Food and Drug Administration Strategic Priorities 2014-2018

DRAFT FOR PUBLIC COMMENT

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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, effectiveness, and quality of products that account for about 20 cents of every dollar spent by Americans each year. These products include human and animal drugs, 80 percent of the food supply, biological products, medical devices, cosmetics, and radiation-emitting products. FDA also regulates tobacco products using a population health standard.

This document provides an overarching Agency-level view of how FDA is addressing the public health challenges we face.

HHS Mission

The HHS mission 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 underlying 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 — domestically and internationally — to protect health, prevent illness, prolong life, and promote wellness.

Organization

Ensuring a safe and nutritious food and feed supply, overseeing the manufacturing, marketing and distribution of tobacco products, and improving access to safe, effective, and innovative medical products requires a strong infrastructure and a dedicated workforce. FDA's seven product and research centers and several major offices (see organization chart in Appendix B) are staffed by more than 14,000 employees worldwide who work together to fulfill FDA's fundamental public health mission.

Working with Other Governmental, Nongovernmental, and Private Partners

FDA works closely with State, local, tribal, Federal and international governments to ensure the maximum impact for the public. FDA also develops partnerships, as appropriate, with the private sector, including regulated industries, academic institutions, trade organizations, advocacy groups, and other nongovernmental organizations. By leveraging resources from organizations and individuals with shared interests, FDA is better able to accomplish our mission through strategies that minimize burden and increase the benefits to the American public.

Strategic Priorities Development

Every four years, FDA updates our strategic priorities document, which describes our work to address complex, multifaceted, and evolving public health issues. Each of the FDA's product and research centers and major offices contributed to the plan's goals, objectives, and strategies. A workgroup with cross-Agency representation ensured that the strategic plan aligns with FDA's annual performance reporting in Congressional Budget Justifications. The plan's goals and objectives describe the approach for focusing FDA efforts to achieve our public health mission and to fulfill our role in supporting the larger mission and strategic goals of HHS. A crosswalk that highlights the relationship between FDA and HHS strategic goals is found in Appendix A.

FDA Strategic Priorities 2014–2018 Structure

The FDA Strategic Priorities 2014–2018 document is divided into two main sections:

1. Cross-Cutting Strategic Priorities and
2. Core Mission Goals and Objectives.

FDA has identified five cross-cutting strategic priorities for the next four years:

1. Regulatory Science
2. Globalization
3. Safety and Quality
4. Smart Regulation
5. Stewardship

FDA's core mission goals and objectives are:

Goal 1: Enhance Oversight of FDA-Regulated Products
Goal 2: Improve and Safeguard Access to FDA-Regulated Products to Benefit Health
Goal 3: Promote Better Informed Decisions about the Use of FDA-Regulated Products
Goal 4: Strengthen Organizational Excellence and Accountability

These strategic priorities as well as core mission goals and objectives provide an integrated framework for understanding how FDA is fulfilling our mission and addressing 21st-century public health challenges.

This framework is meant to be interpreted appropriately for each program area and regulated product. For example, tobacco products are fundamentally different from all other FDA-regulated products. Some language that applies to the products FDA regulates (e.g., access, safety, and quality) does not apply to tobacco products in the same way. Therefore, we have used language that clarifies how tobacco products can be understood within the applicable cross-cutting strategic priorities or core mission goals and objectives of FDA's strategic vision for improved public health.

Implementation

FDA will implement these strategic priorities through a tiered planning framework. Most importantly, FDA senior leadership will integrate them into the annual budget priority setting and formulation processes, and implementation planning. At the program level, each FDA product center and major office will implement program-specific actions and monitor key metrics for progress toward achieving our stated strategic objectives and strategies.

Progress will be monitored by aligning annual executive and employee performance plans and program performance metrics (e.g., annual performance goals in the Congressional Justification budget submission, user fee performance measures, and FDA-TRACK measures) with long-term objectives and strategies. Program performance will be reviewed regularly through the FDA-TRACK initiative and through periodic senior leadership reviews.

FDA Cross-Cutting Strategic Priorities

Regulatory Science

Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, toxicity, public health impact, or performance of FDA regulated products. Advancing regulatory science is fundamental to FDA's core mission of promoting and protecting the public health. As a science-based agency, FDA must have access to the best available scientific data to inform regulatory decision-making and thus improve access to those FDA regulated products that benefit the public health and enhance oversight of all FDA-regulated products.

The 21st century has seen rapid advances in research and new cutting-edge technologies, such as sequencing of the human genome; novel cell and gene therapies; high-throughput screening to quickly conduct millions of genetic, chemical, or pharmacological tests; rapid detection methods; and state-of-the-art electronics and materials science to transform medical devices. Additionally, research into nanotechnology-based materials is providing a better understanding of the safety of nanomaterials used in FDA-regulated products. And expanded research of tobacco products is leading the way for science-based regulation of the manufacturing, marketing, and distribution of tobacco products.

In 2011, FDA developed a Strategic Plan for Regulatory Science[1] that identified plans to close critical gaps in scientific knowledge required to support regulatory decision-making. By closing these gaps, FDA's regulatory science program facilitates translation of new technologies and basic science discoveries into real-world diagnostics, treatments, and cures. It also potentially reduces the time, complexity, and cost of developing products.

Tackling regulatory science needs improves the product development process by:

- Providing new tools, models, and simulations to test medical products
- Increasing the quality and efficiency of clinical trials
- Identifying and evaluating clinical endpoints and related biomarkers for trials in areas where optimal endpoints are lacking.

Similarly, by providing new and innovative tools for review, regulatory science will help FDA reviewers better assess data needs for new products and thus better evaluate new products. Regulatory science tools are essential to speed new safe and effective therapies to patients who need them.

[1] Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268095.htm. Accessed on May 29, 2014.

FDA is also committed to advancing regulatory science to help prevent and respond to outbreaks of foodborne illnesses. According to the Centers for Disease Control and Prevention (CDC) each year roughly 1 in 6 (or 48 million) Americans experience foodborne illnesses, resulting in an estimated 128,000 hospitalizations and 3,000 deaths.[2] Regulatory science will enable FDA to develop methods and apply the newest and best available knowledge to ensure the safety and quality of the nation's food supply. Further, regulatory science will enable FDA to develop and validate rapid detection methods that can be shared with State and local government partners and industry to prevent contamination of the food supply, and improve the ability of those partners and industry to identify the cause of foodborne illness outbreaks.

