STRATEGIC PRIORITIES 2011 – 2015

Responding to the Public Health Challenges of the 21st Century

Department of Health and Human Services
United States Food and Drug Administration

Message from the Commissioner

FDA's mission to protect and promote the public health is more critical than ever. We are positioned at a challenging moment in history and the demands of the 21st century are unprecedented. Together, we must prepare to meet those demands and usher science, public health, and FDA into a new era.

In that spirit, we have developed the following Strategic Priorities document, which outlines the goals and priority areas that will guide our agency through the next five years and beyond. It's no secret that FDA's responsibilities have increased significantly over the past several years. To fulfill the mandates of the Family Smoking Prevention and Tobacco Control Act of 2009, the Food and Drug Administration Amendments Act of 2007, the Patient Protection and Affordable Care Act of 2010, the Food Safety Modernization Act of 2011, and to meet the continuing challenges of regulating in a global market, we must fully commit ourselves to the agency's fundamental mission and to the scientific and public health principles that inform all of our decisions.

We must continue to build a stronger, more effective agency and, as this document outlines, do so in several specific ways. We will strengthen our collaborations with other public health agencies and leverage the expertise and resources of our colleagues at the international, federal, state, and local levels to ensure effective solutions for the American people. We will hold ourselves to the highest standards of transparency and accountability and give our partners and stakeholders insight into our processes and decision making. And we will promote public participation by increasing opportunities for input and feedback, so that we can harness the best ideas from both inside and outside the agency.

I would like to emphasize one priority in particular: Advancing Regulatory Science and Innovation. Science underlies everything we do at this agency and to serve the public health we must have the capacity to effectively oversee the translation of breakthrough discoveries in science into innovative, safe, and effective products and life-saving therapies for the people who need them most.

Finally, I would like to offer my sincere thanks to the team who worked long and hard to prepare this document. My time as Commissioner of Food and Drugs has taught me that FDA is filled with some of the most talented, creative and dedicated public servants I have ever worked with. My hope is that these guidelines will help us work together to promote and protect the public health. That is what the American people demand — and that is what we must deliver.

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

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1.0 Introduction

The U.S. Food and Drug Administration (FDA) is the agency within the U.S. Department of Health and Human Services (HHS) responsible for ensuring the safety and effectiveness of products that account for about 20 cents of every dollar spent by American consumers each year — products that touch the lives of every American every day. These include human and animal drugs, 80 percent of the food supply, biological products, medical devices, cosmetics, radiation-emitting products, and tobacco products.

Ensuring a safe and nutritious food supply and safe, effective, and innovative medical products requires a strong infrastructure and a dedicated workforce. FDA's seven product and research centers and two major offices are staffed by more than 12,000 employees[1] around the world who work together to fulfill FDA's fundamental public health mission: to protect and promote the health of the American people.

FDA's primary responsibility is to protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day. The agency also guides and oversees the development and availability of effective new medical products and new food products that harness the latest advances in science and technology to improve the health and well-being of American consumers.

Today, FDA is facing a critical set of public health challenges; challenges brought about by the unique demands of the 21st century. Science and technology are changing our world in dramatic ways; we are seeing an explosion of knowledge and capabilities emerging from many domains of research and from around the globe. In addition, we live in an increasingly globalized world, which has made ensuring the safety of food, drugs, and devices for the American people a global endeavor that integrates products and people across borders. It is clear that today, FDA's job is fundamentally different — and far more complex — than it was even a few years ago. Although it will not be easy, we will address these challenges and aim to fulfill our mission by embracing innovation and actively pursuing partnerships with federal, state, and local agencies; international authorities; academia; non-government organizations; and the private sector.

This document outlines a path toward achieving FDA's vision for the next five years. We envision a transformed and integrated global food safety system, focused on prevention and improved nutrition. We envision patients and families benefiting from decades of investment in medical science and technology. We also envision a strong field of regulatory science so FDA can ensure the safety and effectiveness of new medical products throughout their life cycles.

We at FDA will use the priorities and goals laid out in this document to improve operating infrastructure, modernize regulatory processes, strengthen our workforce — and, ultimately, better promote and protect the health of the American people.

[1] Number of employees cited here is the full-time equivalent (FTE) staffing level reported in the President's Budget Request All Purpose Table (Total Program Level) of the FY 2012 Food and Drug Administration Congressional Justification, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm242726.htm

1.1 Mission and Vision

HHS Mission

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

FDA Mission

FDA is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

Specifically, FDA is responsible for advancing the public health by:

- Helping to speed innovations that make foods safer and make medicines and devices safer and more effective;
- Ensuring the public has accurate, science-based information they need to use medicines, devices, and foods to improve their health;
- Regulating the manufacture, marketing, and distribution of tobacco products and reducing tobacco use by minors; and,
- Addressing the Nation's counterterrorism capability and ensuring the security of the supply of foods and medical products.

Vision

FDA is dedicated to world-class excellence as a science-based regulatory agency with a public health mission. We aim to provide effective and innovative leadership — both domestically and internationally — to protect health, prevent illness, prolong life, and promote wellness.

1.2 Purpose of this Document

The purpose of this document is to outline FDA's strategic intentions and plans for the next five years (2011 – 2015). This document is intended to communicate the Commissioner's key priorities, including cross-cutting strategic priorities, program-specific strategic goals, and long-term objectives. 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 HHS. Crosswalks that highlight the relationship between FDA and HHS strategic goals and Healthy People 2020 Objectives can be found in Appendix A and Appendix B, respectively.

1.3 Guiding Principles

We are committed to excellence in pursuing our mission and maintaining the public's trust. In doing so, we adhere to several fundamental guiding principles: science-based decision making, innovation/collaboration, transparency, and accountability. These principles govern our deliberations, decision making, and actions and provide the framework for our interactions within FDA, with the public, and with other FDA stakeholders. We recognize that effective communication is the foundation for successfully implementing these principles.

Science-Based Decision Making

FDA has a solemn responsibility to protect and promote the public health. This responsibility requires that FDA base its policies, regulations, and enforcement decisions on sound science. For our decisions to have credibility, we must continue to seek the most current scientific understanding by supporting the work of agency scientists and scientific advisory committees. Strengthening FDA as a public health agency requires a culture that encourages scientific exchange, respects alternative viewpoints along the path of decision making, and protects the integrity of its scientific review processes.

Innovation/Collaboration

We have gained substantial knowledge through more than 100 years of building regulatory programs to ensure the safety and integrity of foods, medical products, and cosmetics. But we also recognize that the promises of science and technology require us to seek new approaches to performing our mission, particularly because competition for scarce public resources makes it difficult to simply scale-up past solutions to meet rising demands. By investing in the field of regulatory science, FDA is fostering innovations that we hope will enhance our effectiveness and productivity for years to come.

We cannot achieve our vision and address the challenges of the 21st century by working alone. To make rapid and efficient improvements in public health and drive innovation, we must harness the best ideas from a broad range of stakeholders and leverage resources through collaboration with other federal, state, and local regulatory and public health agencies; non-government organizations; consumer and patient organizations; academic medical centers and research universities; the private sector; and the public. For example, FDA is collaborating with state and local food safety authorities to develop standards and training that will establish a more integrated and coordinated national food safety system. The Critical Path Initiative (CPI), an agency effort to modernize the sciences for developing, evaluating, manufacturing, and using FDA-regulated products, has long recognized the importance of collaboration to leverage critical expertise and resources in driving scientific innovation. Building on CPI, FDA's Advancing Regulatory Science Initiative recently established a formal collaboration with the National Institutes of Health to advance regulatory science and build the capacity needed to ensure the safety and effectiveness of innovative new products and technologies.

Transparency

One of the most pressing FDA-wide goals is promoting transparency in FDA's operations, activities, processes, and decision making, as well as making information and data available in user-friendly formats while also protecting confidential and proprietary information. Transparency can enhance FDA's work and — more important — increase the trust and confidence of employees, policymakers, stakeholders, and the public. In response to a Presidential memorandum on transparency and open government, FDA established a Transparency Task Force to develop and implement recommendations for making useful and understandable information about FDA activities and decision making more readily available to the public in a timely and user-friendly manner. FDA will continue to engage the public in identifying ways to improve transparency at the agency.

Accountability

Consistent with our strong commitment to public service, we will maintain the highest degree of individual and professional accountability in the quality and ethical conduct of our work. Currently, we set measurable goals and openly monitor performance within the agency to make sure we continue to meet our commitments. We hold staff members and executives accountable for achieving organizational goals through annual performance plans that are aligned with our strategic priorities. And we monitor program performance by holding quarterly meetings with program managers and agency executives and sharing program performance data with the public through a new initiative called FDA-TRACK. We understand the importance of FDA's work to the health and welfare of our nation, and we will continue to hold ourselves accountable for delivering on that responsibility.

2.0 Cross-Cutting Strategic Priorities

The Commissioner has selected five cross-cutting areas to serve as strategic priorities over the next five years. These include efforts to: 1) Advance Regulatory Science and Innovation; 2) Strengthen the Safety and Integrity of the Global Supply Chain; 3) Strengthen Compliance and Enforcement Activities to Support Public Health; 4) Address the Unmet Public Health Needs of Special Populations; and 5) Advance Medical Countermeasures and Emergency Preparedness.

2.1 Advance Regulatory Science[2] and Innovation

Recent innovative breakthroughs in science and technology — ranging from sequencing of the human genome to advances in the application of nanotechnology to new medical products — have the potential to transform our ability to prevent, diagnose and treat disease. These developments will result in moving treatment strategies towards approaches that are tailored or personalized to individual patients, thus maximizing the benefit of treatments while decreasing their safety risks. Similarly, advances in research and information technologies are enabling us to more efficiently identify microbial pathogens, track and trace food contamination outbreaks, develop new approaches to safety assessmant, and determine where foods and other FDA-regulated products are produced or manufactured, stored, how they are transported, where they go and who uses them. These tools also can play an important role in preventive health by enabling more comprehensive immunization strategies, especially in the face of emerging pandemics.

For these advances to reach their full potential, FDA must play an increasingly integral role as an agency that both prtects the public health by ensuring safe and effective products, and promotes the public health by fostering innovative approaches and solutions on behalf of some of the most compelling health and medical changes. FDA must also participate mor actively in the science research enterprise diected towards new treatments and nterventions. We must also modernize our evaluation and approval processes to ensure that innovative products reach the consumers and patients who need them, when they need them. These new scientific tools, technologies, and approaches form the bridge to critical 21st century advances in public health. They form what we call *regulatory science: the science of developing new tools, standards and approaches to assess the safety, effectiveness, quality and performance of FDA-regulated products.*

A robust regulatory science program will strengthen biomedical advances, food safety, and many other aspects of FDA's work. Advances in regulatory science are critical to effectively translate cutting-edge developments in science and technology into promising products and therapies for the Americans who need them. Americans cannot take full advantage of the breakneck speed of biomedical research unless we also achieve innovations in regulatory science. Just as biomedical research has evolved over the past few decades, regulatory science must also evolve in important and powerful ways. As an example, nanomaterials have recently received considerable national and international attention with

2 Regulatory Science encompasses the development and use of new tools, standards, and approaches to more efficiently develop products and to facilitate the evaluation of product safety, effectiveness, quality, and performance.

the development of new and unique hybrid materials to treat disease and as new analytical tools for biotechnology and in the life sciences. Research on nanotechnology-based materials will provide a better understanding of current safety tests and the toxicity of nanomaterials in products for human use, such as over the counter drugs, cosmetics, food ingredients and packaging or dietary supplements.

Stronger regulatory science is necessary to bridge the gap between basic research discoveries and approved drugs, devices, food ingredients and packaging, and biologics. Modernizing toxicology safety assessment is a critical gap in regulatory science because advanced toxicology studies are essential to advance safe product development. Modernizing approaches to toxicology studies will develop new and better ways to predict how novel compounds will behave in humans. These studies will reduce drug and other product development costs; the time to market for new technologies, and help prevent adverse health events.

The National Center for Toxicological Research (NCTR) plays an important role in conducting FDA mission-critical, peer-reviewed, translational research to develop a scientifically sound basis for regulatory decisions and reduce risks associated with FDA-regulated products. This NCTR research evaluates the biological effects of potentially toxic chemicals or microorganisms; defines the complex mechanisms that govern their toxicity; aids in understanding critical biological events in the expression of toxicity; and develops new scientific tools and methods to improve assessment of human exposure, susceptibility, and risk. NCTR works in partnership with each product center within the FDA to expand agency research efforts within the centers to develop new tools and standards for evaluating safety of novel drugs, biologics, or devices.

