Foods Performance Goals

Long Term Goal: Increase access to safe and effective veterinary products, and to safe and nutritious food products, including products for unmet animal and human health needs.

Measure	FY	Target	Result
1. Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (11001) (output) New Measure for FY 2007: Complete review and action on the safety evaluation of 50% of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. Old Measure from FY 2002 to FY 2006: Percentage of food and color additive petitions reviewed and acted on within 360 days of receipt. [Starting in FY 2007, the measure will include indirect food additives which includes food contact substances which were, prior to FY 2007, processed under FDA's Food Contact Substances Notification Program. The Food Contact Substance Notification Program will be discontinued in FY 2007 and will result in the statutorily mandated safety review for food contact substances having to be submitted through the rulemaking process for food and color additives.]	*2007*	50%	10/08
	2006	70%	10/07
	2005	75%	10/06
	2004	75%	89% of 9
	2003	65%	80% of 5
	2002	60%	75% of 8

Data Source: CFSAN's electronic workflow system

Data Validation: The Food Additives Regulatory Management (FARM) Project's electronic information management system is designed to support electronic processing, review, maintenance, and reporting for food ingredient submissions. This includes management of food and color additive petitions, Food Contact Notifications (FCNs) (until FY 2007), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations, by providing modern electronic information management tools necessary for the food ingredient reviewers and managers to maximize their productivity. FARM allows reviewers to spend more time reviewing submissions, since they spend less time searching for, processing, and sharing information. FARM is currently able to support industry electronic submission of food ingredient submissions and correspondence in a consistent/standard electronic format further improving efficiencies for industry and FDA. Freedom of Information (FOI) requests and other communications disclosing information to industry and consumers are done electronically through the FARM System. CFSAN's electronic workflow system within FARM provides real-time tracking information on the progress, status, and timeliness of premarket submissions as well as the capability to generate ad-hoc reports including information and statistics on all significant events during the review process.

Cross Reference: This performance measures support HHS Strategic Goal 2.

Long Term Goal: Increase ability of consumers to make food choices and to use food handling practices associated with health benefits and reduced risk of food-borne and chronic disease.

Measure	FY	Target	Result
2. New Measure for FY 07: Percentage of the approximately 3,000 eligible state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft *Voluntary National Retail Food Regulatory Program Standards* by October 1, 2007 and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards by October 1, 2007. (11010) (outcome) Old Measure from FY 02 to FY 06: Increase risk management strategies and communication to government,	*2007*	9% (270)/ 26%	1/08
	2006	49 out of 56 states & territories / 84%	1/07
	2005	49 States/	48 of out 56 states &

industry and consumers in order to ensure the safety of the nation's food supply by increasing the percentage of the U.S. population that will live in states or territories that have adopted the Food Code.		84%	territories (45 states & 3 territories)/79%
	2004	43 states / 83%	44 states/75%
	2003	42 states	43
	2002	28 states	40
3. Increase consumer understanding of diet-disease relationships (dietary fats and CHD) Long Term Measure: Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease.	*2007*	45%	1/08
	2005	Baseline	32%
Long Term Measure: Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease.	*2007*	81%	1/08
	2005	Baseline	74%
Long Term Measure: Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease.	*2007*	36%	1/08
	2005	Baseline	31%
Data Source: Listing of Jurisdictions Enrolled in the draft Voluntary National Retail Food Regulatory Program Standards: http://www.cfsan.fda.gov/~dms/ret-jur.html. This listing identifies regulatory agencies that have enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments; and develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff who compile the information and maintain the listing.			
Data Validation: Food Code adoption is tracked through the contract with the Association of Food and Drug Officials (AFDO) and measured as a percent of the U.S. Population. A listing of jurisdictions enrolled in the draft voluntary national retail food regulatory program standards can be found on the CFSAN web page at http://www.cfsan.fda.gov/~dms/ret-jur.html. This listing identifies regulatory agencies that have enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments; and develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff who compile the information and maintain the listing.			
Cross Reference: This performance measures support HHS Strategic Goal 2. This goal supports Healthy People 2010 Objectives.			

Long Term Goal: Prevent harm from regulated products by increasing the likelihood of detection and interception of substandard manufacturing processes and products, through efficient and effective risk targeting, external partnering and collaboration.

Measure	FY	Target	Result
4. Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk. (11040) (output)	*2007*	60,000	01/08
	2006	45,000	01/07
	2005	38,000	86,187
	2004	NA	33,111
	2003	NA	NA
	2002	NA	NA
5. Perform import food field exams on products with suspect histories. (11036) (output)	*2007*	71,000	01/08
	2006	73,376	01/07
	2005	60,000	84,997
	2004	60,000	70,926
	2003	48,000	78,659
	2002	24,000	34,447
6. Perform Filer Evaluations of import filers. (19015)	*2007*	1,000	01/08

(output)	*2006*	965	01/07
	2005	1,000	1,407
	2004	1,000	1,745
	2003	NA	NA
	2002	NA	NA
7. Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. (19016) (output)	*2007*	3,000	01/08
	2006	2,992	01/07
	2005	2,000	5,655
	2004	2,000	4,905
	2003	NA	NA
	2002	NA	NA
8. Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (output)	*2007*	5,700	01/08
	2006	5,963	01/07
	2005	6,490	7,568
	2004	6,840	7,597
	2003	6,650	7,363
	2002	6,650	7,442
9. Expand federal/ state/ local involvement in FDA's eLEXNET system by having laboratories submit data in the system; **and,** beginning in FY 2007, expand the capability of the system to provide automated notification of potential events. (19013) (outcome) FY 2007 Measure: The number of analytes and select agents routinely tested and evaluated by eLEXNET pattern-detection algorithms such that departures from normal trends of detection trigger notifications to FDA food safety and security officials.	*2007*	5 analytes and 5 select agents	01/08
	2006	105 labs	01/07
	2005	95 labs	95
	2004	79 labs	79
	2003	54 labs	55
	2002	NA	29
10. Establish and maintain a quality system in the ORA Field laboratories which meets the requirements of ISSO 17025 (American Society for Crime Laboratory Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation.) (11041) (outcome)	*2007*	Maintain accreditation for 13 labs	01/08
	2006	Achieve and maintain accreditation for 13 labs	01/07
	2005	Achieve and maintain accreditation for 6 labs	Achieved accreditation for 5 labs; maintained accreditation for 1 lab
	2004	NA	1
11. Increase laboratory surge capacity in the event of terrorist attack on the food supply.	Baseline and target under development. Expected completion - Sept 06		

Data Source: Field Data Systems.

Data Validation: 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.

Cross Reference: These performance measures support HHS Strategic Goal 2. Performance measure 7 supports Healthy People 2010 Objectives.

1. **Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (Measure: Percentage of food and color additive petitions that were reviewed and acted on within 360 days of receipt.)** (11001)

- **Context of Goal**: In this goal, performance is defined in terms of a review of all parts of a petition. This review would be followed by issuance of a "not approvable" letter, or by publication of a response in the Federal Register, if appropriate.

  This goal refers to completion of the safety evaluation of food and color additive petitions, including those for food contact substances – starting in FY 2007. This includes a review of the information in a filed petition, and one of two conclusions reached: either the petition does not support the requested action and a letter to that effect is transmitted to the petitioner with an explanation of why we reached the conclusion; or based on the review, we are prepared to recommend to the agency officials authorized to sign an order, that the use of the additive be approved (or denied), and communication of this information to the petitioner. It does not include the time to get the order and accompanying rationale for our decision reviewed, signed, and published in the Federal Register.

  Almost uniquely among products FDA regulates, food and color additives are not permitted to be marketed by means of correspondence from the agency to the petitioner . Rather, the statute provides that the agency must, using formal rulemaking, publish in the Federal Register an order laying out the conditions by which anyone (not just the petitioner) may use a food or color additive, or an order denying the request to use a food or color additive, with an explanation in each case of how we came to our conclusions. (Alternatively, a petitioner may choose to withdraw a petition. In that case, the Agency publishes a notice of the withdrawal in the Federal Register). The law also provides a variety of administrative remedies to those who object to FDA's order to permit or deny use of a food or color additive, including stays and administrative hearings. (For example, in the case of a color additive order, any objection automatically stays the regulation). Although objections are not routine, when they occur, they necessitate further "action" on the part of the agency. However, we, and our stakeholders, have considered publication of an order in the Federal Register as "final action."

  We have used the time to complete the evaluation of a petition as the goal because it is relatively unambiguous and measurable. It is also the part of the entire process that is most within the control of the organizations responsible for administering the food and color additive petition review process and thus most amenable to improvement by those organizations. Publishing an order in the Federal Register is subject to factors outside the agency's control. (For example, the statute requires public notice of filing of food and color additive petitions; comments to such filing, which must be reviewed and possibly responded to, may be submitted at any time prior to publication.) Completion of the

safety evaluation is also the step that is most analogous to final action in the case of the dietary supplement process. Because stakeholders are most interested in publication of a final order, we recognize the need to make all involved parties accountable for reducing the total time to publication as much as possible.

The 360-day time frame used in this goal is not the same as the statutory time frame (i.e., 90 days, extendable to 180 days). It is widely recognized that meeting the current statutory time frame is an unrealistic goal for all food and color additive petitions, especially the more complex ones. This was acknowledged in a report from a June 1995 House hearing. Additionally FDA recommended a change from the statutory time frame to '360 days of receipt' in a testimony before the House Committee on Government Reform and Oversight in 1996.

Subsequently, the Food and Drug Administration Modernization Act (FDAMA) established a notification process for food contact substances. The premarket notification program began to operate fully on January 18, 2000. With the full implementation of the premarket notification program, many of the simpler food additive petitions that were completed within 360 days were filed under the notification program, thus decreasing the workload for this goal. While the remaining petitions were in general more complex and took more time to review, once the notification and the recent improvements to the petition review process were well established, FDA's performance on this goal increased substantially toward full performance. The FY 2007 strategic redeployment offsets to fund higher FDA priorities will affect our premarket program by increasing the review time of incoming petitions. The food contact substances notification program will be discontinued in FY 2007. Statutorily mandated safety review for food contact substances will be submitted through the process for food and color additives, which can be a lengthier process.

- **Performance:** As noted, Congress passed, under the FDA Modernization Act of 1997, and implemented in FY 2000, the Food Contact Substance Premarket Notification Program. As a result, we have received fewer petitions than in previous years. Those that we do receive, however, are for direct food additive uses of greater potential public health significance, which generally take more time and effort per petition to complete. Nevertheless, improvements in the petition review process have resulted in the foods program meeting or exceeding our review goals in recent years.

  Due to program changes in FY 2007, our performance targets for the petition receipt cohort of 2006 (which will be under review in 2007) and for the petition receipt cohort of 2007 have been adjusted

2. **Percentage of the approximately 3,000 eligible state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards by October 1, 2007 and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards by October 1, 2007.** (11010)

- **Context of Goal:** FDA is the lead federal agency in a cooperative effort between federal, state, local and tribal regulatory agencies to prevent foodborne illness associated with foods prepared and sold in retail food establishments. State and local governments provide the largest portion of the program's resources and exercise primary regulatory control over the retail segment of the food industry. FDA's ability to leverage its resources and to influence and guide the much larger investment of state, local and tribal programs represents an effective public health partnership.

  For this cooperative endeavor to remain effective in preventing foodborne illness, many aspects of the retail food program must evolve to meet the realities of international trade, new technologies, emerging pathogens, and changing consumer demographics. Budget cuts and competition for funding are forcing state and local governments to re-evaluate their retail food protection programs. In fact, some have even suggested discontinuing these programs.

  It is imperative that FDA find new ways to ensure that the resources expended for retail food safety are directed toward activities that produce the greatest degree of consumer protection. There are approximately 3,000 federal, state, local and tribal regulatory agencies with the direct responsibility for monitoring the one million plus retail establishments in the country.[1]

  It is virtually impossible to achieve the goal of reducing the factors that cause foodborne illness without a mechanism that promotes uniformity and continuous improvement among retail food programs nationwide. Adoption of the Food Code represents a successful federal/state/local/tribal partnership in improving food safety. However, adoption without instituting meaningful foodborne illness interventions and a strong regulatory program infrastructure is not effective. With the current initiative to reduce the occurrence of risk factors known to contribute to foodborne illness, the primary focus is appropriately shifting to measures of success beyond Food Code adoption. These include tracking risk factor occurrences over time by comparing baseline improvements in inspection data and follow-up inspection findings; use of risk-based inspections; applying HACCP principles; and uniformly implementing Food Code provisions.

  FDA Regional Specialists are the front line Agency contacts for the Program Standards and work with jurisdictions to make them aware of the standards and to provide technical assistance. FDA promotes the Program Standards by including it in National and regional presentations about the retail program.

- **Performance:** The FDA Food Code is the foundational document of the FDA National Retail Food Program and represents the Agency's policies and best science-based advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service. The Food Code has long served as the model upon which most state, local and tribal agencies have based their regulations and ordinances for retail

[1] The National Restaurant Association 2005 Restaurant Industry Fact Sheet: http://www.restaurant.org/research/ind_glance.cfm and the Food Marketing Institute 2004 Retail Food Store (grocery) information at http://www.fmi.org/facts_figs/keyfacts/stores.htm

food safety and sanitation. Having a regulatory foundation in place such as the Food Code is a key component of an even larger FDA National Retail Team effort aimed at decreasing foodborne illness, the *Voluntary National Retail Food Regulatory Program Standards*. In FY 2004 - 2005, FDA assisted state programs and provided oversight in implementing the Program Standards. FDA continues to encourage jurisdictions to enroll in the Program Standards while continuing to provide support and guidance to those jurisdictions already enrolled. FDA auditing of those enrolled in the Program Standards will be in accordance with the Standards protocol. For FY 2005 - 2006, work with the Program Standards includes technical assistance and consultation to State and local jurisdictions performing self-assessments and developing strategic work plans using the Program Standards as the foundation for enhancing the effectiveness of their retail food program.

The draft Voluntary National Retail Food Regulatory Program Standards provides a roadmap for the regulatory agencies to focus resources on the reduction of the risk factors most commonly associated with foodborne illness at the retail level. The Program Standards define nine essential elements of an effective regulatory program for retail food establishments, establish basic quality control criteria for each element, and provide a means of recognition for those state, local, and tribal regulatory programs that meet the Standards. The nine program elements addressed by the Program Standards are:

1. Regulatory Foundation (substantially equivalent to the FDA *Food Code*)
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Foodborne Illness Investigation and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

Enrollment of regulatory agencies in the draft Voluntary National Retail Food Regulatory Program Standards will be used as a performance measure. Enrollment is voluntary and constitutes a commitment by a jurisdiction to embark on a continuous improvement process for program management that focuses on the reduction of risk factors known to cause or contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

Jurisdictions participating in the Program Standards also commit to completing the FDA National Registry Report. Data contained in this report will be used to update the FDA *National Registry of Retail Food Protection Programs*, a listing of retail food safety programs that have voluntarily enrolled as participants in the Program Standards. Participating jurisdictions also complete a *Release and agreement with Permission to Publish in the National Registry* form that states their agreement to have the *Self-Assessment* and/or *Verification Audit* findings published in the National Registry.

Concurrently, FDA continues to encourage adoption of the Food Code by State and territorial agencies. Beginning in FY 2004, the FDA tracked the percentage of the U.S. population that resides in States and territories that have adopted the Food Code, either by reference or by incorporating equivalent provisions into their relevant statutes and regulations. Prior to FY 2003, the FDA tracked the number of States and territories in which a primary retail food regulatory agency had adopted the Food Code. We recognize the importance of adoption of the Food Code by all food safety agencies at the federal, state, local and tribal levels as a means to establish a sound regulatory foundation and legal framework for uniformity in achieving the prevention and reduction of foodborne illness and death from food produced at the retail level. As of December 2005, the current enrollment in the Program Standards was 185 jurisdictions. Food Code adoption levels as of August 2005 are at 45 states and 3 territories for a total of 48 of 56 states and territories (86%) that have adopted codes patterned after the 1993, '95, '97, '99, or 2001 versions of the Food Code. It should be noted that 56 states and territories cover a total of 50 states and 6 territories. Those 48 states and territories represent 79% of the US population. We missed our goal of having 49 states/territories adopt the Food Code by one because changes in the state legislation did not take place in time for a change within fiscal year 2005.

3. Increase consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease (CHD), the leading cause of death in the U.S. and one that disproportionately affects African-Americans and Hispanics.

- **Context of Goal:** Coronary Heart Disease (CHD) is the leading cause of death among Americans, accounting for more than 1 in 5 deaths annually. CHD is also the leading cause of premature, permanent disability in the labor force. Dietary factors, especially consumption of some fats, play a significant role in CHD risk.

  One modifiable factor that is important for reducing mortality and morbidity associated with heart disease is consumer understanding of the consequences of dietary choices with respect to CHD. Increased understanding will strengthen motivation to adopt and maintain recommended healthy dietary behavior and to make informed dietary choices.

  The target is directly in line with several of the Department's priorities and strategic goals. First, improving the American diet through informed choice about fats that increase or reduce the risk of heart disease is one of several important steps toward reducing the enormous morbidity and mortality burden of CHD. This burden is borne disproportionately by minority populations, including African-Americans, Hispanics, and Native Americans. As the leading cause of death and a significant cause of illness and disability, CHD also imposes substantial costs on the U.S. health care system.

- **Performance:** Baseline data for FY 2005 developed. Target year for accomplishment FY 2007.

4. **Perform prior notice import security reviews on food and animal feed line entries considered to be at high risk for bioterrorism and/or to present the potential of a significant health risk.** (11040)

- **Context of Goal:** FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. By FY 2007, FDA expects that the PNC will have hired a permanent staff of Reviewers and Watch Commanders that will have achieved the training and gained the experience necessary to expand its scope of targeting to include additional threat parameters.

  The PNC targets food and animal feed commodities that have been identified as high-risk based on either threat assessments that have been conducted or the receipt of specific intelligence indicating the items may cause death, illness, or serious injury due to terrorism or other food related emergencies. The PNC also utilizes the import field exams and filer evaluations by receiving feedback from the Investigators who conduct them and subsequently assessing those individuals or firms that continuously violate the prior notice regulations and the provisions set forth in the Bioterrorism Act, and further targeting those that instigate bioterrorism concerns. Strategies used to ensure effective targeting include:
  - Intelligence regarding countries at risk for terrorism;
  - Intelligence regarding commodities susceptible to, or exploited by, terrorism;
  - Intelligence specific to shipment or shipping entities;
  - Information gleaned from Foreign and Domestic Establishment Inspection Reports that identify security breaches;
  - Sample collection and analysis for counterterrorism;
  - Prior Notice discrepancies reported during import field exams; and,
  - Filer evaluation field audits.

  FDA anticipates that the measures that it uses to assess its success in monitoring the safety and security of imported products will continuously evolve as trade practices and information about risks change.

- **Performance:** In FY 2005, FDA exceeded this goal of 38,000 by conducting 86,187 import security reviews. FDA collaborated with Customs and Border Protection to direct field personnel to hold and examine five suspect shipments of imported food; refused 141 lines of food for prior notice violations; responded to 49,649 phone and e-mail inquiries; and conducted 86,187 intensive security reviews of Prior Notice submissions out of 8,705,847 in order to intercept contaminated products before they entered the food supply.

5. **Perform import food field exams on products with suspect histories.** (19014)

- **Context of Goal:** The events of September 11, 2001 heightened the nation's awareness of security and placed a renewed emphasis on ensuring the safety of the nation's food supply. Import food field exams, along with laboratory analyses, were FDA's major tool to physically monitor import entries prior to the enactment of the Bioterrorism Act of 2002. The role of the import food field exam and the number conducted continues to evolve as trade practices and information about risks change.

  A field examination is a visual examination of the product to determine whether the product is in compliance with FDA requirements and involves actual physical examination of the product for admissibility factors such as storage or in-transit damage, inadequate refrigeration, rodent or insect activity, and lead in dinnerware, odor and label compliance. A field exam cannot be used to test for microbiological or chemical contamination and must be supplemented with other activities.

  The volume of imported food shipments has been rising steadily in recent years, and this trend is likely to continue. FDA-regulated imports have been growing at a 19 percent annual rate. FDA anticipates approximately 12 million line entries of imported food in FY 2007 within a total of over 19 million lines of FDA regulated entries. To manage this ever-increasing volume, FDA uses risk management strategies to achieve the greatest food protection with available resources.

  FDA applies strategies that combine visual inspection for apparent labeling and other visual defects, with risk-based targeting, and selective laboratory analysis to detect chemical and microbiological hazards. FDA cannot rely solely on physical examination to reduce the potential risks from imported foods. Currently, a significant effort is underway to develop appropriate knowledge-based approaches that will give the Agency assurance that it is addressing the most serious risks.

  It is important to recognize that FDA is transforming how it regulates imports by using risk- based information technology to target physical exams and identify the need to collect samples for laboratory analysis. By focusing on risk, FDA works more efficiently to target products. An additional information technology system currently under development is an artificial intelligence tool. This new data mining tool is a risk-based automated system for screening import entries. This system will conduct continuous data mining of FDA's analytical and inspectional data and use existing business rules, multiple data sources, and artificial intelligence to identify products posing the greatest security and safety risk. The prototype will produce two risk scores for every food entry line, one for security and one for safety concerns, which will be used to immediately identify shipments that may be of high risk.

  FDA intends to expand the import data mining prototype to apply risk-based targeting of all types of regulated imports. These risk scores will help FDA target imported products for Agency action. The prototype will greatly enhance the electronic review process already in place at FDA. Entry review decisions made by FDA at border locations will

be greatly enhanced by targeting products that present safety risks based on historical information and current events. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that we conduct 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.

- **Performance:** In FY 2005, FDA exceeded this goal of 60,000 by completing 84,997 field examinations of imported food lines.