Regulatory science advancements can also help FDA reduce sickness and death from tobacco use. Advances in this area will help FDA better understand tobacco products and guide FDA actions to reduce the public health impact from tobacco products in the United States. Although a vast and sound science base exists, new research will provide scientific evidence in several key areas. Research study areas FDA is exploring include:

- Defining the diversity of tobacco products
- Reducing addiction, toxicity and carcinogenicity and
- Defining adverse health consequences.

[2] http://www.cdc.gov/foodborneburden/estimates-overview.html

Globalization

Sweeping economic and technological changes have revolutionized international trade over the last several decades, creating a truly global marketplace for goods and services. Accounting for about 20 percent of all U.S. consumer spending, FDA-regulated products comprise a substantial component of this global economy.

Food and medical products, and their ingredients and components—products that directly and profoundly affect U.S. public health and welfare—are increasingly sourced from abroad. Today, FDA-regulated products originate from more than 200 countries and territories and pass through more than 300 U.S. ports. The number of FDA-regulated shipments has more than tripled from 8 million import entry lines per year a decade ago to more than 29 million entry lines today.

Globalization demands that FDA think, act, and engage globally. FDA's success in protecting the American public depends increasingly on our ability to reach beyond U.S. borders. FDA must engage with our government regulatory counterparts in other nations, as well as with industry and regional and international organizations, to encourage the implementation of science-based standards that ensure the safety and quality of products before they reach the United States.

FDA is working with our many partners to enhance responsibility for and oversight of safety and quality throughout the supply chain. Acknowledging that we cannot respond to these challenges alone, FDA will continue to expand our regulatory presence and partnerships to build a stronger, more secure global product safety net.

FDA is developing an international operating model comprising four pillars:

1. Information-sharing
2. Data-driven risk analytics
3. Enhanced intelligence and
4. The smart allocation of resources through partnerships.

In close partnership with our foreign counterparts, FDA is assembling global coalitions of regulators to build and strengthen the product safety net worldwide. The Global Coalition of Regulatory Science Research, for example, is building a foundation of collaborative research, scientific exchange, and training as a basis for regulatory decision-making. With these coalitions, FDA intends to develop a global data information system and network in which regulators worldwide can regularly and proactively share real-time information and resources across markets.

For example, FDA will work with our partners to identify critical data elements, such as unique facility identifiers, to better standardize reporting and facilitate data exchanges. We will continue to expand our capabilities in intelligence-gathering and use, with an increased focus on risk analytics and modernized information technology (IT) capabilities. These capabilities will enable

FDA to more effectively allocate our resources based on risk, leveraging the combined efforts of government, industry, and public- and private-sector third parties. Taken together, these four pillars will help FDA strengthen our global product safety net.

Safety and Quality

Safety and quality are integral to FDA's mission of promoting and protecting public health. Safety and quality include 1) the practices used to make products, 2) the integrity of the supply chain that delivers these products to their users, and 3) methods for protecting the public, including laboratory sample analyses for select product categories and product safety reporting systems. Safety and quality depend on the farmers who grow the food, the companies that manufacture the products, the suppliers who furnish their many components and ingredients, and the distributors who bring these products to the marketplace.

Building safety and quality into a product or system prevents problems, and the responsibility for this lies with the companies making the products. Unfortunately, serious safety and quality lapses in recent years have presented public health challenges, most notably those involving foodborne illness, drug shortages, and unsafe manufacturing practices of compounded sterile drugs. Food and feed safety and medical product quality problems lead to higher risks to public health, increased costs, shortages and recalls, market damage, and ultimately, loss of consumer trust. New statutory mandates in the FDA Food Safety Modernization Act (FSMA), FDA Safety and Innovation Act (FDASIA), and the Drug Quality and Security Act (DQSA) necessitate that industry and FDA re-think traditional approaches to safety and quality.

In response, FDA plans to focus our efforts on preventing safety and quality issues with FDA-regulated products. FDA will continue to promote the adoption of safety and quality policies, practices, and standards, domestically and internationally, to reduce risks in the manufacturing, production, and distribution of FDA-regulated products.

In the case of tobacco products, "safety" and "quality" assume a much narrower meaning and focus. FDA is authorized to oversee the manufacturing of tobacco products, including efforts to reduce or prevent atypical and unconventional product hazards (such as defects that could pose an immediate threat to human safety). However, this does not mean that the products themselves are safe or that the "quality" of a certain tobacco product affects its public health impact.

FDA is already taking concrete steps to advance safety and quality across the Agency. For example, the Case for Quality Initiative, which includes a voluntary compliance improvement program pilot, promotes medical device quality. The planned Office of Pharmaceutical Quality will highlight and consolidate quality principles and review throughout the drug lifecycle.

FDA is continuing to implement a lifecycle approach for biologics that spans early stage development through postmarket surveillance. FDA is also promoting the judicious use of medically important antimicrobial drugs in food-producing animals. Moreover, implementation of the food and feed safety principles authorized in FSMA will modernize preventive controls of food contamination and advance food safety practices.

Food and feed safety and medical product quality primarily depend on the industry, requiring top-level management commitment; a clear and in-depth knowledge of the product and the

system; supply chain management throughout the entire life of a product; proactive and continuous management of risk; and continuous and consistent monitoring of quality management systems and processes.

Ultimately, industry, regulators, international organizations, health professionals, purchasers, and consumers all have a role in demanding products that are what they say they are and do what they say they will do, delivered through a system that ensures the safety and quality of the product.

Smart Regulation

An increasingly global and complex marketplace, rapidly evolving technologies, and emerging areas of science are having a major impact on FDA's mission to promote and protect the public health. FDA must tackle these new challenges expeditiously, as we continue to meet our core responsibilities. Public trust in FDA oversight supports public confidence in our regulated industries, at home and in the global marketplace. To keep the public trust and maintain FDA's global leadership role in fostering innovation, FDA must employ "smart regulation".

By "smart regulation" we mean that FDA can attain the goal of protecting the public health while encouraging innovation. That is, the goal can be reached through smart, sound, science-based regulation that imposes the most appropriate regulatory framework while minimizing unnecessary burden.

Smart regulation also requires that FDA remain dynamic, that we continually respond to changing situations, new information, and new challenges, and that we always bring to light the best possible science. Regulation done correctly can:

- Provide a pathway toward meaningful innovation
- Instill consumer confidence in products and treatments
- Level the playing field for businesses
- Decrease the threat of litigation and
- Prevent recalls that threaten industry reputation and consumer trust.

