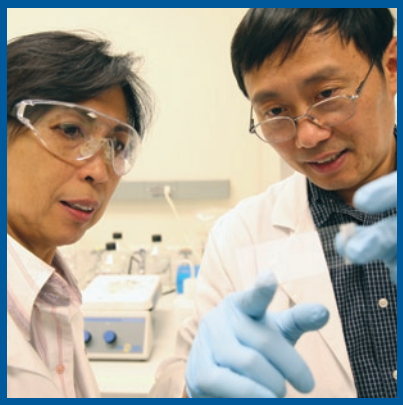



FDA Strategic Action Plan

Charting Our Course for the Future

Fall 2007

Department of Health and Human Services

U.S. Food and Drug Administration

MESSAGE FROM THE COMMISSIONER

I am proud to present the Food and Drug Administration's Strategic Action Plan, which sets forth our long-term strategic goals and objectives. The plan also details specific actions we are committed to taking over the next eighteen months as we carry out our mission of promoting and protecting the public health.

Leading any organization is in some respects analogous to navigating challenging rapids in a white-water raft. Both tasks involve dealing with day-to-day crises (or getting through the toughest rapids on the river) while charting a strategic course that allows the organization to fulfill its mission over the long haul (navigating the raft safely to the chosen destination). Leading the FDA is no exception—and if anything the scope and complexity of our public health responsibilities makes planning ahead an even greater challenge.

This new Strategic Action Plan charts our course for the future, focusing on four strategic goals: strengthening the FDA, improving the safety of patients and consumers, increasing access to new medical and food products, and improving the safety and quality of manufactured products and the supply chain. Each of these goals represents a fundamental public health task that is crucial to fulfilling our mission.

As specific and as detailed as this plan is, however, it will account for nothing unless we use it as a blueprint for our public health work over the next year-and-a-half. For in the end, this Strategic Action Plan is all about trust. It is about establishing trust by doing the right thing, and by doing it in the right way.

If we can accomplish what we propose—and I have no doubt that we can and will—then we will strengthen the trust of the public that we serve.

I would like to thank all the FDA employees from across the agency who contributed their ideas, suggestions, experience and talent to this strategic plan. I would also like to thank each and every FDA employee for their dedication to our public health mission. It is an honor to serve as Commissioner of Food and Drugs, and I look forward to working closely with FDA employees and stakeholders alike as we strive to accomplish all goals of this Strategic Action Plan.

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Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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INTRODUCTION

In this document we describe the FDA Strategic Action Plan, including the long-term mission goals and objectives identified by senior management. These goals and objectives provide the vehicle for focusing agency efforts to achieve FDA's public health mission and to fulfill our role in supporting the larger mission and strategic goals of the Department of Health and Human Services. In this document we also describe the specific actions we will undertake within the next eighteen months, to deliver major progress toward these goals and objectives.

Challenges and Opportunities Facing FDA

FDA must maintain the balance of protecting and promoting public health. US consumers rely on FDA to protect them from unsafe medical products and contaminated food. This is our first and foremost responsibility. We are also charged with promoting public health, by guiding and supporting the continued development and availability of safe and effective new medical technologies and safe and nutritious new food products. We do this to ensure that US consumers benefit from the latest science and technology to improve their health and well being. However, new medical and food technologies will always present uncertainties about benefit versus risk. In determining whether a new product can be marketed to consumers FDA must make a determination of the benefit versus risk based on the best available science. New information may later become available that will require revising our earlier assessment of benefits and risks. Given this reality of advancing science and emerging information, we have come to view our public health responsibilities in terms of the entire life cycle of the product—from the earliest data on benefit-risk to long experience with marketed use, and spanning the supply chain from source of ingredients to point of consumption.

HHS Mission: The HHS mission is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

FDA Mission: The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

To effectively perform our public health mission we must recognize and address important challenges resulting from continuing changes in technology, markets, and consumer needs.

- Patients and consumers, equipped with advanced communication technology and Internet resources, and facing a complex array of health decisions, both need and have come to expect rapid access to more and better information, to inform their choices related to food and medical products.

- A wide array of new science and technology challenge us to create science-led regulation that enables and accelerates—and does not inhibit—the development of a new generation of even safer and more beneficial products.

- The rapid expansion of global markets where ingredients originate, clinical trials are conducted, and products are manufactured, presents the benefit of lower costs but a challenge for regulatory oversight to ensure safety.

- The emergence of new infectious disease and bioterrorism threats demands that the US public health system react quickly and effectively to natural and man-made threats, through better informatics and rapid testing capabilities. It also requires better anticipating and preventing harm through modernized development of new vaccines, antibiotics and other medicines to combat these threats.

Each of these trends provides FDA a challenge but also an opportunity for innovation and more effective use of technology and partnering to achieve our mission. We must also strengthen public confidence in FDA's ability to protect and promote the public health by improving operating infrastructure and modernizing regulatory processes, and maintaining scientific independence.

This strategic action plan marks the path to achieve our vision for FDA in the 21st Century. That vision calls for an organization that is dedicated to excellence as a science-based and science-led regulatory agency that provides global leadership in protecting public health. To do this we will harness the science of molecular medicine and nutritional health. Recognizing that new scientific findings will increase and evolve our knowledge and understanding of product risks and benefits, we will take a comprehensive Quality Systems approach to ensure safety through the entire lifecycle of regulated products. Our quality systems approach will emphasize prevention, improve our capability to detect and isolate problems, involve development of a more robust response capability, and improvement of our ability to facilitate recovery.

We cannot address these challenges and achieve our vision single-handedly. FDA will partner with other public agencies and private entities to implement better systems, facilitate development of new technology to ensure the safety and integrity of the product supply chain, and better-informed, safer product use.

STRATEGIC GOAL 1 STRENGTHEN FDA FOR TODAY AND TOMORRROW

Our vision for FDA in the 21st Century calls for an organization that is dedicated to excellence as a science-based and science-led regulatory agency that provides global leadership in protecting public health. New molecular discoveries and new materials, including bioengineered tissue, and new technologies including nanotechnology, robotics and others are ushering in a new generation of products including therapies for personalized medicine. Evaluating these products will involve many sources of data and conflicting information related to new products and currently marketed ones. New science will raise new questions and new sources of uncertainty about effectiveness and safety. To achieve the best public health protection FDA will need the best scientific talent and expertise, and an environment that applies rigorous standards and encourages vigorous debate.

To ensure the best public protection now and in the future our first goal is to strengthen FDA for today and tomorrow. We'll achieve this goal by pursuing the following objectives:

- Strengthen the scientific foundation of FDA's regulatory mission
- Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.
- Enhance partnerships and communications.
- Strengthen FDA's base of operations.

Signature Initiative: FDA Fellowship Program

Scientific and biomedical advances will create unprecedented demands on FDA's ability to maintain a strong and contemporary workforce. Yet, today, there are few programs equipped to train individuals in regulatory science—how to apply new biomedical discoveries to product evaluation.

