded or unapproved food and medical products entering commerce.

Performance: The FDA exceeded the FY 2010 target by migrating production applications to a Tier IV facility in Ashburn, VA. This facility provides redundant power and cooling and is a state-of-the art facility. This facility is currently performing at 99.9997% uptime. By the end of FY 2011, FDA is targeting 99.9% availability to customers to utilize mission critical applications. For FY 2012, the target is being maintained at the FY 2011 level.

16. 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, is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents," HSPD-8, "National Preparedness," and HSPD-9, "Defense of United States Agriculture and Food." In FY 2009, FDA enhanced the Emergency Operations Network Incident Management System

(EON IMS) and Geographic Information System (GIS) capabilities and continued to coordinate FDA's participation in exercises and work-groups, including National Level Exercises (NLEs).

Performance: In FY 2010 OCM met their target performance measures by piloting a mechanism to use EON IMS to data share with Federal and State counterparts. OCM enhanced surveillance and detection capabilities within the Office of Emergency Operations through the further expansion of GIS, revised and exercised FDA's Emergency Operations Plan, and designed and scheduled training on the plan and its incident specific annexes. OCM coordinated participation in inter-agency work-groups, and implemented an Agency-wide National Incident Management System (NIMS) plan. In FY 2011, OCM will fully implement electronic notifications of Reportable Food Registry Reports to Federal and State Counterparts. In addition OCM will conduct training for FDA staff on the implementation of the FDA Emergency Operations Plan and its incident specific annexes. OCM will expand the geospatial capabilities of EON IMS to increase usage during incident response and recovery. In FY 2012, OCM will enhance FDA's preparedness and planning capabilities by increasing participation in intra/interagency exercises by 25%. OCM will emphasize the evaluation of FDA responses to incidents and exercises by establish a formal evaluation program of incident response and intra/interagency exercises to include mandatory comprehensive lessons learned and after action reporting. OCM will also enhance interoperability of EON IMS with other systems including those administered by other agencies.

FDA Linkages to HHS Strategic Plan

The table below shows the alignment of FDA's strategic goals with HHS Strategic Plan goals.

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
1 Transform Health Care					
1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured					
1.B Improve health care quality and patient safety			X		
1.C Emphasize primary and preventive care linked with community prevention services					
1.D Reduce the growth of health care costs while promoting high-value, effective care					
1.E Ensure access to quality, culturally competent care for vulnerable populations					
1.F Promote the adoption of health information technology					
2 Advance Scientific Knowledge and Innovation					
2.A Accelerate the process of scientific discovery to improve patient care					
2.B Foster innovation at HHS to create shared solutions					
2.C Invest in the regulatory sciences to improve food and medical product safety	X				
2.D Increase our understanding of what works in public health and human service practice					
3 Advance the Health, Safety and Well-Being of the American People					
3.A Ensure the safety, well-being, and healthy development of children and youth					
3.B Promote economic and social well-being for individuals, families and communities					

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults					
3.D Promote prevention and wellness		X		X	
3.E Reduce the occurrence of infectious diseases		X			
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies		X	X		
4 Increase Efficiency, Transparency, and Accountability of HHS Programs					
4.A Ensure program integrity and responsible stewardship of resources					X
4.B Fight fraud and work to eliminate improper payments					
4.C Use HHS data to improve the health and well-being of the American people					
4.D Improve HHS environmental, energy, and economic performance to promote sustainability					X
5 Strengthen the Nation's Health and Human Service Infrastructure and Workforce					
5.A Invest in the HHS workforce to meet America's health and human services needs today and tomorrow					X
5.B Ensure that the Nation's health care workforce can meet increased demands					
5.C Enhance the ability of the public health workforce to improve public health at home and abroad					
5.D Strengthen the Nation's human services workforce					
5.E Improve national, state, and local surveillance and epidemiology capacity		X			

Summary of Full Cost

(Budgetary Resources in Millions)