FDA works hard to maintain the public trust and further our global leadership role in fostering innovation. We achieve this by using smart regulatory approaches to streamline and modernize our regulatory programs and minimize regulatory uncertainty for industry, without compromising public health or safety.

Congress gave FDA new tools in FDASIA and DQSA to help ensure the quality of FDA-regulated medical products. FDASIA authorizes FDA to collect user fees from industry to fund reviews for medical devices, innovative new human prescription drugs, human generic drugs and biosimilar biological products. It also provides new authorities for drug shortages, supply chain safety, device review modernization, and other provisions. The new provisions in the DQSA enhance FDA's ability to reduce the risks associated with drug compounding and the risks of counterfeit and other potentially harmful products from entering the drug distribution supply chain.

FSMA is the most sweeping reform of our food safety laws in more than 70 years. It enables FDA to better protect public health by strengthening the food and feed safety system and focuses FDA on preventing food and feed safety problems rather than mainly reacting to problems after they occur. FSMA also provides FDA with new enforcement authorities designed to achieve high rates of compliance with prevention- and risk-based food and feed safety standards. FSMA will enable FDA to better respond to and contain problems when they do occur. In 2013, FDA published six

foundational proposed regulations, and is making strong progress in establishing an entirely different and more effective integrated food safety system.

The Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) enhance FDA's capacity to maintain a predictable and timely animal drug review process; foster innovation in drug development; and expedite access to new therapies for food-producing and companion animals. These laws authorize FDA to collect fees to enhance the new animal drug review process and the generic new animal drug review process. They will enable FDA to better ensure that new animal drug and generic new animal drug products are safe and effective for animals as well as for humans with respect to animals intended for food production.

In addition, the Family Smoking Prevention and Tobacco Control Act (TCA) authorizes FDA to regulate tobacco product manufacturing, marketing and distribution. Since TCA's enactment, FDA has created the Center for Tobacco Products (CTP) and continues to establish and carry out a consistent, transparent, and predictable public health-based scientific regulatory program. CTP regulates complex and highly engineered tobacco products that previously had not been regulated.

FDA will continue to deploy smart regulatory strategies that are designed for the 21st century to support the best public health outcomes and minimize uncertainty for industry by improving the transparency, consistency, predictability, and efficiency of regulatory requirements, while we protects the public health.

Stewardship

In these challenging fiscal times, maximizing public health value from each Federal dollar has become increasingly important to FDA, as we keep up with the dramatic technological and market-based changes affecting how foods, drugs, biologics, and devices are produced. From personalized medicine and nanotechnology to the globalization of our food and medical product supplies to an array of new laws passed by Congress that expand FDA's oversight responsibilities, these complicated issues are not always supported by additional resources for FDA's new responsibilities. Therefore, it is critical that FDA continue to effectively and efficiently use limited resources to increase productivity while maintaining program integrity.

FDA will continue to prioritize recruiting, developing, and retaining a high-quality workforce; seek operational excellence and accountability from our programs; and foster a culture of collaboration and continuous improvement. FDA is improving systems and processes for hiring, compensating, training, assessing, and retaining staff.

Managing for operational excellence and accountability across strategic program areas will ensure an effective framework for implementing program initiatives identified by FDA centers and major offices. FDA has established operational excellence and accountability objectives to align resource planning, allocation, and management with our strategic priorities to better ensure timely delivery of high-quality services that are critical to fulfilling FDA's mission.

Employing good stewardship requires collaboration across FDA to perform mission-specific core regulatory activities. These activities engage not only the regulatory science disciplines, but also FDA experts in policy, planning, informatics, analysis, management, and communications. FDA is fostering a culture of continuous improvement that includes encouraging programs to prioritize actions that have the most public health impact, communicating with and learning from others to innovate and solve problems, and quickly reassessing when intended outcomes are not achieved. FDA is also developing performance metrics that align with program requirements and cross-cutting priorities to measure progress in achieving strategic goals.

In today's era of budget constraints and ever-increasing requirements to do more with less, it is imperative that FDA identify ways to modernize and maximize efficiency. To this end, FDA is looking at several projects that will help control costs and streamline operations, while maintaining the integrity of programs upon which the public relies, including re-organizing FDA's regulatory and compliance activities around commodity-based and vertically integrated regulatory programs. FDA remains committed to implementing the responsibilities entrusted to us and to improving the lives of the American public.

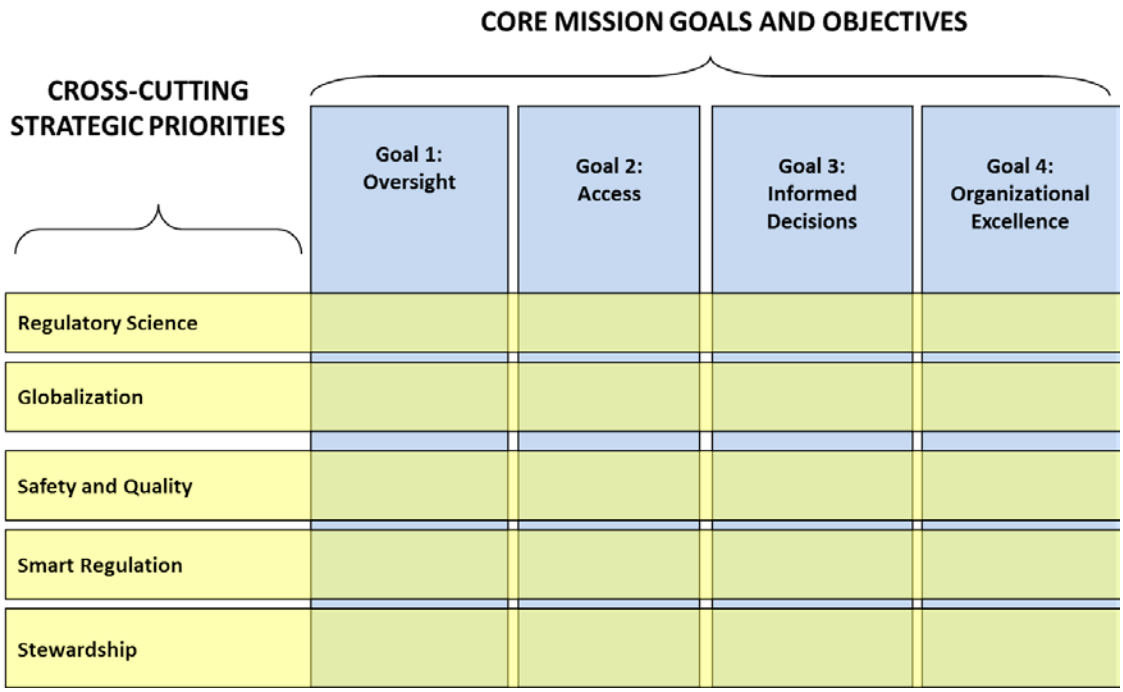
FDA Core Mission Goals and Objectives

The cross-cutting strategic priorities discussed above outline FDA's strategic vision in five key areas that depict how FDA is addressing the public health challenges we face in the coming years.