A new Food and Drug Administration Fellowship Program will be the cornerstone of FDA's personnel succession planning efforts. The goal of this Fellowship Program is twofold: to ensure that FDA has a robust and skilled workforce capable of meeting its mission today and into the future; and to enable FDA to respond quickly to the Agency's hiring and leadership needs, especially in mission critical occupations.

The two-year fellowship program will be designed to recruit and retain prospective candidates from scientific and administrative disciplines essential to fulfilling FDA's mission. This program will provide the candidates a vehicle for developing and enhancing their scientific, regulatory, leadership, and business skills through experiential learning and training. As part of the program, each candidate will be assigned to a position appropriate to their expertise within a Center. In addition to their position within FDA, they will be given other opportunities to augment their skills through rotations, professional forums, and competency training.

Once established, this program will become part of the FDA culture and will provide a mechanism for the FDA to attract individuals with expertise essential to FDA's mission (for example, expertise in cutting-edge scientific disciplines) and who are eligible to become part of the FDA workforce.

OBJECTIVE 1.1

Strengthen the scientific foundation of FDA's regulatory mission.

Our first objective under Goal 1 is to strengthen and sustain FDA's scientific expertise, to be ready to ensure safety and continued development of innovative technology. We will pursue this objective through the development of a new collaborative program that will bring new scientific staff fellows to FDA (see *Signature Initiative: FDA Fellowship Program*, page 4). This program will provide these new scientists and technical experts with valuable experience with regulatory decisions involving path-breaking technologies and critical safety questions. The program will in turn provide FDA with access to new scientific talent with relevant research and applied experience.

To ensure significant progress in strengthening the science base of FDA's mission, we will take the following specific actions within the next 18 months:

Establish Fellowship Program:
The FDA Fellowship program will help build and maintain the FDA workforce for the 21st century. The 2 year Fellowship will be designed to increase the exchange of scientific information between FDA and external entities. It will also facilitate FDA fellows serving as "ambassadors" to academia, industry, health professionals, and other government organizations. In the first year, FDA will appoint approximately 100 fellows to participate in the program. Based on applicant's area of expertise, he/she will be accepted into one of the two following tracks:

1. Scientific Track – provides opportunities for individuals with a science background to learn about and participate in FDA-related regulatory review and research functions and to interact with other public and private sector agency personnel to enhance regulatory science.

2. Administrative Track – provides opportunities for individuals with an administrative background to learn about and participate in various activities aimed at improving the efficiency and effectiveness of operations in the Center/Office to which he/she is assigned.

Next Steps: We will have a business plan established and cleared through FDA by the fourth quarter 2007

Develop FDA Workforce Strategic Plan:
Using the 2007 agency analysis of Areas of Scientific Expertise Needed at FDA, agency management will identify the set of core competencies needed to build and sustain FDA leadership in science-based regulation and program management. This will be used to develop the FDA strategic plan for staff recruitment, training and succession planning for the next five years.

OBJECTIVE 1.2

Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.

To ensure that FDA continues its record of excellence as a regulatory agency, we must apply methods of scientific analysis with consistency, uniformity, and integrity. And though the data we review may be proprietary, our decision processes must be transparent and open to scrutiny, allowing for diverse points of view and vigorous debate. Assessing the risk and benefit of medical products and food ingredients is extremely difficult and requires various individual skills that are integrated and coordinated. At the FDA we can excel as individuals, but patients and the public benefit the most through our close and productive working relationships and interactions. Thus the focus of this objective is the development of effective teams in performing all of our regulatory functions.

To ensure significant progress in cultivating a culture that promotes transparency and effective teamwork, we will take the following specific actions within the next 18 months:

Develop FDA Core Values Statement:
FDA Workplace Culture Initiative Co-Chairs will develop an FDA values statement, based on survey and focus group input of staff throughout the agency, to serve as guiding principles for agency operations. New FDA culture initiatives and the draft Values statement was presented at an All-Hands Broadcast by the FDA Commissioner in September 2007.

Develop FDA Teamwork Best Practices:
The Office of the Commissioner will coordinate a process to identify, document and share teamwork best practices that have been developed and found effective by centers and offices across the agency. This will result in a reference list that will be compiled and shared with center and office managers and posted to the agency intranet.

Strengthen FDA Advisory Committees:
Advisory committees play a vital role in FDA's activities to protect and promote public health. We are committed to making the FDA advisory committee process even stronger and better understood so that the public has confidence in the integrity of advisory committee recommendations. In that spirit, FDA has taken the following recent steps:

- On February 26, 2007, FDA launched a new website designed to provide up-to-date information about FDA advisory committees and to provide an additional recruitment tool for our committees. *www.fda.gov/oc/advisory/vacancies/acvacmain.html*

- On February 28, 2007, FDA published the "Draft Guidance for Industry Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members" *www.fda.gov/oc/advisory/ACGuidanceOnInfo.html*. This guidance describes the process FDA intends to follow when making briefing materials available to the public

- On March 23, 2007, FDA Published a "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees" *www.fda.gov/oc/advisory/waiver/COIguidedft.html*. This draft guidance is intended to provide improved transparency and consistency in the use of waivers of conflicts of interest to enhance public trust in this important function.

Upcoming actions in the next 18 months:

- Draft guidance on the public disclosure of conflict of interest information.

- Finalizing the "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees"

- Finalizing the "Draft Guidance for Industry Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members"

- Internal procedures for addressing security at FDA Advisory Committee meetings.

- Developments and improvements for the FDA Advisory Committee website to enhance transparency to the advisory committee process as well as provide easier access to important information and documentation.

- Electronic applications to improve efficiency of document review, storage and retrieval.

- Increasing recruitment efforts to find members with minimal conflicts of interest to serve on our advisory committees.

OBJECTIVE 1.3
Enhance partnerships and communications.

To better leverage limited resources and maximize protection of public health, we need to build effective partnerships with other organizations with shared goals and capabilities that can enhance the agency's efforts. These collaborations include but are not limited to state and international regulatory partners, to study and monitor medical products throughout their entire life cycle. Working closely with our counterparts abroad, whether in generating data about potential new therapies or monitoring their safe use, represents yet another way this agency strives to carry out its mission of promoting and protecting the public health.

We can also leverage the capabilities of health professionals and the public by providing more and better information related to benefits, risks and safe use of FDA-regulated products.

To ensure significant progress in enhancing partnerships and communications, we will take the following specific actions within the next 18 months:

Establish an FDA Risk Communication Advisory Committee:
By 2008, FDA will establish and convene the first meeting of a new Advisory Committee to help FDA understand the diverse communication needs of the public and patients and the best evidence on risk communication tools and strategies. FDA is establishing this committee partly in response to an Institute of Medicine recommendation in its September 2006 report "The Future of Drug Safety." The committee's advice will help us strengthen the public's ability to use product information to better achieve health benefits and avoid the risks of all regulated products. It will also provide a standing channel for facilitating dialogue with the public concerning our risk communication activities.