	OPDIV		
HHS Strategic Goals and Objectives	**FY 2010**	**FY 2011**	**FY 2012**
1 Transform Health Care			
1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured			
1.B Improve health care quality and patient safety	**$1,829**	**$1,918**	**$2,319**
214208: Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics.	8	8	8
223201: Percentage of Standard NDAs/BLAs within 10 months.	433	470	607
223202: Percentage of Priority NDAs/BLAs within 6 months.	83	90	108
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year.	115	116	149
222303: Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA.	43	46	56
222201: The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database.	23	28	31
222203: The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry.	23	28	31
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots.	65	64	96
292203: Number of safety analyses that are conducted using Medicare and Medicaid SafeRx* pilot.	25	21	23
222302: Percentage of television advertisements requiring submission reviewed within 45 days.	27	27	29
224201: Number of foreign and domestic high-risk human drug inspections.	185	192	231
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt.	64	72	90
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt.	41	44	54
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt.	97	106	131
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date.	23	28	36
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date.	22	27	35
234202: Number of registered domestic blood bank and biologics manufacturing inspections.	29	28	29
234203: Number of foreign and domestic human tissue establishment inspections.	16	16	19
242201: Review adverse event reports to detect animal product hazards early.	55	56	64
243201: Complete review and action on original New Animal Drug Applications (NADAs) & reactivations of such applications received during the fiscal year.	10	10	11

243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year.	3	3	4
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant.	9	9	11
244202: Number of domestic and foreign high risk animal drug and feed inspections.	33	38	47
244203: Number of targeted prohibited material Bovine Spongiform Encephalopathy (BSE) inspections.	40	34	38
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days.	50	48	52
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days.	18	18	19
253205: Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days.	110	106	115
252201: The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit.	29	28	30
252202: By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program.	43	42	44
254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters.	34	34	36
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections.	17	17	18
254201: Number of domestic and foreign Class II and Class III device inspections.	55	62	68
1.C Emphasize primary and preventive care linked with community prevention services			
1.D Reduce the growth of health care costs while promoting high-value, effective care			
1.E Ensure access to quality, culturally competent care for vulnerable populations			
1.F Promote the adoption of health information technology			
2 Advance Scientific Knowledge and Innovation			
2.A Accelerate the process of scientific discovery to improve patient care			
2.B Foster innovation at HHS to create shared solutions			
2.C Invest in the regulatory sciences to improve food and medical product safety	**$114**	**$114**	**$127**
214306: The average number of days to serotype priority pathogens in food (Screening Only).	5	5	8
252101: Number of technical analyses of postmarket device problems and performance.	20	20	26
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals.	20	19	22
262401: Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health.	0	29	28

263101: 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.	34	10	10
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products.	13	7	7
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies.	6	7	9
264101: Develop risk assessment methods and build biological dose-response models in support of food protection.	15	16	17
2.D Increase our understanding of what works in public health and human service practice			
3 Advance the Health, Safety and Well-Being of the American People			
3.A Ensure the safety, well-being, and healthy development of children and youth			
3.B Promote economic and social well-being for individuals, families and communities			
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults			
3.D Promote prevention and wellness	**$895**	**$1,060**	**$1,574**
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt.	21	22	23
214101: 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.	40	40	52
214207: The number of assessments/questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the US relative to public health outcomes.	23	23	39
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease.	29	29	34
214201: Number of prior notice import security reviews.	9	10	11
214202: Number of import food field exams.	112	114	187
214203: Number of Filer Evaluations.	36	37	53
214204: Number of examinations of FDA refused entries.	36	37	53
214205: Number of high risk food inspections.	269	271	366
214206: Maintain accreditation for ORA labs.	217	219	245
244301: The total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events.	4	4	5
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems.	28	31	33
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth.	10	40	92
280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients.	24	66	163
280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18.	24	71	108