The following section focuses on our *core mission goals and objectives*, along with key near-term *strategies* that will move FDA toward that vision. These core mission goals and objectives provide a unifying structure for understanding how FDA's various programs contribute to our mission to protect and promote public health. The goals and objectives are interrelated, and successful achievement of one goal or objective can affect the success of others.

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

Figure 1.



Goal 1: Enhance Oversight of FDA-Regulated Products

FDA's oversight of production, manufacturing, and the global supply chain, and our surveillance of postmarket product use, plays a critical role in ensuring 1) the safety of many FDA-regulated products and 2) compliance with statutory and regulatory requirements for tobacco products and their associated establishments. FDA prevents problems in the supply chain by developing standards and guidance for industry to promote best practices that reduce risk.

FDA protects the safety of patients and consumers through detection and intervention activities, such as inspections of manufacturing or production facilities, active surveillance of adverse events, and monitoring and securing the supply chain, to make sure that unsafe manufacturing conditions are discovered, and unsafe products are removed from the supply chain before they can do harm to the public. If problems evade detection before entering the supply chain, FDA responds as quickly as possible in a targeted manner.

Over the next four years, FDA will pursue four objectives to enhance oversight of FDA-regulated products:

Objective 1.1: Increase the use of regulatory science to inform standards development, analysis, and decision-making

Objective 1.2: Reduce risks in the manufacturing, production, and distribution of FDA-regulated products

Objective 1.3: Strengthen detection and surveillance of problems with FDA-regulated products

Objective 1.4: Improve response to identified and emerging problems with FDA-regulated products

Objective 1.1: Increase the use of regulatory science to inform standards development, analysis, and decision-making

Advancing regulatory science is fundamental to FDA's core mission of protecting and promoting the public health. Rapid advances in research not only provide the opportunity to translate new technologies and basic science discoveries into real-world diagnostics, treatments, and cures – they also have the potential to transform FDA's ability to oversee how FDA-regulated products are produced, manufactured, stored, and transported. Moreover, advances in regulatory science can improve postmarket surveillance to better understand where the products go and who uses them, and to better detect and validate safety and toxicity signals.

Over the next four years, FDA will increase the use of regulatory science to inform standards development, analysis, and decision-making to improve FDA oversight before and after FDA-regulated products enter the marketplace. To this end, FDA will implement the following strategies:

- Evaluate and improve the effectiveness of preventive control standards
- Advance the development of predictive safety models
- Assess and encourage development of new technologies to enable rapid, sensitive, specific, and high throughput testing
- Develop and assess methods to improve safety and toxicity signal detection, refinement, and validation
- Develop improved methods for rapidly detecting, investigating, and stopping foodborne contaminants
- Develop comprehensive regulatory approaches for integrating pre- and post-approval and compliance functions
- Collaborate with the National Institutes of Health (NIH) to support tobacco-related research, including the Population Assessment of Tobacco and Health (PATH) Study and Tobacco Centers of Regulatory Science (TCORS)

Objective 1.2: Reduce risks in the manufacturing, production and distribution of FDA-regulated products

Overseeing the safety of America's food and medical products presents serious challenges. FDA has the mandate and authority to construct a modern food and feed safety system that protects food from farm to table; establishes shared responsibility for food safety among all participants; and strengthens accountability for prevention domestically and internationally.

FDA is building a new food and feed safety system based on preventing food and feed safety problems rather than relying primarily on reacting to problems after they occur. New enforcement authorities are designed to achieve higher rates of compliance with prevention- and risk-based food and feed safety standards. Imported foods will be held to the same standards as domestic foods, and FDA will continue to build an integrated national food and feed safety system in partnership with State and local authorities.

FDA will increase our efforts to prevent problems by focusing on quality and the ability to trace medical products as they are distributed in the United States. FDA will continue to encourage quality focused efforts. For example, FDA is encouraging submission of new drug applications using Quality by Design (QbD) elements – a risk-based approach to pharmaceutical development and manufacturing to help ensure product quality. In addition, the Case for Quality Initiative for medical devices, which includes a voluntary compliance improvement program pilot, aims to reduce the risk of patient harm by helping manufacturers identify and deploy quality-related design and production practices.

FDA is committed to regulating the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use, especially among youth. FDA will continue requiring tobacco product manufacturers to register with FDA as well as report ingredients and harmful and potentially harmful constituents. Furthermore, FDA will continue to establish limits on sale and distribution of tobacco products.

Over the next four years, FDA will implement the following strategies to reduce risks in the manufacture, production, and distribution of FDA-regulated products:

- Adopt science-based regulations that protect the food and feed supplies from contamination
- Increase the number of FDA-regulated products and entities covered by science-based standards, policies, and practices
- Increase government and industry knowledge and understanding of FDA science-based practices and new approaches to safety and quality
- Increase access, sharing, and use of global data from foreign, Federal, State, local and private sources to aid in assessment of risks related to FDA-regulated products
- Reduce availability of substandard and illegally marketed FDA-regulated products

- Foster the judicious use of medically important antibiotics in food- producing animals to minimize the development of antimicrobial resistance
- Promote manufacturing strategies that improve manufacturers' ability to maintain a consistent product
- Improve stakeholders understanding of regulatory requirements and provide direction through new guidance, rules, and standards
- Increase the integration of cutting edge scientific technologies and methods into regulatory oversight and guidance to industry

Objective 1.3: Strengthen detection and surveillance of problems with FDA-regulated products

Global production of FDA-regulated products has quadrupled over the last decade and continues to grow. Historically, FDA's primary tools for protecting public health have been inspections at production facilities and ports of entry. Over time, FDA has developed additional methods for protecting the public, including laboratory sample analyses for select product categories (e.g., foods) and product safety reporting systems.