Further Expand FDA's Formal International Notification and Coordination Process to Help Manage Public Health Concerns Involving FDA-regulated Products:
Recognizing the global environment in which FDA-regulated products are developed, tested, authorized, traded, and used, FDA will further expand its ability to work closely with international counterparts to help manage public health emergencies and other concerns with FDA-regulated products. FDA will meet annually with the European Medicines Agency, the European Union's Directorate General for Health and Consumer Protection (DG-SANCO), the "Quadrilateral" Group (Australia, New Zealand, and Canada), SwissMedic (the Swiss Medical Products Regulatory Authority), Japan, China, and the Trilateral Group (Canada and Mexico) to plan and coordinate information sharing on key public health issues.

Leverage the Resources of Key International Counterparts to Help Make Products and Technologies Available Sooner:
To leverage scientific, human, and financial resources, as well as harness the knowledge and experience of other international authorities, FDA anticipates expanding its work under confidentiality arrangements and implementation plans with key international regulatory

agencies such as the medical products regulatory authorities in Belgium, Denmark, the European Commission, the Netherlands, and New Zealand as well as expanding cooperation with the European Food Safety Authority regarding food safety risks.

OBJECTIVE 1.4
Strengthen FDA's base of operations.

Science-led modernization of FDA regulatory processes will require modernized facilities to support more efficient operations with current-state technologies. It will also require innovative approaches to expand access to scientific expertise to integrate emerging science into regulatory processes. FDA operations in the 21st century will require modern information infrastructure and information management to enable quantum improvements in data-driven regulatory decision processes. It will also require vigorous enterprise-wide management and coordination of resources, especially people, budget, and facilities.

To ensure significant progress in strengthening FDA's base of operations, we will take the following specific actions within the next 18 months:

Modernize FDA's Information Technology platform:

- Agency Wide Approach to IT – Assemble Agency Wide IT Teams across the Centers/Offices to leverage the expertise for systems which perform similar functions through the continuum of products that the FDA Regulates. This will enable synergy and the ability to share data throughout the FDA to identify and mitigate potential signals more effectively and efficiently.

- Information Technology Transformation – To ensure the FDA has the platform required to meet the Agency Wide IT initiatives and to move towards the Bioinformatics era of science based decisions in the 21st Century, we have undertaken the Information Technology Transformation Initiative which will provide the Agency the opportunity to enhance the IT infrastructure while creating a robust foundation to enable interoperability across the FDA.

- Deliver essential computational tools for FDA scientists and professionals which provide robust bioinformatics capabilities to strengthen product development and approval, improve manufacturing and product quality, strengthen post-approval surveillance and safety, support electronic prescribing, and improve clinical decision support.

- Deliver new information technologies, driven by increases in computational power and sheer volumes of data, to continue to accelerate, and transform nearly every aspect of FDA operations, from scientific computing to adverse event detection.

Establish the White Oak campus as the new venue for scientific and cultural synergy:

- Complete the design for the two new life sciences laboratory buildings which will house the research programs of CBER and CDER which are presently housed on the NIH campus. These buildings will provide the opportunity to incorporate advanced laboratory design features and full integration of the center programs, including the integration of CBER researchers and reviewers in a collaborative setting. These buildings will mark a significant advance in FDA's goal of achieving maximum synergy and collaboration among its components as we consolidate on the White Oak campus.

- Plan and execute Phase I of the consolidation of the FDA Biosciences Library at the White Oak Campus. This facility will support FDA regulatory research and review, provide an efficient and inviting environment for agency staff for scientific and regulatory information access and exchange, and provide value-added services and unique information delivery to support our public health mission.

- Expand the capability of the current White Oak Conference Center to support FDA and interagency collaborative initiatives. We will plan and execute an expansion of capability of

the FDA Conference Center at the White Oak Campus to maximize its overall effectiveness in support of research and scientific collaboration. Within the next 18 months, FDA will evaluate and recommend cost effective investments to increase the overall effectiveness of the Conference Center in support of the agency mission. This facility will provide space for increased scientific staff training including computer training rooms to expand staff training in new software tools for scientific research and regulatory review, shared-use meeting space to facilitate internal and external scientific collaboration, large meeting areas for regular scientific conferences and symposia in a location proximate to product reviewers, thus allowing increased participation, and video conference support and capability supporting greater collaboration with national and international scientific colleagues

Improve Property Management:

- Perform a comprehensive revalidation of all facility information in the real property portfolio and improve utilization of personal property.

STRATEGIC GOAL 2 IMPROVE PATIENT AND CONSUMER SAFETY

The quality of information available to guide decisions of medical professionals and consumers on products can vary widely in terms of the information's accessibility and accuracy. All of a product's benefits and risks are not known at the time of pre-market review and our current passive post-market safety surveillance system is inefficient and provides incomplete, sometimes confusing, safety signals. More advanced science (e.g., using biomarkers, genetic testing, etc.) is needed to develop safer products and testing methodologies to guide safe use. Better informatics is needed to enable easy and accurate reporting of any safety problems from regulated products, and to obtain ready access to large population databases for real-time analysis of the clinical context in which the safety problems occur. We also need more effective and timely communications with patients and consumers to explain what is known and not known in a manner that best supports their decision making regarding use of regulated products.

We plan to overcome these challenges by improving scientific methods and technologies and initiating a life cycle approach to ensuring product safety through a vigorous proactive safety program. We will achieve this goal by pursuing the following objectives:

- Strengthen the science that supports product safety
- Improve information systems for problem detection and public communication about product safety
- Provide patients and consumers with better access to clear and timely risk-benefit information for medical products
- Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition

Our recently announced Medical Product Safety Initiative is a signature effort supporting Goal 2 (see *The Future of Drug Safety* below).

The Future of Drug Safety – Promoting and Protecting the Health of the Public
FDA's Response to the Institute of Medicine's 2006 Report

The safety of drugs and other medical products regulated by the U.S. Food and Drug Administration (FDA) has always been, and continues to be, a key focus of FDA's programs. This issue is of vital importance to the health of the United States public and to the mission of FDA. FDA is committed to having a state-of-the-art drug safety system. Emerging science and technology are driving a transformation of all aspects of medicine including drug safety. FDA is keeping pace with this transformation through a series of changes and improvements to its drug safety system.

The Agency will accomplish this transformation by:

A. Strengthening the science that supports the FDA's medical product safety system at every stage of the product life cycle from pre-market testing and development through post-market surveillance and risk management. This includes:

1. Upgrading methods of benefit and risk analysis and risk management
2. Strengthening methods and tools of safety surveillance
3. Developing new scientific approaches to detecting, understanding, predicting, and preventing adverse events

B. Improving communication and information flow among all stakeholders engaged in promoting the safe use of medical products. This includes:

1. Conducting a comprehensive review of current public communication tools
2. Establishing an Advisory Committee on communication
3. Using fees to fund improvements in communication among staff on safety issues
4. Issuing drug safety information guidance
5. Publishing a newsletter on post-market findings
6. Posting reviews of NDA supplements and assessments of post-market safety studies

C. Improving operations and management to ensure implementation of the review, analysis, consultation, and communication processes needed to strengthen the U.S. drug safety system.