6. Perform Filer Evaluations of import filers. (19015)

- **Context of Goal:** 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 maintains an electronic interface with the Department of Homeland Security's Bureau of Customs and Border Protection (CBP), the Automated Commercial System (ACS). After successfully completing an initial evaluation for participation in OASIS, filers may submit import data electronically to FDA through the Automated Broker Interface (ABI) and ACS. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen entry data transmitted by filers to perform various regulatory and service functions. Such screening may assess whether FDA import personnel should review an entry further. The FDA uses OASIS to determine whether an entry should be reviewed "on screen," further supported by entry documentation; physically inspected; sampled; or permitted to proceed into domestic commerce without further evaluation. FDA can use the data in the entry system to track an imported item that negatively affected the public health.

  At a minimum, this procedure requires filers who fail an evaluation to implement an FDA-approved Corrective Action Plan (CAP) and to pass a tightened evaluation (more stringent criteria) before obtaining, maintaining or regaining the privilege of paperless filing. This protects public health by ensuring quality improvement and reporting compliance for imported articles that FDA regulates. It also ensures FDA is notified when articles appear to be violative that have previously been offered for entry.

  ORA continues to develop the policies and practices that govern monitoring filers. Expanded import activities supporting security assignments increase FDA's understanding of the problems associated with appropriate monitoring of Filer activities. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices.

- **Performance:** In FY 2005, FDA exceeded this goal of 1,000 by performing 1,407 filer evaluations. This goal is an agency-wide goal and performance data will include activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program. This goal is shown in the Foods section for illustrative purposes.

7. **Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported.** (19016)

- **Context of Goal:** Because of safety and security concerns it is important for FDA to be sure that these goods do not slip into domestic commerce but are in fact sent out of the country. FDA monitors this activity in conjunction with Customs in a category of action described as "follow up to refusals."

  If a product is refused admission, it must be destroyed or exported under Customs' supervision within 90 days of receiving the Notice of Refusal. FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics, and that responsibility exists until the violative article is either destroyed or exported. 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 ensure 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 product has been destroyed or exported.

- **Performance:** In FY 2005, FDA exceeded this goal of 2,000 by performing 5,655 examinations of FDA refused entries as they were delivered for exportation to ensure that the articles refused by FDA were exported. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program. This goal is shown in the Foods section for illustrative purposes.

8. **Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities with the objective of reducing the health risks associated with food, cosmetics and dietary supplements products.** (11020)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing,

we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about food safety risks.

FDA applies a risk-based strategy to the inspection of the food establishments in its inventory. High-risk foods refer to those that may contain hazards that have a high potential for causing serious adverse health consequences that would result in FDA Class I recalls. These include foods that may contain bacterial or viral pathogens, biological toxins, allergenic substances, bovine spongiform encephalopathy (BSE) infective materials, as well as foods such as infant formula and medical foods due to a potential hazard from the omission or improper fortification of the nutritive ingredients.

High-risk establishments are manufacturers, packers and repackers of foods that include modified atmosphere packaged products; acidified and low acid canned foods; seafood; custard filled bakery products; soft, semi-soft, soft ripened cheese and cheese products; unpasteurized juices; sprouts ready-to-eat; fresh fruits and vegetables and processed fruits and vegetables; shell eggs; sandwiches; prepared salads; infant formula; and medical foods. Additional high-risk products identified in recent years include products whose formulations do not include an allergenic ingredient but, because the product is made in a firm that also makes allergen-containing foods, may inadvertently contain an allergen which is not declared on the label. Common allergenic substances include milk, eggs, fish, crustaceans, tree nuts, peanuts or soybeans. Another class of high risk products is dietary supplements that may contain prohibited cattle-derived ingredients.

As part of FDA's risk-based strategy, FDA recently completed a risk assessment of 23 types of ready-to-eat foods for listeriosis from the pathogen *Listeria monocytogenes*. This assessment ranked risk into categories from very high to low dependant on estimated risk per serving and on an annual basis. There are also foods such as shell eggs and certain produce items that are not ready-to-eat and that have caused outbreaks and are under evaluation.

The approximate annual inspection inventory for this goal is 7,000 firms. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, firms start or stop making high-risk foods, and new high-risk food firms enter the market. 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. As an example, establishments will be subject to differing inspection intervals within this inspection strategy just as Low Acid Canned Food (LACF) establishments have a varying inspection cycle based on risk within the current strategy. Because domestic LACF manufacturers have a long history of exemplary compliance with FDA's good manufacturing practices and individual establishments effectively monitor their individual processing procedures, FDA believes that these establishments need to be inspected only once every three years.

The current risk-based strategy considers food hazard information from various sources such as outbreaks, recalls, and consumer complaints as well as food analysis, epidemiological data, inspectional data and formal risk assessments. This information will be used to update currently listed commodities and establishments as well as the overall high-risk inventory of firms. The strategy includes greater inspection intervals for establishments such as cheese and LACF firms which have achieved a high level of compliance.

- **Performance:** In FY 2005, FDA exceeded this goal of 6,490 by performing 7,568 inspections of high-risk domestic food establishments.

9. **Expand federal/state/local involvement in FDA's eLEXNET system by having laboratories submit data into the system; and, the FY 2007 goal is updated to reflect the addition of a new and changing focus: Provide FDA food safety and security officials with notification of significant departures from normal trends of detection for 5 routinely tested analytes and 5 select agents in foods by incorporating pattern-detection algorithms into the eLEXNET system.** (19013)

- **Context of Goal:** 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. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. eLEXNET activities include:
  - Increased security—the eLEXNET program is the primary communication tool for the Food Emergency Response Network (FERN), a network of federal, state, and local food testing laboratories that will respond in the event of a terrorist incident involving the Nation's food supply. eLEXNET also handles information on methods of sample analyses and reporting of analytical results.
  - Quality—as the number of labs contributing to eLEXNET increases; it becomes increasingly difficult to ensure the quality of the data being entered. In view of the importance that DHS and the National Security Council are placing on this program, ensuring data quality and integrity is vital.
  - Outreach—eLEXNET is a storehouse of useful and timely data that enables health officials to make assessments regarding trends and risks, and provides the infrastructure for an early-warning system that identifies hazardous foods.
  - International collaboration—expansion into international partnerships and strengthening of those that are already being formed, such as the Trilateral Agreement among the U.S., Canada, and Mexico, which will result in a continent-wide food security network.

The eLEXNET program has successfully met its laboratory expansion efforts to populate its database with valuable data for use in threat detection, risk assessment, inspection

planning, and traceback analysis. To date, eLEXNET has obtained the commitment for participation from over 113 laboratories representing multiple government agencies and all 50 states. Of the 113 laboratories, 95 have contributed an extensive amount of food testing data in eLEXNET that is ready for use. By the end of FY 2006, 105 laboratories are expected to provide data into the system continuously.

For FY 2007, the performance goal reflects the next stage in a continuum of activities that strengthen our nation's capability to proactively detect hazards in the food supply. The system will focus its efforts to package and deliver the valuable data that it has collected over the years to better assist food safety and security officials in their decision making processes. eLEXNET will incorporate algorithms and/or functionality that automatically notifies FDA and other officials when detected analytes or agents are in excess of normal trends for a range of commodities. eLEXNET anticipates that the incorporation of these features will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

- **Performance:** FDA met the FY 2005 goal when the system reached 95 laboratories submitting data.

10. Establish and maintain a quality system in the ORA Field Labs which meets the requirements of ISO 17025 (ASCLD for FCC) and obtain accreditation by an internationally recognized accrediting body. (11041)

- **Context of Goal:** 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 will provide a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science.

  An FDA quality management system that is accredited to international standards will enable our managers to better maintain high-quality laboratory operations, to more easily control resources, and to act with more confidence in meeting the needs of their customers and stakeholders. More effective operations will result in greater regulatory impact and better consumer protection. Uniform laboratory procedures will enhance data reliability and resource sharing with our domestic and international partners.

  FDA's quality management systems include risk management principles. Since laboratories receive accreditation for specific test technologies or methods, we will use risk assessment tools to determine which test technologies and/or methods will be accredited. The quality management system incorporates risk management in targeting resources and controlling processes on an ongoing basis. Targeted resources result in laboratories equipped to respond to national emergencies, food-borne outbreaks, and emerging analytical problems. Controlled processes result in documented procedures and activities that withstand domestic and international scrutiny.

Through laboratory accreditation, FDA will maintain its reputation as a source of scientifically sound information and guidance. Other known benefits of quality systems include preservation of institutional knowledge (through process documentation and records) and increased employee satisfaction and retention. Over the long term, the quality management system implemented in FDA laboratories may serve as a model for managing other FDA regulatory and business processes. The 13 ORA Field Laboratories are currently implementing a new quality system in accordance with the updated Laboratory Manual that was issued in August 2003.

Laboratory accreditation is an important commitment by FDA. It recognizes the need for our laboratories to have international recognition and parity; to share data and other information with other accredited labs around the world; to share a common set of policies and procedures in improving operations and harmonization; and, to provide excellent work products that are defensible and consistent. With accredited laboratories, the credibility of FDA's analytical results will be greatly enhanced, both nationally and internationally; and, the reliability of data is critical in facilitating the sharing of data and in FDA and our partners being willing and able to take regulatory actions without duplicating the analyses.

- **Performance:** In FY 2005, FDA maintained accreditation for Denver District Laboratory and achieved accreditation for 5 additional laboratories: Forensic Chemistry Center; Arkansas Regional Lab; Pacific Regional Lab Northwest; San Francisco District Lab; and, Philadelphia District Lab.

11. Increase laboratory surge capacity in the event of terrorist attack on the food supply.

- **Context of Goal:** 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. Once the contaminant and food vehicle have been identified through food surveillance or outbreak investigation, FDA has primary responsibility for distinguishing contaminated food products from safe food products as quickly as possible to protect public health and mitigate disruption in distribution of important foods.

- **Performance:** Baseline and target under development. Expected completion - Sept 06.

Human Drugs Performance Goals

Long Term Goal: Sustain access to safe and effective new products by improving rapid, transparent and predictable science-based review of marketing applications.			
Measure	**FY**	**Target**	**Result**
1. Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. (12001) (Output) (Formerly: Ensure a safe and effective drug supply is available to the public.) Measure 1A: Percentage of Standard NDAs within 10 Months.	*2007*	90%	10/08
	2006	90%	10/07
	2005	90%	10/06
	2004	90%	97% of 94
	2003	90%	100% of 82
	2002	90%	99% of 84
Measure 1B: Percentage of Priority NDAs within 6 Months. (Output)	*2007*	90%	10/08
	2006	90%	10/07
	2005	90%	10/06
	2004	90%	96% of 28
	2003	90%	100% of 19
	2002	90%	100% of 12
2. Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. (12026) (Output) Measure: Number of written requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity.	*2007*	7/7	1/08
	2006	8/8	1/07
	2005	8/7	12/14
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
3. Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. (12003) (Outcome) (Formerly: Ensure safe and effective generic drugs are available to the public.) Measure: Number of months of the average FDA time to approval or tentative approval for the fastest 25% of original generic drugs application.	*2007*	Fastest 25% by .5 mos	1/08
	2006	Fastest 25% by .5 mos	1/07
FY 05 Measure: Complete review and action upon fileable original generic drug applications within 6 months after submission date.	*2005*	90%	6/06
	2004	85%	87% of 543
	2003	80%	90% of 423
	2002	65%	85% of 339
4. Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available. (12048) (Output) Measure: Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was complete review and action. Number of OTC monographs in which there was significant progress on completion.	*2007*	100%/5	1/08
	2006	100%/6	1/07
	2005	100%/6	100%/17
	2004	100%/6	100%/8
	2003	NA	NA
	2002	NA	NA
5. Reduce time to marketing approval for new drugs and biologics. Measure: Reduction in FDA approval time for the fastest 50 percent of priority New Molecular Entities/ Biologics Licensing Applications approved, using the 3-year submission cohort for FY 2005-2007.	*2007*	514 days	09/09
	2006	NA	09/08
	2005	NA	09/07
	2004	NA	09/06
	2003	NA	523 days*
	2002	NA	520 days*

* The reported results represent a three year average calculated using cohort data from the reported year and the two prior years.	*2001*	NA	575 days*
6. Reduce the time to marketing approval or tentative approval for safe and effective new generic drugs. Measure: Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the three year submission cohort for FY 2005 - 2007. * The reported results represent a three year average calculated using cohort data from the reported year and the two prior years.	*2007*	16.4 months	02/10
	2006	NA	02/09
	2005	NA	02/08
	2004	NA	02/07
	2003	NA	02/06
	2002	NA	16.2 months*
	2001	NA	17.6 months*
	2000	NA	17.9 months*
Data Source: Review performance monitoring is being done in terms of cohorts, e.g., FY 2003 cohort includes applications received from October 1, 2002, through September 30, 2003. CDER uses the Center-wide Oracle Management Information System (COMIS) and New Drug Evaluation/Management Information System (NDE/MIS). FDA has a quality control process in place to ensure the reliability of the performance data in COMIS. The Pediatric Exclusivity Database tracks all data regarding pediatric exclusivity as mandated by FDAMA and reauthorized by BCPA. Specifically, this database tracks the number of WRs issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made. The Pediatric Page database captures all information regarding waivers, deferrals, and completed studies for applications that are subject to the Pediatric Research Equity Act. Published monographs that establish acceptable ingredients, doses, formulations, and consumer labeling for OTC drugs.			
Data Validation: The Center-wide ORACLE Management Information System (COMIS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. COMIS is the core database upon which most mission-critical applications are dependent. The type of information tracked in COMIS includes status, type of document, review assignments, status for all assigned reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in COMIS. Document room task leaders conduct one hundred percent daily quality control of all incoming data done by their IND and NDA technicians. Senior task leaders then conduct a random quality control check of the entered data in COMIS. The task leader then validates that all data entered into COMIS are correct and crosschecks the information with the original document. CDER uses the Pediatric Exclusivity database and the Pediatric Research Equity Act Tracking System (PREATS) to track information such as number of written requests issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made as well as information related to the PREA legislation.			
Cross Reference: These performance measures support HHS Strategic Goal 2.			
Long Term Goal: Increase capability to efficiently and cost-effectively maintain an information technology (IT) environment to support FDA business goals.			
Measure	**FY**	**Target**	**Result**
7. Create state-of-the-art information management systems and practices to move to a paperless environment (e-Government). (12051) (efficiency) Measure: Percentage of ANDAs that contain some electronic portion.	*2007*	NA	NA
	2006	NA	NA
	2005	35%	93%
	2004	30%	72.5%
	2003	NA	NA
	2002	NA	NA
Data Source: The CDER Electronic Document Room. This is an Efficiency Goal.			
Data Validation: CDER has instituted multiple layers of verification and validation for ensuring the accuracy of performance information. CDER relies on data extracted from information systems to support demonstrating			

performance toward most performance goals and targets. CDER has developed manuals of policies and procedures (MaPPs) or other standard operating procedures for using or entering data into information systems. There are quality controls built in to the information systems – controls that help ensure the integrity and accuracy of the data entered. CDER has a number of analysts who have expertise in extracting information from these systems. Their knowledge and experience working with the data, and their familiarity and experience with the business of the Center provide another layer of validation. Further, the Center requires a multi-level clearance process for verifying and validating the accuracy of the information provided in the annual performance report.

Cross Reference: This performance measure supports HHS Strategic Goal 8.

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.

Measure	FY	Target	Result
8. Enhance the protection of the American public against the effects of terrorist agents by facilitating the development of and access to medical countermeasures, providing follow-up assessments on therapies, and engaging in emergency preparedness and response activities. (12045) (Output) (Formerly: Facilitate development and availability of medical countermeasures to limit the effects of the intentional use of biological, chemical, or radiologic/nuclear agents.) Measure: Number of medical countermeasures in which there has been coordination and facilitation in development.	*2007*	5	1/08
	2006	5	1/07
	2005	5	11
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA

Data Source: CDC/DHS Strategic National Stockpile (SNS) program, database from Department of Energy/REAC/TS (Oakridge), published guidance for Industry, published Federal Register Notices, CDER internet site http://www.fda.gov/cder/drugprepare/default.htm.

Data Validation: CDER has instituted multiple layers of verification and validation for ensuring the accuracy of performance information. CDER relies on data extracted from information systems to support demonstrating performance toward most performance goals and targets. CDER has developed manuals of policies and procedures (MaPPs) or other standard operating procedures for using or entering data into information systems. There are quality controls built in to the information systems – controls that help ensure the integrity and accuracy of the data entered. CDER has a number of analysts who have expertise in extracting information from these systems. Their knowledge and experience working with the data, and their familiarity and experience with the business of the Center provide another layer of validation. Further, the Center requires a multi-level clearance process for verifying and validating the accuracy of the information provided in the annual performance report.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

Long Term Goal: Sustain access to safe and effective new products by improving rapid, transparent and predictable science-based review of marketing applications.

Measure	FY	Target	Result
9. Improve the Safe Use of Drugs in Patients and Consumers (12007) (Output) (Formerly: Enhance postmarketing drug safety.)	*2007*	Evaluate new processes for communicating risk information and establish timeliness measures for time between identification of safety issues and action on those issues; Collaborate with the Centers for Medicare and Medicaid Services (CMS) on at least one study of a high priority safety issue in the Medicare population	1/08
	2006	Standardize Agency processes and criteria for communicating risk information to patients and healthcare providers	1/07

	2005	Review and provide comments on 100% of Risk Minimization Action Plans (RiskMAPs) for NMEs and for those products for which the sponsor or FDA initiated discussions, in accordance with applicable PDUFA goal dates.	100%

Data Source: CDC/DHS Strategic National Stockpile (SNS) program, database from Department of Energy/REAC/TS (Oakridge), published guidance for Industry, published Federal Register Notices, CDER internet site http://www.fda.gov/cder/drugprepare/default.htm.

Long Term Goal: Improve problem detection and take timely and effective risk management actions with all FDA-regulated products.

Measure	FY	Target	Result
10. Increase the efficiency of the Adverse Event Reporting Process by reducing the average cost associated with turning a submitted Adverse Event Report into a verified record in the database. (12053) (efficiency goal –pending OMB approval) Measure: Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database.	*2007*	$14/per report	01/08
	2006	NA	01/07
	2005	NA	$17.35/per report
	2004	NA	$19.30/per report
	2003	NA	$21.91/per report
	2002	NA	NA
11. Reduce medication errors in hospitals.	Baseline data and performance targets under development. Expected completion - Sept 06		

Data Sources: Adverse Event Reporting System (AERS), OMB Form 300 on Drug Safety, UFMS cost data

Data Validation: AERS, UFMS, and OCIO quality control processes

Cross Reference: This performance measure supports HHS Strategic Goal 2 and 5.

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.

Measure	FY	Target	Result
12. Improve the capability and efficiency of pharmaceutical development and manufacturing. (12052 - Formerly 12016) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	cGMP: Continue progress in implementing an integrated quality management system; implement a risk-based site selection model for inspections based on results of pilot	Progress reported below; pilot implemented

Data Source: Guidance documents. Relevant materials may be found on our website.

Data Validation: CDER has instituted multiple layers of verification and validation for ensuring the accuracy of performance information. CDER relies on data extracted from information systems to support demonstrating performance toward most performance goals and targets. CDER has developed manuals of policies and procedures (MaPPs) or other standard operating procedures for using or entering data into information systems. There are quality controls built in to the information systems – controls that help ensure the integrity and accuracy of the data entered. CDER has a number of analysts who have expertise in extracting information from these systems. Their knowledge and experience working with the data, and their familiarity and experience with the business of the Center provide another layer of validation. Further, the Center requires a multi-level clearance process for verifying and validating the accuracy of the information provided in the annual performance report.

Cross Reference: This performance measure supports HHS Strategic Goal 8.

Long Term Goal: Improve problem detection and take timely and effective risk management actions with all FDA-regulated products.			
Measure	**FY**	**Target**	**Result**
13. Increase risk-based compliance and enforcement activities to ensure drug product quality. (12020) (output) FY 2007 Measure: The number of inspections conducted of foreign and domestic establishments identified as high-risk human drug manufacturers. FY 2006 Measure: The number of inspections conducted of domestic establishments identified as high-risk human drug manufacturers.	2007	500	1/08
	2006	483	1/07
	2005	600	600
	2004	376	481
	2003	365	584
	2002	NA	NA
Data Source: Field Data Systems.			
Data Validation: 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.			
Cross Reference: These performance measures support HHS Strategic Goal 2.			

1. **Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available.** (12001) (Formerly: Ensure a safe and effective drug supply is available to the public.)

- **Context of Goal:** This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes new drug applications. Central to that focus is FDA's commitment to meeting the goals and requirements of the Prescription Drug User Fee Act (PDUFA). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 reauthorized the 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. FDA's timely performance of high-quality drug reviews in recent years reflects the importance of managerial reforms and substantial additional resources provided under the Prescription Drug User Fee Act (PDUFA). Consistent with the PDUFA requirements, a major objective of the human drugs program is to reduce the time required for review of all drugs. A key determinant in knowing if CDER is making progress in reducing time is to measure the time to "first action." The first action is the first regulatory action CDER takes (approvable, not approvable, or approval letter) at the end of the review of the original NDA 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 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. (For example, drugs for Acquired Immune Deficiency Syndrome (AIDS) and cancer typically fall into the priority category.)

- **Performance:** CDER will not have the final performance numbers for FY 2005 until October 2006. The latest information on CDER's performance toward the targets for this performance goal is from FY 2004. In FY 2004, CDER exceeded all PDUFA goals, including first actions on NDAs and BLAs. Review of Biologic License Applications (BLAs) for Therapeutic Biologic Products was transferred from CBER to CDER effective 10/1/2003, and these submissions are included in the table below. Performance toward the standard and priority NDA/BLA submissions, and other PDUFA goals, is provided in the following table:

Fiscal Year 2004 First Action Review Performance
(Performance data as of September 30, 2005)

	Number Filed	2004 Performance Goal	Final Performance
NDAs/BLAs			
Standard	94	90% in 10 mo.	97%
Priority	28	90% in 6 mo.	96%
NMEs/New BLAs			
Standard	15	90% in 10 mo.	100%
Priority	18	90% in 6 mo.	100%

2. Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. (12026)

- **Context of Goal:** The context of the Pediatric Program's performance goal covers the activities and requirements of the various laws passed to ensure safe and effective drug products are available for children. Due to the inadequacy of pediatric use information found in the majority of prescription medications in the United States, Congress passed several legislative initiatives to promote drug development for children. In 1997, the Food and Drug Administration Modernization Act (FDAMA) was signed into law with section 111 providing incentives to manufacturers who conduct studies in children. This incentive program, which provides six months of additional marketing exclusivity in return for conducting pediatric studies requested by the FDA, was reauthorized in January 2002 under the Best Pharmaceuticals for Children Act (BPCA). As a result of these initiatives, the number of ongoing pediatric clinical trials in the last 5 years has increased dramatically. Many of the studies reported to date have yielded new dosing and safety information in labeling. On December 3, 2003, the Pediatric Research Equity Act (PREA) was enacted. This law provides FDA the authority to require pediatrics studies for certain new and already marketed drug and biological products. PREA incorporates many elements of the former "Pediatric Rule" (63 FR 66632, Dec. 2, 1998) that was struck down in U.S. District Court for the District of Columbia on October 17, 2002. The effective date of PREA is retroactive to April 1, 1999, the same date the former Pediatric Rule became effective.