FDA will continue to detect problems with FDA-regulated products and to enhance surveillance activities. FSMA, FDASIA, and TCA, for example, include provisions that permit FDA to further leverage our resources and allow for new approaches to inspections and compliance that will expand available tools and enable FDA to better target limited resources in a risk-based manner.

FDA is working closely with domestic and international partners to increase information-sharing and enhance collaborations on compliance and training efforts to expand the collective safety net. In addition, DQSA gave FDA new tools to detect problems with certain prescription goods and track-and-trace products through the supply chain. With the staged implementation of Unique Device Identifiers over the next seven years, the information base concerning how marketed devices perform will be stronger than ever, enabling swifter, more targeted actions to ensure continued safety and effectiveness of devices.

Postmarket surveillance of FDA's regulated products is a major part of our mission to protect public health. FDA will continue to expand our efforts to move from passive to active surveillance systems. For example, the Sentinel Initiative is a proactive system that complements existing systems that FDA has in place to track reports of adverse events linked to the use of our regulated products. The system enables FDA to actively query diverse automated health care data holders—like electronic health record systems, administrative and insurance claims databases, and registries—to evaluate possible medical product safety issues quickly and securely, while maintaining the privacy of patients. In addition, the National Medical Device Postmarket Surveillance Plan aims to strengthen the medical device postmarket surveillance system in the United States.

Over the next four years, FDA will continue to implement new authorities and capitalize on advances in regulatory science to strengthen our ability to detect problems with FDA-regulated products as well as bolster our postmarket surveillance capacities, by focusing on the following strategies:

- Foster mutually beneficial partnerships for capacity-building, collaboration, and sustainability in laboratory testing
- Monitor Internet sales and promotion of FDA regulated products
- Foster inter-Agency collaboration and sustainability in surveillance of foodborne bacteria on farms and in foods

- Advance surveillance systems for adverse events
- Collaborate with regulatory counterparts to leverage resources and avoid duplication of inspections as well as build a model for mutual reliance by sharing inspection reports.
- Conduct compliance check inspections of tobacco product retailers
- Increase the use of FDA's Sentinel active surveillance system to evaluate medical product safety issues that may require regulatory action
- Improve collaboration with States, localities and other partners to ensure an effective public health safety net.
- Improve risk-based approaches to conducting inspections that maximize public health benefit by ensuring high rates of compliance
- Increase environmental sampling and targeted surveillance to identify violative products

Objective 1.4: Improve response to identified and emerging problems with FDA-regulated products

As an agency that plays a critical, multi-dimensional role in protecting our nation's health and security, FDA is advancing our response and emergency preparedness capabilities. Maintaining and improving FDA's capabilities to respond to public health emergencies is critical to protecting the public health. Whether a foodborne illness outbreak, emerging infectious disease outbreak, contaminated drug or biologic product, faulty medical device, harmful pet food, natural disaster, or an attack with a chemical, biological, radiological or nuclear (CBRN) agent, FDA will continue to be prepared to provide a coordinated response in collaboration with domestic and international partners.

Early detection of illnesses associated with food, tracing the source of the outbreak, and removing the contaminated product from the market, are critical to containing potential risks to the public. FDA will use new enforcement tools that Congress has provided to facilitate faster responses to protect public health. These tools include the ability to:

- Conduct mandatory recalls of unsafe food and feed products
- Prohibit food facilities from distributing food that is likely to cause serious adverse health consequences or death, and
- Suspend the facility's registration.

Congress also empowered us to respond efficiently to problems with medical products by allowing FDA to detain products that are believed to be unsafe and, in certain circumstances, to destroy unsafe or counterfeit products. FDA has used new authorities from FDASIA to take steps to prevent hundreds of shortages of critically needed drugs.

Medical countermeasures (MCMs) are essential for saving lives and maintaining public confidence in our government in the aftermath of a public health emergency involving CBRN threats or naturally occurring emerging infectious diseases. FDA will sustain our comprehensive program to facilitate the development and availability of MCMs. [3]

To build on these efforts, FDA intends to focus on the following strategies over the next four years:

- Improve collaboration and information-sharing among FDA and domestic and international partners on response efforts
- Improve response to foodborne outbreaks with rapid tracing of contaminated foods
- Enhance FDA's ability to prevent and respond to drug shortages

[3] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/default.htm

- Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases
- Enhance the effectiveness of FDA Emergency Response system through increased training and coordination of emergency response coordinators in cooperation/conjunction with other regulatory partners

Goal 2: Improve and Safeguard Access to FDA-Regulated Products to Benefit Health

FDA is responsible for regulating a diverse range of products, from new innovative medical products to nicotine replacement therapies. Thus, the standards that are used to determine whether they are suitable to be marketed to the public are also diverse. FDA pre-market responsibilities include making advancements in regulatory science needed to better evaluate new products, collaborating with our colleagues in private, public, and academic settings to facilitate product development, and ensuring that our product review process is as effective and efficient as possible.

Different FDA programs have varying types and degrees of contributions to this goal and the supporting objectives. FDA's foods program has a fairly limited role in improving access to products, whereas FDA's medical product programs have a major role. In the specific case of tobacco products, it is important to interpret this goal area and the supporting objectives in a narrower and appropriate sense. FDA's authority to regulate tobacco products includes pre-market review of new tobacco products to determine if they are substantially equivalent to existing products, or whether they represent a more distinct type of product that presents a different standard for marketing review. To be clear, currently regulated tobacco products do not benefit health. FDA's responsibility is not to improve access to tobacco products, but to safeguard that access by responsibly controlling it in accordance with FDA's authorities.

Over the next four years, FDA will pursue three objectives to improve and safeguard access to FDA-regulated products that benefit health:

Objective 2.1: Increase regulatory science capacity to effectively evaluate products

Objective 2.2: Improve the effectiveness of the product development process

Objective 2.3: Improve predictability, consistency, transparency, and efficiency of the review process

Objective 2.1: Increase regulatory science capacity to effectively evaluate products

A core responsibility of FDA is to protect patients and consumers by applying the best available science to our regulatory activities and promoting innovation that addresses unmet medical and public health needs. Rapid advances in innovative science are bringing fundamental changes to the way FDA-regulated products are developed, evaluated, manufactured, and used. Evolving areas of science, like cell and gene therapy and nanotechnology, are promising novel opportunities for improving our health while demanding new ways to evaluate the safety and effectiveness of these products. FDA must make decisions based on the best available scientific data and use the best tools, methods, and approaches to assess the safety, efficacy, quality, public health impact, and performance of FDA-regulated products, while fostering and advancing innovation.