1. Engaging external management consultants to develop a comprehensive strategy for improving organizational culture
2. Making specific organizational and management changes to increase communications among review and safety staff
3. Improving our use of Advisory Committees

OBJECTIVE 2.1

Strengthen the science that supports product safety.

The science of safety is still evolving. We will work collaboratively to maximize patient and consumer safety through new and more precise molecular information to predict patient risk, state-of-the-art systems for safety surveillance and effective risk communications, and modernize drug development and regulatory processes using a life cycle approach. Through several new initiatives such as the personalized medicine initiative, FDA will improve the safety, quality, and effectiveness of healthcare through medical products tailored to meet each patient's needs. We will also expand the science that identifies food safety threats, sources of contamination, their mode of spread, and options to prevent contamination and focus the food safety system on prevention rather than reaction.

To ensure significant progress in strengthening the science that supports product safety, we'll take the following specific actions within the next 18 months:

Strengthen the System for Drug Safety:
We will conduct a pilot study to review systematically and collaboratively the safety profiles of new molecular entities (NMEs) on a regularly scheduled basis to determine whether these reviews should be initiated for all NMEs as suggested by IOM in its 2006 report on the Future of Drug Safety. Post marketing evaluations of NMEs will incorporate data from the Adverse Events Reporting System (AERS), data mining analysis, epidemiologic data, post marketing clinical trial information, and a review of the Periodic Safety Update Reports (PSURs) or U.S. Periodic Report, to identify potential safety concerns early in the product life cycle.

Personalize Dosing to Reduce Risk in Warfarin Therapy:
We are collaborating with the C-Path Institute and the University of Utah on the Cardiovascular Drug Safety and Biomarker Research Program to develop a pharmacogenetic algorithm to help personalize dosing of warfarin. Warfarin, a very effective blood-thinner used by roughly two million Americans annually, is the second most common drug implicated in emergency room visits for adverse drug events. Treatment is complicated because about one third of patients receiving warfarin metabolize it quite differently than expected, and may experience recurrent clots associated with strokes due to inadequate dosing, or serious bleeding due to excessive dosing. By developing a pharmacogenomic algorithm for doctors to use to improve warfarin dosing, these adverse events could be significantly reduced, and the costs of treating them could be reduced by more than a billion dollars per year by one estimate.

Enhance Adverse Event Evaluation of Potential Pandemic Influenza Vaccines:
We will develop a pilot program that utilizes a national healthcare organization's database for safety evaluation of potential pandemic influenza vaccines and will assess the feasibility of such programs for other major national databases.

Use New Scientific Tools to Enhance Blood Safety:
We will continue collaborative efforts with the CDC (Centers for Disease Control and Prevention) to identify emerging threats to the nation's blood supply and facilitate the development, evaluation, and deployment of modern technologies that address them. Examples include nucleic acid amplification testing for HIV, hepatitis C, and, most recently, West Nile Virus. An ongoing effort targets new emerging threats such as Chagas disease and malaria.

Issue Final Fresh Cut Produce Guidance:
We will finalize the draft "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide) which is intended to be used in conjunction with the GAPs/GMPs Guide, which covers stages prior to fresh-cut processing, with the current GMPs in 21 CFR Part 110, which contain food safety practices applicable to processors who manufacture, process, pack, or hold processed food, and with the FDA Food Code which focuses on activities at subsequent stages, such as retail.

Develop Protocols for High-Throughput and Novel Technologies for Rapid Pathogen Detection:
We are developing protocols for rapid, high-throughput automated instrumental and computational technologies to determine the presence of biological threats or hoax materials, pathogenic bacteria in complex food mixtures and species-level characterization of bacteria. These techniques incorporate and build upon advanced technologies employed in industry and new technologies under development.

OBJECTIVE 2.2

Improve information systems for problem detection and public communication about product safety.

FDA has long needed to transform its approach for identifying pre- and post-market safety signals. Specifically, we need to develop tools and methods for active post-market surveillance, build pre-competitive data libraries to research safety data across medical products, upgrade existing adverse event reporting systems, and institutionalize these tools throughout FDA business. Over the next several years, FDA will seek access to data bases that will identify the full array of safety problems across populations and sub-populations, develop alternative data mining and signal detection methods for medical products safety analysis, develop data management tools that provide reviewers with current information and the ability to track safety signals over time, and create a single web-based portal, known as MedWatch Plus, for reporting of adverse events associated with all FDA-regulated product, among many other initiatives.

To ensure significant progress in improving the information systems that support product safety, we'll take the following specific actions within the next 18 months:

Enhance and Modernize FDA Product Safety Systems:
We will improve the utility of existing tools for the detection, evaluation, prevention, and mitigation of adverse events, and continue to enhance and improve communication and coordination between post-market and pre-market review staff. Enhancements to the post-market product safety systems will improve the public health by increasing patient and consumer protection while continuing to enable access to needed products.

Build Easier Safety Reporting with MedWatch Plus:
Within the next eighteen months we will make it easier for health professionals and the public to report problems related to the safety of FDA-regulated products, including dietary supplements, by developing a single Internet portal for all health provider and public adverse event reporting.

Begin Building a National Sentinel Network for Patient Safety:
FDA, in coordination with other Federal agencies, recommends assembling an integrated "virtual" national medical product safety network—the Sentinel Network—which would enable the electronic flow of safety information to and from the point of care. The network will build on existing public and private efforts through multiple, broad-based, public-private collaborations.

Expand Agency Officials' Real-Time Access to Information Related to Crises and Emergencies:
The FDA Office of Crisis Management's Emergency Operations Network Incident Management System (EON IMS) captures and stores large volumes of information related to outbreaks, natural disasters and actual or potential FDA-regulated product defects that pose a risk to human or animal health. FDA intends to deploy EON IMS throughout the agency to better manage and coordinate the agency's response to emergencies and to maximize the involvement of key agency decision makers in the agency's crises and emergency response efforts.

Reduce Patient Injury from Medical Devices:
To enhance our ability to increase patient safety with the use of medical devices in the post market area, FDA will complete the initial phase of the medical device Post-Market Transformation effort which includes the development of a matrix structure, developing more effective measures for post-market accountability, enhancing the utility of the Medical Product Surveillance Network (MedSun) programs, and continuing the development of electronic adverse event reporting.

OBJECTIVE 2.3

Provide patients and consumers with better access to clear and timely risk-benefit information for medical products.