Due to the retroactive nature of the legislation, a significant number of previously submitted applications are now subject to the requirements.

- **Performance:** The target for FY 2005 performance was to issue at least 8 written requests for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for 7 drugs that receive pediatric exclusivity. CDER issued Written Requests to sponsors of 12 on-patent drugs and Written Requests for 4 drugs on NIH's annual Priority List, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committees on adverse events for 14 drugs that received pediatric exclusivity.

  In addition, CDER accomplished the following activities in FY 2005:
  - Additional efforts were made related to Written Requests for the study of on-patent drugs in the pediatric population:
    - 40 amendments were issued to sponsors of existing Written Requests.
    - 3 on-patent Written Requests, declined by sponsors, were referred to the Foundation for the NIH.
  - Exclusivity determinations were made once final study reports were submitted:
    - Final study reports were submitted for 9 drugs
    - Exclusivity determinations were made for 14 drugs
    - Exclusivity was granted for 13 drugs
  - Final pediatric labeling information was determined and information disseminated:
    - 16 labeling changes were made and posted on the web
    - Information was disseminated through 22 outside presentations/liaison activities including 4 abstracts published, 6 scientific articles published, 4 poster presentations; and through 2 AAP News vignettes
  - Medical/clinical pharmacology reviews were posted on the web for 21 drugs at the time of action, under the provisions of Section 9 of the BPCA. Related FR notices were published.
  - CDER worked with NIH to publish the annual Priority List of Drugs in the Federal Register, January 27, 2005.

  FDA is using several mechanisms to provide information on products for pediatric use:
  - The Best Pharmaceuticals for Children Act (BPCA), enacted in January 2002, requires that FDA make publicly available a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for supplements submitted under the BPCA. A total of 49 summaries are now posted, regardless of the regulatory action, at http://www.fda.gov/cder/pediatric/Summaryreview.htm.
  - BPCA mandates review of all adult and pediatric adverse event reports for a one-year period after pediatric exclusivity is granted and presentation of these reports to a pediatric advisory committee. As of March 31, 2005, reports have been presented for 34 drugs.
  - FDA is working with companies to put more information on pediatric studies into the label even when the studies did not show efficacy for the indication studied.
  - The Pediatric Research Equity Act (PREA), enacted December 2003, gave FDA the authority to require pediatric studies of certain pharmaceutical products when such studies are needed to ensure the safe and effective use of the products in children.

However, PREA does not require the same public disclosure of pediatric studies that is required under the BPCA.

3. **Improve the efficiency and effectiveness of the generic drug review program to ensure safe and effective generic drug products are available for Americans.** (12003) (Formerly: Ensure safe and effective generic drugs are available to the public.)

- **Context of Goal:** Generic drugs are much appreciated for their cost-effectiveness. According to the Congressional Budget Office, they save consumers an estimated $8 billion to $10 billion a year compared with the price of trade-name products. The basic requirements for approval of generic and trade-name drugs are the same as new drug approvals, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of the original product. Prior to approval, generic drug sponsors are required to demonstrate bioequivalence to the innovator drug product by showing that the active ingredient in their product is absorbed at a rate and extent similar to the innovator counterpart. The approval time is measured from the date the application is received to the date a major action, either an approval or not approvable, is reached.

  This performance goal is an interim step toward achieving the Agency long-term outcome goal to reduce average time to marketing approval or tentative approval for safe and effective new generic drugs. The target for the long-term outcome goal is to reduce the average FDA time to approval or tentative approval for the fastest 70% of original generic drug applications by 1.5 months. The FY 2006 target involves making interim progress toward that target by decreasing the average time for a portion of the fastest approvals and tentative approvals by 0.5 months. Targets for FY 2003 - 2005 for this performance goal involve progressively increasing the percentage of generic drug applications reviewed and acted upon within six months after submission. Reviewing and acting upon more applications in less time should help drive down the average approval time. In FY 2002, the median approval time for generic drugs was 18.3 months. For FY 2003, the median approval time was down by one month to 17.3 months and down another month to 16.3 months for FY 2004.

- **Performance:** FDA exceeded its goal for FY 2004 by acting on 87.4 percent of 543 original applications. FDA also exceeded its goal in FY 2003 by acting on 90 percent of 449 original applications.

4. **Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available.** (12048) (Formerly: Increase the number of drugs adequately labeled available for OTC use)

- **Context of Goal:** Over-the-counter (OTC) drugs play an increasingly vital role in America's health care system. The trend to self-medicate has increased greatly in recent years as health care costs have risen and consumers want to be empowered to treat minor ailments with OTC drug products. However, safety, effectiveness, and proper labeling have not always been characteristic of OTC drug products in the United States. FDA's goal by 2010 is to complete its existing review of OTC drug products, to have considered a number of key foreign drugs for marketing in the United States, and to have considered a number of key potential "prescription

(Rx)-to-OTC" switches. OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients and the dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet the same, uniform criteria. Final monographs (agency final rules) need to be completed for a number of large product categories (e.g., external analgesics, internal analgesics, antimicrobials, oral health care products, laxatives). In the next 7-10 years, FDA plans to complete the initial review of OTC monographs for 29 categories of drug products, thereby eliminating all unsafe and ineffective products from the OTC market.

- **Performance:** FDA exceeded its goal by completing review and action on 100% of Rx-to-OTC switch applications within 10 months of receipt and making significant progress on 17 OTC monographs (Vaginal contraceptive drug products containing Nonoxynol 9; internal analgesic, antipyretic, and anti-rheumatic; laxatives; cold, cough, allergy, bronchodilator, and antiasthmatic healthcare antiseptics; food handlers antiseptics; consumer antiseptics; poison treatment; sunscreens; external analgesics; urinary analgesics; skin protectants; phenylpropanolamine; nasal decongestants; convenience size labeling rule; plaque and gingivitis; benzocaine/weight control). The expansion of the OTC drug review to evaluate foreign OTC drugs is expected to increase switch requests in the near future. While CDER is hoping for a 50 percent increase in applications; however, we do not control the number of applications submitted. FDA recognizes that some of these switch requests involve issues of "OTCness" - determination that the drug is appropriate for OTC use and developing appropriate labeling and other information (such as was done for OTC stop smoking aid products) for safe and effective consumer use of these products without the intervention of a health care professional.

5. Reduce time to marketing approval for new drugs and biologics.

- **Context of Goal:** Reducing unnecessary delays in the approval time for safe and effective drugs that truly represent new therapies [i.e., NMEs and biologics] means earlier patient access for these medicines. Reducing unnecessary delays in drug approval also helps to both control the cost of new drug development, cited as a factor affecting the cost to consumers, and supports market competition among innovators. This is both good for the drug industry and good for consumers. New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition both from new drugs with therapeutic value – but not blockbuster potential, and new innovators that don't have access to the capital available to more established pharmaceutical companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated, helping speed patient access to new drugs, and reducing the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty.

  Additional initiatives are included in the Agency's Strategic Action Plan. Sponsors, for example, may be uncertain about what FDA expects to see in a high quality new drug application, because of a lack of interaction with FDA during development, or lack of clear, timely or consistent FDA-sponsor communication during review. As a result, the submitted application may have deficiencies that could have been avoided or addressed quickly, but instead create unnecessary

delays as they are identified by FDA and then addressed by the sponsor. Although FDA has found that applications can often contain deficiencies that are not so readily addressed, clear understandings of FDA expectations and timely communication between FDA and application sponsors can increase the likelihood that the submitted application contains the necessary information for timely approval on the first review cycle.

The targeted reductions in this FDA outcome goal represent approximately 10.5 percent reductions in total FDA review times for priority and standard NMEs and BLAs. Using Tufts estimates of potential cost reductions by phase of drug development1, a 10 percent reduction in regulatory review time yields a 1.6 percent reduction in total capital costs, now estimated at $802 million, translating to a savings of $12.8 million per NME approved.

- **Performance:** The FDA approval time for the fastest 50 percent of priority NME and biologics licensing applications (BLAs) approved for the FY 2002-2004 cohort is 240 days as compared to 286 days for the baseline FY 2000-2002 submission cohort. This is a reduction of 46 days versus the FY 2005-2007 target of a reduction of 30 days.

6. Reduce the time to marketing approval or tentative approval for safe and effective new generic drugs.

- **Context of Goal:** FDA achievement of this goal will create earlier access to lower cost drug alternatives for patients. The high cost of drugs limits patient access to treatment. The lower income and uninsured populations are particularly affected. Research has shown that 42 percent of the uninsured do not fill prescriptions because of financial reasons. While all state Medicaid programs provide outpatient prescription drug coverage, slightly more than one in four Medicaid patients ages 18-64 could not afford to fill at least one prescription, according to a study by the Center for Studying Health System Change (HSC). Increasing the availability of generic drugs will make many important treatments more affordable to the poor and the elderly and significantly improve access to treatment.

  Prescription drug expenditures remain one of fastest-growing segments of the U.S. health care system. In 2001, a 13.8 percent increase in drug spending accounted for one-fifth of the overall increase in health care spending. State Medicaid programs are particularly challenged with controlling escalating cost of pharmacy benefits and are in serious need of more generic alternatives to high cost brand name drugs to both reduce costs and increase access to treatment. Medicaid spending on outpatient drugs has increased by 18 percent a year from 1997 – 2000, which is close to three times greater than increases in medical care spending.

  Optimal access and use of generic drugs will enable policy decision makers to contain costs in both the Medicare and Medicaid programs. This will only become more important as more of the top selling brand name drugs go off patent over the next few years and if legislation for a Medicare drug benefit is passed by Congress. The National Institute for Healthcare Management has estimated that Medicaid programs could save $1 to $1.5 billion over the next few years if they were to increase their share of generic drug use to 55 percent of their total drug spending. According to researchers at Brandeis University, if a Medicare drug benefit were to be

implemented and the use of generic drugs represented 50 percent of the total prescriptions, approximately $250 billion would be saved over 10 years.

Generic drugs are typically priced between 20 – 50 percent lower than brand name competitors, which represent a significant cost saving to consumers.

- **Performance:** The FDA approval time for the fastest 70 percent of original generic drug applications approved for the FY 2000-2002 cohort is 16.2 months as compared to 17.9 months for the baseline FY 1998-2000 submission cohort. *This is a reduction of 1.7 months versus the FY 2005-2007 target of a reduction of 1.5 months.* However, this progress may not hold in future years.

  Despite all of the efforts to make our review processes more efficient and to decrease review times, FDA is experiencing a growing backlog of applications awaiting review. Beginning in 2003, the number of submissions began increasing rapidly and for FY 2005, the Office of Generic Drugs (OGD) projects over 800 submissions, an over 220% increase from 2002. Recent reports in the press seem to indicate that this trend of unprecedented numbers of submissions may continue for the next few years in part due to increasing numbers of brand name drug patent expirations.

  Increases in appropriated funds in recent years were instrumental in enabling OGD to increase staff to address the backlog of applications that grew in the late 1990's due to insufficient staff levels. As a result of those funds and of the Agency's successful efforts to establish smarter and more efficient review processes, FDA has been able to meet or exceed the statutory goal of taking a first action in the statutory 180 day time frame. Further, as a result of appropriations increases in recent years we have been able to significantly shrink the backlog of applications while also shrinking review times from a median time of 27 months in 1995 to 15.7 months in 2004. Our success in 2004 was demonstrated by our ability to approve 380 generic products in one year – on average, a new generic drug or a new use for an existing generic product was approved each day that year.

  However, with the unprecedented and unpredicted surge in submissions to FDA, the backlog is growing again, and OGD expects that performance toward meeting the statutory timeframes will decrease. Further, FDA expects that progress toward meeting its more meaningful measure of the total time to approval of applications is also in jeopardy. The Generics Review long-term outcome goal targets the 3- year submission cohort for FY 2005-07, exactly the timeframe we expect will cover the incredible surge in submissions.

7. **Create state-of-the-art information and knowledge management systems and practices to move to a paperless environment.** (12051)

- **Context of Goal:** The use of current technology will allow CDER to receive and review regulatory submissions more efficiently. In order to move to a paperless environment in an efficient and cost effective manner, we must develop standards for submission.

- **Performance:** Due to the increase in electronic submissions since 1997, there has been a significant decrease in the average number of paper volumes per NDA submissions. CDER has been receiving an increasing volume of regulatory submissions in electronic format. In FY 2005, CDER significantly exceeded its goal for receipt of abbreviated new drug applications for generic products by receiving over 90% of the applications with some electronic portion.

8. **Enhance the protection of the American public against the effects of terrorist agents by facilitating the development of and access to medical countermeasures, providing follow-up assessments on therapies, and engaging in emergency preparedness and response activities.** (12045)

- **Context of Goal:** The first therapy for those exposed to a biological, chemical, or radiological/nuclear agent is often a drug. FDA has been taking an aggressive and proactive approach to getting information on medical countermeasures into the labeling of already approved drugs. For example, gentamicin has not been FDA-approved for plague, yet is also widely recommend as a preferred therapy by experts. Human clinical trial data are needed to demonstrate safety and efficacy for specific treatments and to identify new therapeutic drug options. In the Federal Government's response to various agents of mass destruction, drugs will be mobilized from the CDC's Strategic National Stockpile (SNS). However, not all drugs in the SNS are FDA-approved for Counterterrorism uses. Identification of these deficits including development of a plan to address these deficits will move the Public Health Service closer to a goal of labeling all drugs that reside in the SNS for Counterterrorism uses.

- **Performance:** Funding over the last five years has strengthened CDER's capability to identify, prepare for, and respond to biological, chemical, and radiological/nuclear threats and incidents. FDA is engaged in many efforts to promote the development of medical countermeasures. The Agency encourages early and frequent interactions with sponsors, whether they are developing a novel compound or a new indication for a previously approved product. Regulatory mechanisms, such as Fast Track Designation, use of surrogate markers, or development under the Animal Efficacy Rule, and guidance documents are available to accelerate submission and review. FDA is actively working to expand the availability of safe and effective medical countermeasures for special populations (e.g., pregnant or lactating women, infants, elderly) through contracts that fund pharmacokinetic and safety studies of antibiotics likely to be used to prevent or treat illness following a terrorist attack. The following list describes the countermeasure performance for FY 2005:
    - Levaquin (levofloxacin) was approved for an additional indication of post-exposure prophylaxis of inhalational anthrax.
    - Cipro (ciprofloxacin) tablets, iv, solution, and oral suspension received approval for revised labeling for the Indications and Usage, Adverse Reactions, and Inhalational Anthrax-Additional Information sections of the package insert based on the information obtained from the Centers for Disease Control and Prevention program evaluation conducted after the bioterrorism events of October 2001. Four generic ciprofloxacin applications were approved.
    - ThyroShield (potassium iodide oral solution) was approved as a thyroid blocking agent for use in radiation emergencies. This oral solution is appropriate for use in children or

in adults who cannot swallow tablets. In February 2005, CDER assisted DHHS in a BioShield procurement of ThyroShield for the Strategic National Stockpile.
- Tentative approvals were granted for Manoplex (insoluble Prussian Blue), Kelacal (pentetate calcium trisodium injection, or calcium DTPA), and Kelazin (pentetate zinc trisodium injection, or zinc DTPA), for treatment of internal radiation contamination.
- CDER continued to facilitate the ongoing human trials of gentamicin in plague in Africa, as well as the monkey studies of gentamicin, ciprofloxacin, levofloxacin, ceftriaxone, and doxycycline in pneumonic plague. These studies were funded in previous years by CDER through interagency agreements with the CDC and NIAID, respectively.

9. Improve the Safe Use of Drugs in Patients and Consumers. (12007)

- **Context of Goal:** FDA recognizes now, more than ever, the need for protecting and advancing the public health, and the Agency has been focusing on new and better ways to perform this mission. Recently, the Department and FDA have announced new important efforts that the Agency is undertaking to improve its ability to monitor and respond to emerging drug safety information. These steps will ensure both a better internal process of deliberation of drug safety issues that ensures appropriate and independent consideration of all issues as well as a stronger ability to gather data about drug safety issues once a drug has been approved. Most importantly, we are working toward a policy of more transparency to ensure that patients and physicians have the most up-to-date and complete information necessary to make their treatment decisions. This new Drug Safety Initiative will give patients, healthcare professionals, and other consumers quick and easy access to the most up-to-date and accurate information on medicines and make FDA's drug review, approval, and monitoring programs as transparent a possible. FDA will be creating a Drug Watch Web Page that will include emerging information for both previously and newly approved drugs about possible serious side effects or other safety risks that have the potential to alter the benefit/risk analysis of a drug, affect patient selection or monitoring decisions, or that can be avoided through measures taken to prevent or mitigate harm. New communication channels will also include:
  - Healthcare Professional Information Sheets. One-page information sheets for healthcare professionals for all drugs on FDA's Drug Watch and all drugs with Medication Guides (FDA-approved patient labeling) containing the most important new information for safe and effective product use, such as known and potential safety issues based on reports of adverse events, new information that may affect prescribing of the drug, and the approved indications and benefits of the drug.
  - Patient Information Sheets. One-page information sheets for patients containing new safety information as well as basic information about how to use the drug in a consumer friendly format for all products on Drug Watch.

To demonstrate our commitment and to measure our progress on this initiative, we have proposed a performance target for FY 2006 that focuses on the establishment of the new risk communication processes. For example, we will establish criteria for determining what drug products should be listed on the Drug Watch and for using drug labeling "black box warnings" to communicate safety information. The targeted increase for the Office of Drug Safety for FY 2006 will directly support performance toward the FY 2006 target. In FY 2007, with base budget resources, we expect to be able to continue progress on this initiative, and we commit to

evaluating our new risk communication processes and to establishing timeliness measures for the time between when we identify a drug safety issue and the time when we communicate the risk information to the public. Further, in FY 2007, with an increase in funding for Drug Safety, we expect to be able to expand our understanding of, involvement in, and access to external population-based and "linked" databases (such as the CMS Medicare/Medicaid database) which represent the future of more thorough and continued monitoring of drug products after they are marketed. Key information regarding the safety of drug products is available in these types of databases.

- **Performance:** The FY 2005 target for this performance goal involves reviewing and providing comments on Risk Minimization Action Plans (RiskMAPs) for new molecular entities (NMEs) and for those products for which the sponsor or FDA initiated discussions, in accordance with applicable PDUFA. CDER met this performance target. Further, CDER is making progress toward the new drug safety initiative described within the context of the goal to improve the safe use of drugs. For example, we are updating drug safety information on certain drug products -- including new molecular entities, drugs with medication guides, and drugs with known safety issues -- and making that available to consumers in a new, user friendly format. We have recently updated our website (http://www.fda.gov/cder/drugSafety.htm) to reflect our advancements to date.

10. Increase the efficiency of the Adverse Event Reporting Process by reducing the average cost associated with turning a submitted Adverse Event Report into a verified record in the database. (12053)

- **Context of Goal:** A crucial part of FDA's mission is to perform pre-market and post-market safety and efficacy assessments of human drugs and therapeutic biologics. Clinical trials that lead to formal marketing approval only begin to quantify the safety and efficacy of a given pharmaceutical compound or biological product. The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product in order 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. These unexpected safety problems, called adverse events, must be reported to FDA in order for the agency to carry out its mission of performing post-marketing safety surveillance (PMSS). The Adverse Event Reporting System (AERS) is a computing system that FDA staff uses to carry out the PMSS function.

  The AERS system is a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. The information captured in the AERS system 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. In FY 2005, about 94% of the adverse event reports relating to drugs and therapeutic biologics were submitted by manufacturers, who are required to submit expedited reports of serious events within 15 days, and periodic reports for less serious events. The remaining 6% of the drug and therapeutic biologic adverse event reports received by FDA are "direct" reports from health care providers, pharmacists, and citizens, which must be re-keyed into the AERS system. Overall, only about 29% of the total adverse event reports were

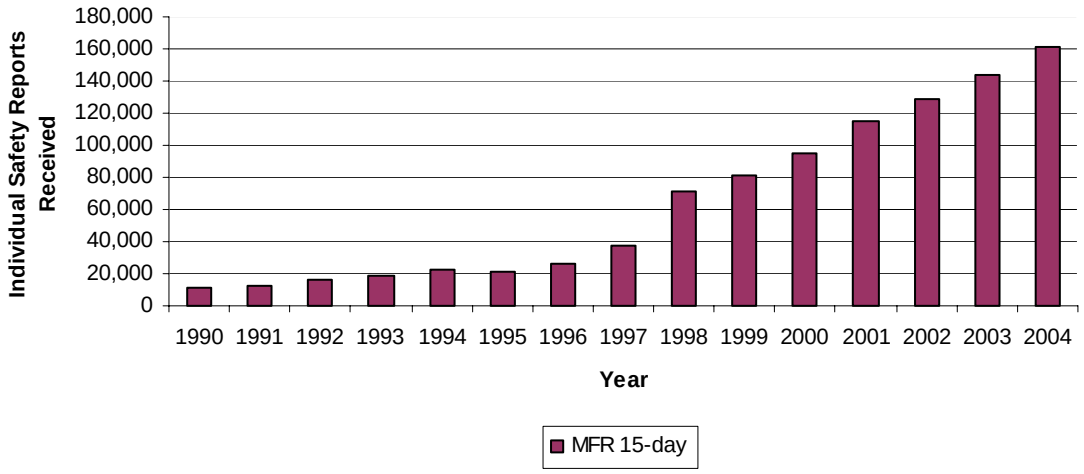
submitted electronically in FY 2005. However, FDA received slightly over half of the expedited reports electronically.