Over the next five years, FDA will create and implement a strategic plan for expanding and modernizing the field of regulatory science within the agency. This plan will complement each of FDA's Center's program-specific strategic plans, which focus on advancing scientific approaches and tools critical for FDA to translate science into regulation and public health. In addition, FDA will develop an innovation strategy that focuses on its role in facilitating the development of new biomedical products and emerging technologies. At the same time, we will work to strengthen science as a whole within FDA. The agency charged with judging the safety and effectiveness of drugs and other medical products — and monitoring the safety of those products as long as they are on the market — must possess a scientific capability equal to that task and become engaged in mission-critical fields of applied research, including systems biology, wireless healthcare devices, nanotechnology, medical imaging, robotics, cell- and tissue-based products, regenerative medicine, and combination products. In that spirit, FDA has already begun identifying strategies to recruit and retain outstanding scientists and will work collaboratively with other agencies, industry, and academia to define and advance science in high-priority areas critical to the health of individuals, the national healthcare system, and global public health.

The strategic plan for advancing regulatory science will pave the way for a range of regulatory activities, including setting standards for products that address unmet public health needs, identifying and mitigating the spread of disease using informatics, modernizing

toxicology and hazard assessments, protecting the food supply, and regulating tobacco. The plan will enable FDA to leverage the latest in science and technology, along with FDA know-how, to bring a new generation of medical products — personalized therapies, stem-cell therapies, and genetic diagnostics, among others — to the American people.

Signature Initiative

SCIENTIFIC COMPUTING INITIATIVE

FDA houses the largest known repository of clinical data — unique, high-quality data on the safety, effectiveness and performance of drugs, biologics and devices, both before and after approval. Despite the availability of these data, questions about subpopulation responses and underlying placebo effects remain unanswered. FDA data could be used to address fundamental questions about patient subsets who respond in varying ways to new therapies, or for whom a drug is more or less safe. In October 2010, FDA competitively awarded funds to a Johns Hopkins University-led research team to advance Patient Centered Outcomes Research (PCOR) by leveraging FDA's immense stores of data. The Partnerships in Comparative Effectiveness Science (PACES) initiative will facilitate the development of PCOR studies, which will allow FDA to better understand which interventions are most effective for patients under specific circumstances — a key part of the FDA's public health mission. The standardization of FDA data, coupled with a better understanding of clinical interventions, has the potential to ultimately transform the regulatory review and decision-making process.

The electronic receipt of study data is vital to the efficiency of the medical product review and approval process, as is developing an environment conducive to analyses of large data sets. The ultimate goal of having the ability to review multiple studies that can be compared and analyzed requires data harmonization and standardization such that comparisons between data can be made effectively. The data must then be organized in a common database so that it can be queried by topic and analyzed to address key questions. These goals require investments in informatics hardware and software and the development of standardized data models for relational databases and scientific computing. FDA has sponsored the development of a clinical trials repository that will be capable of handling this task.

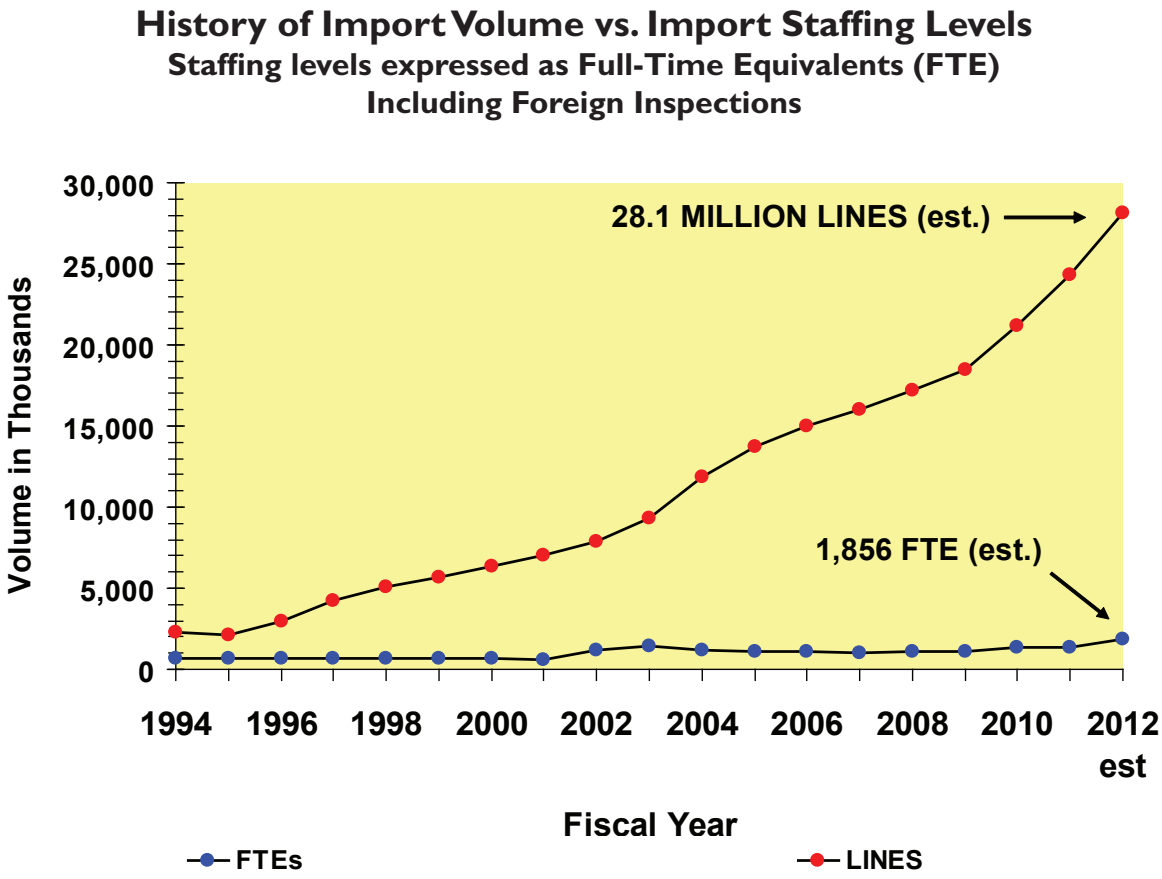
2.2 Strengthen the Safety and Integrity of the Global Supply Chain

Today, maintaining the safety of America's food and medical products is a serious challenge. Complex global supply chains, international trade, the foreign sourcing and manufacture of regulated products, and the increase in the volume and complexity of imported products have forced FDA to reevaluate its approach to supply-chain safety. We have seen the warning signs: contaminated heparin, melamine-tainted pet food, counterfeit glucose test strips, to name just a few. Globalization presents a host of internal and external challenges to the design, development, manufacturing, and distribution of regulated food and medical products — challenges that make critical the prevention, detection, intervention, and response to product safety.

More than 20 million import lines of food, devices, drugs, and cosmetics arrived at U.S. ports of entry in Fiscal Year (FY) 2010, more than three times the number of imports 10 years ago. Today, there are more than 130,000 importers of record and about 300 ports of entry in the United States. The array of regulated products comes from 300,000-plus facilities in more than 150 different countries.

Challenges Presented by Globalization

- Increasing volume of imported products
- Greater complexity in imported products
- More foreign facilities supplying the United States
- Incomplete regulatory information about supply chains
- Patch work of foreign, federal, and state oversight of product safety
- Greater opportunities for economic adulteration and intentional fraud
- National security threats
- Enforcement tools that do not reflect today's commercial practices
- Corporations lacking accountability
- Current import regulatory system, an honor system



The growing challenges of globalization have far outstripped the FDA's resources for inspection and quality monitoring, and the inability to maintain adequate oversight means potential risk to consumers grows every year. Addressing these challenges will require a paradigm shift — to a focus on prevention, on stopping threats before they ever become reality. The border must be viewed as a final checkpoint for preventive controls, rather than the primary line of defense against unsafe imports.

FDA must require more — and better — information about product supply chains and monitor this information throughout the product life cycle, and regulatory standards must foster corporate responsibility to identify, protect, and control risks. Such an effort will entail more strategic and consistent coordination among foreign, federal, and state counterparts. FDA needs novel and updated compliance and enforcement tools, a greater global safety net that includes a global alliance of regulators, coordination of activities with international capacity-building and standards-setting organizations, adequate funding to allow for inspections, examinations and sample collections and analysis, and updated systems, including IT support, to assist with the increased workload. These changes are essential if we are to protect product safety in a way that Americans expect and deserve.

Signature Initiative

ANALYTICAL TOOLS INITIATIVE

FDA continues to implement the Analytical Tools Initiative (ATI), established to explore new or previously unused technologies for analysis and directed screening in the field and for rapid or high throughput analysis in the laboratory. The ATI was established to bridge the gap between industry/academia and FDA scientists on new technologies and applications to FDA-regulated products. The ATI's main objective is to provide rapid analytical tools for field investigators and/or FDA scientists.

In support of this initiative, FDA is assessing tools for the field investigator and analyst. Field-deployable kits and instruments are being evaluated to incorporate into the "investigator's toolbox" to be used at the site of sample collection. Instruments for the laboratory, such as hand-held devices, are also being evaluated to enhance laboratory capacity and capability.

FDA is training field staff on the use of Counterfeit Detector 3 (CD3), a hand-held device for import personnel to detect suspected counterfeit drugs and/or packaging. FDA is also training field staff on the use of a portable X-ray Fluorescence (XRF) device capable of detecting toxic elements in imported products such as foods and dietary supplements. The focus of interest for toxic elements is primarily for the five elements: Lead (Pb), Cadmium (Cd), Mercury (Hg), Arsenic (As), and Selenium (Se); although additional media and analyte targets may be identified in the future.

Once training is completed, these devices will be deployed to investigators located at ports of entry to assist with efforts to ascertain the safety of products offered for import.

2.3 Strengthen Compliance and Enforcement Activities to Support Public Health

To protect the public health FDA must act swiftly and aggressively to guarantee effective enforcement of and compliance with FDA laws and regulations. FDA enforcement actions affect not only the manufacturing and distribution of foods, drugs, biologics, medical devices, tobacco, and cosmetics, but also their development and marketing. Enhancing FDA's compliance and enforcement programs will strengthen the agency's focus on preventing problems and responding rapidly when violations occur.

FDA is implementing a number of new programs designed to sharpen the effectiveness and timeliness of its regulatory, compliance, and enforcement systems. The agency established deadlines for industry to respond to significant inspection findings, which enable FDA to take enforcement action more rapidly if a manufacturer has not corrected violations documented after an inspection. FDA has implemented processes to prioritize follow-up inspections *after* the agency has issued a Warning Letter, classified a major recall, or taken other significant enforcement and compliance actions. These processes will ensure that violative products are no longer available to the American public and that necessary corrective actions are taken to prevent harmful products from being manufactured and sold.

With the enactment of the FDA Food Safety Modernization Act on January 4, 2011, FDA is now authorized to mandate a recall of unsafe food if a food company fails to do it voluntarily. The law also provides a more flexible standard for administrative detention (the procedure FDA uses to keep suspect food from being moved); allows FDA to suspend the registration of a food facility associated with unsafe food, thereby preventing it from distributing food; and directs the agency to improve its ability to track both domestic and imported foods.

Another important component of FDA's enforcement program is protecting the public health through criminal prosecution. FDA's criminal enforcement program uses stringent sanctions, including prison sentences, fines, restitution and forfeiture to deter conduct that violates FDA-enforced laws. These sanctions are made public, thereby informing consumers and helping to ensure greater compliance to protect the public health. The success of FDA's criminal enforcement efforts sends a clear message to would-be violators: crimes involving FDA regulated products will not be tolerated.

Ensuring that products are effective and that they are safely manufactured and delivered to the American consumer requires the cooperation of a broad network of FDA field offices, local, state, and territorial regulatory authorities, and foreign government officials. In the next five years, FDA will work more closely with these regulatory and enforcement partners to share laboratory and enforcement data. This increased collaborative approach will enable faster identification of threats to the public health and quicker response times, and will strengthen our ability to ensure appropriate corrective actions are taken to reduce the likelihood of harmful products being manufactured and distributed.