FDA's responsibility to ensure safe use of medical products does not end at the pharmacy or retail shelf. Even the safest medical product can be dangerous if used at the wrong dose, by the wrong person, or in the wrong way. Often, the risk-to-benefit balance is not clear. As medical products and medical science become increasingly complex, and as patients increasingly use multiple medical products at once, patients and their health care providers must make difficult treatment choices in the face of significant unknowns.

To ensure significant progress in improving communications on the benefit versus risk of medical products we'll take the following specific actions within the next 18 months:

Publish an electronic Newsletter on Post-market Drug Safety Findings:
In 2007, we plan to regularly publish an electronic newsletter on the FDA Web site containing summaries of the results, including methods, of FDA post marketing drug reviews. The sum-

maries will not include confidential commercial or predecisional information. We believe it is important, particularly for healthcare professionals, for FDA to make readily available and easily accessible the results of our post marketing reviews of adverse events. In addition, this regular newsletter will contain information on emerging safety issues, as well as provide information on recently approved products both to inform providers and to encourage reporting to FDA.

Risk Communication Advisory Committee:
Communicating the risks and benefits associated with FDA-regulated products is essential to help consumers and health care professionals make informed decisions. On June 4, 2007, FDA established its Risk Communication Advisory Committee, which will help FDA better understand risk communication needs and priorities of the general public; advise FDA on the development of strategies to communicate product risks and benefits; and make recommendations to FDA on what current research suggests about crafting risk and benefit messages, as well as how to most effectively communicate specific product information to vulnerable audiences. The Risk Communication Advisory Committee is expected to hold its first meeting in the first quarter of 2008.

OBJECTIVE 2.4

Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.

FDA will change the strategy of the food safety program from a reactive system to a proactive system that is focused on prevention. We will be working with industry, other federal agencies and international health organizations to identify problems sooner, improve communication and ensure rapid notification of risks from tainted food products. We will promote health by assuring that our food is not only safe but nutritious. Our Food Protection Plan represents a major new effort in this area (see S*ignature Initiative: Food Protection plan* below).

We are also working to develop a new generation of validated risk communication methods that will increase the public's ability to use product information to improve diet and health and to reduce the risk of food borne illness. We will also promote healthy choices by ramping up efforts to educate the American public on the relationship between diet and disease and enhancing consumer nutritional information.

Signature Initiative: Food Protection Plan
Within its current regulatory framework, FDA has accomplished much to ensure the safety and security of human and animal foods. Nevertheless, it is clear that global food sources along with new methods of production, distribution and consumer demand combined with an increasingly susceptible population means we are continually dealing with new challenges and risks to the safety and security of the Nation's food supply. Having a safe and secure food supply is critical for public health and the economy of the United States, and as part of our national infrastructure of vital commodities.

To respond to today's challenges, FDA will focus a greater emphasis on preventing food safety problems before they occur and, if prevention fails, responding rapidly to minimize the public health impact. This shift to prevention is at the core of FDA's proposed food protection strategy which will be accomplished through prevention, interventions, and response.

To strengthen its efforts to prevent contamination, FDA plans to strengthen support of food industry efforts to build safety into products manufactured either domestically or imported. The FDA will work with industry, state, local, and foreign governments to identify vulnerabilities and will look to industry to mitigate those vulnerabilities, using effective methods such as preventive controls.

The plan's intervention element emphasizes focusing inspections and sampling based on risk at the manufacturer and processor level, for both domestic and imported products,

that will help verify the preventive controls. This approach is complemented by targeted, risk-based inspections at the points where foreign food products enter the United States, including ports.

The plan calls for enhancing FDA's information systems related to both domestic and imported foods to better respond to food safety threats and communicate during an emergency.

The Food Protection Plan's three core elements—prevention, intervention, and response—incorporate four cross-cutting principles for comprehensive food protection along the entire production chain:

- Focus on risks over a product's life cycle from production to consumption;
- Target resources to achieve greatest risk reduction;
- Use interventions that address both food safety (unintentional contamination) and food defense (deliberate contamination); and
- Use science and employ modern technology, including enhanced information technology systems.

To ensure significant progress in improving the information on food safety and nutrition we'll take the following specific actions within the next 18 months:

Promote Healthy Choices by Enhancing Consumer Nutrition Information:
For the past several years, FDA has been actively involved in labeling and risk communication efforts aimed at increasing the knowledge of the American consumer about the relationship between diet and disease. In 2007, FDA will conduct a study to assess how effective these efforts have been by evaluating the American consumer's understanding of the relationship between diet and heart disease.

Enhance the Safety of Fresh Produce by Engaging Public Input:
FDA is committed to receiving and considering the input from its stakeholders on important food safety issues such as risks associated with food-borne illnesses. In 2007, FDA will hold two public hearings concerning the safety of fresh produce. The purposes of the hearings are for FDA to share information about recent outbreaks of food-borne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and other scientific information about: current agricultural and manufacturing practices used to produce, harvest, pack, cool, process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures by FDA to enhance the safety of fresh produce.

STRATEGIC GOAL 3 INCREASE ACCESS TO NEW MEDICAL AND FOOD PRODUCTS

Between 1994 and 2003, public and private biomedical research funding in the United States doubled (when adjusted for inflation, from $37 billion to $94 billion). This investment is already paying off, in the form of new information about the human genome, new biomedical materials, and molecular-level analysis. But this biomedical revolution has not delivered on its promise of better health and health care. New medical product submissions to FDA are flat or declining, and 2004 was a new low world-wide in the number of new molecular entities launched. Many diseases still lack effective treatment, while the cost of new medical product development is higher than ever.

Through Strategic Goal 3, FDA science will become a bridge to medical product innovation and the era of personalized medicine, and help Americans have greater access to benefits from the National Institutes of Health's investment in biomedical research. FDA can harness the new genetic and molecular sciences, new advances in imaging and bioinformatics, and other biomedical breakthroughs to create a new generation of cutting edge scientific regula-

tory standards that provide both predictability and enhanced efficiencies for product development. Such standards will incorporate new tools that better predict a product's efficacy and/or safety, and do so earlier in the development process. This will help sponsors shorten medical product development time, identify unpromising products earlier in development, and get more products with more promise into the development pipeline.

Specific examples of such tools—new biomarkers, better clinical trial designs and endpoints, in silico testing, standards to accelerate review of generic animal drugs—are included in the Action Items, below.

OBJECTIVE 3.1

Increase the number of safe and effective new medical products available to patients.

Through concrete actions such as the following, FDA will create a new generation of product development science, so that product sponsors will have the information and predictability they need to increase the efficiency and effectiveness of their product development strategies.

Signature Initiative: Critical Path for New Products

The FDA's Critical Path Initiative harnesses the latest discoveries – in genomics, proteomics, tissue engineering, imaging, and bioinformatics – to improve the efficiency and effectiveness of product development, evaluation, and manufacture.