FDA must keep pace with and use these new scientific advances to protect and promote the nation's health. FDA has made considerable investments in regulatory science to help translate new technologies and basic science tools into real-world diagnostics, treatments, and cures. To further advance these efforts, FDA will use our knowledge base, laboratories, scientific computing capabilities, and expertise, while leveraging resources and collaborating with domestic and international partners in government, academia, and the private sector.

To ensure that the United States remains a leader in innovation, FDA will continue to increase regulatory science capacity and effectively evaluate FDA-regulated products. Over the next four years, FDA will focus on implementing the following strategies:

- Increase collaboration, training, and information-sharing with the scientific community, industry, and other regulatory bodies
- Advance product development tools that can help lead to life-improving and life-saving medicines, and reduce the time, complexity, and cost of medical product development
- Strengthen an infrastructure that supports high-quality, state-of-the-art scientific investigations
- Modernize the bioinformatics infrastructure to apply the most recent data to the areas such as systems biology, food and feed safety, genomics, pharmacogenomics, predictive toxicology, neurological function, and translational bio-imaging
- Support public–private partnerships to advance regulatory science, including the Medical Device Innovation Consortium (MDIC)
- Improve the efficiency and validity of toxicity evaluations for dietary supplements, food ingredients, and food additives

Objective 2.2: Improve the effectiveness of the product development process

Although FDA has made tremendous strides in recent years in the review of new drugs, and now leads the world in both timeliness and quantity of significant new drugs approved for marketing, in the past decade, the overall development of some products crucial to public health, such as antibiotics, has slowed significantly. Some stakeholders suggest that current costs of bringing a new medical product to market are a major barrier to investment, including those for uncommon diseases, unmet needs, and special populations. Inventors of candidate artificial organs, bioengineered tissues, and other novel products face serious challenges. If biomedical science is to deliver on its promise, scientific creativity and effort must also focus on improving the medical product development process itself, with the explicit goal of robust development pathways that are efficient and predictable and result in products that are safe, effective, and available to patients. Although FDA's primary responsibility is to review the safety and effectiveness of new medical products developed by industry, the Agency is also committed to assisting product developers in translating discoveries in basic science into new therapies that will save lives and improve health care.

New scientific discoveries—in fields like genomics, imaging, and informatics (e.g., bioinformatics, the analysis of biological information using computers and statistical techniques) —can be applied during development to improve the accuracy of tests that predict the safety and efficacy of potential medical products. FDA is leveraging the knowledge gained from these emerging scientific fields to enhance the tools FDA uses to evaluate drugs, biologics, and medical devices.

FDA will continue pursuing initiatives focused on product development, such as the Drug Development Tools Qualification Program, which was established to bring FDA scientists together with external scientists and clinicians to develop and standardize biomarkers. In addition, FDASIA established a breakthrough pathway for drug products that holds real promise to offer substantial improvements over available therapies to treat serious conditions. Sponsors of products that are designated as breakthrough products can take advantage of all the features of fast track designation, and receive more intensive guidance from FDA to help them design an efficient drug development program, beginning as early as phase one clinical trials.

Over the next four years, FDA will focus on ways to improve the effectiveness of the product development process by implementing the following strategies:

- Improve the evaluation of methods, tools, models (e.g., animal, physiological, computer-based) that are used in the development and testing of medical products
- Advance the development of medical products for rare diseases
- Enhance communication between FDA and sponsors during the medical product development process

- Facilitate the application of advanced technologies and methods and relevant scientific discoveries—such as newly identified clinical biomarkers, adaptive clinical trial designs and genomics—to regulated medical products
- Improve tools and approaches needed to catalyze the development of personalized medicine

Objective 2.3: Improve the predictability, consistency, transparency, and efficiency of the review process

A major component of fostering innovation and improving access to FDA-regulated products that benefit the public health will involve improving the predictability, consistency, transparency, and efficiency of the review process. FDA recognizes that in the current economic climate, given the limited availability of investment capital for medical product development, early clarification of regulatory requirements is critical.

The timely review of the safety and effectiveness of new human and animal drugs, biologics, and medical devices is central to FDA's mission to protect and promote the public health. The user fee programs for these medical products provide resources that enable FDA to hire additional reviewers and support staff and upgrade our information technology systems. In return for additional resources, FDA has agreed to certain review performance goals and taking regulatory actions in predictable timeframes. These changes have greatly improved the approval process and enabled FDA to speed the application review processes without compromising the Agency's high standards for ensuring the safety, efficacy, and quality of new medical products before approval.

FDA further recognizes that increasing communication between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process. Multiple review cycles are sometimes encountered for applications that contain outstanding deficiencies or require additional discussions between FDA and the applicant. This represents an inefficient use of resources if resolution of these issues could have been achieved before the first cycle goal date. FDA is working to make the review process more transparent and increase productive communication with sponsors. The Prescription Drug User Fee Amendments of 2012 (PDUFA V) allows for a new review model for New Molecular Entity New Drug Applications (NME NDAs) and original Biologic License Application (BLAs) that provides opportunities for increased interaction during the regulatory review. The Medical Device User Fee Amendments of 2012 (MDUFA III) includes a commitment to develop a new Good Review Management Practices guidance document for devices. Additionally, ADUFA III discontinues end-review amendment procedures and replaces them with a process for shorter review times for reactivations and resubmissions.

FDA is committed to achieving the long-term goal of improving the exchange, review, and management of information associated with human and animal drug and biologic applications throughout the product life cycle through strategic investments in automated, standards-based IT.