2.4 Expand Efforts to Meet the Needs of Special Populations

Therapeutic breakthroughs and clear and timely public health information should be available to all Americans. There are numerous challenges to achieving this goal. For example, historically women and minorities have been underrepresented in clinical trials, making it difficult to assess whether a medical product will be safe and effective for them. Underrepresentation is also true for the pediatric population because many medical products are tested only in adults. Questions regarding effectiveness, pediatric dosing and side effects for drugs often go unanswered. Similarly, medical devices are often not tested in or sized for a relevant pediatric population. Assuring that products are safe and effective for people with rare diseases is particularly challenging, because the patient populations are too small to support standard clinical trials. For these groups, there may be fewer — or riskier — available therapies.

As we entered the 21st century most therapies being used in children still had not been adequately studied. As a result of legislative research incentives and mandates, there have been more than 385 labeling changes with new pediatric information. Over 15% of the studied products were shown not effective in children and 20% had new safety information specific for children identified.

Despite this progress, much work remains to be done. Over the next five years we need to develop validated endpoints for neonates if we are to more effectively treat this vulnerable population. We also need to explore why so many products that work in adults appear to not work in children — is it dosing, differences in pathophysiology, or for medical devices the need to incorporate new design concepts? Additional efforts will focus on understanding the long-term safety of products, including devices, used chronically in children. The limited number of children with certain conditions means pediatric trials require many sites and are global in nature. In efforts to ensure children are enrolled in scientifically and ethically sound trials, FDA will expand its collaboration with the European Union, Japan, Australia, and Canada, and will establish liaisons for collaboration with other countries.

FDA will be supporting scientific advances in women's health through grants for FDA and collaborative regulatory science research. Building on ongoing activities, we will also plan to host new internal and external scientific dialogues and workshops to identify gaps and opportunities in women's health research.

The challenges are not only scientific. FDA must make available targeted public health information that is appropriate for the target population. Language barriers create additional challenges. FDA is planning an array of targeted activities to meet these challenges.

FDA created a new Office of Minority Health in 2010 to address an array of challenges to reduce health disparities in the United States. FDA will have a focal point for the ongoing and new activities to meet the public health needs of minority populations. FDA is already undertaking obesity prevention programs targeting minority populations. We are part of a coalition of Latino consumers and providers called "Latino Initiatives Committee Por Tu Familia," which plans educational workshops to promote healthy behaviors. FDA manages partnership agreements with national and community-based organizations to increase access to FDA health information for Hispanic Americans, Asian-Americans and Pacific Islanders, and Native Hawaiians. We are exploring additional partnerships to improve health literacy for underserved populations and to diversify options for FDA's distribution of health information.

FDA recognizes that communications must be adapted to meet the needs of many groups who differ with respect to literacy, language, culture, race/ethnicity, disability, and other factors. As part of FDA's Strategic Plan for Risk Communication, FDA committed to specific actions designed to improve our capacity to effectively communicate with different populations. These include: training FDA staff on health literacy and basic risk communication principles, considerations, and applications; partnering with consumer and patient organizations to increase availability of FDA communications in a variety of languages and for literacy-challenged audiences; and regularly measuring plain language and appropriate reading level for audiences targeted by communications.

Social media tools can help meet some of FDA's communication challenge. We are planning to use social networks to create a virtual community of organizations and individuals to disseminate FDA science-based information on women's health. We will also be collaborating with other government partners, to integrate FDA information on women's health into their programs.

Signature Initiative

SCIENTIFIC INNOVATION FOR RARE DISEASE THERAPIES

An estimated 6,000 rare diseases, most of which are serious or life-threatening, affect more than 25 million Americans. Because each disease, by definition, affects fewer than 200,000 Americans, market incentives may be insufficient to drive the investment needed to develop medical products to prevent, diagnose, and treat these conditions. Because the patient populations are small, product testing presents significant scientific challenges calling for innovative approaches. FDA has identified this issue as a priority and is taking steps to meet the needs of these patients.

Perhaps our best known work to advance therapeutics for rare diseases is our Orphan Product Program. This program fosters clinical studies of promising therapies, designates eligible orphan products, and confers marketing exclusivity for orphan drugs and other benefits designed to spur product development. This important program anchors FDA's efforts to meet the public health needs of people with rare diseases.

We are working to build on this foundation. For example, FDA established two new expert review groups, the Rare Disease Review Group and the Neglected Disease Review Group, consisting of FDA staff scientists from an array of pre-clinical and clinical disciplines. These groups are currently evaluating FDA activities and will be recommending options to the FDA Commissioner for further supporting and facilitating the development and evaluation of medical products for these conditions. As part of this review, the groups will take into account the recommendations of the 2010 Institute of Medicine (IOM) study of national policy for rare disease research and related medical product regulation.

In February 2010, FDA created a position of Associate Director for Rare Diseases in the Center for Drug Evaluation and Research (CDER), to help develop scientific and regulatory innovations for development and evaluation of new treatments for patients with rare diseases. Building on this new capacity, FDA is planning a series of scientific workshops to address important and difficult rare disease research issues and is developing a "rare disease database" to establish the natural history of rare diseases to assist with planning trials to test rare disease therapies. We are enhancing collaborations to increase transparency, share advice, and establish new programs with an array of public and private research and patient advocacy groups.

2.5 Advance Medical Countermeasures and Emergency Preparedness

The events of 9/11 and the subsequent bioterrorist attack involving the mailing of anthrax-containing envelopes forever changed the way Americans view public health and their personal security. Despite considerable financial and human resource investments since 2001, the United States does not yet have the range of medical countermeasures (MCMs) it requires to rapidly and effectively respond to a deliberate chemical, biological (such as anthrax or smallpox), radiological or nuclear event or naturally-occurring infectious disease outbreaks. There are few FDA-approved MCMs (drugs, vaccines, diagnostic tests, personal protective equipment, and supplies) to respond to these types of public health emergencies. Moreover, there is limited capability to rapidly develop a new MCM in response to a new or emerging threat, and only limited capacity to ramp up production of existing MCMs once an event is detected. The complex regulatory pathway required for approval of these types of medical products is one major contributing factor to the limited availability of MCMs.

On August 19, 2010, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius released a report of an extensive review of the federal government's processes and infrastructure required to develop, approve, and stockpile MCMs. The review identified FDA as one of the most critical components of the Nation's Public Health Emergency Medical Countermeasures Enterprise. FDA is responsible for evaluating medical product safety and effectiveness; as a result, FDA has significant understanding of the challenges associated with product development. The development and regulatory review of these products requires specialized knowledge and scientific expertise. Harnessing FDA knowledge and expertise in the form of a comprehensive MCM initiative will help to establish regulatory pathways based on the most advanced scientific foundations available, accelerate MCM development towards approval, and realize the promise of new technologies for faster development and flexible, rapidly scalable manufacturing of vaccines and other MCMs.

To help achieve these goals, FDA must work closely with its federal government Enterprise partners, as well as industry and academia. To this end, FDA has developed a MCM Action Plan with 3 pillars:

1. Enhancing the Regulatory Review Processes for MCMs

   To advance high priority Enterprise MCMs and related technologies, FDA will establish multidisciplinary Public Health and Security Action Teams that will tackle the range of regulatory, scientific and policy issues facing MCM development and approval. These Action Teams will ensure consistent regulatory approaches and efficient implementation of best regulatory review practices while fostering proactive communication with sponsors and federal government partners. These Action Teams will also allow FDA to anticipate challenges that inevitably emerge during product development and, by engaging with Enterprise partners, address issues that contribute toward delays in MCM development.

2. Advancing Regulatory Science for MCM Development and Evaluation

   FDA's MCM regulatory science program will be implemented through internal and collaborative research, as well as through partnerships with academia, federal government agencies and industry to explore solutions to complex scientific regulatory problems and to identify situations in which the application of new science could simplify or speed product development and/or the regulatory process.

3. Optimizing the Legal, Regulatory and Policy Framework for Effective Public Health Response

   To ensure that laws and policies adequately support preparedness and response, FDA will conduct a review of the strengths and weaknesses of existing legal and policy approaches to MCM development, distribution, dispensation, post-use surveillance and data collection and, where needed, develop new approaches.

MCMs are essential for saving lives and maintaining public confidence in our government in the aftermath of a public health emergency involving chemical, biological, radiological or nuclear threats or naturally-occurring emerging infectious diseases. FDA will establish a comprehensive program to support the federal government's efforts in achieving the vision of the Nation's MCM Enterprise: "Our Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease."[3] In addition, FDA is working with the Office of the Assistant Secretary for Planning and Evaluation to develop innovative strategies that promote the development of antibiotics to treat resistant organisms. In the area of critical trial design for studying new antibacterial drugs, FDA is updating its guidance documents and also is involved in work assessing new endpoints for clinical trials of antibacterial drugs.

FDA also remains committed to advancing its emergency preparedness and response capabilities. Integrating outputs of the efforts above with efforts to maintain and improve FDA's capabilities for responding to emergencies are critical to the agency fulfilling its public health protection responsibilities. Whether a natural disaster, foodborne illness outbreak, contaminated drug or biologic product, faulty medical device or harmful pet food, FDA must be prepared and have the needed resources and tools available to provide a coordinated response across field and headquarters organizational components. In order to accomplish this, FDA will continue to provide the needed training and information management tools needed for emergency response planning and critical decision making. Additionally, FDA will continue to expand its emergency exercises and after-action review programs to strengthen preparedness and make improvements for future responses.

In addition to the five priorities discussed above, "Manage for Operational Excellence and Accountability" is another essential cross-cutting area, which is one of the four strategic goals that will be addressed in the next section.

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[3] United States. Dept. of Health and Human Services. Assistant Secretary for Preparedness and Response. *The Public Health Emergency Medical Countermeasures Enterprise Review*. Washington: GPO, 2010. Print.

Figure 1. FDA Program and Priority Framework

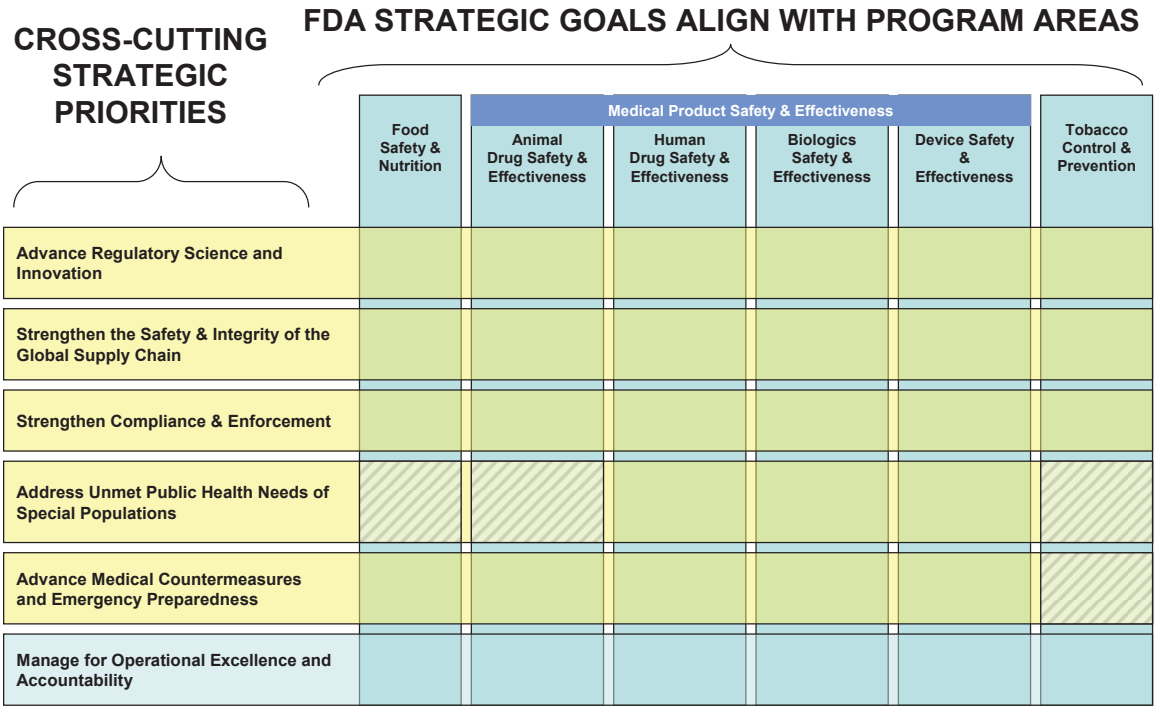


Figure 1 depicts the relationship between the cross-cutting strategic priorities and the strategic goal areas discussed in the next section.

