STATEMENT

BY

LESTER M. CRAWFORD, DVM, Ph.D.

COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION,

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR THE

THE HOUSE AGRICULTURE, RURAL DEVELOPMENT,

AND RELATED AGENCIES APPROPRIATIONS

SUBCOMMITTEE

Introduction

Mr. Chairman, members of the Committee, I am honored to testify on FDA's FY 2006 President's budget request. Let me begin by conveying my appreciation to the Subcommittee members for providing the Food and Drug Administration (FDA) with several key increases in the FY 2005 appropriation and in H,R, 2744, which passed the House in June. In FY 2005, we received increases for food defense, medical device review, Bovine Spongiform Encephalopathy, medical countermeasures, and the FDA consolidation project at White Oak. In your FY 2006 bill, we received important increases, including $5 million for our Drug Safety, $5.9 for Medical Device Review, $4.1 million for White Oak, $4.1 million for GSA Rent, $5.0 million for Buildings and Facilities, and also the user fee increases that we requested.

These increases will allow FDA to continue to meet an expanding range of challenging public health issues. I can assure you that FDA will continue to spend these resources wisely. I believe that the American people would be impressed if they really knew how much return on investment they get from FDA.

I am fully aware of the difficult funding decisions you face in the current session, and I believe that every dollar invested in FDA's programs can have a positive public health impact – from the consumer, to the farmer, to the drug and medical device manufacturer and beyond. FDA plays a lead role in protecting and advancing the public health of the United States.

Our mission is to ensure that U.S. consumers continue to enjoy the safest food, and the most effective medical supplies in the world, and that we continue to foster medical product innovation. We have a strong track record of accomplishment. Near the beginning of FY 2004, we unveiled a comprehensive strategic action plan to "protect and advance America's health" in the 21st century. Our plan outlined a series of specific steps to combat the increasingly complex public health challenges we face as a nation -- and to capitalize on the myriad of health innovations occurring each day -- in order to help U.S. consumers live longer, healthier, and happier lives.

FDA's 2006 President's Budget Request

Our FY 2006 Budget request maximizes the performance of our on-board assets -- the greatest of which is our scientific staff -- and focuses additional requests on the areas of highest risk and highest yield. Overall, our FY 2006 request is for $1.50 billion in budget authority, a $50 million increase above FY 2005. Total funding, including user fees, is $1.881 billion, $81 million above FY 2005. Key budget authority increases include: $30.074 million for Food Defense, $5.996 million for Medical Device Review, $5.0 million for the Office of Drug Safety ($6.5 million including user fees), $4.1 for rental costs, and $7.0 million for Buildings and Facilities. The proposed budget allows FDA to continue to work towards meeting statutory regulatory responsibilities while initiating new efforts to address challenges that fall within our mission. Now I'd like to tell you more about these proposed increase requests.

Food Defense

In the post 9-11 environment, FDA has made fundamental changes in how we implement our mission of protecting the food supply. We are doing this so that all U.S. consumers can have confidence that their food is not only safe, but also secure. We are requesting a $30 million increase for food defense, to build upon gains achieved with food defense funds appropriated in FY 2005. Funds requested directly support Homeland Security Presidential Directive-9, which established the national policy to protect the Nation's food and agriculture system from terrorist attacks. FDA and the USDA, in conjunction with the White House Homeland Security Council, have continued to coordinate efforts to protect the agricultural and food sectors.

FDA is responsible for ensuring the safety of approximately 80 percent of the nation's food supply. The possibility of food products being used as a vehicle for attack is a major concern. The direct effects on public health, adverse impacts on public confidence in the U.S. food supply, and economic impacts on the food industry are all potentially devastating. Over the past year, we have implemented major enhancements to our food safety and security program.

Shortly after 9/11, FDA focused its Food Security resources on traditional tools to bolster the security of the Nation's food supply. Since then, FDA has conducted classified assessments of strengths and vulnerabilities in the U.S. food system, and has structured its Food Defense plans accordingly. This risk-based strategy deals with the risks of contamination of both imports and domestically produced and processed foods. FDA has also instituted new systems that give advance notice of upcoming food imports, improving FDA's ability to target inspections.