Over the next four years, FDA will improve predictability, consistency, transparency, and efficiency of the review process by implementing the following strategies:

- Improve review efficiency through electronic submission of drug application data
- Implement an electronic Managed Review Process (eMRP) to promote efficient review of products

- Improve review efficiency through data standardization and data integrity requirements
- Increase consideration of health disparities and health outcomes in regulatory decision-making
- Develop proactive communication processes with industry and the public, including consumers of limited English proficiency, on the premarket review process and status of submissions.
- Continue to improve the substantial equivalence review process for tobacco products, including reducing backlog and time to completion

Goal 3: Promote Better Informed Decisions About the use of FDA-Regulated Products

FDA recognizes the invaluable role we play in providing the American public with timely, accurate, and useful information about FDA-regulated products. As consumers, patients, health professionals, and purchasers gain access to relevant information about foods, medical products, and tobacco products, they are better able to make informed decisions about whether or how to use these products. For this reason, FDA believes that clear communication about our regulatory and scientific decisions, policies, and standards, as well as the products we regulate is vital. FDA will continue to work in collaboration with partners inside and outside of the Federal government to determine innovative and effective ways to provide better information to the public and to develop outreach and other tools that can assist in better decision-making.

Over the next four years, FDA will pursue three objectives to promote better informed decisions about the use of FDA-regulated products:

Objective 3.1: Strengthen social and behavioral science to help patients, consumers and professionals make informed decisions about regulated products

Objective 3.2: Improve patient and provider access to benefit–risk information about FDA-regulated products

Objective 3.3: Improve safety and health information provided to the public

Objective 3.1: Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products

FDA supports informed decision-making with a foundation of rigorous science, thoughtfully applied, to communication about and review of our regulated products. FDA social scientists, economists, and behavioral scientists build that scientific foundation to inform decision-making about communications and other related effects of FDA actions. Social sciences can support FDA's decision-making and that of our stakeholders, including health care professionals, patients, consumers, and regulated industry.

FDA social and behavioral scientists develop experiments, surveys, and focus group inquiries to learn how target audiences respond to FDA and industry communications, and how prospective users approach the use of regulated products. FDA scientists also seek to learn what our stakeholders consider important factors for balancing benefit and risk in particular situations. FDA scientists need to be exacting in study design and analysis, and at the same time innovative in using flexible methods of information-gathering.

Over the next four years, FDA will continue to strengthen social and behavioral science by implementing the following strategies:

- Implement major communications programs based on formative research[4], including an evaluation plan
- Explore and test interdisciplinary approaches of integrating qualitative and quantitative social science data with traditional and social media analysis and pharmacoepidemiological data to assess communication effectiveness in the use of regulated products
- Analyze the intersection of economic and behavioral effects of health and safety information about regulated products
- Increase our understanding of patients and health care provider perspectives on benefits and risks, including exploring how characteristics of individuals and different medical conditions affect risk tolerance
- Deepen our understanding of how health care providers regard various types of regulated products, such as biosimilar biologic products
- Support and encourage research to validate health benefits resulting from consumer dietary changes

[4] Formative research is the basis for developing effective strategies, including communication channels, for influencing behavior change. It helps researchers identify and understand the characteristics —interests, behaviors and needs— of target populations that influence their decisions and actions.

Objective 3.2: Improve patient and provider access to benefit–risk information about FDA-regulated products

Today, tens of millions of people in the United States depend on FDA-regulated medical products to sustain their health—as many as 3 billion prescriptions are written annually. Too many people, however, suffer unnecessary injuries, and some die as a result of preventable errors. FDA believes that many of these risks are manageable if parties committed to the safe use of FDA-regulated medical products work together.

For example, the Safe Use Initiative was created to facilitate public and private collaborations within the health care community. The goal is to reduce preventable harm by identifying specific, preventable medication risks and by developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. FDA will continue to pursue initiatives aimed at protecting public health through effective communication.

Similar efforts are underway to enhance FDA's risk communication for drugs, biologics, and devices. FDA recognizes that it is imperative that health professionals and patients have access to the right kind and amount of data and information necessary to make decisions about how to prevent, mitigate, or treat their medical conditions. FDA will continue to explore potential analytical and communication approaches to develop and incorporate uncertainty in the assessment of benefits and risks.

Over the next four years, FDA will improve access to benefit-risk information by implementing the following strategies:

- Enhance communication of FDA's benefit-risk assessment for approved products
- Enhance patient access to prescription medication benefit and risk information
- Use and monitor social media, e-mail, and web sites to disseminate FDA risk communication alerts and safety information to stakeholders
- Ensure public and stakeholder awareness of medical product quality and integrity issues through effective consumer communications and through news media
- Disseminate FDA product information through partnerships with stakeholders and outreach at national meetings and conferences
- Standardize and better integrate Risk Evaluation Mitigation Strategy (REMS) into the health care system
- Improve tools used for prescriber-to-patient counseling

Objective 3.3: Improve safety and health information provided to the public

FDA is committed to promote healthful dietary practices through truthful and informative labeling for human and animal foods. American consumers can use this information to make healthier choices about the food they and their pets eat and help reduce the risk of chronic disease and facilitate optimal health. For example, FDA is making concerted efforts to provide the public with readily available nutrition information, with efforts that include updates to the Nutrition Facts label and restaurant and vending machine calorie labeling.

FDA also has a responsibility to provide the American public with factual and accurate information about tobacco products. This new oversight role for tobacco products allows FDA to provide the public with much-anticipated information on the harmful and potentially harmful constituents in tobacco and tobacco smoke in a way that is understandable and not misleading to the public.

FDA will continue to develop a strategy to address the safety and health information needs and concerns of both internal and external audiences. FDA will monitor and evaluate current platforms to collect and share safety information, such as MedWatch, and determine how to provide timely, clear, and concise information to the right audiences.

Over the next four years, FDA will improve safety and health information by implementing the following strategies:

- Improve consumer access to and use of accurate nutrition information
- Implement sustained public education campaigns on the harms of tobacco products
- Expand use of social media, the FDA web site and FDA's Consumer Updates to communicate safety and health information
- Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity
- Ensure patient and health professional awareness of medical products risks and parameters for safe use
- Conduct effective risk communications related to outbreaks and contamination incidents
- Improve safety and health information for consumers with limited English proficiency

Goal 4: Strengthen Organizational Excellence and Accountability

FDA's vast oversight responsibilities include protecting a majority of our nation's food supply, all medical products, cosmetics, radiation-emitting products, and now, tobacco products. With new authorities granted through FSMA and FDASIA, FDA must meet our public health responsibilities while operating with limited resources.

FDA recognizes the importance of being a good steward of resources – both taxpayer dollars and user fees from industry – to achieve our mission. As our responsibilities increase and resources remain limited, it is even more vital for FDA to maintain organizational excellence and accountability to the American public. FDA continues development of the workforce, systems, and infrastructure needed to address the emerging, complex challenges brought by the current operating environment.