3.0 Strategic Goals and Long-Term Objectives

3.1 Advance Food Safety and Nutrition[4]

FDA recognizes the need for a comprehensive food safety system from farm to table that is prevention-oriented and based on sound science and risk-based principles. A prevention-oriented food safety system will allow FDA to shift focus into ensuring systems are in place to prevent harm, rather than only reacting to harm once it has been identified. The findings of the President's Food Safety Working Group identified three core principles required to transition to a modern and coordinated food safety system: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. For a food safety system to be effective, all involved must play their respective roles — from the agricultural producers to the food processors, warehousers, transporters, retailers, and consumers. And FDA must establish science-based preventive controls and achieve high rates of compliance both domestically and internationally and ensure adequate scientific capacity to support public health decision making. The recently passed FDA Food Safety Modernization Act gives FDA new authorities to help achieve our goals and improve the safety of the food supply.

> "FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world."
>
> **Dr. Margaret Hamburg**, before the Senate Committee on Health, Education, Labor and Pensions, October 2009

Advancing food safety and nutrition is and will continue to be a primary FDA focus. With the creation of the Office of Foods and the One Mission, One Program Initiative, we are unifying the FDA Foods Program and enhancing its ability to meet today's great challenges and opportunities in food and feed safety, nutrition, and other critical areas. The FDA Food Program includes three major operating units — the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the foods-related activities of the Office of Regulatory Affairs (ORA). The Program also draws on the resources and expertise of FDA's National Center for Toxicological Research (NCTR) and key Office of the Commissioner (OC) staff offices. The One Mission, One Program Initiative focuses on how these organizations can work together to implement the FDA Food Safety Modernization Act and the vision of an integrated, prevention-oriented, and risk-based food safety system.

Desired Public Health Outcomes

- **Reduce adverse health effects and deaths from unsafe food and feed**
- **Reduce the rates of chronic diseases associated with food by providing consumer nutrition information that supports choice of a healthy diet by the U.S. population**

[4] For purposes of this document, the term "food" includes human food, animal food/feed (including pet food), components, i.e. ingredients, of both food and feed, and dietary supplements for humans, except as otherwise noted.

3.1.1 Ensure the Safety of the Food Supply from Farm to Table

FDA recognizes that to ensure the safety of foods and fulfill its public health mission, the agency must embrace new approaches. FDA will focus on building a prevention-oriented, science- and risk-based food safety system. This will include development and training in new inspection approaches. The foundation of FDA's approach is ensuring that preventive controls are in place, from production (or farm) through consumption (or table). The goal is to identify potential threats to the food supply and to counteract them before they harm American consumers. To ensure the safety of the food supply, FDA has aligned its priorities to three long-term objectives 1) establishing standards for science-based preventive controls throughout the farm to table continuum; 2) achieving high rates of compliance with preventive control standards, both domestically and internationally; and 3) ensuring adequate scientific capacity to support risk-based public health decision making.

Trends and Challenges

FDA works to ensure that the nation's food supply is safe, sanitary, wholesome, and accurately and otherwise properly labeled and in doing so has seen a number of recent trends and challenges:

- Increased globalization and complexity of the food supply chain;
- Declining resources for food safety activities;
- Continually evolving technologies around and threats to the food supply; and,
- Emerging food safety hazards.

Increased globalization and complexity of the food supply chain is a major challenge to ensuring the safety of imported products. Globalization is primarily responsible for the ever-increasing volume and diversity of foods entering the United States. Currently, FDA has limited ability to monitor the safety of imported food and can only physically examine about 2 percent of the products exported by foreign food facilities annually. In the last five years, the number of imported food entries has doubled and more than 240,000 foreign establishments in 200 countries and territories export foods to the United States each year. The safety of food imports is essential to public health and to public confidence in America's food supply. To respond to this challenge, FDA will establish a comprehensive prevention-focused imported food safety program as mandated by the FDA Food Safety Modernization Act. This initiative will shift the burden of import compliance from the limited FDA inspection force to importers and other stakeholders participating in the foreign food supply chain. It will improve consumer protection by allowing FDA to make better-informed decisions about the admissibility of imported food and allow FDA to target products that pose the greatest risk. The current scope of this program will cover imported foods and drugs intended for food-producing animals.

Multiple federal, state, territorial, tribal, and local regulatory agencies have some oversight over the food supply, including more than one million food establishments (restaurants, grocery stores, cafeterias, schools, and correctional facilities), more than 150,000 domestic registered food facilities and two million farms. FDA and its regulatory and public health partners often work independently, under different legislative authorities, and may have

differing objectives and perspectives on priorities. As envisioned in the FDA Food Safety Modernization Act, FDA is working to build an integrated national food safety system with the federal, state, territorial, tribal, and local regulatory agencies to enhance and leverage state and local food safety efforts. We are also working to develop greater capacity to detect and contain foodborne outbreaks for the benefit of consumers and the food industry. The integrated national food safety system is designed to unify and strengthen foodborne disease surveillance, investigation, and response systems to fully exploit the power of new technology and advanced methods to reduce the burden of foodborne disease.

The threats to the food supply are constantly changing, and new food safety hazards are emerging. The technologies used to produce and process foods are becoming increasingly complex and require specialized training of FDA investigators to evaluate whether production and processing technologies are adequately controlling foodborne pathogens. Laboratory techniques must also be developed to ensure that timely and accurate tests are available to FDA both for routine inspection sampling and in the case of a foodborne illness outbreak investigation.

The variety of agents associated with foodborne illness has grown over the last few decades, and new threats, such as melamine and cyanuric acid, continue to emerge. In addition, changes in consumption and availability of food mean more consumers are eating ready-to-eat foods, eating outside of the home, and eating fresh fruit and vegetables year-round. FDA provides consumers with clear information about the most important safe food handling, preparation, and storage practices, and provides accurate and timely food safety information to the public in the event of an outbreak. FDA will play an enhanced leadership role on food-safety education and work in partnership with the food industry, consumer, and public health organizations; educators; state and local food safety partners; and other federal agencies to elevate the contribution of consumer education to reducing foodborne illness.

Table 1. Summary of Long-Term Objectives for Food Safety

Long-Term Objectives	Key Strategies
3.1.1.1 Establish standards for science-based preventive controls throughout the farm to table continuum	• Prioritize development of targeted preventive control standards to address highest risks first • Identify and prioritize knowledge gaps • Measure the public health effects of the preventive controls
3.1.1.2 Achieve high rates of compliance with preventive control standards both domestically and internationally	• Utilize resources and information from public health, industry, and regulatory partners to create an integrated food safety system • Create a modernized inspection, investigation, and enforcement system • Improve incident preparedness, response, and communication • Develop and begin implementing an import oversight plan
3.1.1.3 Ensure adequate scientific capacity to support risk-based public health decision making	• Strengthen predictive capabilities and enhance risk analysis to improve decision making • Prioritize, integrate, and enhance regulatory research and methods development

3.1.2 Promote Healthy Dietary Practices and Nutrition

The public health focus of the Foods Program also centers on the promotion of healthful dietary practices through truthful and informative labeling on packaged and other foods. American consumers can use this information to make healthier choices about the food they eat and help them reduce the risk of chronic disease and facilitate optimal health. Reducing the chronic disease burden of the U.S. population depends, in large part, on consumers having the knowledge to make wise food choices as well as the motivation to make those choices consistently at all stages of their lives. To promote healthy dietary practices and nutrition, FDA has aligned its priorities to support two goals: 1) to increase the availability of safe and nutritious new food products; and 2) to provide clear and timely information to promote better nutrition and reduce the risk of chronic diseases, such as obesity, by strengthening food labeling to promote healthful dietary practices.

Trends and Challenges

According to data from the CDC, chronic diseases cause 7 out of 10 deaths each year and account for about 75 percent of the $2 trillion that America spends on healthcare each year. Excesses in intake of calories, dietary fat, sodium, and certain carbohydrates are linked to chronic diseases — obesity, diabetes, and hypertension — that are reaching epidemic proportions. CDC data indicate that more than 30 percent of the American adult population, or 60 million people, are obese. Policy and environmental change initiatives that make healthy choices in nutrition and physical activity available, affordable, and easy will likely prove most effective in combating obesity and chronic disease.

Efforts to update the Nutrition Facts panel and FDA's proposed rules on restaurant menu and vending machine labeling will also enable FDA to address the public health problems of obesity and chronic disease by improving nutrition information readily available to consumers — an essential tool for consumers to construct healthier diets. These initiatives will also encourage the reduction of levels of sodium in processed and restaurant foods. Moreover, several education and outreach efforts, such as the educational program, SPOT THE BLOCK, a school-based program and teacher professional development program on nutrition developed with the National Science Teachers Association, and the Web-based program, Healthy Weight Management, are underway to promote healthful choices by consumers and build awareness of nutrition labels.

FDA will also focus its efforts to address the public health problem of chronic disease by reducing the levels of sodium in processed and restaurant foods. This initiative will empower consumers and also motivate food producers to develop more healthful food products.

Alongside efforts to modernize nutrition labeling of foods, FDA will undertake similar efforts in pet food labeling to protect and improve animal health. FDA is leading efforts in new pet food labeling regulations and other initiatives to provide factual and pertinent nutritional information to pet owners and allow them to make better choices in pet food products to improve the health and well being of animals.

Table 2. Summary of Long-Term Objectives for Dietary Practices and Nutrition

Long-Term Objectives	Key Strategies
3.1.2.1 Provide clear and timely information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity	• Improve nutrition labeling on food packages and on restaurant menus as a tool for consumers seeking to construct healthier diets • Implement the revised pet food labeling and definitions and standards for animal feed ingredients
3.1.2.2 Encourage product reformulation to increase the availability of nutritious food products	• Establish a sustained, multi-faceted coordinated effort to reduce the level of sodium in processed food • Foster improved product formulation through labeling and other initiatives

Signature Initiative

FOODS – FDA FOOD SAFETY MODERNIZATION ACT

The passage of the FDA Food Safety Modernization Act, the first major overhaul of our food safety law in over 70 years, transforms FDA's food safety program by providing it with new public health mandates and enhanced tools for ensuring the safety of the food supply in the 21st Century. The central purpose of the new law is to better protect public health by preventing food safety problems, rather than primarily reacting to problems after they occur.

Preventive controls

For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls.

- The legislation transforms FDA's approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It does so by requiring food facilities to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take any corrective actions that are necessary.
- It also requires FDA to establish science-based standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious illnesses or death.

Inspection and Compliance

The legislation recognizes that inspection is an important means of holding industry accountable for their responsibility to produce safe products. FDA will meet this expectation by:

- Applying its inspection resources in a risk-based manner
- Innovating in its inspection approaches to be the most efficient and effective with existing resources

Imported Food Safety

The legislation provides significant enhancements to FDA's ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year. More specifically, relative to import food safety, the legislation:

- Requires importers to perform supplier verification activities to ensure imported food is safe
- Authorizes FDA to refuse admission to imported food if the foreign facility or country refuses to allow an FDA inspection
- Authorizes FDA to require certification, based on risk criteria, that the imported food is in compliance with food safety requirements
- Provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program through which imports may receive expedited review of their shipments if the importer has taken certain measures to assure the safety of the food

Enhanced Partnerships

The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies – Federal, state, local, territorial, tribal, and foreign – to achieve our public health goals. It also recognizes the importance of building the capacity of state, local, territorial and tribal food safety programs. Among other provisions, it directs the Secretary to improve training of state, local, territorial and tribal food safety officials and authorizes grants for training, conducting inspections, building capacity of labs and food safety programs, and other food safety activities.