First Steps:

Starting with medical products, in 2004, FDA issued a report outlining the path for identifying scientific hurdles that impede medical product development, and calling for a national effort to modernize the product development sciences. FDA issued a follow-up report in March 2006, describing 76 concrete scientific impediments to product development identified by our outside stakeholders and inside experts.

Today:

FDA, through an array of public-private partnerships, has initiated efforts to solve more than a dozen of these hurdles. The Initiative has rapidly matured and is now poised to yield benefits across all medical product areas. In addition, FDA recognized that the need to modernize the product evaluation sciences is not limited to human medical products, and has added veterinary and food product regulatory science to the Initiative.

Today, FDA is building on its unique position to work with outside stakeholders to identify areas ripe for improvement, and to coordinate, develop, and/or disseminate solutions to scientific hurdles that are impairing the efficiency of developing and evaluating FDA regulated products.

Tomorrow's Promise – Personalized Medicine:

Many Critical Path tools (such as new biomarkers and more informative clinical trial designs) also produce enhanced information about the safety and efficacy of the product, information that health care providers can use to tailor therapies to the individual needs of patients—the foundation of personalized medicine.

For example, better methods for selecting patients and assessing their responses during a clinical trial can translate directly to better methods of diagnosing and monitoring patients in the clinic, and better methods for targeting treatments to the patients who are most likely to benefit. Such tools will help bring individualized medicine into the physician's office, to help shape the medical practice of the future.

To ensure significant progress in improving the medical product review process we will take the following specific actions within the next 18 months:

Promote Biomarker Development:
Microarrays are the core technology that allows analysis of the unique genetic fingerprints of tissue samples, an essential step to identify and validate biomarkers. Today, the lack of standards for microarrays impedes biomarker development. Over the next 18 months, through partnerships with industry, academia, and others, FDA will establish consensus standards for analysis of microarray data.

Oncology Biomarker Qualification Initiative:
FDA will expand its collaboration with the National Cancer Institute and the Centers for Medicare and Medicaid Services to qualify cancer biomarkers that could be useful in research, product assessment, and decisions about evidence-based coverage.

New Trial Designs for a New Era:
As science identifies new biomarkers and innovators develop novel products, old trial designs will not produce optimal information about the risks and benefits of investigational products. Medical product innovators urgently need new trial designs. However, the rigorous work to ensure that they produce valid, reproducible, and unbiased results is labor intensive and time consuming. FDA will develop new regulatory standards and guidances that promote sponsors' use of innovative clinical trial designs that more reliably assess the safety and effectiveness candidate medical products.

Improve Cardiac Drug Stent Design and Use:
FDA will develop components of a simulation model of drug eluting stent behavior in adults and children, and develop open-source imaging software to assess stent performance. Over time, this work will result in new guidance for industry on using the simulation model to predict device performance, to help accelerate sponsors' efforts to develop new, safer stent products.

Reducing Drug-Induced Liver Injury:
Drug-induced liver injury is one of the most common severe adverse effects attributable to prescription drugs. FDA will collaborate with the National Institutes of Health, academia, industry and others to develop a computer model that will help researchers identify early signs of liver toxicity. This will help sponsors identify unsafe products earlier in development, and help clinicians detect drug-induced liver toxicity before significant damage has occurred.

OBJECTIVE 3.2

Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

FDA will modernize the scientific tools that support product review, and the corresponding review processes, to reflect the new generation of product evaluation tools and the innovative products we expect to see over the next decade. To ensure transparency, FDA will publish new guidances to reflect these changes.

To ensure significant progress in improving the medical product review process we will take the following specific actions within the next 18 months:

Pre-market Information Tracking Warehouse:
FDA will integrate information about medical device pre-market decisions into a single, comprehensive pre-market tracking warehouse that FDA staff can access and query using sophisticated analysis and reporting tools. By expanding reviewer access to relevant information, this comprehensive information set will reduce the time needed by reviewers to conduct the research required to make decisions on pre-market submissions.

Bioinformatics to Support Drug Innovation:
FDA will collaborate with the National Cancer Institute to implement an electronic drug review process using common solutions and data standards. First steps include establishing

a web-based clinical investigator reporting system (called FIREBIRD), and a database for the management and analysis of study data.

Promote Innovative Tissue Engineering Products:
Create an interdisciplinary Tissue Engineering Review Team, to focus on scientific challenges facing development, evaluation, and manufacturing of these emerging products.

Developing a Review Pathway for Nanotechnology:
Nanotechnology holds great promise for improving medical product design and development, but today the safety and performance properties of nanotechnology materials are not well understood. FDA will develop the foundation for analyzing nanomaterials, beginning with developing a better understanding of nanoparticle behavior in biological fluids and tissues, and potential mechanisms of action and toxicity in humans.

New Efficiencies in Review of Generic Animal Drugs:
FDA will develop new standards for the types of acceptable generic animal applications and requirements for evaluation, to help make generic products available sooner.

Combination Products Tracking System:
Ensuring consistent, appropriate, and timely premarket review of combination products can be challenging, due to the need for cross-center collaboration. To facilitate the inter-Center consultation and collaboration processes and provide for a more efficient and timely review process for these applications, the Office of Combination Products will pilot test, evaluate, and implement a web-based tracking system.

OBJECTIVE 3.3
Increase access to safe and nutritious new food products.

FDA will encourage the development and acceptance of innovative food products that enhance the availability of safe, nutritious foods through the development of new or revised standards, guidance, recommendations, or other tools. We will explore novel scientific approaches (e.g. nutrigenomics) to better understand how the unique attributes of individuals affect the assessment of safety of foods, food components, nutrients, and dietary supplements. We will also work with international and intergovernmental bodies such as Codex Alimentarius on the harmonization of international standards, guidance, recommendations, and risk analysis principles.

To ensure significant progress to increase access to safe and nutritious food products we will take the following specific actions within the next 18 months:

Enhance the Food Additives Regulatory Management (FARM) Electronic Management System:
FDA will upgrade the FARM system and related databases that are designed to support electronic processing, review, maintenance and reporting for direct and indirect food ingredient submissions. This work will improve operational efficiency and reduce the amount of time it takes to ensure safety of new food ingredients.

STRATEGIC GOAL 4 — IMPROVE THE QUALITY AND SAFETY OF MANUFACTURED PRODUCTS AND THE SUPPLY CHAIN

FDA's oversight of manufacturing, production, and the supply chain plays a critical role in assuring the safety of food, cosmetics, and radiation-emitting devices, and assuring the quality and safety of medical products. FDA prevents problems in the supply chain by developing standards and guidance for industry to promote best practices that reduce risk. We protect

the safety of patients and consumers through intervention activities, such as inspection of the manufacturing supply chain, to make sure that unsafe manufacturing conditions are discovered and unsafe products are removed from the supply chain before they can do harm. As a final line of protection, FDA responds as quickly as possible in a targeted manner so that any problems that do slip through our system of protections are contained and mitigated, allowing more rapid recovery of normal economic and social activities.