The manual entry of data into AERS is time-consuming and costly. Overall, the operating costs of the activities and systems covered by this goal represent approximately 12% of FDA's estimated total annual expenditures on post-market drug safety activities. The costs included in the measure include both information system operation and maintenance, as well as scientific and technical staff time to process the records and perform quality control.

The current AERS system was released in November 1997 to support post-market safety surveillance. Initially, AERS captured information from over 200,000 adverse event reports per year and enabled electronic retrieval of information for agency reporting of adverse reactions to drugs and therapeutic biologics marketed in the United States. Since that time the total number of adverse event reports has grown to over 400,000 per year. Moreover, between 1992 and 2004, the number of manufacturer reports of serious and unexpected adverse events (the so-called Manufacturer 15-day reports, which represent a subset of the total number of adverse event reports) has grown almost 9-fold (see the figure below). The current cost of processing each AER presents a major obstacle to FDA's ability to keep up with and analyze the rapidly increasing volume of reports and to rapidly identify, assess, and manage emerging safety risks.

FDA is making the AERS system 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 re-keying, to increase the number of submissions that are "pre-MedDRA coded," along with other efficiencies. These system improvements will allow the FDA to reduce the average cost and time associated with turning a submitted Adverse Event Report into a verified record in the database. This improvement in efficiency will allow scientists and statisticians to access safety information sooner, and will free up resources that can be redirected to risk analysis activities that directly improve our ability to recognize and respond to drug safety problems.

- **Performance:** The average cost associated with turning a submitted Adverse Event Report into a verified record in the database has been decreasing since FY 2003 due to FDA efforts to streamline its business processes and improve the information systems that are used to process records. In FY 2003, the cost per report was $21.91/per report. In FY 2004, the cost per report was $19.30/per report. In FY 2005, the cost per report was $17.35/per report. FDA expects to achieve further improvements in efficiencies due to improved automation of the submission and validation processes, and outreach to improve adoption of electronic submissions. The proposed FY 2007 target represents almost a 20% reduction in cost per adverse event report compared to the FY 2005 level.



11. Reduce medication errors in hospitals.

- **Context of Goal:** In November 1999, the Institute of Medicine released a report estimating that as many as 98,000 patients die from medical errors in hospitals alone. Many of these deaths, as well as additional non-fatal illnesses, are associated with errors involving FDA regulated medical products, especially medications. A significant percentage of drug related mortality and morbidity results from errors that are preventable. In addition to their human cost, these errors impose significant economic costs on the U.S. health care system.

  The Secretary of Health and Human Services has directed FDA to promulgate the bar coding regulation to reduce preventable errors from medical products. This rule is anticipated to enable the uptake and use of bar code scanners that will allow a health professional to compare the bar code on a human drug product to a specific patient's drug regimen and then verify that the right patient is receiving the right drug, at the right dose, via the right route, at the right time. Research to date has demonstrated the ability of bar code scanners at the point of care to intercept errors in dispensing and administration of medication and prevent related adverse events. The implementation of this rule will be a big step forward for FDA in improving patient safety. The total cost of preventable adverse events has been estimated at $17 Billion. Preventing 11 percent of adverse drug events related to medication errors in half of all the hospitals in the U.S. will significantly reduce the related morbidity, mortality and health care costs.

- **Performance:** Baseline data and performance targets under development. Expected completion - Sept 06.

12. Improve the capability and efficiency of pharmaceutical development and manufacturing. (12016)

- **Context of Goal:** The focus of this performance goal for 2005 is on the Agency's current good manufacturing practices (cGMP) initiative. On August 21, 2002, FDA announced a major new initiative on regarding pharmaceutical manufacturing, "Pharmaceutical GMPs for the 21st Century: A Risk-Based Approach." The program has several ambitious objectives. One is to ensure that regulatory review and inspection policies are based on state-of-the-art pharmaceutical science and to encourage the adoption of new technological advances by the pharmaceutical industry. FDA will determine the best pathway to better integrate advances in quality management techniques, including quality systems approaches, into the Agency's regulatory standards and systems for the review and inspection processes. Additionally, risk-based approaches, that focus both industry and agency attention on critical areas, will be implemented.

- **Performance:** Key activities toward accomplishing the performance goal for improving the capability and efficiency of pharmaceutical development and manufacturing are associated with the current Good Manufacturing Practices (cGMP) Initiative. On February 20, 2003, the Food and Drug Administration (FDA) released its progress report on a major initiative concerning the regulation of drug product quality. The two-year program, launched on August 21, 2002, applies to human drugs and biologics and veterinary drugs and has several objectives. One is to ensure

that regulatory review and inspection policies are based on state-of-the-art pharmaceutical science and to encourage the adoption of new technological advances by the pharmaceutical industry. FDA is working toward integrating advances in quality management techniques, including quality systems approaches, into the Agency's regulatory standards and systems for the review and inspection processes. Additionally, implementation of risk-based approaches, that focus both industry and agency attention on critical areas are underway. Lastly, the Agency is committed to enhancing the consistency and coordination of its drug quality regulatory programs.

In FY 2005, FDA performed the following activities toward meeting this goal:

- Evaluated comments on the draft quality system guidance document issued in September 2004, advanced the revision of the draft;
- Established the CGMP Question and Answer Guidance Program under an internal SOP, initiated drafting of a CDER MaPP for the program;
- Advanced to Step Three for the International Conference on Harmonisation (ICH) Q8 guidance project on Product Development and the ICH Q9 guidance project on Risk Management;
- Established the ICH Q10 guidance project on quality systems and secured the approval of the concept paper on the project;
- Completed the first Pharmaceutical Inspectorate class training component and initiated the on-the-job training/detail training component;
- Contributed to the ongoing internal quality system reviews of warning letter procedures and recall procedures;
- Completed review of comments on the proposal to revise the 21 CFR Part 11 Electronic signatures regulation, and initiated drafting of the revision;
- Completed the pilot program for use of the risk-based computer model for selection of sites for CGMP inspection, found the pilot to be successful, added refinements to the model for including field alert activity and drug quality defect activity as factors affecting risk, and implemented the model as the routine risk tool for inspection site selection; used the model for preparation of the inspection plan being implemented for FY2006.

13. Increase risk-based compliance and enforcement activities to ensure drug product quality. [Inspections of foreign and domestic establishments identified as high risk human drug manufacturers.] (12020)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that present the highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly,

including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about drug safety risks.

For FY 2005, FDA developed a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The model includes risk factors relating to the facility, such as compliance history, and to the type of drugs manufactured at the facility. For FY 2006, FDA will continue to improve the quantitative risk model, which may also include risk factors relating to the manufacturing processes and the level of process understanding. The targets continue the trend of measuring performance toward inspecting the highest-risk establishments.

The risk prioritization scoring methodology was applied to about 800 non-US facilities manufacturing drugs for the US market (the number of drug facilities that received an inspection by FDA in recent years). Of these 800, approximately 500 scored high enough to be included in the domestic U.S. priority. In addition, about 50 percent of all non-U.S. sites are active pharmaceutical ingredient (API) manufacturers and about 55 percent of our annual inspections are of facilities that process APIs. FDA does not inspect non-U.S. facilities at the same frequency expected for U.S. facilities.

For FY 2007, FDA proposes to inspect, as part of this goal, a combination of both foreign and domestic facilities that are ranked the highest risk by the risk prioritization scoring model. This inclusion of foreign facilities would permit more consistent coverage of non-U.S. sites predicted to have a similar public health impact as we have experienced as a result of our inspections of domestic U.S. sites in FY 2005 and FY 2006.

- **Performance:** FDA met the FY 2005 goal by inspecting 600 high-risk firms.

Biologics Performance Goals

Long Term Goal: Sustain access to safe and effective new products by providing rapid, transparent and predictable science-based review of marketing applications.			
Measure	**FY**	**Target**	**Result**
1. Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months; and review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (13001) Measure 1A: Percentage of Standard Applications within 10 Months. (Output)	*2007*	90%	6/08
	2006	90%	6/07
	2005	90%	6/06
	2004	90%	100% of 6
	2003	90%	100% of 4
	2002	90%	100% of 6
Measure 1B: Percentage of Priority Applications within 6 Months. (Output)	*2007*	90%	4/08
	2006	90%	4/07
	2005	90%	4/06
	2004	90%	100% of 1
	2003	90%	100% of 4
	2002	90%	100% of 3
2. Complete review and action on standard PDUFA efficacy supplements within 10 months; and review and act on priority PDUFA efficacy supplements within 6 months of receipt (13002) Measure 2A: Percentage of Standard Efficacy Supplements within 10 Months. (Output)	*2007*	90%	6/08
	2006	90%	6/07
	2005	90%	6/06
	2004	90%	100% of 7
	2003	90%	100% of 13
	2002	90%	83% of 7
Measure 2B: Percentage of Priority Efficacy Supplements within 6 Months: (Output)	*2007*	90%	4/08
	2006	90%	4/07
	2005	90%	4/06
	2004	90%	None Submitted
	2003	90%	100% of 2
	2002	90%	100% of 4
3. Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date. (13005) Measure 3A: Percentage of BLA Submissions within 12 months. (Output)	*2007*	50%	11/08
	2006	90%	11/07
	2005	90%	11/06
	2004	90%	100% of 1
	2003	90%	100% of 5
	2002	90%	100% of 5
Measure 3B: Percentage of BLA Supplements within 12 months. (Output)	*2007*	75%	11/08
	2006	90%	11/07
	2005	90%	11/06
	2004	90%	100% of 542
	2003	90%	100% of 530
	2002	90%	99% of 469

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.			
Measure	**FY**	**Target**	**Result**
4. Increase manufacturing diversity and capacity for pandemic influenza vaccine production through interacting with vaccine researchers and developers and issuing guidance and other documents and through global vaccine response coordination to facilitate the development and expedite the evaluation of cell-based technologies and dose-sparing approaches, such as the use of adjuvants. (13030) (Output)	*2007*	Issue one guidance or concept paper to facilitate development of non-egg-based influenza vaccines; evaluate the potency of monovalent influenza vaccines from at least three manufacturers by using quality system guidelines; demonstrate two new or improved methods for improved influenza vaccine manufacture; develop at least four influenza virus vaccine strains optimized for growth in non-egg culture systems by using quality systems guidelines.	11/08
	2006	Develop a concept paper on clinical data needed to support license of new trivalent vaccines and of pandemic vaccines; draft a guidance on cell substrates to facilitate development of non-egg-based influenza vaccines; co-sponsor two workshops with WHO on pandemic vaccines.	11/07
	2005	NA	NA

Long Term Goal: Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.			
Measure	**FY**	**Target**	**Result**
5. Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) Measure 5A: The number of inspections conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments. (Output)	*2007*	1,175	1/08
	2006	1,128	1/07
	2005	1,257	1,392
	2004	1,319	1,444
	2003	1,331	1,594
	2002	1,331	1,419
Measure 5B: The number of human tissue inspections	*2007*	325	1/08
	2006	250	1/07
	2005	NA	NA
	2004	NA	NA

conducted to enforce the new regulations. (Output)	*2003*	NA	NA
	2002	NA	NA
Data Source: CBER's Regulatory Management System and Field Data Systems.			
Data Validation: The Center for Biologics Evaluation and Research (CBER) uses various databases to manage its diverse programs and to assess performance. The principal CBER database is the Regulatory Management System-Biologics License Application (RMS-BLA). The RMS-BLA is CBER's new VAX-based, Oracle database that is used to track all biologics license applications, and supplement submissions; provide information to facilitate the review process (product, application status, milestone tracking, facility, review committee, industry contacts, and other information); and produce a wide variety of management reports. The Regulatory Information Management Staff (RIMS) monitors and is responsible for maintaining data quality and integrity in RMS-BLA. The Biologics Investigational New Drug Management System (BIMS) is CBER's VAX-based, Oracle database that is used to track all Investigational New Drug Applications (IND), Investigational Device Exemption (IDE), and Master Files (MF) submissions; provide product, application status, and other information to facilitate the review process; and produce a wide variety of management reports. There are numerous mechanisms established for quality control in Document Control Center , the application review offices, the Regulatory Information Management Staff, and several built into BIMS itself. The Blood Logging and Tracking System (BLT) records and tracks the various applications reviewed by the Office of Blood Research and Review. The Office also has an NDA tracking system. The data retrieved from these systems are reviewed and validated by the RIMS and the application review offices. If errors are detected, they are corrected. Federal regulations (21 CFR, Part 600.14 and 606.171) require reporting of deviations in the manufacture of biological products that affect the safety, purity, or potency of the product. The Biological Product Deviation Reports (BPDRs) (previously called error and accident reports) enable the Agency to evaluate and monitor establishments, to provide field staff and establishments with trend analyses of the reported deviations and unexpected events, and to respond appropriately to reported biological product deviations to protect the pubic health The Biologics Program relies in the Office of Regulatory Affairs' Field Accomplishments and Tracking System (FACTS) to register and record biologics manufacturing establishment inspection and compliance data. FACTS versions 1 and 2 together will replace the several dozen applications that comprise the current Field Information System (FIS).			
Cross Reference: These performance measures support HHS Strategic Goal 2.			

Note about Baseline Data: In several years of the program, performance (Baseline Data) exceeds the projected performance goals. The PDUFA III goals were set forth in letters from the Secretary of Health and Human Services to Congressional Committee Chairmen. FDA developed these goals in consultation with the pharmaceutical and biological prescription drug industries. "NA" means the goal is not applicable in that fiscal year.

The PDUFA application-review performance goals measure time to first action, not final action. The term "complete review and action on" is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval. The performance goals and this definition were developed in consultation with the industry and Congress, and are contained in the Secretary's commitment letter to the Chairman of the Energy and Commerce Committee of the House of Representatives, and the Chairman of the Labor and Human Resources Committee of the Senate. This definition enables to the Agency to approve only safe and effective products without having to issue not-approvable decisions on applications that are in some way not in condition for approval.

1. **Complete review and action on standard original PDUFA NDA and BLA submissions within 10 months; and review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt.** (13001)

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

- **Performance:** CBER has met or exceeded these performance goals since 1994. These applications are tracked by year of receipt, which is the cohort year. The cohort-year review performance is not available until the prescribed review time, i.e., 10 months after receipt, is expired. The FY 05 performance data for standard applications will be available November 2006. In FY 2004, CBER exceeded its goal by completing review and action on 100% of 6 Standard applications within 10 months, and reviewing and acting on 100% of 1 Priority application within 6 months.

2. **Complete review and action on standard PDUFA efficacy supplements within 10 months; and review and act on priority PDUFA efficacy supplements within 6 months of receipt.** (13002)

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

- **Performance:** CBER has met or exceeded most of these performance goals since 1994. The cohort-year review performance is not available until the prescribed review time, i.e., 10 months after receipt, is expired. The FY 05 performance data for standard efficacy supplements will be available June 2006. In FY 2004, CBER exceeded its goal by completing review and action on 100% of 7 Standard PDUFA efficacy supplements within 10 months.

3. **Complete review and action on complete blood bank and source plasma BLA submissions, and BLA supplements within 12 months after submission date.** (13005)

- **Context of Goal:** In FY 2007, CBER has reduced the targets for this goal from 90% to 50% for blood bank and source plasma BLA submissions, and from 90% to 75% for BLA supplements. As a result of strategic redeployment, the target for this goal needed to be reduced.

- **Performance:** These applications are tracked by year of receipt, which is the cohort year. The FY 05 performance data for supplements will be available November 2006. In FY 2004, CBER exceeded its goal by reviewing and acting on 100% of 1 complete submission within 12 months, and reviewing and acting on 100% of 542 supplements within 12 months after submission date.

4. **Increase manufacturing diversity and capacity for pandemic influenza vaccine production through interacting with vaccine researchers and developers and issuing guidance and other documents and through global vaccine response coordination to facilitate the development and expedite the evaluation of cell-based technologies and dose-sparing approaches, such as the use of adjuvants.** (13030)

- **Context of Goal:** The Biologics Program has received appropriated funding to establish the infrastructure and surge capability to react to a potential disease pandemic. Influenza pandemics are explosive global events in which most, if not all, persons worldwide are at risk for infection and illness. Unlike the gradual changes that occur in the influenza viruses that appear each year during "flu season," a pandemic influenza virus represents a major, sudden shift in the virus' structure that increases its ability to cause illness in a large proportion of the population. During previous influenza pandemics, large numbers of people fell ill, sought medical care, were hospitalized and died. Because the current vaccines do not contain strains that will protect against such a pandemic, pandemic strain-specific-vaccines must be produced, likely on short notice. FDA has provided new and accelerated pathways to facilitate their rapid production and evaluation, and is working with partners to facilitate new technologies that could increase manufacturing flexibility and capacity. The Biologics Program pandemic prevention activities include:

    - Working with HHS to develop the operational implementation of the pandemic plan policies on vaccines;
    - Working with CDC, NIH, WHO and industry to facilitate availability of vaccines suitable for the H5N1 avian influenza viruses that continue to circulate in Asia;
    - Working with sponsors of INDs to facilitate the initiation of clinical trials through the review process as well as informal guidance as necessary;
    - Working with WHO and others to promote global harmonization and cooperation in pandemic vaccine development;
    - Involved with several groups, (CDC, academia, etc) to perform additional studies to prepare strains for influenza A virus subtypes with pandemic potential;
    - Perform serologic testing to determine whether current vaccines produce antibodies that can inhibit the new influenza viruses considered for use in vaccines. Similar work would be needed to prepare for pandemic situations that might arise from, for example, the continued circulation of avian influenza viruses in Asia; and
    - Produce, calibrate, and distribute reagents to be used in determining the potency of vaccines. For each new virus included in vaccine, the reagents include a virus-specific preparation of influenza antigens and a virus –specific antiserum. CBER also provides the antiserum to CDC and WHO for national and international surveillance of influenza viruses. Work has been done to prepare some reagents for influenza A subtypes H5 and H9. Because the identity of an influenza strain that may emerge into a pandemic cannot be predicted, additional reagents will need to be prepared.

- **Performance:** FDA's role is critical in assuring that we have the needed tools to prepare for emerging infectious disease threats, such as safe and effective vaccines against pandemic flu. FDA will implement an enhanced and sustained preparedness effort to:

- Collaborate with the private sector, CDC and NIAID to rapidly prepare and test pandemic influenza vaccine virus seed strains and provide related reagents to assure potency, effectiveness, safety and efficient manufacturing for all recognized pandemic threat strains;
- Allow rapid review of new manufacturers, facilities and products, and use new vaccine technologies to facilitate HHS preparedness efforts, including HHS and NIH Requests for Proposals (RFPs) and contracts;
- Advise national and international public health groups such as WHO, CDC, NIH and the National Vaccine Program Office in selecting new influenza viruses for vaccine manufacturing and to prepare for pandemic influenza; and,
- Promote global regulatory and industrial cooperation, information sharing, guidance, harmonization and quality in pandemic vaccine development and manufacturing efforts.

5. **Increase risk based compliance and enforcement by inspecting the highest risk registered domestic blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and, by conducting human tissue inspections to enforce the new regulations.** (13012)

- **Context of Goal:** Inspections for this goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure purity of biological products. There are currently an estimated 2,450 establishments in the Biologics program inventory covered under this regulation. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments.

  Beginning in FY 2006, the human tissue inspections have been added to this goal because they are of high priority due to the potential for associated adverse health events. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of our 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 establishment inspections and investigations to determine if human tissues for transplantation are in compliance with the tissue regulations. FDA determines if establishments are properly testing and screening tissue donors, and evaluates whether establishments are properly recovering tissues from donors as well as properly storing and transporting the tissues. Monitoring the recovery and processing of human tissue and the testing and screening of donors is critical to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health.

  Many of these firms are relatively new, small, unaware of the specifications of the new regulations, and have never been inspected previously. There are about 2,000 human tissue establishments currently registered.

- **Performance:** In FY 2005, FDA exceeded this goal of 1,257 by inspecting 1,392 blood banks, source plasma and biologics manufacturing establishments.

Animal Drug and Feeds Performance Goals

Long Term Goal: Increase access to safe and effective veterinary products, and to safe and nutritious food products, including products for unmet animal and human health needs.

Measure	FY	Target	Result
1. Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (14020) (output) Measure: Complete review and action on original NADAs & reactivations of such applications received during FY 2007.	*2007*	90% w/in 200 days	01/09
	2006	90% w/in 230 days	01/08
	2005	90% w/in 270 days	01/07
	2004	90% w/in 295 days	100% w/in 295 days

Data Source: Submission Tracking and Reporting System (STARS).

Data Validation: 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.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

Long Term Goal: Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.

2. Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) Measure 2A: The number of inspections conducted of registered animal drug and feed establishments. (output)	*2007*	651	01/08
	2006	618	01/07
	2005	688	772
	2004	703	773
	2003	721	847
	2002	720	804
Measure 2B: The number of targeted BSE inspections conducted of all known renderers, protein blenders, and feed mills processing products containing prohibited material. (output)	*2007*	527	01/08
	2006	527	01/07
	2005	580	588
	2004	647	647
	2003	880	880
	2002	1305	1282

Data Source: Field Data Systems.

Data Validation: 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.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

1. Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (14020)

Context of Goal: The Animal Drugs and Feeds Program initiated a user fee program upon passage of the FY 04 appropriation. The user fee program reflects the implementation of a five-year plan to improve the performance for animal drug review. ADUFA permits collection of application, product, establishment, and sponsor fees to

enhance the animal drug review process. The benefits provided by the user fee program include: shorter review times; a more predictable and stable review process; and, an overall reduction in drug development time.

The FY 04, FY 05, FY 06 and FY 07 targets reflect performance measures consistent with the goals industry has agreed upon for user fees. The target represents one of the user fee goals and reflects the Center's move toward completion of 90% of specified new animal drug submission reviews within statutorily mandated time frames over a five-year period under ADFUA.