3.2 Promote Public Health by Advancing the Safety and Effectiveness of Medical Products

A key priority for FDA is improving the safety and effectiveness of medical products, both through rigorous review of clinical studies and manufacturing process information before products are approved as well as through monitoring actual patient experiences and manufacturing quality once they are on the market. FDA aims to fulfill FDA's public health mission by supporting smart prescribing, working to prevent intentional and unintentional misuse, educating consumers on safe use, and readily recognizing and responding to emerging safety concerns. We are also fostering the development of innovative new therapies by setting clear standards and guidelines for evaluating safety and effectiveness so that the regulatory process can keep pace with advances in science and technology. By taking advantage of improvements in scientific computing and by developing affiliated technologies (e.g., improved product tracking methods), FDA is working to develop a new generation of information collection and analysis methods to improve our understanding of the real-world health outcomes from medical products. The long-term goal is to identify product problems sooner and to gain a richer understanding of how medical products affect populations and subpopulations every day. This way, we can not only take any necessary immediate actions to protect the public health, but also use that knowledge to support improvements in medical product development and health care delivery practices.

Desired Public Health Outcomes

- **Increase years of healthy life by increasing access to life-saving and life-enhancing medical products**
- **Reduce the number of deaths and injuries associated with the quality and unsafe use of FDA-regulated medical products**

3.2.1 Advance Human Drug Safety and Effectiveness

The Human Drugs Program performs an essential public health task by ensuring that drugs available to consumers are safe and effective. We regulate over-the-counter and prescription drugs, including biological therapeutics and generic drugs. FDA's authorities also include review of products not typically considered to be medicinal. For example, fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens qualify as drugs and are subject to the regulatory review process. The Human Drugs Program evaluates all new and generic drugs prior to entering the market and serves as a consumer watchdog for the more than 10,000 currently marketed drugs to ensure they continue to maintain approved standards.

Trends and Challenges

> According to Dr. Hamburg, "we are in the beginning of a new era for drug safety where protecting public health means that FDA's responsibility doesn't end when we grant a product market approval; that is merely the first check point in ensuring safety."

The drug review process has evolved considerably since passage of the Federal Food, Drug, and Cosmetic (FD&C) Act in 1938. Initially, drug applications were only required to contain an investigational drug's safety information. In 1962, the Kefauver-Harris Amendments to the FD&C Act required data to support a drug's effectiveness for its intended use. The drug development and distribution landscape has changed dramatically over the same period of time, and today, FDA's responsibility and reach is global: up to 40 percent of the drugs Americans take are imported and up to 80 percent of the active pharmaceutical ingredients in those drugs originate from foreign sources.

The drug review life cycle begins during the premarket investigational phase and continues through postmarket manufacturing inspections and adverse events monitoring. New challenges posed by globalization, out-sourcing, and increasingly large, multi-facility clinical trials require FDA to refocus its drug review process into one that enables full product life cycle review. Multi-disciplinary review teams are involved in different facets of the regulatory review process. As a result, it is critical that decision-making on a drug product throughout its life cycle be clearly documented, communicated, and well-supported.

FDA has a three-pronged plan to achieve its mission to ensure consumer access to safe and effective drugs. They are illustrated by the long-term objectives captured in Table 3 below and the key strategies associated with each objective.

Table 3. Summary of Long-Term Objectives for Human Drugs

Long-Term Objectives	Key Strategies
3.2.1.1 Promote public health by ensuring the availability of safe and effective new drugs	• Identify and develop new scientific methods, models, and tools to improve the quality, safety, predictability, and efficiency of new drug development • Conduct rigorous science-based premarket review to ensure that drugs that will be marketed to the public are safe and effective • Ensure patient awareness of drug benefits and risks through effective communication of drug information
3.2.1.2 Protect public health by ensuring the quality and integrity of marketed drug products	• Secure the global supply chain to ensure that drugs are being manufactured and distributed to conform to established quality standards • Improve drug quality oversight capacity through expanded use of risk-based methods • Ensure public awareness of drug quality and integrity issues through effective consumer communications
3.2.1.3 Protect public health by promoting the safe use of marketed drugs	• Conduct postmarket surveillance to ensure early detection of new safety signals • Conduct rigorous studies to understand new drug safety signals and effectively manage emerging risks • Ensure patient and health professional awareness of drug risks and parameters for safe use • Oversee drug promotion and marketing to ensure that marketed drug labeling and advertising are truthful and not misleading

Signature Initiative

QUALITY SYSTEMS FOR THE HUMAN DRUGS PROGRAM

The Human Drugs Program is designing a quality systems framework to enhance regulatory review and cross-cut business processes in support of consistent, scientifically sound, high-quality work products. This framework will enable a culture of continual process review and improvement, with performance measures that focus attention on how to best accomplish the program's mission.

The new quality system will be supported by a set of strategic objectives designed to ensure that the program has the correct set of expertise, strong management, integrated supporting infrastructure, and clear lines of communication to support rigorous, well-informed decision-making.

3.2.2 Advance Biologics Safety and Effectiveness

The Biologics Program is responsible for protecting and enhancing the public health through the regulation of biological and related products, including blood, vaccines, allergenics, tissues, and cellular and gene therapies, and works with other federal agencies, foreign governments, and international organizations such as the World Health Organization (WHO). The program reviews and licenses safe and effective new biological products. The program also plays an important role in protecting the public against threats to the safety of blood, blood products, tissues, cellular and other products from emerging infectious diseases. Additionally, the program facilitates the critical process to license safe and effective biological products to protect the public against agents of bioterrorism.

Trends and Challenges

FDA responds to the challenges of pandemic influenza, bioterrorism, and emerging infectious diseases by facilitating the development of products to protect the public against these threats and approving products that have been demonstrated to be safe and effective. FDA has facilitated the development of influenza pandemic vaccines through expedited regulatory pathways and supports efforts to increase manufacturing capacity using both new and existing technologies and to develop faster methods for testing the potency of influenza vaccines. As a member of the FDA team, the Biologics Program works with the Public Health Emergency Medical Countermeasures Enterprise and industry on a broad array of projects aimed at making our nation better prepared for threats of biological, chemical, and radiological/nuclear terrorism through the development of new countermeasures.

FDA has worked in the global community to improve human health in the world's populations over many years — it is clear that protection of global public health against infectious disease threats leads to improved public health in the United States as well. With the advent of a globalized enterprise for the development and marketing of medical products in the 21st century, that paradigm has vastly expanded in scope, requiring greater engagement with our global partners. Serving as a WHO Collaborating Center for Biological Standardization, FDA will continue its substantial contribution to WHO's biologics portfolio, including efforts to develop standards for biological products, its regulatory capacity-building initiatives, and its vaccine prequalification process, which is a cornerstone of global access to vaccines. Not-for-profit foundations and other non-governmental organizations are increasingly important contributors to global efforts to facilitate the development of medical products for the world's unmet needs and have newly recognized the need to address regulatory pathways as part of their efforts. Harmonization of existing product standards and prospective harmonization in newly emerging therapies remains an important means to facilitate global access to safe and effective products, as is sustaining regulatory dialogue on important scientific and regulatory concerns on globally marketed products. FDA will improve its coordination and management of these rapidly growing international arenas and continue exploring creative new paradigms to respond to these needs.

Ensuring the safety of biological products is a core mission strengthened by the Food and Drug Administration Amendments Act of 2007 (FDAAA). As authorized by FDAAA, FDA is conducting collaborative pharmacoepidemiological research to test hypotheses on potential biological product safety issues arising from clinical trials and reports of adverse events linked to the use of those products. FDA is striving to build product safety for biological products through their life cycle.

Advances in science and technology show great promise for the development of new safe and effective biological products. FDA is working to address the use of advanced technologies and methods and relevant scientific discoveries — such as newly identified clinical biomarkers, adaptive clinical trial designs, and genomics — in regulatory guidance documents for industry. FDA will advance regulatory research that supports 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. Continued updating of FDA's business practices will improve the connectivity of agency databases, simplifying the storage, tracking, and retrieval of review documents and communications. Timely integration of advanced methods into product review will require sustained efforts.

Under the recently enacted Patient Protection and Affordable Care Act (Public Law 111-148), FDA has been given the authority and responsibility to regulate Biosimilar Biological Products, a newly defined class of medical products.

FDA is carefully evaluating the newly enacted biosimilar provisions contained in the health care legislation to determine how best to implement these new provisions. FDA has established a cross-center working group that has been charged with the responsibility for establishing policies and procedures to implement the new provisions in a manner that best serves the public health.

For FDA to perform its role effectively in regulating the biologics industry, FDA has developed the following objectives and key strategies shown in Table 4.

Table 4. Summary of Long-Term Objectives for Biologics

Long-Term Objectives	Key Strategies
3.2.2.1 Increase the nation's preparedness to address threats as a result of bioterrorism, pandemic and emerging infectious diseases	• Increase the nation's preparation for pandemic influenza • Facilitate development, evaluation, and availability of high-priority medical products (including medical countermeasures) • Develop reagents, evaluate new methods, and implement policies that maintain a continued safe and adequate supply of blood and tissues during emergencies
3.2.2.2 Improve global public health through international collaboration, including research and information sharing	• Promote research and information-sharing globally to address diseases and emerging threats impacting human populations • Facilitate global access to vaccines and biological products that address critical health needs • Harmonize existing regulatory standards, where feasible, and work towards prospective harmonization of standards on new biological product areas to promote global public health • Cooperate with international scientific efforts to establish and maintain reference materials and standards for biologics
3.2.2.3 Enhance the ability of advances in science and technology to facilitate development of safe and effective biological products	• Integrate genomics, proteomics, high-sensitivity gene sequencing and other cutting-edge scientific technologies into regulatory oversight to expedite product development and review • Improve the evaluation of effectiveness of products in clinical trials through the use of biomarkers and adaptive designs • Advance regulatory research to facilitate product review, including development of relevant animal models
3.2.2.4 Ensure the safety of biological products	• Facilitate increased biologics manufacturing capacity and improved product quality • Improve the use of healthcare data to enhance monitoring the safety and quality of licensed biological products • Enhance statistical data analysis and mathematical models for improved epidemiological and risk assessments of regulated products • Promote safe product use through effective risk management and risk communication

Signature Initiative

STEM CELL INITIATIVE

Stem cells are specialized cells that have the remarkable potential to develop into many different cell types in the body. Stem cell therapies aim to harness the power of different cell types to fight disease, restore normal function, repair injuries, replace lost cells, and regenerate failing organs.

On March 9, 2009, the President issued Executive Order (EO) 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, which lifted the ban on federal funding for promising embryonic stem cell research. FDA regulates stem cells as a novel biologic therapy; in fact, the agency's authority extends to products comprised of, or derived from, human cells, tissues, or cellular or tissue-based products, and gene therapy products. Because of the advancing state of science and the EO, FDA anticipates a significant increase in new investigational drug applications and biologics license applications for stem cell products. With more submissions, FDA also anticipates increased inquiries from the scientific community and stakeholders requesting input on product development, required preclinical studies, clinical trial design, and regulatory policy.

The Biologics Program's Stem Cell Initiative will enable FDA to interact with industry and other stakeholders and better anticipate scientific and regulatory challenges that may arise in the review of investigational and licensing applications for novel stem cell products — and advance scientific and regulatory policy. This initiative will promote dialogue and educational efforts with the scientific and product development communities and foster partnerships and collaborations with experts in the field. The educational exchange will benefit both FDA and stakeholders, as it will ensure that product development proceeds with an appropriate understanding of the regulatory requirements.

These efforts of promoting dialogue and education and fostering partnerships and collaborations can be achieved through short- and long-term projects led by FDA staff, such as workshops, webinars, and guidance development. In addition to these efforts, FDA may collaborate with experts in the field through development of outside partnerships and an expanded fellowship program.

Much work remains to understand how to use stem cells for therapies to treat disease, and it is imperative that FDA remain up-to-date on scientific development in this rapidly developing area so that policies reflect the most current scientific knowledge. To stay at the forefront and address regulatory science gaps in our understanding of stem cell-based therapies, FDA is also expanding in-house research while working collaboratively with other government agencies, such as the National Institutes of Health and the National Institute of Standards and Technology, to identify, develop, and evaluate methods to characterize products that will be predictive of clinical function.

3.2.3 Advance Animal Drug Safety and Effectiveness

The Animal Drugs and Feeds Program is responsible for fostering public and animal health by regulating the drugs, devices, and food additives used to feed and sustain animal health and by enforcing applicable legislative provisions. It therefore plays a prominent role in the strategic areas of Food Safety and Nutrition, as well as Drug and Device Safety and Effectiveness.

> CVM is responsible for regulating drugs, devices, and food additives given to, or used on, over 150 million companion animals, plus billions of poultry, cattle, swine, and minor animal species.