FDA faces a variety of strategic challenges in meeting this area of our mission. The technologies used to produce FDA-regulated products have been changing more rapidly, which means that FDA's work force must adapt and continue to learn to keep up with the state of science and technology. We now live in a fast-paced global economy, where the sources of products and their ingredients come from all over the world, and finished products made in America are distributed around the world. Moreover, economic development has increased the volume and variety of regulated products, which drives up the regulatory workload. Solutions to these challenges will come from a variety of directions, including:

- better information technology to increase productivity and enable better risk-based targeting;
- new rapid analysis techniques that allow FDA to isolate problems faster and more specifically;
- development of modern continuous manufacturing technologies, which present opportunities for remote automated monitoring; and
- greater collaboration and partnering among local, state, and international regulators to ensure effective coordination and leveraging of resources.

Signature Initiative: Harmonized Tracking of FDA Regulated Entities

As part of FDA's public health mission, we have a responsibility to efficiently detect counterfeit, adulterated, misbranded, or illegally marketed or imported products, and to intervene before they cause harm. Moreover, we need to respond quickly to minimize harm and isolate the problem in the event of an emergency that involves any hazardous FDA-regulated products that may have reached the marketplace. Therefore, it is critical that the Agency have accurate, complete, and up-to-date information on every regulated firm, facility, and establishment, as well as the products that are produced or flow through those facilities or establishments.

Currently, FDA addresses these tracking needs through a multitude of methods and databases that have evolved separately within each regulatory program over many years. Under the new Harmonized Tracking of FDA Regulated Entities initiative, FDA will harmonize and modernize the information management and business processes for tracking regulated establishments and their products. This will improve the regulatory processes that ensure product quality by making them more efficient, more reliable, and more consistent across the Agency. Two components of this initiative are the Electronic Drug Establishment Registration and Product Listing initiative, which covers human and animal drugs and biologics, and the electronic Medical Device Registration and Listing initiative.

Under these initiatives, FDA will use technology and business process improvement techniques to transition from outdated paper-based systems to harmonized electronic systems that ensure quick access to all product and establishment information. These systems will provide for electronic input and access to complete information developed in part through electronic labeling. This will greatly improve the efficiency and effectiveness of operations involving the screening of imported products, review of regulated products, identification and monitoring of violative products, and recall of inappropriate or defective products. The harmonized systems will provide a master inventory of products and establishments, eventually allowing the elimination of inefficient paper registration and listing forms, so that FDA can focus more of its resources directly on safety and public health issues. The harmonized systems will be cost effective for both industry and the government because the data reporting elements will be streamlined to avoid duplication of data reported to other pro-

gram databases, and they will provide accurate, complete, and up-to-date information on all FDA regulated firms, facilities, and establishments and their marketed products.

Given the trends and challenges we face, FDA has formulated the following strategic objectives in this goal area.

OBJECTIVE 4.1

Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

One of the most important tools FDA has to protect public health is the development of science-based guidance and standards that help industry to efficiently comply with FDA regulations, as well as guide them toward best practices. As science and technology advances, and as economic and social trends evolve, FDA must continually evaluate the standards and guidance to ensure that we are promoting the best and most current recommendations. Investment in prevention is a high priority, as that yields the greatest payoffs to public health.

To ensure significant progress in modernizing science-based standards and tools to prevent safety problems we will take the following specific actions within the next 18 months:

Modernize Standards for Pharmaceutical Quality:
FDA will conduct a variety of studies to evaluate how the concepts and approaches used in the current Good Manufacturing Practices (cGMPs) regulations (21CFR 211) may be applied to production of drug products for use in Phase 1 studies.

Novel Technologies for Quality Evaluations of Complex Biological Products:
FDA is developing and evaluating methods using novel technologies for adaptation to the regulatory setting of quality evaluations for complex biological products (e.g., vaccines, blood-products and cell-tissue-gene-therapies).

Enhance Tracking of Participation in the Voluntary National Retail Food Regulatory Program:
FDA promotes uniformity among retail food safety programs throughout the state, local, and tribal governments in the U.S. and its Territories through the standards development, outreach, and education programs under the Voluntary National Retail Food Regulatory Program. FDA will build a model for tracking the percentage of the American population covered by the program's standards, and develop baseline data that will help track progress toward increasing participation.

OBJECTIVE 4.2

Detect safety problems earlier and better target interventions to prevent harm to consumers.

No prevention program is perfect; hence FDA also focuses on a second line of protection by intervening when problems are detected—before the problem can cause harm. Through more advanced risk-based targeting of inspections, more efficient and accurate inspection and compliance protocols, and more rapid analysis methods, we seek to improve our ability to prevent exposure to harmful products.

To ensure significant progress to better target interventions we will take the following specific actions within the next 18 months:

Develop Risk-Based Modeling to Identify Inspection Priorities:
To maximize the public health impact of limited inspection and compliance resources, FDA is developing advanced analytic tools, including artificial intelligence, data mining, and risk-

signal detection, to prioritize and focus inspection and compliance work, including import screening. Field committees in each of the major product areas are identifying options for additional steps to make inspection and compliance priorities in a systematic, transparent and data-driven manner.

Take Action to Eliminate Marketed Unapproved Drugs:
FDA will continue to use a risk-based, multi-pronged approach to tackling the problem of marketed, unapproved drugs. Unapproved drugs may not meet modern standards for safety, efficacy, quality, and labeling. FDA has been moving aggressively to tackle this problem, using enforcement, incentives, and education. Further progress in this area, by whatever means are effective, is a critical component of ensuring drug safety and quality.

Implement New Import Safety Strategic Framework:
FDA anticipates following a new direction in the future for regulating imports, as outlined in the Report to the President, *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety.* It is a risk-based strategy that shifts the focus from interdiction at the border to prevention with verification. It will utilize data from all points in the full import life cycle—from production, manufacture, transport, distribution, and consumption—to assist in targeting the highest risk imported products for review, and facilitating the entry of low-risk products. On November 6, 2007, *The Action Plan for Import Safety (www.importsafety.gov/report/actionplan.pdf)* was released which provides specific short- and long-term recommendations to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. Within two years, accomplishments will be made in the areas of foreign operations, border operations, imported products in domestic commerce, information technology, and applied science and technology.

OBJECTIVE 4.3

Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.

Despite everyone's best efforts, accidents can happen. FDA also devotes its attention to improving our ability to respond quickly and effectively when unsafe food or medical products do make their way into the market.

To ensure significant progress to respond more quickly and effectively to emerging safety problems, we will take the following specific actions within the next 18 months:

Create a Multidisciplinary Integrated Vaccine Safety Team:
FDA has progressively strengthened and formalized its inter-disciplinary and collaborative systems approach to safety and emergency response and communications, creating standing teams where components from multiple offices and disciplines share and respond to the same information and identify data and policy needs. The creation of a Vaccine Safety Team will complete FDA's formalization of its multi-disciplinary, integrated safety teams including the Tissue Safety and Blood Safety Teams.