280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use.	10	47	110
3.E Reduce the occurrence of infectious diseases	**$136**	**$137**	**$174**
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Campylobacter species.	34	34	44
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing Escherichia coli O157:H7.	34	34	44
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Listeria monocytogenes.	34	34	44
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Salmonella species.	0	0	0
212409: Decrease the rate of Salmonella Enteritidis (SE) illness in the population (cases per 100,000).	34	34	44
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies	**$58**	**$59**	**$66**
234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production.	38	37	44
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week).	20	21	21
4 Increase Efficiency, Transparency, and Accountability of HHS Programs			
4.A Ensure program integrity and responsible stewardship of resources			
4.B Fight fraud and work to eliminate improper payments			
4.C Use HHS data to improve the health and well-being of the American people			
4.D Improve HHS environmental, energy, and economic performance to promote sustainability			
5 Strengthen the Nation's Health and Human Service Infrastructure and Workforce			
5.A Invest in the HHS workforce to meet America's health and human services needs today and tomorrow			
5.B Ensure that the Nation's health care workforce can meet increased demands			
5.C Enhance the ability of the public health workforce to improve public health at home and abroad			
5.D Strengthen the Nation's human services workforce			
5.E Improve national, state, and local surveillance and epidemiology capacity	**$2**	**$3**	**$3**
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange.	2	3	3
Total	**$3,033**	**$3,290**	**$4,262**

Findings and Recommendations for FDA Evaluations Completed in FY 2010

1. Safety and Transparency of Pediatric Drug Trials

Purpose Medication adverse events in children often differ from those in adults, particularly those that are neuropsychiatric in nature. Although this information is provided to FDA, it may not be disseminated in reputable journals. Therefore, FDA decided to quantify the frequency and type of new safety information arising from studies performed under the auspices of the Pediatric Exclusivity Program, to describe the dissemination of these findings in the peer-reviewed literature and compare this with the FDA review, and to describe their effect on pediatric labeling.

Findings A total of 137 labeling changes were identified, with 8 selective serotonin reuptake inhibitors excluded from the review, for a total of 129 labeling changes evaluated.
Thirty-three products (26 percent) had pediatric safety information added to the labeling. Of these, 12 products had neuropsychiatric safety findings and 21 had other important safety findings. Only 16 of 33 of these trials (48 percent) were reported in the peer-reviewed literature; however, 7 of 16 focused on findings substantively different from those highlighted in the FDA reviews and labeling changes.

Labeling changes for pediatric use demonstrate that pediatric drug studies provide valuable and unique safety data that can guide the use of these drugs in children. Unfortunately, most of these articles are not published, and almost half of the published articles focus their attention away from the crucial safety data.

Recommendations

No recommendations were presented in the study.

2. Final Report to the FDA Science Board: Research, Support Programs, and Alignment with Regulatory Responsibilities of the Center for Food Safety and Applied Nutrition (CFSAN)

Purpose The review of CFSAN's science and research program was completed by the CFSAN Research Review Subcommittee of the FDA Science Board, with the results shared with the full FDA Science Board. The purpose of the review was to provide recommendations and observations to improve and strengthen CFSAN's science and research program to increase its capacity to support CFSAN's mission.

Findings Non-laboratory research, especially in areas where food science, nutrition, and consumer areas integrate and connect, appears to receive lower priority and attention. Applied research areas related to food science, food processing, food technology and nutritional science with regulatory implications also appear to receive less attention.

Risk, regulatory science, and consumer communication, including evaluation of the impact of communication on consumer understanding and behavior appear to lack the attention and resources required for the current challenges.

Increased connectivity, interaction, alignment, and visibility within CFSAN and with

other key external and professional organizations, at the national and international levels are essential, but insufficient within the current structure and focus.

Programmatic and regulatory outcomes related to CFSAN's role and responsibilities for research prioritization appear to lack insufficient focus.

Since 2002, the number of research FTEs at CFSAN has remained essentially the same despite the fact that the Center's responsibilities have continued to increase. Resources (number, depth, and subject matter expertise) are lacking at multiple levels, and will likely become more acute as the demand grows for expertise in areas of cutting-edge science.

There was insufficient support staffing in administrative and technical positions. The ratio of scientists to support staff was unbalanced and inefficient.

A separate review of the Office of Cosmetics should be done to address any outstanding issues and concerns (e.g., regulatory authority, framework).