The Animal Drugs and Feeds Program is responsible for regulating drugs, devices, and food additives given to, or used on, over 150 million companion animals (e.g., cats and dogs), plus billions of poultry, cattle, swine, and minor animal species.

FDA approvals affect several hundred animal drug applications, including generics, for companion and food-producing animals, and FDA approves many of these drugs for administration through animal feed. FDA's review process requires efficiently evaluating new animal drugs, some of which represent innovative new technologies. FDA also conducts surveillance, monitors compliance to prevent marketing of unsafe products, and coordinates enforcement actions against products associated with adverse events.

Trends and Challenges

FDA faces a "revolution" of new science technologies and emerging regulatory science questions for today and tomorrow. The central challenge for FDA is to protect consumers by making use of the best possible science while supporting the efficient development of new products. Due to its broad regulatory mission, FDA scientists must stay current with respect to emerging technologies developed by academia and regulated industries while concurrently maintaining expert competencies in established technologies. The capacity to meet these requirements is dependent upon program growth in emerging areas such as nano-technology, biosensors, proteomics, genomics, and metabolomics. The capacity to continue such innovation requires the infusion of new ideas through scientific exchange and adoption of next generation high-throughput analytical technologies.

FDA is interested in increasing the availability of legally marketed new animal drugs. There are a significant number of unapproved new animal drugs that are being sold and marketed to animal owners and veterinarians, including new animal drugs compounded from bulk drug substances. The Agency is concerned that the safety and effectiveness of these marketed products has not been demonstrated. FDA recognizes that the continued availability of a number of these products is important to meet the health needs of animals. The focus is not on revising the current new animal drug approval process. FDA is interested in examining additional mechanisms that utilize FDA's existing regulatory framework as well as novel strategies not currently employed by the agency to increase the number of approved or otherwise legally marketed animal drugs. In that spirit, FDA

plans to ask stakeholders for ideas on pathways to increase the number of legally marketed animal drug products. In addition, FDA is working on and developing an enforcement strategy for the removal of unapproved animal drugs. This two-prong approach will help ensure that safe and effective new animal drugs are legally available and that unsafe or ineffective products are not manufactured and distributed.

To minimize the development of antimicrobial resistance, FDA believes that additional steps need to be taken to ensure the judicious use of medically important antimicrobial drugs in animal agriculture. FDA is providing a framework to inform the public as well as shape policy regarding the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. The framework includes phasing in measures that would limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health and that include veterinary oversight or consultation. The recommended limitations reduce overall medically important antimicrobial drug use levels, thereby reducing antimicrobial resistance, while still maintaining the availability of these drugs for appropriate use. FDA remains committed to working with animal drug sponsors, the veterinary and public health communities, the animal agriculture community, and all other interested stakeholders in developing a practical strategy to address antimicrobial resistance concerns that is protective of both human and animal health.

The animal drug review life cycle begins during the pre-market investigational phase and continues through post-market activities, including adverse event monitoring. The new challenges posed by innovative new technologies and increased globalization requires a review process that draws together both pre- and post-market functions, helps prioritize and manage risk, and optimizes the use of resources. FDA will use a comprehensive regulatory approach for integrating pre- and post-approval and compliance functions for animal drug products. The Animal Drugs and Feeds Program plans to explore optimum approaches for implementing and integrating product life cycle processes, addressing the needs of small sponsors, and identifying and optimizing potential for collaborative review processes throughout the organization. With the integration of facilities, the exchange of scientific information, and of staff expertise, potential problems with regulated products will be identified sooner in the life cycle of a product and can be dealt with quickly.

Safe animal feed and pet food helps ensure healthy animals and people. Establishing a framework for coordinating federal and state veterinary diagnostic laboratories to respond to high priority chemical and microbial feed contamination events will further strengthen our ability to prevent the occurrence of feed safety problems and if necessary to respond quickly to animal injury and death. Veterinary diagnostic laboratories examine animal tissues for infectious agents, toxins, and other causes of disease in diagnostic samples submitted by veterinary practitioners serving pet owners and other animal owners. FDA plans to initiate strategic alliances with state veterinary diagnostic laboratories and develop a mechanism to support state veterinary diagnostics laboratories. This network will provide the means for quick identification of reports of animal injury associated with animal feed contamination and establish protocols for immediate veterinary diagnostic reporting to FDA.

In support of its mission, the Animal Drugs and Feeds Program established goals and objectives to ensure that resources are planned, allocated, and managed commensurate with the agency's public health responsibility for evaluating, approving, and monitoring animal drugs, food additives, feed ingredients, and animal devices. Table 5 summarizes the Animal Drugs and Feeds Program objectives and key strategies.

Table 5. Summary of Long-Term Objectives for Animal Drugs

Long-Term Objectives	Key Strategies
3.2.3.1 Enhance knowledge of emerging science and technologies	• Develop/expand science education and outreach programs focused on emerging science • Incorporate/expand emerging science into regulatory mission requirements • Adopt next generation high-throughput analytical technologies
3.2.3.2 Reduce risk of harm from substandard and illegally marketed animal drugs	• Develop a regulatory framework for legal marketing of unapproved drugs • Develop a work plan for addressing unapproved new animal drugs • Develop an enforcement strategy that addresses the illegal compounding of new animal drugs
3.2.3.3 Ensure the judicious use of medically important antimicrobials	• Issue final guidance on the judicious use of medically important antimicrobial drugs in food-producing animals • Develop and issue additional guidance for industry regarding implementation of the recommendations outlined in the judicious use guidance • Work collaboratively with other agencies and FDA stakeholders in implementing sound strategies for phasing in the judicious use guidance recommendations • Issue revised order of prohibition on extra-label use of cephalosporin drugs • Evaluate data on the use of antimicrobials in ethanol production
3.2.3.4 Increase access to safe and effective animal drugs and reduce risk of harm from unsafe use of marketed animal drugs	• Facilitate increased biologics manufacturing capacity and improved product quality • Improve the use of healthcare data to enhance monitoring the safety and quality of licensed biological products • Enhance statistical data analysis and mathematical models for improved epidemiological and risk assessments of regulated products • Promote safe product use through effective risk management and risk communication
3.2.3.5 Enhance response to food/ feed and drug safety events	• Establish partnerships with veterinary diagnostic laboratories in developing the Veterinary Laboratory Response Network (VEtlRN) to respond to high priority chemical and microbial feed/ drug contamination events • Develop risk-based preventive controls for animal feed facilities to ensure the safety of animal feed

Signature Initiative

BIOTECHNOLOGY PROGRAM PROCESS

FDA is piloting a program grounded in risk-based, full life cycle regulatory oversight and a team-based review process to further strengthen the Animal Drugs and Feeds Biotechnology Program. It is based on having a complete understanding of the nature of genetically engineered animals and the potential risks they may pose pre- and post-market (safety) and making sure that the introduced traits continue to be appropriately expressed (effectiveness).

Part of the goal of the pilot program is to maximize the existing resources across the Animal Drugs and Feeds Program in a matrixed format by engaging professionals with the appropriate expertise regardless of their administrative unit, to enhance the continuity of pre- and post-market activities and to provide internal peer review of the Center's assessments and actions. The pilot program uses a matrix format for all offices within the Animal Drugs and Feeds Program during a product's evaluation life cycle. Because of its interdisciplinary nature, FDA's current veterinary biomedical and food safety capacities are challenged by their traditional administrative structures; this pilot program has been established to find an effective mechanism to improve the agency's ability to address this technology in an efficient and proactive manner.

With the approval of the first "biopharm" animal in February 2009, FDA demonstrated to the fledgling industry that not only are such applications theoretically possible, but approvals would be issued by the agency, along with the requirement for regulatory oversight. In addition, the genetically engineered animals that have been in development for several years are now reaching regulatory maturity.

3.2.4 Advance Medical Device Safety and Effectiveness

FDA's Medical Device Program protects and promotes the public health by ensuring the safety, effectiveness and quality of all medical devices — from very simple items like tongue depressors or thermometers to very complex technologies such as heart pacemakers and dialysis machines. The Medical Device Program also protects the public from unnecessary exposure to radiation from radiation-emitting products, such as microwave ovens, cell phones, x-ray equipment, lasers, medical ultrasound and MRI machines, and many other consumer, industrial, and medical products. In addition, the program monitors mammography facilities to make sure their equipment is safe and properly run.

The device program's public health mission focuses on all the stages in a product's life cycle, from development and design through obsolescence. We monitor medical devices and radiological products for continued safety once they are in use, foster medical device innovation, and provide the public with the accurate, science-based information needed to improve health.

Trends and Challenges

In a rapidly and continuously evolving scientific and global-market landscape, the device program is taking steps to meet challenges for the 21st century. Two significant efforts that will help the device program meet the challenges of the future include: 1) activities to improve the quality, consistency, and predictability of regulatory decision-making, and 2) activities to facilitate medical device innovation.

By strengthening our premarket review programs, we are working to improve the predictability, consistency, and transparency of our regulatory decision making in the context of a rapidly changing scientific landscape. The goals and actions FDA will undertake are part of the key strategy, "Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions." As part of this strategy, FDA completed a comprehensive assessment of the 510(k) program and our use of science in our regulatory decision making and then announced steps it will take to improve the predictability, consistency, and transparency of our premarket review programs.

Our responsibility to the public is: 1) to protect public health by ensuring the safety and effectiveness of medical devices and using enforcement tools wisely and 2) to promote public health by facilitating innovation and fostering a culture of quality and prevention among industry. To fulfill this two-fold mandate, we must embrace both parts of our mission. Although FDA and other government partners have important collaborative roles to play in the life cycle of a medical device, the government may be able to do more to encourage the development of innovative medical devices. The goals and actions FDA will undertake under this initiative are part of the key strategy, "Proactively Facilitate Innovation and Address Unmet Public Health Needs." As part of this strategy, FDA plans to work with our federal government partners and external constituencies to facilitate the development of innovative medical technologies and devices.

Table 6. Summary of Long-Term Objectives for Medical Devices

Long-Term Objectives	Key Strategies

3.2.4.1 Fully implement a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device's cycle	• Enhance and integrate premarket, postmarket, and compliance information and functions by taking actions to:
	  • Strengthen Premarket Review
	  • Align scientific resources throughout program
	  • Optimize data collection and analysis
	  • Address challenges associated with globalization
	  • Enhance compliance capability

3.2.4.2 Proactively facilitate innovation and address unmet public health needs	• Foster development of innovative medical devices • Develop a personalized medicine program

Signature Initiative

STRENGTHENING MEDICAL DEVICES PREMARKET REVIEW —510(K) AND SCIENCE REPORTS

To fully implement a total product life cycle approach means that, at any stage of a device or radiation-emitting product's life cycle, FDA must make well-supported regulatory decisions that take into consideration all the relevant information available to us. Two major components of this long-term objective are our efforts to strengthen premarket review and to incorporate new science as predictably as is feasible into our decision making.

In September 2009, the 510(k) Working Group was charged with evaluating how well the 510(k) program was meeting its public health goals and exploring actions CDRH should take to strengthen it. At the same time, the Task Force on the Utilization of Science was charged with making recommendations on how the Center can quickly incorporate new science — including evolving information, novel technologies, and new scientific methods — into its decision making in as predictable a manner as is practical. These two groups outlined their findings and recommendations in two reports, "CDRH Preliminary Internal Evaluations (Volumes I and II)," that were released August 2010. The overall objective of the reports was to foster medical device innovation and improve patient safety.

FDA solicited and received a range of perspectives in developing the reports and on the recommendations contained in the preliminary reports at two public meetings and three town hall meetings, through three open public dockets and many meetings with stakeholders. Focusing efforts on making significant progress to implement actions that will have the greatest impact on fostering medical device innovation, enhancing regulatory predictability, and improving patient safety, in January 2011, FDA released its "Plan of Action for Implementation of 510(K) and Science Recommendations." The document outlines which recommendations from the preliminary reports FDA intends to implement in 2011, as well as the projected timeline for completion or reaching a major milestone.

In addition to the FDA reports, the Institute of Medicine (IOM) is conducting an independent evaluation of the 510(k) program, and is expected to issue its report in mid-2011.

3.3 Establish an Effective Tobacco Regulation, Prevention, and Control Program

> FDA issued a final rule containing a broad set of requirements to significantly curb access to, and the appeal of, cigarettes and smokeless tobacco products to children and adolescents. Published March 19, 2010, the new rule became effective on June 22, 2010.