FDA will target our use of recruitment and retention flexibilities to our mission-critical occupations to encourage use that is consistent and appropriate to recruit and retain the nation's top talent. The Agency aims to ensure we remain an employer of choice. FDA will work in partnership with innovative organizations and leaders in the public and private sector to develop and implement large-scale improvements to our systems and infrastructure.

FDA affirms our commitment to create a positive work environment; evolve management systems that are robust and secure; and invest in the infrastructure needed to enhance our public health mission.

Over the next four years, FDA will pursue three objectives to strengthen organizational excellence and accountability:

Objective 4.1: Recruit, develop, retain, and strategically manage a world-class workforce

Objective 4.2: Improve the overall operation and effectiveness of FDA

Objective 4.3: Invest in infrastructure to enhance productivity and capabilities

Objective 4.1: Recruit, develop, retain, and strategically manage a world-class workforce

A key component of FDA's ability to respond to the emerging challenges presented by today's complex, globalized regulatory environment is our ability to attract and retain a talented and diverse workforce. FDA uses a fully integrated, Agency-wide human capital management program to aggressively recruit, hire, develop, and retain skilled, high-performing employees so that FDA possesses the capabilities and capacities required to meet the breadth and depth of our legislative requirements. This management program includes leadership development, career management, performance management, and succession planning to harness employees' insights and experiences to help develop high-impact solutions to important public health and regulatory challenges.

Over the next four years, FDA will continue to make progress by implementing the following strategies:

- Hire and retain highly qualified scientific, medical, analytical, legal and management talent
- Track development and advancement of science and research expertise in the internal workforce through succession planning and executive development plans
- Develop mechanisms to promote cross-disciplinary, regulatory-science training and research to address gaps and challenges posed by novel products
- Foster a culture of participation, collaboration, and excellence
- Promote equality, fairness, understanding, and acceptance of diversity at FDA
- Improve opportunities for continuous learning, career development, and work–life balance throughout the FDA workforce

Objective 4.2: Improve the overall operation and effectiveness of FDA

FDA must take a horizontal and cross-cutting approach to management to improve our overall operational effectiveness and efficiency. FDA will maintain a culture of continual business process improvement to identify opportunities to streamline and add value. These improvements will be supported by collaboration and knowledge management tools and will encourage input from FDA programs, stakeholder, and advisory groups, such as the FDA Science Board, to help define and meet FDA's 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 mission-critical business processes.

Over the next four years, FDA will continue to make progress by implementing the following strategies:

- Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision-making
- Improve management and program effectiveness and make optimal use of FDA program resources
- Continue the development and implementation of quality approaches for review activities and other key center operations
- Develop and implement an evidence-based resource planning model that connects performance measures and outputs to public health outcomes
- Establish a process and management structure to enhance risk-based decision-making
- Provide information technology tools to enable collaboration
- Implement robust compliance, internal control, and risk management strategies, including compliance with ethical standards and avoidance of employee conflicts of interest
- Implement enhanced modernized management systems
- Define and implement distinct commodity-based (e.g., drugs, medical devices, foods) and vertically-integrated regulatory programs with well-defined leads, coherent policy, and strategy development, and a delayered management structure

Objective 4.3: Invest in infrastructure to enhance productivity and capabilities

FDA continues to prioritize crucial investments in both IT and real estate infrastructure to better support our goals and mission. FDA is finalizing our work on an ambitious IT infrastructure modernization program to lay the foundation for modern, networked computing and shared data resources. This migration will enhance FDA's technical ability and provide high performance programs and data storage designed to allow for greater collaboration with stakeholders across government and globally while protecting systems from internal and external security and privacy threats. FDA is also near completion of facilities and laboratory improvements and alterations that are necessary to support our strategic priorities.

Over the next four years, FDA will continue to make progress by implementing the following strategies:

- Provide facilities, in particular modern laboratory space, that meet the demands of FDA's scientific mission
- Implement an IT modernization program to provide state-of-the-art integrated information and shared data resources
- Develop or improve on methods to share data and informatics approaches within and outside of FDA
- Improve environmental and energy performance to promote sustainability
- Work toward more efficient and cost-effective procurement to improve economic performance
- Foster a secure, safe, and healthy work environment for FDA employees
- Secure mission-critical and sensitive assets and information

Appendix A: Crosswalk between FDA's Strategic Goals and Objectives and HHS's Goals and Objectives

HHS Strategic Goals and Objectives	FDA Strategic Goals and Objectives												
	1.1	**1.2**	**1.3**	**1.4**	**2.1**	**2.2**	**2.3**	**3.1**	**3.2**	**3.3**	**4.1**	**4.2**	**4.3**
1: Transform Health Care													
1B: Improve health care quality and patient safety		X	X						X	X			
1E: Ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations						X			X				
1F: Improve health care and population health through the meaningful use of health information technology			X										
2: Advance scientific knowledge and innovation													
2B: Foster and apply innovative solutions to health, public health, and human service challenges	X	X			X	X		X					
2C: Advance the regulatory sciences to enhance food safety, improve product development, and support tobacco regulation	X	X	X		X	X	X	X	X	X			
2E: Improve laboratory, surveillance, and epidemiological capacity			X	X									
3: Advance the health, safety, and well-being of the American people													
3D: Promote prevention and wellness across the lifespan	X	X	X							X			
3E: Reduce the occurrence of infectious diseases	X	X	X	X						X			
3F: Protect American's health and safety during emergencies, and foster resilience to withstand and respond to emergencies				X	X	X	X						

HHS Strategic Goals and Objectives	FDA Strategic Goals and Objectives												
	1.1	**1.2**	**1.3**	**1.4**	**2.1**	**2.2**	**2.3**	**3.1**	**3.2**	**3.3**	**4.1**	**4.2**	**4.3**
4: Ensure efficiency, transparency, accountability, and effectiveness of HHS programs													
4A: Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance and risk management												X	X
4B: Enhance access to and use of data to improve HHS programs and support improvements in the health and well-being of Americans												X	X
4C: Invest in the HHS workforce to help meet America's health and human service needs											X		
4D: Improve HHS environmental, energy, and economic performance to promote sustainability												X	X

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Appendix B: Food and Drug Administration Organizational Chart