Recommendations

- Create opportunities to meet with and participate in scientific exchanges with world experts from academia, other governmental organizations, and industry to consider topics relevant to the research agenda for CFSAN's regulatory science mission.
- Establish a formalized process for identifying and prioritizing emerging issues to include representatives from both internal and external stakeholders and include means to systematically capture and evaluate concerns that may arise from either scientific, regulatory, or societal challenges.
- Create a Board of External Scientific Counselors to provide rigorous, ongoing review of science with CFSAN.
- Develop a list of organizations against which to benchmark CFSAN's research planning process.
- Establish a competitive, nationwide extramural research program as part of the FDA budget request.
- Build capacity to advance and lead new regulatory science in those areas key to CFSAN's mission to include risk analysis, food safety, food science, food processing, nutrition, communication science, and regulatory science.

3. Risk Evaluation and Mitigation Strategies (REMS) Retrospective Regulatory Decision Analysis

Purpose The Food and Drug Administration Amendments Act of 2007 (FDAAA) provided the United States Food and Drug Administration (FDA) with additional requirements, authorities, and resources in both pre- and post-market drug safety, including authorities to require Risk Evaluation and Mitigation Strategies (REMS). REMS can include a Medication Guide,

Patient Package Insert, a communication plan, or other elements to assure safe use (ETASU). This study, conducted by Booz Allen Hamilton (BAH), focused on REMS with elements to assure safe use due to their complexity and the unique decision-making challenges they pose.

Findings Due to the small size of the study cohort, no conclusions were made about how these factors influenced FDA's decision making or how these factors changed over time.

Based on the analysis of FDA's review documents, the factors were grouped into six categories: 1) Specific adverse events, 2) Overall risk profile, 3) Ability to mitigate risk, 4) Efficacy and benefit, 5) Characteristics of the disease the product treats, and 6) Characteristics of the product.

In the process of analyzing the factors cited in the review documents, it was determined that the documents had not adequately captured all of the reviewers' considerations.

Recommendation

- Conduct further study to comprehensively identify reviewers' considerations in determining whether or not to implement a REMS with ETASU.

4. Office of Generic Drugs Backlog Analysis

Purpose Stakeholders have expressed concern about FDA's backlog of unreviewed Abbreviated New Drug Applications (ANDAs), which appears to have grown dramatically in the past several years.

Findings FDA's old tracking system, COMIS, had *undercounted* the number of applications in the backlog by failing to count as part of the backlog those applications that had pending reviews in disciplines other than chemistry.

FDA's new tracking system, DARRTS, *overcounted* the number of applications in the backlog, as it did not permit reviewers to issue "complete response" letters as they had in the past.

Recommendation

- To help improve the tracking of DARRTS applications in the future, replace the existing backlog measure with two new measures: 1) *Application Backlog*: the number of applications with unfinished reviews, and 2) *Review Backlog:* the number of unfinished reviews.

5. Office of Generic Drugs Consult Process

Purpose During the 2007 Generic Drug User Fee negotiations, industry sought goals for timelines to resolve Office of Generic Drugs (OGD) consults to Office of New Drugs (OND). The user fee negotiations were unsuccessful, and no timelines for consults were established. This study intended to study the OGD consults process and its performance to OND and other offices in preparation for new user fee negotiations.

Findings Depending on the level of difficultly and the priority given to the consults, completing a consult can take anywhere from a few days to several years.

Generally, consultative reviewers have been responsive to consult requests, particularly when Abbreviated New Drug Applications (ANDAs) are close to approval.

Median consult completion times range from 3 to 6 months. However, consults can slow the approval decision process when the need for a consult is recognized late in the review process, because the reviewer's workload is so great, and because the reviewer has conflicting priorities.

Recommendations

No recommendations were presented in the study.

6. Task Force on the Utilization of Science in Regulatory Decision Making – Preliminary Report and Recommendations

Purpose The Task Force on the Utilization of Science in Regulatory Decision Making was convened in September 2009 to review how the Center for Devices and Radiological Health (CDRH) uses science in its regulatory decision making process, and to make recommendations on how the Center can quickly incorporate new science —including evolving information, novel technologies, and new scientific methods — into its decision making, while also maintaining as much predictability as is practical.

Preliminary Findings

It is difficult for CDRH staff to efficiently and effectively obtain complete information about the risks and benefits of regulated products across the total product life cycle. This can lead to unnecessary delays and burdens during premarket review and make it challenging for CDRH to identify and respond to postmarket trends quickly and appropriately.