Enhance the FERN Lab capability:
Improve the capacity and information sharing capabilities of the Food Emergency Response Network (FERN) laboratory system, which provides critical laboratory analysis and surge capacity in response to food-related emergencies, including a potential terrorist attack or large scale food borne disease outbreak. Expansion of FERN lab capability includes continuing to develop and validate essential methods to increase the number of highly toxic poisons and pathogens that can be rapidly detected in food; working to increase the FERN capabilities and capacities by providing validated rapid methods to member labs, as well as training and proficiency testing with those methods; and developing the capacity to analyze large numbers of samples to assure the food supply is safe. By the end of FY 2008, FDA funding of cooperative agreements with FERN labs will increase the laboratory surge capac-

ity of the FERN to allow for more rapid detection and identification of highly toxic poisons and radioactive contamination in food and to more swiftly respond to potential terrorist attacks and other food-related emergencies.

Harmonized Tracking of FDA Regulated Entities:
FDA will harmonize and modernize the information management and business processes for tracking regulated establishments and their products. This will improve the regulatory processes that ensure product quality by making them more efficient, more reliable, and more consistent across the Agency. The first two components of this initiative to be implemented will be the Electronic Drug Establishment Registration and Product Listing initiative, which covers human and animal drugs and biologics, and the electronic Medical Device Registration and Listing initiative.

Improve Product Quality through Public Health Diplomacy:
FDA will develop and implement cooperation initiatives with counterpart regulatory agencies that are strategically important because of the products they export to the U.S. Through the leadership of the Office of the Secretary of the Department of Health and Human Services, FDA is negotiating cooperation agreements with the Government of China to improve the safety of food, feed, cosmetic, and medical products exported to the U.S. In FY 2008, FDA will initiate a series of activities to meet specific targets in accordance with the agreements.

CONCLUSION

As FDA celebrates more than 100 years of service to the American people as the world's gold standard regulatory agency, it looks to the future. The future holds unprecedented promises for healthier and safer lives for everyone. The products of explosive progress in science and technology have made that future a possibility and not just a promise, but the pathway requires FDA to look ahead to being a bridge and not a barrier to the delivery of safe and nutritious food and lifesaving medical and health products to the people we serve. This strategic plan marks the path to achieve our vision for an organization that is dedicated to excellence as a science-based and science-led regulatory agency that provides global leadership in protecting public health. In this document we presented the goals and objectives that frame our efforts and identified the milestones we will achieve to mark major progress over the next eighteen months.

APPENDIX A FDA STRATEGIC GOALS AND OBJECTIVES ALIGNED WITH DHHS STRATEGIC GOALS

DHHS Strategic Goals	DHHS Strategic Objectives	FDA Strategic Goals	FDA Long-term Objectives
1: Health Care - Improve the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care.	1.2: Increase healthcare service availability and accessibility	3: Increase Access to New Medical and Food Products	3.1: Increase the number of safe and effective new medical products available to patients.
	1.3: Improve health care quality, safety, cost, value	2: Improve Patient and Consumer Safety	2.1: Strengthen the science that supports product safety
			2.2: Improve information systems for problem detection and public communication about product safety.
			2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products.
		3: Increase Access to New Medical and Food Products	3.1: Increase the number of safe and effective new medical products available to patients.
			3.2: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.
			3.3: Increase access to safe and nutritious new food products
		4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	4.1: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.
			4.2: Detect safety problems earlier and better target interventions to prevent harm to consumers.
			4.3: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.
	1.4: Recruit, develop, and retain a competent health care workforce.	1: Strengthen FDA for Today and Tomorrow	1.1: Strengthen the scientific foundation of FDA's regulatory mission.
			1.2: Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.
			1.4: Strengthen FDA's base of operations

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DHHS Strategic Goals	DHHS Strategic Objectives	FDA Strategic Goals	FDA Long-term Objectives
2: Public health promotion and protection, disease prevention, and emergency preparedness - Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental, and terrorist threats.	2.1: Prevent the spread of infectious diseases	2: Improve Patient and Consumer Safety	2.2: Improve information systems for problem detection and public communication about product safety.
			2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products
			2.4: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.
		3: Increase Access to New Medical and Food Products	3.1: Increase the number of safe and effective new medical products available to patients.
			3.3: Increase access to safe and nutritious new food products.
		4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	4.2: Detect safety problems earlier and better target interventions to prevent harm to consumers.
			4.3: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.
	2.2: Protect public against injuries and environmental threats	2: Improve Patient and Consumer Safety	2.2: Improve information systems for problem detection and public communication about product safety.
			2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products
			2.4: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.
	2.3: Promote and encourage preventive health care, including mental health, lifelong health behaviors, and recovery.	2: Improve Patient and Consumer Safety	2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products.
			2.4: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.
	2.4: Prepare and respond to natural and manmade disasters	2: Improve Patient and Consumer Safety	2.2: Improve information systems for problem detection and public communication about product safety.
			2.4: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.
		3: Increase Access to New Medical and Food Products	3.1: Increase the number of safe and effective new medical products available to patients.
		4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	4.3: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.

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DHHS Strategic Goals	DHHS Strategic Objectives	FDA Strategic Goals	FDA Long-term Objectives
4: Scientific Research and Development – Advance scientific and biomedical research and development related to health and human services	4.1: Strengthen the pool of qualified health and behavioral science researchers;	1: Strengthen FDA for Today and Tomorrow	1.1: Strengthen the scientific foundation of FDA's regulatory mission.
			1.2: Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.
	4.2: Increase basic scientific knowledge to improve human health and development;	1: Strengthen FDA for Today and Tomorrow	1.1: Strengthen the scientific foundation of FDA's regulatory mission.
			1.3: Enhance partnerships and communications.
		2: Improve Patient and Consumer Safety	2.1: Strengthen the science that supports product safety
		3: Increase Access to New Medical and Food Products	3.1: Increase the number of safe and effective new medical products available to patients.
		4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	4.1: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.
	4.3: Conduct and oversee applied research to improve health and well-being;	1: Strengthen FDA for Today and Tomorrow	1.1: Strengthen the scientific foundation of FDA's regulatory mission.
			1.3: Enhance partnerships and communications.
		2: Improve Patient and Consumer Safety	2.1: Strengthen the science that supports product safety
		3: Increase Access to New Medical and Food Products	3.2: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.
		4: Improve the Quality and Safety of Manufactured Products and the Supply Chain	4.1: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution
	4.4: Communicate and transfer research results into clinical, public health, and human service practice.	1: Strengthen FDA for Today and Tomorrow	1.2: Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensure integrity and accountability in regulatory decision making.
			1.3: Enhance partnerships and communications.
		2: Improve Patient and Consumer Safety	2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products.

Department of Health and Human Services
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
www.fda.gov