As mandated by the Federal Food, Drug and Cosmetic Act, a new animal drug may not be sold in interstate commerce unless it is the subject of an approved New Animal Drug Application (NADA). An approved NADA means the product is safe and effective for its intended use and that the methods, facilities and controls used for the manufacturing, processing and packaging of the drug are adequate to preserve its identity, strength, quality and purity.

When a new animal drug application is submitted, CVM evaluates the information contained or referenced in the application. A determination is made whether the application is approved or not approved. The sponsor receives a letter informing them either of the approval or describing the deficiencies in the application. The "days to review" refers to the time it takes to review and take an action on the original submission, or if needed, on subsequent recycles. This is different from total approval time, which is the time it takes from the original receipt of the application until it is finally approved, which may take more than one review cycle. This includes the time we spend reviewing the application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the not approved letter(s) and to resubmit the application for review.

FDA is encouraging sponsors to use the phased review process for new animal drug applications. An Investigational New Animal Drug (INAD) file or submission is established at the request of the sponsor to archive all sponsor submissions for a phased drug review, including: request for interstate shipment of an unapproved drug for study, protocols, technical sections, data sets, meeting requests, memos of conference, and other information. Phased review has removed a common bottleneck caused by the fact that a sponsor had to wait until all technical sections were reviewed before FDA would render an opinion on the sufficiency of an application. As a result, the technical section in the application that required the longest review could stymie progress on other sections. Under phased review, sponsors can coordinate submission of each technical section as the work for that section is completed. In addition, the direct review program, when linked with phased review, has resulted in significantly improved and more interactive communication between sponsor and reviewer, enabling a more efficient and logical review process.

- **Performance:** The final performance update for FY 2004 indicates FDA exceeded all ADUFA performance goal(s). FDA reviewed and acted on all seven (7) original NADAs

and reactivations of such applications received during FY 2004 within 295 days. Final performance numbers for FY 2005 will not be available until January 2007. However, as of September 30, 2005, the preliminary performance assessment for FY 2005 indicates FDA has exceeded the ADUFA goal(s). Additional information will be available in the FY 2005 ADUFA Performance Report.

ADUFA Performance Cohort	**FY**			
Application/Submission Type:	Goal: Review & Act On		# Reviewed & Acted On	Perf. As of 9/30/05
New Animal Drug Applications (NADAs)				
NADAs & reactivations	FY 04	90% w/in 295 days	7	100%
	FY 05	90% w/in 270 days	1	100%
Administrative NADAs & reactivations	FY 04	90% w/in 90 days	10	100%
	FY 05	90% w/in 85 days	6	100%
New Animal Drug Application Supplements & Reactivations				
Non-manufacturing *(Safety & Efficacy)*	FY 04	90% w/in 320 days	14	100%
	FY 05	90% w/in 285 days	3	100%
Manufacturing	FY 04	90% w/in 225 days	363	99%
	FY 05	90% w/in 190 days	297	100%
Investigational New Animal Drug (INAD) File Submissions				
Data *(Studies)*	FY 04	90% w/in 320 days	243	100%
	FY 05	90% w/in 285 days	162	100%
Protocols	FY 04	90% w/in 125 days	173	99%
	FY 05	90% w/in 100 days	148	99%

2. **Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009)**

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for greatest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better address and communicate to our stakeholders about animal drugs and feed safety risks.

  One part of this goal includes inspections done by FDA directly, or through state contracts or partnership agreements, on manufacturers, repackers and relabelers of animal drugs, and manufacturers and growers requiring a Medicated Feed Mill License. The approximate statutory inspection inventory for this goal is 1,300 firms.

  FDA developed a comprehensive public protection strategy of education, inspection and enforcement action. These activities will 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.

  FDA and states under contract and partnership conduct over 7,000 BSE inspections each year. FDA will continue to update and improve the inventory of firms with information from the mandatory feed registration system from states and other sources. The current inventory of renderers and feed mills processing products containing prohibited materials is approximately 530. The FY 2005 BSE funding increase supported increases in FDA BSE investigational staff; initiated improvements in BSE data collection through the Electronic State Access to FACTS (eSAF) database; funded cooperative agreements in eight (8) states for BSE monitoring and control infrastructure improvements; enhanced state and federal information on the inventory of animal feed firms and firms handling prohibited materials; and strengthened state infrastructure to monitor and respond to feed contamination with prohibited materials.

- **Performance:** In FY 2005, FDA exceeded this goal of 688 by inspecting 772 registered animal drugs and feed establishments; and, FDA completed the inspection of all 588 firms (8 added due to inventory increase) known to process with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

Medical Devices Performance Goals

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.			
Measure	**FY**	**Target**	**Result**
1. Percentage of Expedited PMAs reviewed and decided upon within 300 days; Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1 (15033) (Outcome) *Measure 1A*: Percentage of Expedited PMAs reviewed and decided upon within 300 days.	*2007*	90%	9/09
	2006	80%	9/08
	2005	70%	9/07
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
Measure 1B: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1 (Outcome)	*2007*	90%	9/08
	2006	80%	9/07
	2005	NA	NA
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
2. Percentage of Premarket Approval Application of an estimated 80 (PMA) first actions reviewed and acted upon within 180 days. (15001) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	NA	NA
	2004	90%	93% of 39
	2003	90%	97.7% of 43
	2002	90%	97% of 33
3. Percentage of 180 day PMA supplements reviewed and decided upon within 180 days./1 (15031) (Outcome)	*2007*	90%	1/09
	2006	80%	1/08
	2005	80%	1/07
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
4. Percentage of an estimated 725 PMA supplement final actions reviewed and acted upon within 180 days. (15009) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	NA	NA
	2004	95%	96% of 111
	2003	95%	95.5% of 157
	2002	90%	95% of 498
5. Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days./1 (15032) (Outcome)	*2007*	80%	1/09
	2006	75%	1/08
	2005	75%	1/07
	2004	NA	NA
	2003	NA	NA
	2002	NA	NA
6. Percentage of an estimated 4,325 510(k) (Premarket Notification) final actions reviewed and acted upon within 90 days. (15002) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	NA	NA
	2004	95%	100% of 3,377
	2003	95%	99% of 4328
	2002	95%	100% of 4322

7. Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. (15025) (Output)	*2007*	295	1/08
	2006	278	1/07
	2005	295	335
	2004	295	354
	2003	295	364
	2002	290	358
8. Reduce the average time for marketing approval for safe and effective new devices. Measure: Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. * The reported results represent a three year average calculated using cohort data from the reported year and the two prior years.	*2007*	290 days	09/09
	2006	NA	09/08
	2005	NA	09/07
	2004	NA	09/06
	2003	NA	334 days*
	2002	NA	338 days*
	2001	NA	320 days*

Data Source: CDRH Premarket Tracking System and Receipt Cohorts and Field Data Systems.

Data Validation: 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 after the end of the goal year.

Cross Reference: These performance measures support HHS Strategic Goal 2.

NOTES:

/1 DECISION GOALS applied to MDUFDA will be based on baseline data collected in FY 2003 and FY 2004. Decision goals identify the number of days for FDA to perform a complete review and issue a decision letter. Decision letters include: approval, approvable, approvable pending GMP inspection, not approvable and denial.

PMA first actions include: approval, approvable, approvable pending GMP inspection, not approvable, denial or "major deficiency letter.

PMA Supplement final actions include: approval, approvable, approvable pending GMP inspection, not approvable, or denial.

510(k) first actions include: SE, NSE, or "additional information" letter.

Long Term Goal: Improve problem detection and take timely and effective risk management actions with all FDA-regulated products.

Measure	FY	Target	Result
9. Percentage of inspection and product testing coverage of the Radiological Health industry (estimated 2,000 electronic products). (15027) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	10%	10% of 2,000
	2004	10%	10% of 2,400
	2003	10%	14% of 2,000
	2002	NA	5% of 2,000

10. Percentage of an estimated 9,100 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (15007) (Outcome)	*2007*	97%	1/08
	2006	97%	1/07
	2005	97%	97% of 9,100
	2004	97%	97% of 9,100
	2003	97%	97% of 9,200
	2002	97%	97% of 9,008
11. Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005) (Output) FY 05 Measure: Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers.	*2007*	1,300	1/08
	2006	1,234	1/07
	2005	1,104	1,265
	2004	1,110	1,414
	2003	1,080	1,428
	2002	1,049	1,062
12. Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 7% of an estimated 2,500 firms. (15005.02) (Output)	*2007*	NA	NA
	2006	NA	NA
	2005	175	230
	2004	225	295
	2003	225	225
	2002	225	209

Data Source: CDRH Radiological Health Data Systems and the Mammography Program Reporting and Information System (MPRIS)

Data Validation: 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.

Cross Reference: These performance measures support HHS Strategic Goal 2.

Long Term Goal: Improve problem detection and take timely and effective risk management actions with all FDA-regulated products.

Measure	FY	Target	Result
13. Expand actively participating sites in MedSun Network. (15012) (Outcome)	*2007*	Expand actively participating sites in MedSun Network to 76%	1/08
	2006	Expand actively participating sites in MedSun Network to 71%	1/07
	2005	350 facilities	354 facilities
	2004	240 facilities	299 facilities
	2003	180 facilities	206 facilities
	2002	80 facilities	80 facilities
14. Increase by 50% the patient population covered by active surveillance of medical product safety by 2008.	Baseline data and performance targets under development. Expected completion- Sept 06		

Data Source: CDRH Adverse Events Reports

Data Validation: 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.
Cross Reference: This performance measure supports HHS Strategic Goal 5.

1. **Complete Review and Decision on 90% of Expedited PMAs within 300 days; and Review and Decision on 90% of Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions of received within 320 days/1.** (15033)

- **Context of Goal:** 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. PMAs involve potentially high-risk devices with the most chance of significantly improving the treatment of patients. The steps taken in MDUFMA that will reduce approval times for PMA applications are expected to reduce approval times for all filed applications, while recognizing that some applications may not ultimately meet FDA's standards for safety and effectiveness and that performance measures based on all applications will take more time to observe.

  The FDA will achieve this goal by reducing unnecessary cycles, through encouraging and supporting higher-quality applications and more efficient resolution of outstanding issues. For example, MDUFMA encourages more pre-submission meetings, especially for expedited products. FDA will use these interactions with sponsors to clarify requirements and improve the quality of applications so that there are fewer cases where FDA needs to stop the review clock and go back to sponsors to ask for more information. FDA is also using a collaborative process by leveraging with outside experts.

  The MDUFMA legislation includes a required statutory minimum "trigger" amount of funds that must be appropriated each year for FDA's medical device and radiological health program; if this appropriation trigger is not met, FDA is not authorized to collect and spend user fees. In FY 2007, this trigger will be met at the Congressional Justification funding levels and performance will remain at the levels outlined in the MDUFMA legislation.

- **Performance:** The current baseline FDA marketing decision time for standard PMAs is 320 days. The approval of some key PMAs had been delayed, for example in the cardiac area, because CDRH did not have sufficient staff to handle simultaneous reviews that required the same review expertise. MDUFMA resources will be used both for new hires and to expand external expertise.

2. **Complete Review and Action on 90% of Premarket Approval Application of an estimated 80 (PMA) first actions within 180 days.** (15001)

- **Context of Goal:** Complete review and action constitutes the comprehensive review of the application package initially received by FDA and FDA's response back to the device sponsor. PMAs involve potentially high-risk devices with the most chance of significantly improving the

treatment of patients. It is essential that FDA complete the review process for these products quickly and thoroughly. FDA anticipates significant complexity of PMAs. For example, many new devices will incorporate computer technology as part of the diagnostic capability of the device itself and continuing improvements in image technology will require more sophisticated review skills. In addition, 40 percent of PMAs are breakthrough technologies and approximately 35 percent are from first-time submitters. These factors add time to the normal review process. For FY 2005, this goal was dropped and replaced with goal 15033.

- **Performance:** This goal was completed successfully in FY 2004 with 93% of PMA first actions occurring in 180 days. The medical device program attained this goal in FY 2003 by completing review and action on 97.7% of PMA first actions within 180 days.

3. **Complete Review and Decision on 90% of 180-day PMA supplements within 180 days.** (15031) Note: Workload is anticipated to increase in FY 2007 due to advances in technology.

- **Context of Goal:** 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. Real-time PMA Supplement review is a regulatory tool that gives sponsors the option of participating in "real-time" reviews of certain device changes. These reviews are conducted by teleconference or face-to-face, which gives manufacturers an opportunity to discuss all of FDA's review issues at one time. The MDUFMA legislation includes a required statutory minimum "trigger" amount of funds that must be appropriated each year for FDA's medical device and radiological health program; if this appropriation trigger is not met, FDA is not authorized to collect and spend user fees. In FY 2007, this trigger will be met at the Congressional Justification funding levels and performance will remain at the levels outlined in the MDUFMA legislation.

- **Performance:** This goal will begin to report performance in FY 2005.

4. **Complete Review and Action on 95% of an estimated 725 PMA supplement final actions within 180 days.** (15009)

- **Context of Goal:** Complete review and action constitutes the comprehensive review of the application package initially received by FDA and FDA's response back to the product sponsor. PMA supplements 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 products that already have been approved, 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. Real-time PMA Supplement review is a regulatory tool that gives sponsors the option of participating in "real-time" reviews that are conducted by teleconference or face-to-face. This gives manufacturers a chance to discuss all of FDA's review

issues at one time. In FY 2001, sponsors of over 25 percent of the 641 PMA supplements used the real-time review option, mostly by teleconference. For FY 2005, this goal was dropped and replaced with goal 15031.

- **Performance:** In FY 2004, this goal was completed successfully with 96% of PMA supplemental final actions occurring in 180 days. The CDRH met the target for this goal, completing review and action on 97% for the applications received in FY 2003.

5. **Complete Review and Decision on 80% of 510(k)s (Premarket Notifications) within 90 days.** (15032)

- **Context of Goal:** 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**.** The MDUFMA legislation includes a required statutory minimum "trigger" amount of funds that must be appropriated each year for FDA's medical device and radiological health program; if this appropriation trigger is not met, FDA is not authorized to collect and spend user fees. In FY 2007, this trigger will be met at the Congressional Budget funding level and performance will remain at the levels outlined in the MDUFMA legislation.

- **Performance:** This goal will begin reporting performance for the FY 2005 cohort.

6. **Complete Review and Action on 95% of an estimated 4,325 510(k) (Premarket Notification) final actions within 90 days.** (15002)

- **Context of Goal:** Complete review and action constitutes the comprehensive review of the application package initially received by FDA and FDA's response back to the product sponsor. This is an FY 1999 goal, dropped in FY 2000, and picked back up for FY 2001, FY 2002, FY 2003 and FY 2004 as a more meaningful measure of performance in this area. This goal for final actions on 510(k)s within 90 days addresses the statutory requirement to review a 510(k) within 90 days. Pressures to improve review time will be increased in FY 2005 to meet MDUFMA goals. As directed by OMB, this goal was dropped for FY 2005 in order to streamline FDA's Performance Plan.

- **Performance:** This was completed successfully in FY 2004 with 100% of 510 (k) completed within 90 days. This performance has resulted, in part, from FDA utilizing innovative ways to improve review efficiency.

7. **Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.** (15025)

- **Context of Goal**: In FY 2007, FDA plans to conduct 280 domestic and 15 foreign Bioresearch Monitoring (BIMO) inspections for a total of 295. Traditionally, FDA's approach to BIMO

inspections focused on data audits of Premarket Approval (PMA) applications. While this permitted FDA to provide review divisions with a validation of the data submitted in marketing applications, these inspections were retrospective and had little impact on ongoing clinical trials. Beginning in FY 2004, FDA began assigning inspections earlier in the process, during the investigational device exemption (IDE) phase. This has a greater impact by identifying systemic problems and focusing on exploitable or vulnerable populations. The focus of these inspections is informed consent, IRB review and approval, data monitoring, and data collection rather than data verification. CDRH has approximately 1,000 active Investigational Device Exemptions (IDEs) of high-risk investigational devices (e.g., artificial hearts, drug eluting stents). FDA is interested in expanding its presence with the regulated industry through a risk-based inspection strategy. This strategy places more emphasis on (1) the detection of scientific misconduct, (2) data auditing and validation to support the device review process (greater importance on time constraints of MDUFMA and studies relying principally on foreign data), (3) innovative devices with high public health impact, and (4) vulnerable populations (elderly, minorities, pediatrics, etc.).

- **Performance**: In FY 2005, FDA exceeded this goal of 295 by conducting 335 medical device related BIMO inspections.

8. Reduce the average time for marketing approval for safe and effective new devices.

- **Context of Goal:** MDUFMA commits FDA to significant improvements in device review performance. This is important to the entire device industry, which is expanding in size and technical complexity. The industry is relying on FDA to take a leadership role in regulating a rapidly emerging frontier of medical device technology with timeliness, quality, scientific consistency, and international harmonization. Most of the device industry is small and rapidly changing. Many small and new start-up firms rely heavily on FDA for guidance and outreach, and the reviews from these firms take extra FDA time and energy.
    - About 25 percent of PMAs are for breakthrough technologies; and
    - Over 25 percent of PMAs are from first-time submitters.

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

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

  The implementation of MDUFMA has allowed FDA to take steps to improve its device review program by analyzing the application review process and taking action to reduce multi-cycle reviews. MDUFMA requires more pre-submission meetings, especially for expedited products. CDRH will use these interactions with sponsors to clarify requirements and improve the quality of applications. FDA is also taking steps to improve the quality of reviews. CDRH is piloting an

after the fact quality review system to review a sample of reviews to assess the quality of the review and the scientific consistency of the review process and the review decision. The results of this study should be available by the end of FY 2005. This information will be shared with reviewers to improve reviews.

- **Performance:** The FDA approval time for the fastest 50 percent of Expedited PMAs approved for the FY 2001-2003 cohort is 275 days as compared to 360 days for the baseline FY 1999-2001 submission cohort. *This is a reduction of 85 days versus the FY 2005-2007 target of a reduction of 30 days.* CDRH initially calculated the baseline data for this goal, time to approval for the fastest fifty percent of expedited PMAs, for the time period of FYs 1999 – 2001.

9. Maintain inspection coverage and product testing coverage of the Radiological Health industry at 10% of an estimated 2,000 electronic products. (15027)

- **Context of Goal:** FDA is seeing a resurgence of problems in both the medical and consumer radiological product area such as widespread new uses for fluoroscopy by relatively untrained practitioners, increasing the risk of overexposure and high emission rates from consumer products. FDA has monitored cases of unnecessary radiation emitted during fluoroscopy. Principal risks to patients from overexposure include long-term possibilities for cancer induction and a short-term potential for skin burns. FDA has promulgated new regulations that require more restrictive specifications for new fluoroscopy equipment. FDA estimates the new regulations can spare 723 lives per year from radiation-induced cancer, recognizing that long-term radiation-induced cancers take 30 years on average to emerge after exposure. FDA has also established a working collaborative with the American College of Cardiologists to educate these frequent fluoroscopy users. FDA also receives approximately 5,000 electronic product reports yearly. Since FDA can't review these on a one-by-one basis, FDA selects product areas that require immediate attention by testing specific automatic screening criteria for electronic reports.

- **Performance:** In FY 2005, FDA met this goal by inspecting 10% of 2,000 radiological health firms. Accomplishment varies by industry for non-medical electronic products, averaging 10% overall. FDA initiates activities to prioritize and leverage its radiation protection efforts with state governments, professional societies, and other federal agencies. This compliance status was estimated by CDRH's Office of Communication, Education and Radiation Programs by reviewing inspection reports from FDA and State inspectors and product testing reports submitted by industry.

10. Ensure at least 97% of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems. (15007)

- **Context of Goal:** 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 were performed by trained inspectors with FDA, with State agencies under contract to FDA, and with States that are certifying agencies. State inspectors do approximately 90 percent of inspections. Inspectors performed 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 2005 by ensuring that 97 percent of an estimated 9,100 mammography facilities met inspection standards with less than 3 percent level 1 (serious) problems. Inspection data continue to show facilities' compliance with the national standards for the quality of mammography images. Improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. FDA works cooperatively with the States to achieve this goal.

11. Utilize Risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about device safety risks.

  This goal includes inspections done by FDA directly, or through state contracts or partnership agreements on Class II and III domestic and foreign medical device manufacturers. Class II and III medical devices pose the most significant risk because failures of these devices are likely to cause significant temporary or permanent injury, or death. The approximate annual inspection inventory for this goal is 8,100 domestic and foreign firms. The approximately 4,000 Class I lower-risk domestic firms are not inspected on a routine basis. These firms will be inspected on a "for cause" basis to follow up on problems identified in recalls or reported by the public.

- **Performance:** FDA exceeded the FY 2005 domestic medical device performance goal of 1,104 by inspecting 1, 265 domestic high-risk Class II and Class III medical device manufacturers. FDA exceeded the FY 2005 foreign medical device performance goal of 175 by inspecting 230 manufacturers.

12. Utilize Risk management to target inspection coverage for Class II and Class III foreign medical device manufacturers. (15005.02)

- **Context of Goal:** This goal has been incorporated with the domestic device inspection goal for FY 2006 and FY 2007. This goal includes joint inspections of high-risk device manufacturers

with European Union Conformance Assessment Bodies, although implementation of the Mutual Recognition Agreement with the EU has not been as successful as anticipated. Most choose not to participate but cite a preference for an FDA inspection. In the long term, if the MRA is successfully implemented, it could reduce the number of foreign firms that FDA will need to inspect. FDA supports a web site dedicated to MRA activities, including the implementation plan, eligible device lists, MRA meeting minutes, and the list of nominated US and EU Conformity Assessment Bodies (CABs) that are participating in confidence building activities. The web site is: http://www.fda.gov/cdrh/mra/index.html.

- **Performance:** FDA exceeded the FY 2005 foreign medical device performance goal of 175 by inspecting 230 manufacturers.

13. Expand actively participating sites in MedSun Network to 76%. (15012)

- **Context of Goal:** 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. FDA estimates that there may be as many as 300,000 injuries and deaths each year associated with device use and misuse. FDA has developed a long-term goal to increase the percent of the population covered by active surveillance, which will allow for more rapid identification and analysis of adverse events. FDA's long-term goal is: "***Increase by 50% the patient population covered by active surveillance of medical product safety by 2008"***.