It is difficult for CDRH staff to share scientific knowledge across the Center, in part due to staffing limitations, and to tap meaningful external scientific expertise in a timely manner.

CDRH has not yet articulated a business process to be followed across the Center for evaluating new scientific information and determining when that information warrants certain types of action, such as a change in premarket evidentiary expectations.

When new scientific information changes CDRH's regulatory thinking, it is challenging for the Center to communicate the change and its basis to all affected parties in a meaningful and timely manner.

Preliminary Recommendations

- Take proactive steps to improve the quality of premarket data, particularly clinical data; address review workload challenges; and develop better data sources, methods, and tools for collecting and analyzing meaningful postmarket information.

- Conduct an assessment of CDRH's staffing needs to accomplish its mission-critical functions and prepare for anticipated scientific challenges.

- Take steps to improve knowledge management within CDRH and make better use of experts outside of the Center, in part by developing a web-based network of external experts, using social media technology.

- Establish a CDRH Science Council, comprised of experienced employees and managers and under the direction of the Deputy Center Director for Science, to help ensure consistency across the Center in responding to new scientific information.

- Make use of more rapid tools for broad communication on regulatory matters in addition to continuing ongoing efforts to streamline guidance development.

- Adopt a uniform template and terminology for such letters, including clear and consistent language to indicate that CDRH has changed its regulatory expectations, the general nature of the change, and the rationale for the change.

- Continue ongoing efforts to increase the transparency of decision making processes and rationale, in order to clarify the basis for any action CDRH takes in response to new scientific information.

7. 510(k) Premarket Notifications Working Group – Preliminary Report and Recommendations

Purpose The 510(k) Working Group was convened in September 2009 as part of a two-pronged, comprehensive assessment of the 510(k) process. The other component of this assessment is an ongoing independent study by the Institute of Medicine (IOM) that is expected to conclude in the summer of 2011. The 510(k) Working Group was charged to evaluate the 510(k) program and explore actions the Center for Devices and Radiological Health (CDRH) could take to strengthen the program and improve the consistency of its decision making, with a principal focus on actions the Center could take in the short term under its existing statutory authority.

Preliminary Findings

Key terms in the statutory definition of "substantial equivalence" have not been consistently interpreted by CDRH. In particular, there is insufficient clarity about what constitutes the same versus a new "intended use," and about when "different technological characteristics" raise "different questions of safety and effectiveness." Ambiguity at these critical decision points, at times, has contributed to inconsistency in CDRH's 510(k) decision making.

While the concept of "substantial equivalence to a predicate" is generally reasonable, CDRH's application of this standard has, in certain cases, raised concerns. Concerns have been raised that current FDA regulations and practice may allow for some types of predicate comparisons that are insufficient to *consistently* provide such assurance, including the use of predicates that have been withdrawn from the market due to issues of safety or effectiveness and the use of so-called "split predicates," a term that refers to using one predicate as the

basis for a comparison with respect to "intended use" and another predicate as the basis for a comparison with respect to "technological characteristics."

In general, most instances where concerns were raised by industry and CDRH staff about problems with the 510(k) program involved the small subset of devices for which staff requested clinical information, either to answer questions appropriate for a substantial equivalence determination. Also involved concerns sometimes in cases where the sponsor had no advance notice that such information would be needed or to answer questions more appropriate for the de novo classification process. Both scenarios have contributed to less predictability and longer time-to-decision in the 510(k) program.

CDRH has a need for more robust systems and tools for quality assurance in the 510(k) program. Quality and consistency depend on a highly qualified, well-trained, and well-supported review staff, and on appropriate oversight.

There are insufficient tools and metrics in place to assess the consistency of decision making across the 510(k) program, and to track the program's public health impact quantitatively. Although CDRH collects information on device performance in the postmarket setting, important limitations, including the inability to consistently link postmarket events to specific 510(k)s, make this information, in isolation, an unreliable measure of program effectiveness.

Preliminary Recommendations

- Clearly define what constitutes the same versus a new "intended use," and about when "different technological characteristics" raise "different questions of safety and effectiveness" in guidance and training for review staff and industry.