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, and FDA gained regulatory authority over tobacco products. Congress authorized the creation of the Center for Tobacco Products, or CTP, to oversee the implementation of the law. With more than 400,000 Americans losing their lives to tobacco-related illness each year and 4,000 children a day trying their first cigarette, the need for effective federal regulation has never been greater.

CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

CTP's leadership team has been laying the foundation for regulating tobacco products by using a new population health standard. FDA's action agenda rests on these public health principles: 1) developing and implementing science-based policy, regulations, and programs; 2) educating the public about tobacco products and their harms and risks; and 3) rigorously enforcing the law. Together, these principles form the framework for effective regulation of tobacco products — the nation's leading cause of preventable death.

Trends and Challenges

Because there is no known safe tobacco product, the Tobacco Control Act establishes a new regulatory standard for FDA product regulation will be based on whether it is "appropriate for the protection of the public health," rather than the "safe and effective" standards used to guide drug or device regulations. This standard is to be based on available medical, scientific and other technological evidence to protect the public health and determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products.

Additionally, FDA is also examining how to best fulfill its mission in partnership with Federal, State, and local public health agencies. These agencies play a vital role in informing and protecting American consumers from the harmful effects of tobacco, and their work is fundamental to FDA's success. The nation's 1-2 million tobacco product retailers are important new partners in FDA's efforts to decrease youth initiation through tobacco product regulations. CTP is conducting an unprecedented outreach effort to receive input, keep stakeholders informed, and educate consumers. FDA is committed to providing Americans with the information they need to protect their children and to make choices about tobacco use for themselves.

By focusing on the risk of tobacco products, crafting communication strategies to reduce product initiation and use, developing its research agenda, and collaborating with its partners FDA is committed to making the suffering caused by tobacco products a part of America's past — not its future.

Desired Public Health Outcomes

- **Reduce the number of deaths and diseases associated with the use of tobacco products**
- **Reduce the number of youth accessing and using tobacco products in the United States**

Table 7. Summary of Long-Term Objectives for Tobacco

Long-Term Objectives	Key Strategies
3.3.1 Develop and implement science-based policy, regulations, enforcement strategies, and compliance programs to protect the public health	• Develop a science base for the regulation of tobacco products • Based on the best science, use tobacco products regulatory authorities provided in the Tobacco Control Act to reduce the health consequences of tobacco use on the population by developing and issuing regulations and guidance to implement statutory and regulatory provisions • Develop and implement rigorous compliance and enforcement programs to protect the public health
3.3.2 Provide the public with accurate, trustworthy, and accessible information about tobacco products	• Develop a research and an evaluation agenda for effective communication and public education strategies • Develop a communication and public education strategy to address the public health risks of tobacco products • Develop a communication and public education strategy to help reduce the initiation and use of tobacco products • Develop opportunities to collaborate with other partners to further the Center's mission and public health goals • Commit to transparency with the public and other stakeholders

3.4 Manage for Organizational Excellence and Accountability

Managing for operational excellence and accountability across strategic program areas will ensure an effective framework for implementing the program initiatives within the Office of the Commissioner (OC) and across FDA centers and field offices. The agency has established operational excellence and accountability objectives to ensure that resources are planned, allocated, and managed to best ensure delivery of the services that are critical to the fulfillment of FDA's mission.

Human Capital Management

FDA's ability to recruit, develop, and retain a diverse workforce depends on a fully integrated, FDA-wide human capital management program that aggressively recruits, hires and retains skilled high-performing employees who can meet current and future challenges of the agency. Successful recruitment, training and development including leadership development, career management, performance management, and succession planning will enable FDA to retain a high performing and diverse workforce. FDA has established a strategic human capital plan that incorporates workforce and succession planning to assist in identifying and prioritizing our human capital needs. FDA will target its use of recruitment and retention flexibilities to FDA's mission critical occupations and ensure that they are used consistently and appropriately to recruit and retain the nation's top talent to ensure we are an employer of choice and that we meet our critical mission in serving the American public. FDA will work in partnership with OPM and HHS to maximize the use of the Hiring Reform initiatives which include more efficient processes in hiring and on-boarding talent. The new HHS Accelerated Hiring Process was implemented in July 2010 on an agency-wide level. In FY 2011, using this new process, FDA will assess baseline data using FDA-TRACK and FDA will develop and implement, in collaboration with HHS, improved agency-wide policies and procedures that will fully support all new timelines and processes. FDA will also continuously evaluate and improve our human capital planning processes to ensure we achieve the goal of being an "employer of choice" within the public health and safety community—an agency that recruits, develops, retains, and rewards high-performing employees. FDA will continue to be one of America's best places in Government to work.

Financial Management

FDA will ensure program integrity and responsible stewardship through effective administration of our fiduciary responsibilities. FDA will ensure that financial statements are accurate, financial data of a proprietary nature is protected, corporate accounting adheres to prevailing standards and requirements, and accurate financial information is reported on a timely basis to stakeholders inside and outside FDA. The agency's vision is based on the principle that every person involved in the financial process plays a part in ensuring the integrity of financial data and compliance with financial regulations, and accordance with appropriation law. FDA will work collaboratively to promote an agency-wide

understanding of financial management principels; strengthen financial management systems, practices, controls, and reporting to ensure financial accountability; meet statutory and regulatory requirements; and provide timely, reliable, and useful financial information. This work will ensure protection of the agency's financial resources in an ethical and transparent manner on behalf of the agency's mission.

Information Technology (IT)

Effective IT support and strategic planning is critical to accomplishing FDA's goals and mission. FDA's current five-year Information Technology Strategic Plan (ITSP) under development will identify FDA IT goals and speak to the support function of not only the FDA strategic priorities outlined by this document, but also of HHS goals.

FDA IT Goals will directly support FDA's mission by:

- Developing an IT action plan that optimizes the use of IT resources to support FDA (and HHS) business priorities and goals, seeking to develop and implement technology solutions that grow as FDA's needs change;

- Partnering with programs and industry to provide the innovative information technology that makes it possible to collaborate across government and globally;

- Maintaining a secure environment in which security, privacy, and confidentiality are addressed in accordance with U.S. Government laws, regulations, and directives; and,

- Managing IT projects and investments to demonstrate progressive incremental improvements supporting achievement of FDA program and high-priority initiative objectives.

FDA is near of completion of an ambitious infrastructure modernization program to lay the foundation for modern, networked computing and shared data resources. The transformation of our infrastructure through the migration to new, modernized data centers will enhance our technical ability to improve our information systems to support mission needs. These data centers will also give us the high performance and data storage we need today and are designed to accommodate our growth as FDA changes to meet its public health mission. The modern, fault-tolerant architecture of these data centers protects our systems from internal and external security threats, and the robust electrical and cooling support systems ensure continuous operations under adverse conditions.

Real Property Infrastructure

FDA will ensure that the facilities and laboratories that are necessary to support its strategic priorities are incorporated at the inception of program development. Accomplished through facilities improvements and alterations to address new requirements, the solicitation of adequate laboratory capabilities from the private sector, and agreements with other Federal, State, and local agencies with the appropriate capabilities, FDA will consistently improve its ability to meet the facility needs for its dynamic goals.

Strategic Communications

For FDA to achieve its mission of promoting and protecting the public health, the agency must have a well-defined communications strategy to address the information needs and concerns of both internal and external audiences. An FDA strategic communication strategy will ensure the agency has clear and concise messages about its work and will ensure those messages reach the right audiences using the most effective channels.

Process Improvement

The agency will maintain a culture of continual business process improvement to strengthen the overall operation and effectiveness of FDA. Business process improvements supported by collaboration and knowledge management tools will foster input from FDA programs, stakeholder, and advisory groups, such as the FDA Science Board, to help define and meet FDA scientific, regulatory and administrative needs and priorities. Collaboration supporting scientific outreach, training, and research and development activities will advance FDA's mission with sister agencies, global regulatory partners, academia, innovators, and consumers. The ability to better coordinate efforts will increase quality, productivity, and transparency for selected business processes.

Open Government

President Obama has committed his Administration to an unprecedented level of openness in government. Following the leadership and commitment of President Obama and HHS Secretary Kathleen Sebelius to transparent and open government, FDA launched FDA's Transparency Initiative in June 2009.

As detailed in the HHS Open Government Plan, FDA will move forward to implement a series of changes to foster open government, including the continued development of FDA Basics, a Web-based resource that provides basic information about the agency and its work, and FDA-TRACK, FDA's agency-wide program performance management system. When fully implemented, FDA-TRACK will monitor more than 90 FDA program offices through key performance measures that will be gathered on a monthly basis.

FDA will explore additional strategies to enhance transparency of FDA's operations and decision making processes, including the recommendations of the Transparency Task Force to make more information about the regulatory process available to the public, to better

explain the basis for FDA's decisions, and to improve transparency to industry to foster a more efficient and cost-effective regulatory process. FDA will continue to seek input from the public and pursue opportunities to collaborate with others so that the agency can more effectively protect and promote the public health.

Table 8. Summary of Long-Term Objectives for Operational Excellence and Accountability

Long-Term Objectives	Key Strategies
3.4.1 Recruit, develop, retain, and strategically manage a world-class workforce	• Establish and implement Strategic Human Capital Plan • Use recruitment and retention flexibilities that are targeted to FDA's mission critical occupations and promote inclusion and diversity at all levels of the workforce • Partner with HHS to implement strategies that promote improvements in the accelerated hiring process • Implement hiring strategies to ensure a diverse FDA workforce that is reflective of the nation and comply with Presidential Executive Orders regarding equal opportunity employment
3.4.2 Ensure program integrity and responsible stewardship through effective administration of fiduciary responsibilities	• Ensure vigorous oversight of financial reporting process to sustain a culture of honesty and high ethical standards • Implement timely, collaborative, and transparent financial planning process that ensures most effective allocation of limited resources to support the FDA's mission • Strengthen financial management systems, practices, controls, and reporting to ensure financial accountability; meet statutory and regulatory requirements; and provide timely, reliable, and useful financial information
3.4.3 Implement an IT modernization program to support state-of-the-art networked information and shared data resources	• Manage IT products and services to create a secure, reliable, and effective computing environment • Provide effective services based on continuous, customer-focused improvement of IT management processes • Ensure that agency program and administrative components work collaboratively and proactively to plan and implement effective solutions
3.4.4 Ensure facilities infrastructure provides dynamic capabilities	• Coordinate available laboratory capabilities with stated research agenda and mission critical laboratory needs • Implement modernization of current laboratory infrastructure/ inventory
3.4.5 Improve the management of FDA by providing ongoing oversight, evaluation, and analysis of policies and programs and by ensuring effective strategic communications	• Evaluate and improve key agency communication channels, including the FDA website • More effectively coordinate development and execution of internal and external agency communications • Implement the FDA Strategic Plan for Risk Communications
3.4.6 Foster a culture of continual business process improvement to improve the overall operation and effectiveness of FDA	• Implement program performance management through the FDA-TRACK initiative • Conduct targeted program evaluations and business process improvement projects
3.4.7 Improve transparency, collaboration, and participation	• Implement the recommendations of the Commissioner's Transparency Task Force • Implement FDA's responsibilities under the HHS Open Government Plan

4.0 Implementation

FDA will implement the agency's Strategic Priorities through a tiered planning framework. First — and above all — the senior leadership of FDA will integrate these priorities into annual budget formulation and implementation planning. At the program level, each Center and the Office of Regulatory Affairs will develop plans that reflect program-specific strategies and metrics for monitoring progress toward achieving strategic objectives. And at the agency level, cross-program work groups will develop plans — such as the Strategic Plan for Risk Communication, Strategic Human Capital Plan, and the Information Technology Strategic Plan — to address cross-cutting strategies. FDA plans to make the program level and cross-cutting implementation plans available on the FDA public website by early 2012.

OC will coordinate the alignment of program-specific and cross-program strategies with the goals and priorities of the Secretary of Health and Human Services and other government-wide priorities. Progress will be monitored by aligning annual executive performance plans and program performance metrics with long-term objectives and strategies. Program performance will be reviewed on a quarterly basis through the FDA-TRACK initiative and through periodic senior leadership reviews.