  MedSun is a critical component towards achieving this long-term goal. FDA is using MedSun to reducing device-related medical errors; serve as an advanced warning system; and create a two-way communication channel between FDA and the user-facility community. MedSun is designed to train hospital personnel to accurately identify and report injuries and deaths associated with medical products. Data collection began in March 2002 and continues to date, along with recruitment of participating centers. In FY 2005, FDA expanded the network to 354, and replaced those facilities that choose to leave. This completed the planned expansion of the network to the total target number specified in the initiative. FDA is now turning its focus to increasing the number of active facilities (facilities that have been enrolled for longer than a year and submit at least one report per year).

  The goal for FY 2006 will be to *increase the number of facilities that are actively participating in the MedSun Network from 66% to 71%.* In FY 2007, the target would be to further *increase the number of facilities that are actively participating in the MedSun Network to 76%.* FDA plans to use the cohort of 350 facilities to pilot the effectiveness of various incentives, to pilot use of the MedSun facilities as a laboratory to obtain specific medical product information, and to pilot various types of feedback intended to encourage reporting by the facilities. FDA will continue to research and develop improved feedback mechanisms to the participating facilities about problems with medical devices The agency will implement targeted surveillance of different parts of hospitals (e.g., ICU, Operating Room, etc.), and of particular devices; and will also continue to explore how to improve reporting from hospital laboratories (LabSun), develop educational materials to raise awareness about the need to report device problems within

institutions and to FDA, and continue the successful audio conferences which discuss items of interest to biomedical engineers.

- **Performance:** In FY 2005, FDA exceeded its MedSun recruitment goal by recruiting a total of 354 facilities.

14. Increase by 50% the patient population covered by active surveillance of medical product safety by 2008.

- **Context of Goal:** Historically, FDA has relied on spontaneous reporting systems to ascertain risks associated with regulated medical products, and more recently dietary supplements and foods. However, there is considerable evidence that the spontaneous reporting systems for adverse events and medical product problems do not allow for an adequate characterization of the true safety profile for these products. These systems largely depend on health care providers taking time away from the delivery of health care to complete reports, which means there are many adverse events that go unreported. In addition, many events that are reported may be coincidental, not causally related to the use of the product. However, these systems can provide valuable information, particularly on rare, serious adverse events that may be caused by the product.

  The Agency needs to maximize the efficiency and effectiveness of the spontaneous reporting systems, and at the same time increase active surveillance through prospective data collection through hospitals participating in MedSun, CDC surveillance systems and direct access to safety data through health care providers' information systems. Active surveillance will allow FDA to better ascertain risks associated with medical products and focus its resources on the highest impact problems.

- **Performance:** Baseline data and performance targets under development. Expected completion - Sept 06.

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NCTR Performance Goals

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.

Measure	FY	Target	Result
1. Use new technologies (toxicoinformatics, proteomics, metabolomics, and genomics) to study the risk associated with how an FDA-regulated compound or product interacts with the human body. (16014) (output)	*2007*	Test systems biology in the drug review process to assess value in drug review and approval.	1/08
	2006	Present one finding utilizing novel technologies to assess changes in genes and pathology, and the relationship between chemical exposure, toxicity and disease.	1/07
	2005	Develop at least one protocol (proof of concept) to aid in defining drug toxicity studies and studies into mechanistic age-associated degenerative disease.	Three protocols were developed in the Division of Systems Toxicology, including studies of biomarkers of liver toxicity and disease, PPARg agonist effects on rat liver gene expression and age-associated changes in gene expression in F344 rats.
	2004	Use toxicoinformatics, combining information technology with toxicity data, to assess human risk for one regulated product (proof of concept)	Used biologically-based models of cancer-causing mutations to study skin tumor induction by regulated physical and chemical products.
2. Develop computer-based models and infrastructure to predict the health risk of biologically active products. (16003) (output)	*2007*	Demonstrate the utility of ArrayTrack in the regulatory environment.	1/08
	2006	Interpret at least one toxicology study at the molecular level utilizing the DNA microarray database (ArrayTrack).	1/07
	2005	Develop a computer-based system to integrate databases, libraries and analytical tools to support risk analysis and assessment.	ArrayTrack has been developed and implemented as a fully integrated system for microarray data management, analysis and interpretation.
	2004	Expand current technologies to include risk assessment for two biologically active products of interest to the FDA.	Modeled *in vivo* gene mutation and genotoxicity data to gain insight into the mechanism of action and relative risk posed by liver and lung carcinogens.
	2003	Maintain existing computational databases of estrogenic and androgenic compounds for use by reviewers.	The data is available for public access and allows for integration of information across health research fields.

	2002	Maintain existing computational databases of estrogenic and androgenic compounds for use by reviewers.	Developed an integrated Toxicoinformatics System that includes a central data archive, mirrored public databases, and analysis functions.

Data Source: NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; and manuscripts prepared for publication in peer-reviewed journals.
Use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; NCTR Project Management System; peer-review through the FDA/NCTR Science Advisory Board; presentations at national and international meetings.

Cross Reference: These performance measures support HHS Strategic Goal 2.

Long Term Goal: Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.

Measure	FY	Target	Result
3. Develop risk assessment methods and build biological dose-response models in support of Food Security. (16007) (output)	*2007*	Through collaborative efforts, use flow cytometry to facilitate isolation of single bacteria from contaminated samples for rapid bacterial identification and for pyrolysis mass spectrometry.	1/08
	2006	Demonstrate one utility of an oligonucleotide-microarray method as an integrated strategy to respond to antibiotic resistant agents in foodborne pathogens and bioterror agents.	1/07
	2005	Develop molecular method (oligo-microarray) to detect and monitor foodborne pathogenic bacteria.	In collaboration with CFSAN, scientists in the Division of Microbiology developed and validated a Salmonella biochip using microarray technology for rapid and accurate identification of virulence and antimicrobial resistance genes in Salmonella.
	2004	Under the Food Safety Initiative, establish a nutrition program in collaboration with other centers to address the risk associated with obesity in children, nutrition in pregnant women and poor nutrition in sub-populations; and initiate analysis on samples requiring high levels of containment in an accredited biosafety level 3 (BL-3) facility	Collaborative efforts that support this goal / target include participation on a committee involving CFSAN, CVM, and NCTR. This committee has prepared a white paper entitled, "Filling Critical FDA-Related Food and Nutrition Research Gaps." Analyzed surrogate microbes to test methodology as well as the public health risk for foodborne hazards.

	2003	Identify and characterize the role antibiotic resistance plays in emerging and evolving foodborne diseases.	Studies are being conducted to determine whether antimicrobial resistance occurs in bacteria isolated from animal feeds containing antibiotics and to identify the pattern of resistance.
	2002	Report at scientific meetings and/or publish preliminary results on the development of new methodologies to identify genetically modified foods, drug residues in foods and antibiotic-resistant strains of bacteria.	Researchers published approximately 50 publications and made approximately 20 presentations relating to food safety.
4. Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. (16012) (output)	*2007*	Develop a novel and efficient carbon nanomaterial research method in collaboration with outside entities for the synthesis and chemical modification of unusual materials (i.e., nanofibers used in explosive detectors).	1/08
	2006	Present one finding utilizing neuropathology and behavioral risk evaluation in the prediction of human outcome to food-borne toxicants.	1/07
	2005	Present one finding using neural imaging to identify neurotoxicity in exposed populations.	Preliminary studies were conducted in the Division of Neurotoxicology to develop methods for multiple neuroimaging approaches in adult nonhuman primates. Functional data acquisition was accomplished utilizing positron emission tomography (PET).
	2004	Apply neural imaging to identify and quantify neurotoxicity in exposed populations; and upgrade NCTR's animal quarantine facility to conduct animal research requiring BL3 containment in order to evaluate the effect of bioterrorism agents contaminating the food supply.	A proposal was generated that is designed to determine the reversibility of the development of the effects of the dissociative anesthetic, ketamine, with the use of MicroPET imaging techniques. A portion of the quarantine facility has been "up graded" to conduct animal BSL3) *cryptosporidia* studies.
	2003	Develop one instrumental rapid sensor detection method. Outfit upgraded laboratory, provide for supplies (agents, chemicals/pathogens) and construct library databases of proteins and test to find toxin	The Pyrolysis MAB MS computational system was installed and generating data that shows a very rapid characterization of potential bioterror bacterial strains is possible. Staff was recruited

		related markers; Recruit additional expertise in Computational Science, Chemistry and Microbiology.	and the BSL-3 laboratory will be ready for use by mid 2004.
	2002	Continue development of solid-phase colorimetric bacterial detection system. Acquire high-resolution mass spectrometer for use with protein from bacteria, food toxins and genomics studies. Upgrade existing laboratory facilities to BSL-3 to support BSE/TSE and microbial bioterrorism work. Recruit additional expertise in Computational Science, Chemistry and Microbiology.	Scientists are working on streamlining this methodology for use on meat as well as seafood. Equipment was purchased and calibrated. An outside firm assessed the NCTR facility for laboratory architecture and requirements; and, a floor plan was developed. One computational scientist, three chemists and two microbiologists were hired.

Data Source: NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board; presentations at national and international scientific meetings; and manuscripts prepared for publication in peer-reviewed journals.
NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board, the NTP Scientific Board of Counselors, and the Food Safety Initiative Coordinating Committee; presentations at national and international scientific meetings; and manuscripts prepared for publication in peer-reviewed journals.

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

Cross Reference: These performance measures support HHS Strategic Goal 2.

1. **Use new technologies (toxicoinformatics, proteomics, metabolomics and genomics to study the risk associated with how an FDA-regulated compound or product interacts with the human body.** (16014)

- **Context of Goal:** Staying abreast of new technologies in science is important for the Agency to protect public health. This goal is designed to establish core competencies within the FDA that can form a foundation for future high technology science thus harnessing technology to apply to the drug approval process. Techniques developed under this goal will utilize the emerging knowledge of the human genome and rapid biological analyses to improve human health, and to insure the safety of marketed products.

- **Performance:** NCTR developed a unique and sophisticated analytical infrastructure to assess the safety of FDA-regulated products using genomics, proteomics and metabolomics in conjunction with traditional biomarkers of safety. The development of this research approach is directed toward creation of a more relevant and quantitative risk assessment paradigm. A systems biology approach to toxicity testing will provide data that will be more easily extrapolated to the human, making data interpretation more facile and relevant. The result will be new disease markers and drug targets that aid in design of products to prevent, diagnose and treat disease. Systems toxicology provides a step on the critical path toward applying novel technologies used in the evaluation of safety assessment in emerging issues of potential risks. Scientists are actively pursuing collaborations in the systems biology realm of research with industry, academia, and within FDA.

2. **Develop computer-based models and infrastructure to predict the health risk of biologically active products.** (16003)

- **Context of Goal:** Using a scientifically based endocrine disruptor knowledge base (EDKB), FDA-regulated drugs, food additives, and food packaging have been shown to contain estrogenic activity. This raised the level of concern regarding adverse effects on human development/reproduction and contributions of these compounds to high incidences of cancer and/or risk of other diseases. Following the success achieved with the EDKB, NCTR scientists will identify and predict, using knowledge bases, whether the increased exposure to naturally occurring and other synthetic products can adversely impact public health.

- **Performance:** The development of the knowledge base for assessing risk associated with other regulated products continues. NCTR developed an integrated Toxicoinformatic System that includes a central data archive, mirrored public databases, and analysis functions. The central data archives contain a set of relations databases that store experimental information. These databases are continually being updated, enhanced with new linkages and additional experimental data and are being used to assess compounds for NCTR, CFSAN, CDER, EPA and the European Committee for Validating Alternative Methods. Scientists used biologically based models of skin tumor development that use oncogene and tumor suppressor gene mutation frequency to describe skin tumor development. Comparisons will be made between spontaneous tumor induction, after treatment with simulated solar light (as would be encountered in a tanning salon), and after simulated solar light in combination with various cosmetic products. Modeling

also was performed with a number of model toxicants, including riddelline, a food contaminant that is a liver carcinogen and 1,6-dinitropyrene, a combustion product that is a lung carcinogen. FDA reviewers are being trained on the software, ArrayTrack, a fully integrated system for microarray data management, analysis, and interpretation; and, are using it as a pilot for assessing voluntary pharmacogenomic data submissions from industry to the Agency.

3. **Develop risk assessment methods and build biological dose-response models in support of Food Security.** (16007)

- **Context of Goal:** The Agency is mandated by law to assure that the American public is eating safe food. Therefore, the Agency must strengthen its scientific basis for food security policies and regulatory decisions through the development of novel, vigorous risk assessments (models and techniques) and through the use of artificial intelligence and computational science for risk assessments. Concurrently, the Agency must accelerate the identification and characterization of mechanisms and methods development/ implementation to support surveillance and risk assessment for imported foods and/or microbial contamination.

- **Performance:** Researchers at the NCTR, the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM) are continuing to perform studies on bacterial identification techniques both in the food supply and in microbial contamination. This research includes the elucidation of the mechanisms of resistance to antimicrobial agents among bacteria from poultry and vegetables. Microbiological experiments have been conducted that suggest a technique to reduce or eliminate contamination of the environment in agricultural uses of clinically important antibiotic drugs. The pattern of resistance development in bacteria found in animals fed antibiotic and differences in survival rates of drug-resistant pathogens compared to non-resistant pathogens will continue to be studied. Efforts included the evaluation of various molecular methods to detect and identify the foodborne pathogens *Campylobacter* and *Salmonella* species and *Vibrio parahaemolyticus* from various foods and environmental matrices. Development of the Salmonella biochip for rapid and accurate identification of virulence and antimicrobial resistance genes in Salmonella assists in meeting the future challenges of food biosecurity. The joint effort between NCTR and CFSAN microbiologists will be useful in transferring microarray technology to the FDA field laboratories and law enforcement mobile labs.

4. **Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment.** (16012)

- **Context of Goal:** Identification of biomarkers is important because it will allow rapid identification of and response to potential contamination. These proteins identify specific genes that are potential targets for introduction of foodborne pathogenicity. The methodology as well as the biomarkers will be useful for rapid identification of hazards. Scientists will be able to expand a novel approach pioneered at the NCTR to rapidly identify biomarkers of toxicity associated with biological warfare agents. These types of agents used by bioterrorists would be difficult to detect using existing technology. This research is conducted in collaboration with the Centers for Disease Control (CDC), the Department of Defense (DOD), Naval Research Labs, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Food

Safety and Applied Nutrition (CFSAN). The chemistry and microbiology programs compared novel mass spectrometric methods with cultural methods, serological tests and molecular genetic methods for rapid identification of foodborne pathogens. This method will reduce analysis time of contaminated food to a few hours which will protect public health in a suspected bioterrorist attack. NCTR has upgraded the Center's Biosafety Level-3 animal quarantine facility and will utilize the laboratory to evaluate the effect of possible contamination agents. NCTR has developed a multidisciplinary approach integrating neurochemical/neurobiological (including genomics and proteomics), neuropathological, neurophysiological, and behavioral assessments to determine adverse effects and explore modes of neurotoxic action. Unique features of NCTR's neurotoxicology research efforts are the capabilities to determine target-tissue chemical concentrations and cellular level interactions of neurotoxicants and to reduce the uncertainty associated with extrapolating findings across species by effectively using rodent and nonhuman primate animal models as well as humans, wherever possible.

- **Performance:** Studies are being conducted to compare and contrast several new mass spectrometry techniques to more rapidly evaluate microbial risk. Scientists have shared expertise and laboratory infrastructure to prevent or minimize threats from bioterrorism through the development of a Memorandum of Agreement with the Arkansas Department of Health. Scientists also developed in collaboration with the Arkansas Regional Laboratory a method for microbial isolation that dramatically reduces analysis time of contaminated food to only a few hours vs. 2-3 days. Preliminary neuroimaging studies conducted in the Division of Neurotoxicology at the NCTR include developing methods for multiple imaging approaches in adult nonhuman primates. These studies include risk assessment in primates exposed to cocaine during development while others served as non-dosed controls. Functional data acquisition was accomplished with 18F-fallypride for dopamine D2 receptors and FECNT for dopamine transporters using positron emission tomography (PET). Further studies using fMRI are planned.

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Combined ORA Performance Goals

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

Long Term Goal: Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.

Measure	FY	Target	Result
1. Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. (15025) (output)	*2007*	295	01/08
	2006	278	01/07
	2005	295	335
	2004	295	354
	2003	295	364
	2002	290	358

Data Source: Field Data Systems.

Cross Reference: This performance measure supports HHS Strategic Goal 2.

Long Term Goal: Prevent harm from regulated products by increasing the likelihood of detection and interception of substandard manufacturing processes and products, through efficient and effective risk targeting, external partnering and collaboration.

Measure	FY	Target	Result
2. Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk. (11040) (output)	*2007*	60,000	01/08
	2006	45,000	01/07
	2005	38,000	86,187
	2004	NA	33,111
	2003	NA	NA
	2002	NA	NA
3. Perform import food field exams on products with suspect histories. (11036) (output)	*2007*	71,000	01/08
	2006	73,376	01/07
	2005	60,000	84,997
	2004	60,000	70,926
	2003	48,000	78,659
	2002	24,000	34,447
4. Perform Filer Evaluations of import filers. (19015) (output)	*2007*	1,000	01/08
	2006	965	01/07
	2005	1,000	1,407
	2004	1,000	1,745
	2003	NA	NA
	2002	NA	NA
5. Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported. (19016) (output)	*2007*	3,000	01/08
	2006	2,992	01/07
	2005	2,000	5,655
	2004	2,000	4,905
	2003	NA	NA
	2002	NA	NA
6. Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. (11020) (output)	*2007*	5,700	01/08
	2006	5,963	01/07
	2005	6,490	7,568
	2004	6,840	7,597
	2003	6,650	7,363
	2002	6,650	7,442

7. Expand federal/ state/ local involvement in FDA's eLEXNET system by having laboratories submit data in the system; **and,** beginning in FY 2007, expand the capability of the system to provide automated notification of potential events. (19013) (outcome) FY 2007 Measure: The number of analytes and select agents routinely tested and evaluated by eLEXNET pattern-detection algorithms such that departures from normal trends of detection trigger notifications to FDA food safety and security officials.	*2007*	5 analytes and 5 select agents	01/08
	2006	105 labs	01/07
	2005	95 labs	95
	2004	79 labs	79
	2003	54 labs	55
	2002	NA	29
8. Increase risk-based compliance and enforcement activities to ensure drug product quality. (12020) (output) FY 2007 Measure: The number of inspections conducted of foreign and domestic establishments identified as high-risk human drug manufacturers. FY 2006 Measure: The number of inspections conducted of domestic establishments identified as high-risk human drug manufacturers.	*2007*	500	01/08
	2006	483	01/07
	2005	600	600
	2004	376	481
	2003	365	584
	2002	NA	NA
9. Increase risk-based compliance and enforcement activities by inspecting the highest risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. (13012) Measure 9A: The number of inspections conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments. (output)	*2007*	1,175	01/08
	2006	1,128	01/07
	2005	1,257	1,392
	2004	1,319	1,444
	2003	1,331	1,594
	2002	1,331	1,419
Measure 9B: The number of human tissue inspections conducted to enforce the new regulations. (output)	*2007*	325	01/08
	2006	250	01/07
	2005	NA	NA
10. Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009) Measure 10A: The number of inspections conducted of registered animal drug and feed establishments. (output)	*2007*	651	01/08
	2006	618	01/07
	2005	688	772
	2004	703	773
	2003	721	847
	2002	720	804
Measure 10B: The number of targeted BSE inspections conducted of all known renderers, protein blenders, and feed mills processing products containing prohibited material. (output)	*2007*	527	01/08
	2006	527	01/07
	2005	580	588
	2004	647	647
	2003	880	880
	2002	1305	1282
11. Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005) (output)	*2007*	1,300	01/08
	2006	1,234	01/07
	2005	1,104	1,265
	2004	1,110	1,414
	2003	1,080	1,428

FY 05 Measure: Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers.	*2002*	1,049	1,062
12. Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 7% of an estimated 2,500 firms. (15005.02) (output)	*2007*	NA	NA
	2006	NA	NA
	2005	175	230
	2004	225	295
	2003	225	225
	2002	225	209
13. Establish and maintain a quality system in the ORA Field laboratories which meets the requirements of ISSO 17025 (American Society for Crime Laboratory Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation.) (11041) (outcome)	*2007*	Maintain accreditation for 13 labs	01/08
	2006	Achieve and maintain accreditation for 13 labs	01/07
	2005	Achieve and maintain accreditation for 6 labs	Achieved accreditation for 5 labs; maintained accreditation for 1 lab
	2004	NA	1
14. Increase laboratory surge capacity in the event of terrorist attack on the food supply.	Baseline and target under development. Expected completion - Sept 06		
Data Source: Field Data Systems.			
Data Validation: 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.			
Cross Reference: These performance measures support HHS Strategic Goal 2. Performance measure 6 supports Healthy People 2010 Objectives.			

1. **Conduct Medical Device Bioresearch Monitoring (BIMO) inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.** (15025)

- **Context of Goal**: In FY 2007, FDA plans to conduct 280 domestic and 15 foreign Bioresearch Monitoring (BIMO) inspections for a total of 295. Traditionally, FDA's approach to BIMO inspections focused on data audits of Premarket Approval (PMA) applications. While this permitted FDA to provide review divisions with a validation of the data submitted in marketing applications, these inspections were retrospective and had little impact on ongoing clinical trials. Beginning in FY 2004, FDA began assigning inspections earlier in the process, during the investigational device exemption (IDE) phase. This has a greater impact by identifying systemic problems and focusing on exploitable or vulnerable populations. The focus of these inspections is informed consent, IRB review and approval, data monitoring, and data collection rather than

data verification. CDRH has approximately 1,000 active Investigational Device Exemptions (IDEs) of high-risk investigational devices (e.g., artificial hearts, drug eluting stents). FDA is interested in expanding its presence with the regulated industry through a risk-based inspection strategy. This strategy places more emphasis on (1) the detection of scientific misconduct, (2) data auditing and validation to support the device review process (greater importance on time constraints of MDUFMA and studies relying principally on foreign data), (3) innovative devices with high public health impact, and (4) vulnerable populations (elderly, minorities, pediatrics, etc.).