- Consider taking steps, through guidance, to set forth factors regarding when a device should not be used as a predicate. Such factors should be well-reasoned, well-supported, and established with input from a range of stakeholders, and unintended consequences should be carefully considered.

- Explore the possibility of explicitly disallowing the use of "split predicates."

- Explore the possibility of developing guidance to define, as a heuristic, a subset of class II devices called "class IIb" devices, for which clinical information, manufacturing information, or, potentially, additional evaluation in the postmarket setting, would typically be necessary to support a substantial equivalence determination.

- Enhance CDRH's support for training and professional development for review staff.

- Develop program metrics and better systems for continuous monitoring of 510(k) program performance and effectiveness, in part through the oversight of a new CDRH Science Council comprised of experienced reviewers and managers, under the direction of the Deputy Center Director for Science.

GAO High Risk List Items

Issue - Transforming Federal Oversight of Food Safety

According to the recent CDC study, each year, about 48 million people contract a food borne illness in the United States; about 128,000 require hospitalization; and about 3,000 die. GAO has stated that the fragmented U.S. system of oversight has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.

Five Major GAO Concerns

1. Improving legislative authorities
2. Streamlining regulatory jurisdiction with other agencies
3. Improving recall implementation
4. Expanding inspectional capacity
5. Improving interagency coordination

FDA Actions:

1. Improving legislative authorities
    a. Food Safety Modernization Act of 2010 was signed into law on January 4, 2011.
2. Streamlining Jurisdiction
    a. President's Food Safety Working Group
    b. FDA & National Oceanic and Atmospheric Administration (NOAA) have Memorandum of Understanding (MOU)
    c. Ongoing work with USDA
        i. Better coordination on eggs
3. Improving recall implementation
    a. New legislation provides mandatory authority
    b. Reportable Food Registry in effect
    c. www.foodsafety.gov with national reach for consumers
    d. Petnet system for pet recalls under development; pet widget launched
    e. Transparency proposal
4. Expanding Inspectional Capacity
    a. Funding increases permitted hiring more than 700 investigators between FY 2007 and FY 2009, and an additional 274 in FY 2010. Food inspections now increasing.
    b. Risk-based inspectional plan
    c. PREDICT for imports – deployed in Los Angeles, New York, Seattle and San Francisco – and now starting to deploy further after delays
    d. National egg inspection plan: 600 largest egg facilities by end of CY 2011
    e. Partnerships – significant work on integrated food safety system with states and localities
5. Improving Interagency Coordination
    a. Food Safety Working Group
    b. Coordinated incident response team
        i. Example: egg recall
    c. Federal, state and local system planning

More information about specific milestones the agency will accomplish to achieve this goal can be found here:

http://www.whitehouse.gov/omb/expectmore/issue_summary/issue_31.html
http://www.whitehouse.gov/omb/expectmore/issue_summary/issueDetailedPlan_31.pdf

Issue – Protecting Public Health through Enhanced Oversight of Medical Products

The Food and Drug Administration (FDA) ensures the safety and effectiveness of medical products– drugs, biologics, and medical devices– marketed in the United States, whether they are manufactured in domestic or foreign establishments. The agency's responsibilities begin long before a product is brought to market and continue after a product's approval. In recent years FDA's responsibilities have grown with the passage of laws containing new requirements, the complexity of products submitted to FDA for approval, and the globalization of the medical products industry. Many, including FDA's own Science Board and the National Academy of Sciences' Institute of Medicine have questioned FDA's ability to continue to adequately fulfill its mission.