Appendix A:
FDA Strategic Goals and Long-Term Objectives Aligned to HHS Strategic Goals and Objectives

HHS Strategic Goals	HHS Strategic Objectives	FDA Strategic Goals	FDA Long-Term Objectives
1: Transform Health Care	1B: Improve healthcare quality and patient safety	3.2: Promote Public Health By Advancing the Safety and Effectiveness of Medical Products	3.2.1: Advance human drug safety and effectiveness 3.2.2: Advance biologics safety and effectiveness 3.2.3: Advance animal drug safety and effectiveness 3.2.4: Advance medical device safety and effectiveness
		2. 2: Cross-cutting - Strengthen the Safety and Integrity of the Global Supply Chain	[See various program strategies that address the Global Supply Chain]
		2.3: Cross-cutting - Strengthen Compliance and Enforcement Activities to Support Public Health	[See various program strategies that address Compliance and Enforcement]
		2.4: Cross-cutting - Address the Unmet Public Health Needs of Special Populations	[See various program strategies that address Special Populations]
	1F: Promote the adoption and meaningful use of health information technology	3.4: Manage for Organizational Excellence and Accountability	3.4.3: Implement an IT modernization program to support state-of-the-art networked information and shared data resources

Appendix A: *(continued)*

HHS Strategic Goals	HHS Strategic Objectives	FDA Strategic Goals	FDA Long-Term Objectives
Goal 2: Advance Scientific Knowledge and Innovation	2B: Foster innovation at HHS to create shared solutions	3.4: Manage for Organizational Excellence and Accountability	3.4.7: Improve transparency, collaboration, and participation
	2C: Invest in the regulatory sciences to improve food and medical product safety	2.1: Cross-cutting – Advance Regulatory Science and Innovation	[See various program strategies that address regulatory science capacity]
3: Advance the Health, Safety, and Well-Being of the American People	3D: Promote prevention and wellness	3.1: Advance Food Safety and Nutrition	3.1.2: Promote healthful dietary practices and nutrition
		3.3: Establish an Effective Tobacco Regulation, Prevention and Control Program	3.3.1: Develop and implement science-based policy, regulations, enforcement strategies, and compliance programs to protect the public health
			3.3.2: Provide the public with accurate, trustworthy, and accessible information about tobacco products
	3E: Reduce the occurrence of infectious diseases	3.1: Advance Food Safety and Nutrition	3.1.1: Ensure the safety of the food supply from farm to table
	3.6: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies	3.1: Advance Food Safety and Nutrition	3.1.1: Ensure the safety of the food supply from farm to table
		3.2: Promote Public Health By Advancing the Safety and Effectiveness of Medical Products	3.2.2: Advance biologics safety and effectiveness
		2.5: Cross-cutting - Advance Medical Countermeasures and Emergency Preparedness	[See various program strategies that address Medical Countermeasures and Emergency Preparedness]

Appendix A: *(continued)*

HHS Strategic Goals	HHS Strategic Objectives	FDA Strategic Goals	FDA Long-Term Objectives
4: Increase Efficiency, Transparency, and Accountability of HHS Programs	4A: Ensure program integrity and responsible stewardship of resources	3.4: Manage for Organizational Excellence and Accountability	3.4.2: Ensure program integrity and responsible stewardship through effective administration of fiduciary responsibilities
			3.4.5: Improve the management of FDA by providing ongoing oversight, evaluation, and analysis of policies and programs and by ensuring effective strategic communications
			3.4.6: Foster a culture of continual business process improvement to improve the overall operation and effectiveness of FDA
			3.4.7: Improve transparency, collaboration, and participation
5: Strengthen the Nation's Health and Human Services Infrastructure and Workforce	5A: Invest in the HHS workforce to meet America's health and human service needs today and tomorrow	3.4: Manage for Organizational Excellence and Accountability	3.4.1: Recruit, develop, retain, and strategically manage a world-class workforce

Appendix B:

Crosswalk of FDA Strategic Goals and Long-Term Objectives with Related Healthy People 2020 Objectives

The Healthy People initiative is a collaborative health promotion and disease prevention effort with a vision towards a healthier nation. It is a comprehensive set of goals and objectives aimed at improving health and eliminating health disparities over the course of a decade. With established base-lines, measurable targets, and an implementation strategy for each objective, progress is monitored throughout the decade. FDA is committed to promoting and protecting the public health by aligning its strategic priorities with Healthy People wherever possible. FDA has lead or co-leadership on three Healthy People 2020 focus areas: Food Safety, Nutrition and Weight Status, and Medical Product Safety. FDA staff are working on other important focus areas including, Blood Disorders and Blood Safety, Tobacco Use, Health Communication and Health IT, Genomics, Global Health and Preparedness.

FDA Strategic Goals/ Long-Term Objectives	FDA Desired Public Health Outcomes	Healthy People 2020 Objectives
3.1.1: Ensure the Safety of the Food Supply from Farm to Table	Reduce adverse health effects and deaths from unsafe food and feed	• FS HP 2020-3. Reduce infections caused by key pathogens transmitted commonly through food • FS HP2020–6. Increase the proportion of consumers who follow key food safety practices
3.1.2: Promote Healthful Dietary Practices and Nutrition	Reduce the rates of chronic diseases associated with food by providing consumer nutrition information that supports choice of a healthy diet by the U.S. population	• NWS HP2020–5. Reduce the proportion of children and adolescents who are overweight or obese • NWS HP2020–9. Reduce consumption of saturated fat in the population aged 2 years and older • NWS HP2020–10. Reduce consumption of sodium in the population aged 2 years and older
3.2: Promote Public Health By Advancing the Safety and Effectiveness of Medical Products	Increase years of healthy life by increasing access to life-saving and life-enhancing medical products	• MPS HP2020-4. Increase the use of safe and effective medical products that are associated with predictive biomarkers
	Reduce the number of deaths and injuries associated with the quality and unsafe use of FDA-regulated medical products	• MPS HP2020-3. Reduce the number of adverse events from medical products • MPS HP2020-5. Reduce emergency department visits for common, preventable adverse events from medications • BDBS HP2020–8. Reduce the proportion of persons who develop adverse events resulting from the use of blood and blood products
3.3: Establish an Effective Tobacco Regulation, Prevention and Control Program	Reduce the number of deaths and diseases associated with the use of tobacco products Reduce the number of youth accessing and using tobacco products in the U.S.	• TU HP2020–5. Reduce tobacco use by adults • TU HP2020–6. Reduce tobacco use by adolescents • TU HP2020–7. Reduce the initiation of tobacco use among children, adolescents, and using tobacco young adults

For the complete list of Healthy People 2020 Objectives, please visit:
http://www.healthypeople.gov/2020/default.aspx

Appendix C:
Crosswalk between FDA's Strategic Planning Documents
Previous Strategic Action Plan Framework vs. Current Strategic Priorities Framework

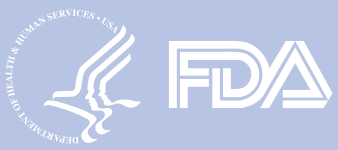
Previous Strategic Action Plan Framework	Current Strategic Priorities Framework
1.1: Strengthen the scientific foundation of FDA's regulatory mission	*Cross-cutting*: Advance Regulatory Science and Innovation; see also various medical product strategies
	3.1.1.3: Ensure adequate scientific capacity to support risk-based public health decision making
	3.2.3.1: Enhance knowledge of emerging science and technologies
	3.4.1: Recruit, develop, retain, and strategically manage a world-class workforce
1.2: Cultivate a culture that promotes transparency, effective teamwork, and mutual respect and ensures integrity and accountability in regulatory decision making	3.4.7: Improve transparency, collaboration, and participation
1.3: Enhance partnerships and communications	3.2.2.1: Increase the nation's preparedness to address threats as a result of bioterrorism, pandemic and emerging infectious diseases
	3.2.2.2: Improve global public health through international collaboration including research and information sharing
	3.4.5: Improve the management of FDA by providing ongoing oversight, evaluation, and analysis of policies and programs and by ensuring effective strategic communications
	3.4.7: Improve transparency, collaboration, and participation
	Cross-cutting: Advance Medical Countermeasures and Emergency Preparedness
	Cross-cutting: Strengthen the Safety and Integrity of the Global Supply Chain
1.4: Strengthen FDA's base of operations	3.4.1: Recruit, develop, retain, and strategically manage a world-class workforce
	3.4.2: Ensure program integrity and responsible stewardship through effective administration of fiduciary responsibilities
	3.4.3: Implement an IT modernization program to support state-of-the-art networked information and shared data resources
	3.4.4: Ensure facilities infrastructure provides dynamic capabilities
	3.4.6: Foster a culture of continual business process improvement to improve the overall operation and effectiveness of FDA

Appendix C: *(continued)*

Previous Strategic Action Plan Framework	Current Strategic Priorities Framework
2.1: Strengthen the science that supports product safety	*Cross-cutting:* Advance Regulatory Science and Innovation
	3.2.1.3: Protect public health by promoting the safe use of marketed drugs
	3.2.2.2: Improve global public health through international collaboration, including research and information sharing
2.2: Improve information systems for problem detection and public communication about product safety	3.2.1.3: Protect public health by promoting the safe use of marketed drugs
	3.4.3: Implement an IT modernization program to support state-of-the-art networked information and shared data resources
2.3: Provide patients and consumers with better access to clear and timely risk-benefit information for medical products	3.2.1.3: Protect public health by promoting the safe use of marketed drugs
	3.2.2.4: Ensure the safety of biological products
	3.2.4.1: Fully implement a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device's cycle
	3.2.3.3: Ensure the judicious use of medically important antimicrobials
2.4: Provide consumers with clear and timely information to protect them from foodborne illness and promote better nutrition	3.1.2.1: Provide clear and timely information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity
3.1: Increase the number of safe and effective new medical products available to patients	3.2.1.1: Promote public health by ensuring the availability of safe and effective new drugs
	3.2.2.1: Increase the nation's preparedness to address threats as a result of bioterrorism, pandemic and emerging infectious diseases
	3.2.2.3: Enhance the ability of advanced science and technology to facilitate development of safe and effective biological products
	3.2.3.2: Reduce risk of harm from substandard and illegally marketed animal drugs
	3.2.3.4: Increase access to safe and effective animal drugs and reduce risk of harm from unsafe use of marketed animal drugs
	3.2.4.1: Fully implement a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device's cycle
	3.2.4.2: Proactively facilitate innovation and address unmet public health needs
	Cross-cutting: Expand Efforts to Meet Needs of Special Populations

Appendix C: *(continued)*

Previous Strategic Action Plan Framework	Current Strategic Priorities Framework
3.2: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science	3.2.2.3: Enhance the ability of advanced science and technology to facilitate development of safe and effective biological products
3.3: Increase access to safe and nutritious new food products	3.1.2.1: Provide clear and timely information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity
	3.1.2.2: Encourage product reformulation to increase the availability of nutritious food products
4.1: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution	3.1.1.1: Establish standards for science-based preventive controls throughout the farm to table continuum
	3.1.1.2: Achieve high rates of compliance with preventive control standards both domestically and internationally
	3.2.1.2: Protect public health by ensuring the quality and integrity of marketed drug products
	3.2.2.3: Enhance the ability of advanced science and technology to facilitate development of safe and effective biological products
	3.2.3.2: Reduce risk of harm from substandard and illegally marketed animal drugs
4.2: Detect safety problems earlier and better target interventions to prevent harm to consumers	3.1.1.1: Establish standards for science-based preventive controls throughout the farm to table continuum
	3.1.1.2: Achieve high rates of compliance with preventive control standards both domestically and internationally
	3.2.3.2: Reduce risk of harm from substandard and illegally marketed animal drugs
	3.2.3.4: Increase access to safe and effective animal drugs and reduce risk of harm from unsafe use of marketed animal drugs
	3.2.4.1: Fully implement a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device's cycle
	Cross-cutting: Strengthen Compliance and Enforcement Activities to Support Public Health
4.3: Respond more quickly and effectively to emerging safety problems, through better information, better coordination, and better communication	3.1.1.2: Achieve high rates of compliance with preventive control standards both domestically and internationally
	3.2.2.1: Increase the nation's preparedness to address threats as a result of bioterrorism, pandemic and emerging infectious diseases
	3.2.3.5: Enhance response to food/feed and drug safety events
	Cross-cutting: Advance Medical Countermeasures and Emergency Preparedness
	Cross-cutting: Strengthen the Safety and Integrity of the Global Supply Chain



Department of Health and Human Services
United States Food and Drug Administration