- **Performance**: In FY 2005, FDA exceeded this goal of 295 by conducting 335 medical device related BIMO inspections.

2. **Perform prior notice import security reviews on food and animal feed line entries considered to be at high risk for bioterrorism and/or to present the potential of a significant health risk.** (11040)

- **Context of Goal:** FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. By FY 2007, FDA expects that the PNC will have hired a permanent staff of Reviewers and Watch Commanders that will have achieved the training and gained the experience necessary to expand its scope of targeting to include additional threat parameters.

  The PNC targets food and animal feed commodities that have been identified as high-risk based on either threat assessments that have been conducted or the receipt of specific intelligence indicating the items may cause death, illness, or serious injury due to terrorism or other food related emergencies. The PNC also utilizes the import field exams and filer evaluations by receiving feedback from the Investigators who conduct them and subsequently assessing those individuals or firms that continuously violate the prior notice regulations and the provisions set forth in the Bioterrorism Act, and further targeting those that instigate bioterrorism concerns.

  Strategies used to ensure effective targeting include:
  - Intelligence regarding countries at risk for terrorism;
  - Intelligence regarding commodities susceptible to, or exploited by, terrorism;
  - Intelligence specific to shipment or shipping entities;
  - Information gleaned from Foreign and Domestic Establishment Inspection Reports that identify security breaches;
  - Sample collection and analysis for counterterrorism;
  - Prior Notice discrepancies reported during import field exams; and,
  - Filer evaluation field audits.

FDA anticipates that the measures that it uses to assess its success in monitoring the safety and security of imported products will continuously evolve as trade practices and information about risks change.

- **Performance:** In FY 2005, FDA exceeded this goal of 38,000 by conducting 86,187 import security reviews. FDA collaborated with Customs and Border Protection to direct field personnel to hold and examine five suspect shipments of imported food; refused 141 lines of food for prior notice violations; responded to 49,649 phone and e-mail inquiries; and conducted 86,187 intensive security reviews of Prior Notice submissions out of 8,705,847 in order to intercept contaminated products before they entered the food supply.

3. **Perform import food field exams on products with suspect histories.** (19014)

Context of Goal: The events of September 11, 2001 heightened the nation's awareness of security and placed a renewed emphasis on ensuring the safety of the nation's food supply. Import food field exams, along with laboratory analyses, were FDA's major tool to physically monitor import entries prior to the enactment of the Bioterrorism Act of 2002. The role of the import food field exam and the number conducted continues to evolve as trade practices and information about risks change.

A field examination is a visual examination of the product to determine whether the product is in compliance with FDA requirements and involves actual physical examination of the product for admissibility factors such as storage or in-transit damage, inadequate refrigeration, rodent or insect activity, and lead in dinnerware, odor and label compliance. A field exam cannot be used to test for microbiological or chemical contamination and must be supplemented with other activities.

The volume of imported food shipments has been rising steadily in recent years, and this trend is likely to continue. FDA-regulated imports have been growing at a 19 percent annual rate. FDA anticipates approximately 12 million line entries of imported food in FY 2007 within a total of over 19 million lines of FDA regulated entries. To manage this ever-increasing volume, FDA uses risk management strategies to achieve the greatest food protection with available resources.

FDA applies strategies that combine visual inspection for apparent labeling and other visual defects, with risk-based targeting, and selective laboratory analysis to detect chemical and microbiological hazards. FDA cannot rely solely on physical examination to reduce the potential risks from imported foods. Currently, a significant effort is underway to develop appropriate knowledge-based approaches that will give the Agency assurance that it is addressing the most serious risks.

It is important to recognize that FDA is transforming how it regulates imports by using risk-based information technology to target physical exams and identify the need to collect samples for laboratory analysis. By focusing on risk, FDA works more efficiently to target products. An additional information technology system currently under development is an artificial intelligence tool. This new data mining tool is a risk-based automated system for screening import entries. This system will conduct continuous data mining of FDA's analytical and

inspectional data and use existing business rules, multiple data sources, and artificial intelligence to identify products posing the greatest security and safety risk. The prototype will produce two risk scores for every food entry line, one for security and one for safety concerns, which will be used to immediately identify shipments that may be of high risk.

FDA intends to expand the import data mining prototype to apply risk-based targeting of all types of regulated imports. These risk scores will help FDA target imported products for Agency action. The prototype will greatly enhance the electronic review process already in place at FDA. Entry review decisions made by FDA at border locations will be greatly enhanced by targeting products that present safety risks based on historical information and current events. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that we conduct 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.

- **Performance:** In FY 2005, FDA exceeded this goal of 60,000 by completing 84,997 field examinations of imported food lines.

4. **Perform Filer Evaluations of import filers.** (19015)

- **Context of Goal:** 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 maintains an electronic interface with the Department of Homeland Security's Bureau of Customs and Border Protection (CBP), the Automated Commercial System (ACS). After successfully completing an initial evaluation for participation in OASIS, filers may submit import data electronically to FDA through the Automated Broker Interface (ABI) and ACS. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen entry data transmitted by filers to perform various regulatory and service functions. Such screening may assess whether FDA import personnel should review an entry further. The FDA uses OASIS to determine whether an entry should be reviewed "on screen," further supported by entry documentation; physically inspected; sampled; or permitted to proceed into domestic commerce without further evaluation. FDA can use the data in the entry system to track an imported item that negatively affected the public health.

  At a minimum, this procedure requires filers who fail an evaluation to implement an FDA-approved Corrective Action Plan (CAP) and to pass a tightened evaluation (more stringent criteria) before obtaining, maintaining or regaining the privilege of paperless filing. This protects public health by ensuring quality improvement and reporting compliance for imported

articles that FDA regulates. It also ensures FDA is notified when articles appear to be violative that have previously been offered for entry.

ORA continues to develop the policies and practices that govern monitoring filers. Expanded import activities supporting security assignments increase FDA's understanding of the problems associated with appropriate monitoring of Filer activities. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices.

- **Performance:** In FY 2005, FDA exceeded this goal of 1,000 by performing 1,407 filer evaluations. This goal is an agency-wide goal and performance data will include activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program. This goal is shown in the Foods section for illustrative purposes.

5. **Conduct examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported.** (19016)

- **Context of Goal:** Because of safety and security concerns it is important for FDA to be sure that these goods do not slip into domestic commerce but are in fact sent out of the country. FDA monitors this activity in conjunction with Customs in a category of action described as "follow up to refusals."

  If a product is refused admission, it must be destroyed or exported under Customs' supervision within 90 days of receiving the Notice of Refusal. FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics, and that responsibility exists until the violative article is either destroyed or exported. 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 ensure 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 product has been destroyed or exported.

- **Performance:** In FY 2005, FDA exceeded this goal of 2,000 by performing 5,655 examinations of FDA refused entries as they were delivered for exportation to ensure that the articles refused by FDA were exported. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program. This goal is shown in the Foods section for illustrative purposes.

6. **Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities with the objective of reducing the health risks associated with food, cosmetics and dietary supplements products.** (11020)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about food safety risks.

  FDA applies a risk-based strategy to the inspection of the food establishments in its inventory. High-risk foods refer to those that may contain hazards that have a high potential for causing serious adverse health consequences that would result in FDA Class I recalls. These include foods that may contain bacterial or viral pathogens, biological toxins, allergenic substances, bovine spongiform encephalopathy (BSE) infective materials, as well as foods such as infant formula and medical foods due to a potential hazard from the omission or improper fortification of the nutritive ingredients.

  High-risk establishments are manufacturers, packers and repackers of foods that include modified atmosphere packaged products; acidified and low acid canned foods; seafood; custard filled bakery products; soft, semi-soft, soft ripened cheese and cheese products; unpasteurized juices; sprouts ready-to-eat; fresh fruits and vegetables and processed fruits and vegetables; shell eggs; sandwiches; prepared salads; infant formula; and medical foods. Additional high-risk products identified in recent years include products whose formulations do not include an allergenic ingredient but, because the product is made in a firm that also makes allergen-containing foods, may inadvertently contain an allergen which is not declared on the label. Common allergenic substances include milk, eggs, fish, crustaceans, tree nuts, peanuts or soybeans. Another class of high risk products is dietary supplements that may contain prohibited cattle-derived ingredients.

  As part of FDA's risk-based strategy, FDA recently completed a risk assessment of 23 types of ready-to-eat foods for listeriosis from the pathogen *Listeria monocytogenes*. This assessment ranked risk into categories from very high to low dependant on estimated risk per serving and on an annual basis. There are also foods such as shell eggs and certain produce items that are not ready-to-eat and that have caused outbreaks and are under evaluation.

  The approximate annual inspection inventory for this goal is 7,000 firms. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, firms start or stop making high-risk foods, and new high-risk food firms enter the market. 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. As an example, establishments will be subject to differing inspection intervals within this inspection strategy just as Low Acid Canned Food (LACF) establishments have a varying inspection cycle based on risk within the current strategy. Because domestic LACF manufacturers have a long history of exemplary compliance with FDA's good manufacturing practices and individual establishments effectively monitor their individual processing procedures, FDA believes that these establishments need to be inspected only once every three years.

The current risk-based strategy considers food hazard information from various sources such as outbreaks, recalls, and consumer complaints as well as food analysis, epidemiological data, inspectional data and formal risk assessments. This information will be used to update currently listed commodities and establishments as well as the overall high-risk inventory of firms. The strategy includes greater inspection intervals for establishments such as cheese and LACF firms which have achieved a high level of compliance.

- **Performance:** In FY 2005, FDA exceeded this goal of 6,490 by performing 7,568 inspections of high-risk domestic food establishments.

7. **Expand federal/state/local involvement in FDA's eLEXNET system by having laboratories submit data into the system; and, the FY 2007 goal is updated to reflect the addition of a new and changing focus: Provide FDA food safety and security officials with notification of significant departures from normal trends of detection for 5 routinely tested analytes and 5 select agents in foods by incorporating pattern-detection algorithms into the eLEXNET system.** (19013)

- **Context of Goal:** 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. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system.

  eLEXNET activities include:
  - Increased security—the eLEXNET program is the primary communication tool for the Food Emergency Response Network (FERN), a network of federal, state, and local food testing laboratories that will respond in the event of a terrorist incident involving the Nation's food supply. eLEXNET also handles information on methods of sample analyses and reporting of analytical results.
  - Quality—as the number of labs contributing to eLEXNET increases; it becomes increasingly difficult to ensure the quality of the data being entered. In view of the importance that DHS and the National Security Council are placing on this program, ensuring data quality and integrity is vital.

- Outreach—eLEXNET is a storehouse of useful and timely data that enables health officials to make assessments regarding trends and risks, and provides the infrastructure for an early-warning system that identifies hazardous foods.
- International collaboration—expansion into international partnerships and strengthening of those that are already being formed, such as the Trilateral Agreement among the U.S., Canada, and Mexico, which will result in a continent-wide food security network.

The eLEXNET program has successfully met its laboratory expansion efforts to populate its database with valuable data for use in threat detection, risk assessment, inspection planning, and traceback analysis. To date, eLEXNET has obtained the commitment for participation from over 113 laboratories representing multiple government agencies and all 50 states. Of the 113 laboratories, 95 have contributed an extensive amount of food testing data in eLEXNET that is ready for use. By the end of FY 2006, 105 laboratories are expected to provide data into the system continuously.

For FY 2007, the performance goal reflects the next stage in a continuum of activities that strengthen our nation's capability to proactively detect hazards in the food supply. The system will focus its efforts to package and deliver the valuable data that it has collected over the years to better assist food safety and security officials in their decision making processes. eLEXNET will incorporate algorithms and/or functionality that automatically notifies FDA and other officials when detected analytes or agents are in excess of normal trends for a range of commodities. eLEXNET anticipates that the incorporation of these features will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

- **Performance:** FDA met the FY 2005 goal when the system reached 95 laboratories submitting data.

8. **Increase risk-based compliance and enforcement activities to ensure drug product quality.** [Inspections of foreign and domestic establishments identified as high risk human drug manufacturers.] (12020)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that present the highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about drug safety risks.

For FY 2005, FDA developed a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The model includes risk

factors relating to the facility, such as compliance history, and to the type of drugs manufactured at the facility. For FY 2006, FDA will continue to improve the quantitative risk model, which may also include risk factors relating to the manufacturing processes and the level of process understanding. The targets continue the trend of measuring performance toward inspecting the highest-risk establishments.

The risk prioritization scoring methodology was applied to about 800 non-US facilities manufacturing drugs for the US market (the number of drug facilities that received an inspection by FDA in recent years). Of these 800, approximately 500 scored high enough to be included in the domestic U.S. priority. In addition, about 50 percent of all non-U.S. sites are active pharmaceutical ingredient (API) manufacturers and about 55 percent of our annual inspections are of facilities that process APIs. FDA does not inspect non-U.S. facilities at the same frequency expected for U.S. facilities.

For FY 2007, FDA proposes to inspect, as part of this goal, a combination of both foreign and domestic facilities that are ranked the highest risk by the risk prioritization scoring model. This inclusion of foreign facilities would permit more consistent coverage of non-U.S. sites predicted to have a similar public health impact as we have experienced as a result of our inspections of domestic U.S. sites in FY 2005 and FY 2006.

- **Performance:** FDA met the FY 2005 goal by inspecting 600 high-risk firms.

9. **Increase risk based compliance and enforcement by inspecting the highest risk registered domestic blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and, by conducting human tissue inspections to enforce the new regulations.** (13012)

- **Context of Goal:** Inspections for this goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure purity of biological products. There are currently an estimated 2,450 establishments in the Biologics program inventory covered under this regulation. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments.

  Beginning in FY 2006, the human tissue inspections have been added to this goal because they are of high priority due to the potential for associated adverse health events. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of our 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 establishment inspections and investigations to determine if human tissues for transplantation are in compliance with the tissue regulations. FDA determines if establishments are properly testing and screening tissue donors, and evaluates whether establishments are properly recovering tissues from donors as well as properly storing and transporting the tissues. Monitoring the recovery and processing of human tissue and the testing and screening of donors

is critical to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health.

Many of these firms are relatively new, small, unaware of the specifications of the new regulations, and have never been inspected previously. There are about 2,000 human tissue establishments currently registered.

- **Performance:** In FY 2005, FDA exceeded this goal of 1,257 by inspecting 1,392 blood banks, source plasma and biologics manufacturing establishments.

10. Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. (14009)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for greatest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better address and communicate to our stakeholders about animal drugs and feed safety risks.

  One part of this goal includes inspections done by FDA directly, or through state contracts or partnership agreements, on manufacturers, repackers and relabelers of animal drugs, and manufacturers and growers requiring a Medicated Feed Mill License. The approximate statutory inspection inventory for this goal is 1,300 firms.

  FDA developed a comprehensive public protection strategy of education, inspection and enforcement action. These activities will 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.

  FDA and states under contract and partnership conduct over 7,000 BSE inspections each year. FDA will continue to update and improve the inventory of firms with information from the mandatory feed registration system from states and other sources. The current inventory of renderers and feed mills processing products containing prohibited materials is approximately 530. The FY 2005 BSE funding increase supported increases in FDA BSE investigational staff; initiated improvements in BSE data collection through the Electronic State Access to FACTS (eSAF) database; funded cooperative agreements in eight (8) states for BSE monitoring and control infrastructure improvements; enhanced state and federal information on the inventory of

animal feed firms and firms handling prohibited materials; and strengthened state infrastructure to monitor and respond to feed contamination with prohibited materials.

- **Performance:** In FY 2005, FDA exceeded this goal of 688 by inspecting 772 registered animal drugs and feed establishments; and, FDA completed the inspection of all 588 firms (8 added due to inventory increase) known to process with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

11. Utilize Risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign). (15005)

- **Context of Goal:** Important features of the risk-based strategy for this goal will be reducing the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for highest risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. We note that these goals were reported in previous years as inspection of a fixed percentage of the inventory of establishments. However, given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments. We have reformulated the goals accordingly, including prior years for comparability. This strategy will also allow FDA to better communicate to our stakeholders about device safety risks.

  This goal includes inspections done by FDA directly, or through state contracts or partnership agreements on Class II and III domestic and foreign medical device manufacturers. Class II and III medical devices pose the most significant risk because failures of these devices are likely to cause significant temporary or permanent injury, or death. The approximate annual inspection inventory for this goal is 8,100 domestic and foreign firms. The approximately 4,000 Class I lower-risk domestic firms are not inspected on a routine basis. These firms will be inspected on a "for cause" basis to follow up on problems identified in recalls or reported by the public.

- **Performance:** FDA exceeded the FY 2005 domestic medical device performance goal of 1,104 by inspecting 1, 265 domestic high-risk Class II and Class III medical device manufacturers. FDA exceeded the FY 2005 foreign medical device performance goal of 175 by inspecting 230 manufacturers.

12. Utilize Risk management to target inspection coverage for Class II and Class III foreign medical device manufacturers. (15005.02)

- **Context of Goal:** This goal has been incorporated with the domestic device inspection goal for FY 2006 and FY 2007. This goal includes joint inspections of high-risk device manufacturers with European Union Conformance Assessment Bodies, although implementation of the Mutual Recognition Agreement with the EU has not been as successful as anticipated. Most choose not to participate but cite a preference for an FDA inspection. In the long term, if the MRA is successfully implemented, it could reduce the number of foreign firms that FDA will need to inspect. FDA supports a web site dedicated to MRA activities, including the implementation

plan, eligible device lists, MRA meeting minutes, and the list of nominated US and EU Conformity Assessment Bodies (CABs) that are participating in confidence building activities. The web site is: http://www.fda.gov/cdrh/mra/index.html.

- **Performance:** FDA exceeded the FY 2005 foreign medical device performance goal of 175 by inspecting 230 manufacturers.

13. Establish and maintain a quality system in the ORA Field Labs which meets the requirements of ISO 17025 (ASCLD for FCC) and obtain accreditation by an internationally recognized accrediting body. (11041)

- **Context of Goal:** 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 will provide a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science.

  An FDA quality management system that is accredited to international standards will enable our managers to better maintain high-quality laboratory operations, to more easily control resources, and to act with more confidence in meeting the needs of their customers and stakeholders. More effective operations will result in greater regulatory impact and better consumer protection. Uniform laboratory procedures will enhance data reliability and resource sharing with our domestic and international partners.

  FDA's quality management systems include risk management principles. Since laboratories receive accreditation for specific test technologies or methods, we will use risk assessment tools to determine which test technologies and/or methods will be accredited. The quality management system incorporates risk management in targeting resources and controlling processes on an ongoing basis. Targeted resources result in laboratories equipped to respond to national emergencies, food-borne outbreaks, and emerging analytical problems. Controlled processes result in documented procedures and activities that withstand domestic and international scrutiny.

  Through laboratory accreditation, FDA will maintain its reputation as a source of scientifically sound information and guidance. Other known benefits of quality systems include preservation of institutional knowledge (through process documentation and records) and increased employee satisfaction and retention. Over the long term, the quality management system implemented in FDA laboratories may serve as a model for managing other FDA regulatory and business processes. The 13 ORA Field Laboratories are currently implementing a new quality system in accordance with the updated Laboratory Manual that was issued in August 2003.

  Laboratory accreditation is an important commitment by FDA. It recognizes the need for our laboratories to have international recognition and parity; to share data and other information with other accredited labs around the world; to share a common set of policies and procedures in

improving operations and harmonization; and, to provide excellent work products that are defensible and consistent. With accredited laboratories, the credibility of FDA's analytical results will be greatly enhanced, both nationally and internationally; and, the reliability of data is critical in facilitating the sharing of data and in FDA and our partners being willing and able to take regulatory actions without duplicating the analyses.

- **Performance:** In FY 2005, FDA maintained accreditation for Denver District Laboratory and achieved accreditation for 5 additional laboratories: Forensic Chemistry Center; Arkansas Regional Lab; Pacific Regional Lab Northwest; San Francisco District Lab; and, Philadelphia District Lab.

14. Increase laboratory surge capacity in the event of terrorist attack on the food supply.

- **Context of Goal:** 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. Once the contaminant and food vehicle have been identified through food surveillance or outbreak investigation, FDA has primary responsibility for distinguishing contaminated food products from safe food products as quickly as possible to protect public health and mitigate disruption in distribution of important foods.

- **Performance:** Baseline and target under development. Expected completion - Sept 06.

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Other Activities Performance Goals

Long Term Goal: Improve the efficiency and effectiveness of program management through focused performance budget and financial management strategies, aligned with FDA and HHS business strategies.			
Measure	**FY**	**Target**	**Result**
1. Increase the number of Commercial Activities that will be reviewed for competitive sourcing. (19003) (Efficiency)	*2007*	Review and Compete 154 FTE per "Green" Plan	01/08
	2006	Review and Compete 175 FTE	01/07
	2005	(combined with FY 04) Conduct Clerical Study via competition of 350 FTE.	(combined with FY04)
	2004	(combined with FY 05) Conduct Clerical Study via competition of 350 FTE	350 FTE
	2003	Review 145.7 FTE	167 FTE
	2002	Review 72.7 FTE	63 FTE
2. Maintain percentage of contract dollars allocated to performance based contracts (19006) (Efficiency)	*2007*	NA	NA
	2006	NA	NA
	2005	50%	50%
	2004	40%	50%
3. FDA's implementation of HHS's Unified Financial Management System (19017) (Efficiency)	*2007*	FDA will finalize its decision on an activity-based costing application and make it operational for its user fee programs.	01/08
	2006	FDA will pilot an activity-based costing application integrated with HHS UFMS project as part of Prescription Drug User Fee Act III. The UFMS and its FDA modules will be operational in FY05 allowing FDA's legacy system core financial system to be decommissioned during the first quarter of FY 2006	01/07
	2005	FDA will implement a new core financial management system as part of the HHS UFMS project. The General Ledger and the Payroll interface will be implemented Oct. 1, 2004, and the remaining modules will be implemented April 1, 2005.	Goal accomplished through various activities discussed under Performance text.