Six Major GAO Concerns

1. Inspecting foreign manufacturers
2. Monitoring postmarket safety
3. Reviewing promotional materials for medical products
4. Overseeing clinical trials
5. Ensuring that high-risk types of medical devices are approved through the most stringent premarket review process
6. Establishing basis for assessing resource needs

FDA Actions

1. Inspecting foreign manufacturers
   - Improving data systems: electronic registration of device and drug manufacturers
   - Increased coordination and data sharing with foreign regulatory authorities
   - New dedicated foreign inspection staff (2/09)
   - Voluntary audit submission
   - Policy analysis on supply chain weaknesses
   - 2010 GAO report on foreign drug inspections acknowledges that FDA has increased its rate of foreign inspections and improved the data systems it uses to manage its foreign inspection program
2. Monitoring Postmarket Safety
   - Transformed system of monitoring postmarket commitments
   - Under Food and Drug Administration Amendments Act of 2007, FDA can now require postmarket studies
   - Sentinel system expanding
   - Major external review of FDA systems for adverse event reports and epidemiological analyses planned
   - Institute of Medicine (IOM) report on using data for postmarket safety decision-making
3. Reviewing promotional materials for medical products
   - New tracking of responsiveness to advance submissions
   - Outreach to help professionals report false or misleading promotions
     - "Bad Ad Campaign"
   - Cross-agency review of advertising and promotion activities
4. Overseeing clinical trials
   - Revamped debarment and disqualification procedures
   - Number of debarment actions has risen considerably and times for resolving both disqualification and debarment actions have been reduced significantly
   - Series of new guidances and regulations to strengthen FDA oversight
   - Clinical Trials Transformation Initiative underway
   - New Good Clinical Practice coordination effort with European agency (EMEA) 9/09

5. High Risk Medical Devices
    - This was a FY 2010 strategic priority for Center for Devices and Radiological Health
    - August 25, 2010 proposed rule will require the filing of a Premarket Approval notice of completion of a product development protocol for four class III preamendments device types identified by GAO
    - This proposed rule represents the most recent of FDA's efforts to address the 25 device types identified in GAO's 2009 report
6. Assessing Resource Needs
    - Booz Allen just completed resource estimation study that addresses GAO-identified gaps
    - FDA reviewing results of study and will be able to brief GAO at a later time

FDA Assessment

- Major challenges still facing food and medical product safety
- Substantial initiatives underway to address gaps
- Progress in many areas

More information about specific milestones the agency will accomplish to achieve this goal can be found here:

http://www.fda.gov/downloads/Safety/SafetyofSpecificProducts/UCM184049.pdf

http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/SafetyFirst/default.htm

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm

Discontinued Goal Table

Measure	FY	Target	Result
Center for Drug Evaluation and Research			
223207: 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. *(Outcome)*	*2007*	514 days	392 days (Target Met)
	2006	N/A	456 days (Historical Actual)
	2005	N/A	639 days (Historical Actual)
223208: 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. *(Outcome)*	*2007*	16.4 months	19.8 months (Target Not Met)
	2006	N/A	17.4 months (Historical Actual)
	2005	N/A	17.8 months (Historical Actual)
National Center for Toxicological Research			
264201: Develop standard biomarkers to establish risk measures for FDA-regulated products. (Output)	*2012*	N/A	N/A
	2011	N/A	N/A
	2010	1) MicroArray Quality Control (MAQC)—develop draft guidelines for applying microarray standards 2) Identify gender-specific biomarkers that enable improved risk/benefit decisions for treatments	1) MAQC-II completed, findings published, and NCTR is currently engaging the scientific community to develop guidelines to ensure the reproducibility of genomic research (Target Met) 2) Identified 1,640 different sex-expressed genes, all potential sex-specific biomarkers for improved risk/benefit decisions. (Target Met)
	2009	Evaluate biological effects of manganese nanoparticles	Publish research paper showing manganese, copper, and silver nanoparticles altered 11 genes associated with neuro-degeneration (Target Met)
	2008	Develop microarray data standards	Submitted 15 manuscripts on the MAQC-II results and published four manuscripts (Target Met)
	2007	Conduct research on carbon nanomaterials methods and ketamine	1) Initiated ketamine-induced neurotoxicity in primate model (Target Met) 2) Developed synthesis methods for nanotubes (Target Met)

Measure	FY	Target	Result
Office of the Commissioner			
291403: Number of Business Process Improvement Projects supported through start of Implementation. *(Output)*	*2012*	N/A	N/A
	2011	N/A	N/A
	2010	15	15 (Target Met)
	2009	N/A	13 (Historical Baseline)
	2008	N/A	10 (Historical Baseline)
	2007	N/A	N/A