	2004	FDA will hold a conference room pilot to prototype the design and configuration of UFMS. Begin development of FDA's unique interfaces and test global interfaces.	Goal accomplished through various activities discussed under Performance text.
4. Reduce Administrative Staff. (efficiency goal – OMB approved)	*2005*	2623	2379
	2004	2855	2766
	2003		3086
Data Source: 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.			
Data Validation: FDA will ensure consistency in the tracking and reporting of the administrative management performance goals. In addition, FDA is taking steps to routinely monitor this data and take appropriate actions as needed. Data is from a variety of sources for these performance goals including the Annual Chief Financial Officer's Report, Civilian and Commission Corps personnel databases, monthly and annual full-time equivalent (FTE) reports and data-runs, the FDA FAIR Act Inventory and the FY 2001 FDA Workforce Restructuring Plan, monthly statements from bank card companies and the FDA Small Purchase System.			
Cross Reference: These performance measures support HHS Strategic Goal 8. Measures 1,2 and 3 are **Efficiency Goals**.			

Long Term Goal: Increase capability to efficiently and cost-effectively maintain an information technology (IT) environment to support FDA business goals.			
Measure	**FY**	**Target**	**Result**
5. Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack. (19008) (Output)	*2007*	Enhance functionality and continue deployment of the Emergency Operations Network Incident Management System throughout the Agency (HQ, Centers, Field offices). Coordinate FDA's participation in exercises, including Topoff 4 Conduct and participate in exercises and workgroups related to emergency preparedness and response and counterterrorism. Continue implementing the requirements of HSPD 12 by installing access control devices at FDA facilities including select agent laboratories.	01/08

	2006	Enhance functionality and continue deployment of the Emergency Operations Network Incident Management System throughout the Agency (HQ, Centers, Field offices). Revision of national and Agency emergency response and crisis management plans. Conduct and participate in exercises and workgroups related to emergency preparedness and response and counterterrorism. Begin implementation of the Federal Information Processing Standard 201 to remain in compliance with the requirements of HSPD-12.	01/07
	2005	Develop the Agency's Emergency Operations Network Incident Management System (EON IMS).	Goal accomplished. EON IMS version 2.2 was implemented in March 2005 and used during the April 2005 TOPOFF 3 Exercise.
	2004	Develop Crisis Management Plan for CT. Develop the Agency's Emergency Operations Network.	Goal accomplished through various activities discussed under Performance text.
Data Source: Office of Crisis Management/Office of Emergency Operations.			
Data Validation: 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 are drawn from a variety of sources for these performance goals, including the Annual Chief Financial Officer's Report, Civilian and Commission Corps personnel databases, monthly and annual full-time equivalent (FTE) reports and data-runs, the FDA FAIR Act Inventory and the FY 2001 FDA Workforce Restructuring Plan, monthly statements from bank card companies and the FDA Small Purchase System.		
Cross Reference: These performance measures support Strategic Goal 8.			

1. **Increase the number of Commercial FTE that will be reviewed for competitive sourcing.** (19003)

- **Context of Goal:** FDA annually searches its FAIR inventory for those commercial positions that have not undergone a competitive sourcing study. The objective of this search is to identify a sufficient number of positions that would fulfill FDA's requirement in meeting the OMB and DHHS established goal of reviewing all commercial positions by FY2013. The commercial positions are presented to FDA senior management in the form of logical business units to

determine what will be reviewed that year. FDA is required under OMB's Green Plan to compete a minimum of 154 commercial FTEs each year until all commercial positions have been competed. The selected commercial business unit is announced for review and is then subjected to A-76 competitive sourcing competition either as one or more standard and/or streamline cost comparisons.

- **Performance:** FDA successfully completed the FY04 and FY05 review of its 350 FTE Clerical Support Services function. The review determined that the FDA's Most Efficient Organization (MEO) would provide that service. This brings the total number of commercial FTE's reviewed to date to 580 FTE out of a baseline of 1,543 commercial FTE's. An additional 175 FTE will be reviewed in FY06 as FDA competes the operations and maintenance of its primary information technology infrastructure.

2. **Maintain percentage of contract dollars allocated to performance-based contracts.** (19006)

- **Context of Goal:** FDA is aligning itself with the OMB goals of awarding 40 percent of eligible contract dollars to firms using performance based contracts by FY 05 and will strive to meet this target for FY 06 as well. This will lead to greater accountability of services provided by contractors, and increased efficiency. It should also be noted that not all contract dollars are eligible for this initiative.

- **Performance:** In FY 05, the FDA has awarded 50% of our eligible contract dollars to firms using performance-based contracts. In FY 04, FDA exceeded the target of 40% of eligible contract dollars awarded as performance-based contracts. FDA reviews each contract to determine if it is a candidate for performance based contracting. If so, the agency provides the contract's objectives and requests the contractor to provide the method(s) to meet the objective. Once the agency and contractor agree, FDA personnel regularly evaluate the contractor's performance. If necessary, the agency invokes a previously negotiated financial penalty against the contractor for failing to meet the objective(s). This allows the agency and contractor to assure high performance.

3. **FDA's Implementation of HHS' Unified Financial Management System.** (19017)

- **Context of Goal:** 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.

- **Performance:** UFMS went live at FDA on schedule in April 2005. Part of the FDA Go-Live in April included the interfacing and implementation of iProcurement for purchasing requisition processing and funds control, and Prism for procurement processing. FDA was the first OPDIV to implement these HHS standard products. FDA successfully submitted its year end financial statements meeting the Departments delivery dates. Participated in the Departments top down

consolidated audit which resulted in the Department once again receiving an Unqualified Audit opinion.

FDA finalized the design and configuration of UFMS and begin the electronic interfaces for FDA's existing financial applications in FY 2004. FDA will acquire and implement a new core financial management system and related financial modules (accounts receivable, accounts payable, budget execution, and user fees) as part of the UFMS project in FY 2005. FDA will pilot an activity-based costing (ABC) application as part of the Prescription Drug User Fee Act III in FY 2006. FDA hopes to finalize the ABC financial module and make it operational for all of its user fee programs in FY 2007. FDA finalized its design and configuration of UFMS in February 2004. From that time until mid- December, progress was made to prepare for the interface testing. On December 17, UFMS teams at FDA performed integration testing on the UFMS. In FY 03 major components of data cleanup were completed. Travel Manager implementation has been complete throughout the Agency in preparation of UFMS.

4. **Reduce Administrative Staff.**

- **Context of Goal:** This FDA long term goal supports the Department's priorities including: strengthening management; consolidating management functions; completing competitive sourcing; and achieving administrative efficiencies. Additionally, it is part of FDA's implementation of the President's Management Agenda. Reaching this goal is a stretch because FDA already has low administrative overhead and has an extensive field operation that requires logistical support –provided by staff with positions classified as administrative—in order to effectively perform its public health protection function. In fact, FDA already has the second lowest percentage of administrative positions to mission critical positions in the Department in FY 03: FDA at 29.6 percent compared to CMS – 46.4 percent, NIH – 46 percent and CDC – 42.2 percent.

- **Performance:** FDA met this goal in both FY 2004 and FY 2005.

5. **Enhance the Agency Emergency preparedness and response capabilities to be better able respond in the event of a terrorist attack.** (19008)

- **Context of Goal:** The Office of Crisis Management (OCM) includes the Office of Emergency Operations and the Office of Security Operations. OCM and its offices will continue to develop and implement goals that serve to improve and enhance the Agency's response capabilities to a terrorist attack. These activities continue to include the development of the Emergency Operations Network Incident Management System (EON IMS) which will provide seamless access to all FDA offices to enable them to respond quickly to the full range of FDA emergencies. The EON IMS will facilitate FDA's ability to integrate emergency related data and expertise in response to an incident of national significance as required by the National Response Plan and National Incident Management System (HSPD-5 and HSPD–8).

  The Network will be supported by an information technology infrastructure that will provide decision makers with quick access to emergency documents and information from all pertinent agency sources, as well as provide federal, state, local and international authorities with advisory information.

Other initiatives that enhance the Agency's preparedness and response include:

- Reviewing and revising the FDA Crisis Management Plan and Emergency Response Plans;
- Conducting inter and intra-Agency terrorism and emergency response exercises;
- Updating technology and equipment for the Office of Emergency Operations and the Office of Security Operations;
- Continuing to install access control devices at FDA facilities including select agent laboratories in accordance with HSPD 12
- Strengthening the coordination for inter and intra-Agency response involving laboratory testing;
- Strengthening collaborations with science and public health, law enforcement, intelligence and international communities;
- Continuing the development of the Agency's Emergency Operations Network Incident Management System;

- **Performance:** In FY05, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 2.2. The system, fully certified and accredited in September, 2004, remains in use by the FDA Office of Crisis Management/Office of Emergency Operations. Shortly after version 2.2 was launched in March 2005, the EON IMS was used in the TOPOFF 3 Congressionally mandated exercise. It facilitated FDA's management of huge amounts of data related to two hypothetical terrorist events. The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the management and coordination of the Agency's response to incidents regarding FDA regulated commodities, including outbreaks, natural disasters, e.g., hurricanes and actual or potential product defects that pose a risk to human or animal health. OCM used the mapping capabilities of EON IMS to generate geo-coded maps, which proved instrumental in the Agency's development of inspection plans and assignments related to Hurricanes Katrina and Rita.

  OCM issued the final version of FDA's Crisis Management Plan (Version 2.3) in March 2005. The plan provides the Agency with a structured methodology that enables FDA to respond to crisis situations that are beyond the capabilities of existing FDA emergency response resources. It incorporates elements describing the process by which the Agency identifies a crisis as well as the role of crisis communications in FDA's response to a crisis.

  In FY05, the Emergency Operations Center updated its technological infrastructure furthering the Agency's emergency preparedness capabilities in the event of a large-scale disaster or attack. The Office of Crisis Management continued to engage in partnerships and cooperative efforts to further the development of the HHS Strategic Exercise Plan and a Food and Agriculture Annex to the National Response Plan and to work with federal, state, local and international groups to develop best practices for emergency preparedness and response and develop exercises. OCM participated fully in two major emergency preparedness and response exercises – TOPOFF 3 and the HHS Public Affairs OPDIVs Exercise. As follow-up to TOPOFF 3 exercise, participated in three-day T3 Large Scale Game Exercise.

Summary of Measures and Results Table

	Measures	Total Reported		Total Met	Total Not Met		
FY	Total in Plan	Results Reported	% Reported	Met	Improved	Total Not Met	% Met
2002	69	69	100%	66	3	3	95%
2003	70	70	100%	65	5	5	92%
2004	53	53	100%	52	1	1	98%
2005	47	33	70%	32	1	1	97%
2006	44		0%				
2007	51		0%				

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Disposition of FY 2006 Performance Goals

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
Center for Food Safety and Applied Nutrition				
11001	Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. Measure: Complete review and action on the safety evaluation of 75% of food and color additive petitions within 360 days of receipt	Revised	Complete review and action on the safety evaluation of 70% of food and color additive petitions within 360 days of receipt	Target reduced due to strategic redeployement of resources to highest priority areas.
11010	Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the nation's food supply. Measure: Increase the percentage of the U.S. population that will live in states that have adopted the Food Code to 49 States/ 84%	Unchanged		
11040	Perform prior notice import security reviews on 38,000 food and animal feed line entries considered to be at high risk for bioterrorism and/or present the potential of a significant health risk.	Revised	Perform prior notice import security reviews on 45,000 food and animal feed line entries considered to be at risk for bioterrorism and/or present the potential of a significant health risk.	The target has been revised upward now that ORA has a complete year of experience in conducting prior notice activities.
11036	Perform 60,000 import food field exams on products with suspect histories.	Revised	Perform 73,376 import food field exams on products with suspect histories.	We have observed increased numbers of import food field exams in FY 2005 and expect that attrition will not be reflected until FY 2007. It is possible that more field exams are being performed in FY 2005 because travel funds are not available to fund inspections and other activities. The lack of travel funds will play a role in the FY 2006 activities.
19015	Perform at least 1,000 Filer Evaluations under new procedures.	Revised	Perform 965 Filer Evaluations of Import Filers.	The target has been reduced to reflect the impact of the 2005 natural disasters in the Southeastern U.S. on FDA operations.
19016	Conduct 2,000 examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported.	Revised	Conduct 2,992 examinations of FDA refused entries as they are delivered for exportation to ensure that the articles refused by FDA are being exported.	The target was increased because in FY 2004, the first year of performance under this goal, the actual performance was higher than originally estimated.

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
11020	Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. Measure: Inspect 95% of estimated 6,800 high-risk domestic food establishments once every year.	Revised	Conduct postmarket monitoring, food surveillance, inspection, and enforcement activities to reduce health risks associated with food, cosmetics and dietary supplements products. Measure: Inspect 5,963 high-risk domestic food establishments.	The target has been reduced to reflect the impact of the 2005 natural disasters in the Southeastern U.S. on FDA operations.
19013	Expand federal/state/local involvement in FDA's eLEXNET system by having 105 laboratories submit data in the system.	Unchanged		
11041	Establish and maintain a quality system in the ORA Field Labs which meets the requirements of ISO 17025 (American Society for Crime Lab Directors for the Forensic Chemistry Center) and obtain accreditation by an internationally recognized accrediting body (American Association for Laboratory Accreditation). Measure: Achieve and maintain accreditation for 13 laboratories.	Unchanged		
Center for Drug Evaluation and Research				
12001	Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available. Measure: Meet PDUFA III commitments for the review of original NDA submissions by including: Standard NDAs within 10 months: FY 06: 90% and Priority NDAs within 6 months: FY 06: 90%	Unchanged		

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
12026	Increase the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. Measure: Issue at least 10 written requests (WRs) for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for at least 10 drugs that receive pediatric exclusivity.	Unchanged		
12003	Improve the efficiency and effectiveness of the generic drug review program to ensure safer and more effective generic drug products are available for Americans. Measure: Decrease the average FDA time to approval or tentative approval for the fastest 70% of original generic drugs applications by 0.5 months.	Revised	Measure: Decrease the average FDA time to approval or tentative approval for the fastest 25% of original generic drugs applications by 0.5 months.	Target reduced due to strategic redeployement of resources to highest priority areas.
12048	Improve the efficiency and effectiveness of the over-the-counter (OTC) drug review program to ensure a safe and effective drug supply is available. Measure: Complete review and action on 100% of Rx-to-OTC Switch applications within 10 months of receipt. Make significant progress on completing 6 OTC monographs.	Unchanged		
12045	Enhance the protection of the American public against the effects of terrorist agents by facilitating the development of and access to medical countermeasures, providing follow-up assessments on therapies, and engaging in emergency preparedness and response activities. Measure: Coordinate and facilitate development for at least 6 medical countermeasures.	Unchanged		
12007	Improve the Safe Use of Drugs in Patients and Consumers. Measure: Review and provide comments on 100% of Risk Minimization Action Plans (RiskMAPs) for NMEs and for those products for which the sponsor or FDA initiated discussions, in accordance with applicable PDUFA goal dates.	Revised	Measure: Standardize Agency processes and criteria for communicating risk information to patients and healthcare providers.	Targets are being incrementally revised to bring the goal closer to an outcome goal.

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
12020	Increase risk-based compliance and enforcement activities to ensure product quality. Measure: Inspect 65% of the establishments identified as high-risk.	Revised	Increase risk-based compliance and enforcement activities to ensure drug product quality. Measure: The number of inspections conducted of domestic establishments identified as high-risk human drug manufacturers.	Given the fluctuation in the inventory, the inspection resources available, and the risk-based prioritization approach that FDA is developing, we believe that it is more appropriate to state the goal in terms of the number of inspections of the highest-risk establishments.
Center for Biologic Evaluation and Research				
13001	Complete review and action on 90% of standard original PDUFA NDA/BLA submissions within 10 months; and review and act on 90% of priority original PDUFA NDA/BLA submissions within 6 months of receipt.	Unchanged		
13002	Complete review and action on 90% of standard PDUFA efficacy supplements within 10 months; and review and act on 90% of priority PDUFA efficacy supplements within 6 months of receipt.	Unchanged		
13005	Complete review and action on 90% of complete blood bank and source plasma BLA submissions, and 90% of BLA supplements within 12 months after submission date.	Unchanged		

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
13030		New	Increase manufacturing diversity and capacity for pandemic influenza vaccine production through interacting with vaccine researchers and developers and issuing guidance and other documents and through global vaccine response coordination to facilitate the development and expedite the evaluation of cell-based technologies and dose-sparing approaches, such as the use of adjuvants. Targets: Develop a concept paper on clinical data needed to support license of new trivalent vaccines and of pandemic vaccines; draft a guidance on cell substrates to facilitate development of non-egg-based influenza vaccines; co-sponsor two workshops with WHO on pandemic vaccines.	This goal was added to account for the increase in resources received for pandemic flu. In order to assess progress towards goal attainment, targets were selected that were directly related to the strategies that will be implemented.
13012	Meet the biennial inspection statutory requirement by inspecting 50% of the approximately 2,600 registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination.	Revised	Increase risk-based compliance and enforcement activities by inspecting the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments to reduce the risk of product contamination; and by conducting human tissue inspections to enforce the new regulations. Measure: The number of inspections (1,128) conducted of the highest-risk registered blood banks, source plasma operations and biologics manufacturing establishments. Measure: The number of human tissue inspections (250) conducted to enforce the new regulations.	A new measure was added to this goal to 1) focus on human tissue inspections; 2) continue our progress towards risk-based inspection measures; and, 3) accurately reflect the performance that is attainable with current resources.
Center for Veterinary Medicine				
14020	Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. Measure: Complete review and action on 90% of original NADAs and reactivations of such applications received in FY 2006 within 230 days.	Unchanged		

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
14009	Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. Measure: Maintain biennial inspection coverage by inspecting 50% of 1,390 registered animal drug and feed establishments; and conduct targeted BSE inspections of 100% of all known renderers and feed mills processing products containing prohibited material.	Revised	Ensure the safety of marketed animal drugs and animal feeds by conducting appropriate and effective surveillance and monitoring activities. Measure: The number of inspections (618) conducted of registered animal drug and feed establishments. Measure: The number of targeted BSE inspections (527) conducted of all known renderers, protein blenders, and feed mills processing products containing prohibited material.	This goal is revised to state the goal in terms of the number of inspections. The number of facilities is continuing to show a downward trend.
Center for Devices and Radiological Health				
15033	Complete Review and Decision on 80% of Expedited PMAs within 300 days.	Revised	Percentage of Expedited PMAs reviewed and decided upon within 300 days; Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1 *Measure 1A*: Percentage of Expedited PMAs reviewed and decided upon within 300 days *Measure 1B*: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 320 days./1	Measure 1B was added
15032	Complete Review and Decision on 75% of 510(k)s (Premarket Notifications) within 90 days	Revised	Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 days./1	Separated goal statement from the measure.
15027	Maintain inspection and product testing coverage of Radiological Health industry at 10% of an estimated 2000 electronic products.	Dropped		Goal has been dropped in order to streamline the Performance Plan.
15007	Ensure at least 97% of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems.	Revised	Percentage of an estimated 9,100 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems	Separated goal statement from the measure.

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
15012	Expand implementation of MedSun to a network of 350 facilities. Measure: Maintain a cohort of 350. Roll-out non-performers and replace with new sites to maintain the 350.	Revised	Expand actively participating sites in the MedSun Network to 71%.	Expansion of the network to the total target number of sites specified in the initiative will be achieved in FY 2005. In FY 2006, FDA will change its focus to increasing the number of active facilities.
15025	Conduct 295 domestic and foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.	Revised	Conduct 278 domestic and foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.	The target has been reduced to reflect the impact of the 2005 natural disasters in the Southeastern U.S. on FDA operations.
15005.01	Utilize Risk management to target inspection coverage for Class II and Class Ill domestic medical device manufacturers at 20% of an estimated 5,540 firms.	Revised	Utilize risk management to target inspection coverage for Class II and Class III medical device manufacturers (domestic and foreign).	The Medical Device domestic inspection goal and the foreign inspection goal have been combined into one overall risk-based goal in order to continue our progress towards risk-based inspection measures.
15005.02	Utilize Risk management to target inspection coverage for Class II and Class Ill foreign medical device manufacturers at 7% of an estimated 2,500 firms.	Dropped		The FY 2006 and FY 2007 targets have been dropped for this goal. In FY 2006 and beyond, these inspections will be included in goal 15005.01 above.
National Center for Toxicological Research				
16014	Use new technologies (toxicoinformatics, proteomics, metabolomics, and genomics) to study the risk associated with how an FDA-regulated compound or product interacts with the human body. Measure: Present one finding utilizing novel technologies to assess changes in genes and pathology, and the relationship between chemical exposure, toxicity and disease.	Unchanged		
16003	Develop computer-based models and infrastructure to predict the health risk of biologically active products. Measure: Interpret at least one toxicology study at the molecular level utilizing the DNA microarray database (ArrayTrack).	Unchanged		

Goal ID	Original Goal Statement as stated in FY 06 Congressional Justification	Disposition	Revised FY 2006 Targets	Explanation
16007	Develop risk assessment methods and build biological dose-response models in support of Food Security. Measure: Demonstrate one utility of an oligonucleotide-microarray method as an integrated strategy to respond to antibiotic resistant agents in foodborne pathogens and bioterror agents.	Unchanged		
16012	Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. Measure: Present one finding utilizing neuropathology and behavioral risk evaluation in the prediction of human outcome to food-borne toxicants.	Unchanged		
Other Activities				
19006	Maintain 50% percentage of contract dollars allocated to performance based contracts	Dropped		FDA routinely meets or exceeds this goal. The targets for FY 2006 and FY 2007 have been dropped.
19017	FDA's implementation of HHS's Unified Financial Management System. Measure: FDA will pilot an activity-based costing application integrated with HHS UFMS project as part of Prescription Drug User Fee Act III. The UFMS and its FDA modules will be operational in FY05 allowing FDA's legacy system core financial system to be decommissioned during the first quarter of FY 2006	Unchanged		
19008	Enhance the Agency Emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack. Measure: Enhance functionality and continue deployment of the National Incident Management System throughout the Agency (HQ, Centers, Field offices).	Unchanged		