Implementing FDA's strategy is an Administration priority, and we have requested an increase of $30 million for this activity. Within the $30 million increase, $20 million will support a national network known as the Food Emergency Response Network (FERN). FERN will increase our analytic surge capacity in the event of terrorist attack by developing adequate laboratory testing capacity for biological, chemical and radiological threats and targeted food defense research efforts. This will enable us to test thousands of food samples within a matter of days in the event of an act of terror or other emergency, and quickly determine what food is safe, and what food is contaminated. We will complement this network with a strong research program to develop effective protection strategies to shield the food supply from terrorist threats. FDA seeks to detect contaminants more quickly and, where possible, modify food processing in ways that would neutralize pathogens before they caused harm. The FY 2006 budget contains an additional $5.6 million for targeted food defense research on prevention technologies, methods development, determination of infectious dose for certain agents when ingested with food, and agent characteristics within specified foods. The budget request proposes a $3.0 million increase to improve coordination and continue integrating our food defense capabilities with the Department of Homeland Security's, as part of the government-wide Bio-Surveillance Initiative. Finally, we have asked for $1.5 million to upgrade our crisis management capabilities so that we are prepared to minimize the impacts of potential problems with the food supply.

Medical Device Review

To provide more timely and cost-effective review of new medical devices, we have worked to implement the 2002 Medical Device User Fee and Modernization Act (MDUFMA), which allows us to collect user fees from companies that submit medical device applications. In

FY 2006, we are requesting an increase of $5.996 million to continue to meet the FY 2006 performance and funding expectations in MDUFMA. In May 2005, the Department of Labor released the April Consumer Price Index for All Urban Consumers (CPI-U), and this index was higher than the estimate used to determine the trigger level specified in MDUFMA. This MDUFMA trigger establishes the minimum funding level for FDA's Devices and Radiological Health Program activities in order for FDA to continue to collect and expend device user fees. As a result of the CPI-U released in May, the new calculation for the FY 2006 Device and Radiological Health Program activites is $1.831 million higher than the $5.996 million request. In FY 2006, we will use appropriated amounts and $40.3 million in medical device user fees to conduct device review, which is an increase of $6.362 million over FY 2005.

These additional funds will be used to hire more staff and to develop better systems to support more effective and timely review. The law requires us to pursue a complex and comprehensive set of review goals. Each year brings additional goals, and the goals become more aggressive. We must report on performance relative to the specified goals at the end of each year.

We have also committed to two ambitious long-term goals for reducing average total approval time for medical device premarket applications, and have already achieved one of these goals, even though it was targeted for fiscal years 2005-2007. It is for a 30-day reduction in average approval time for premarket applications given expedited approval, which is similar to priority approval for drugs and biologics. We have already achieved that goal -- a 33-day reduction in average approval time compared with the baseline of fiscal years 1999-2001.

Office of Drug Safety

FDA approves medical products after a sponsor demonstrates that they are safe and effective. However, the full magnitude of potential risks does not always emerge during the clinical trials that are conducted to evaluate safety and effectiveness. Monitoring the safety of marketed products requires close collaboration between our clinical reviewers and safety staff to evaluate and respond to adverse events identified in ongoing clinical trials or reported to us by physicians and their patients.

Ensuring drug product safety is a mission-critical function of FDA's Center for Drug Evaluation and Research (CDER), and is an important component of both the premarket and postmarket review process. FDA is requesting a $6.5 million increase to strengthen the drug safety functions within CDER's Office of Drug Safety (ODS), of which $5.0 million is in budget authority and $1.5 million increase is in PDUFA user fees. One of ODS' primary roles is to provide expertise in the review of postmarketing safety data and to maintain and coordinate CDER's postmarketing surveillance and risk assessment program. ODS plays a significant role in the CDER drug safety mission. However, their role is only a small subset of the total effort expended and resources spent by CDER on drug safety.

This increase will allow us to hire additional staff to manage and lead safety reviews, provide further expertise in critical areas such as risk management, risk communication and epidemiology, and allow increased access to a wide range of clinical, pharmaceutical and administrative databases. It will also help increase transparency by sharing drug safety

information sooner and more broadly and strengthening FDA's post-market surveillance capacity, using a network of information sources to analyze postmarket drug safety information. The requested increase will also support patient safety initiatives and extend partnerships with the Centers for Medicare and Medicaid Services, the Agency for Health Research Quality and other HHS agencies.

White Oak Move

FDA is continuing the White Oak Consolidation project, which upon completion will house over 7,700 staff in 2.3 million square feet of space. By the end of FY 2005, the campus will have almost 700,000 square feet completed with 1,850 staff on site. The new buildings will eventually replace all 40 of the existing fragmented facilities in 16 locations that support the Office of the Commissioner and all of our Centers and the Field headquarters except the Center for Food Safety and Applied Nutrition and the National Center for Toxicological Research. This project will allow FDA to standardize and modernize document handling, provide shared use facilities such as libraries and conference areas, further reduce redundancies in administrative tasks and allow conversion to a single computer network. In FY 2005, over 1,700 review staff are moving to White Oak, so a significant portion of costs are being financed by PDUFA fees. FY 2006 costs need to be financed through budget authority. As a result, FDA requests an increase of $4.128 million in additional budget authority, to provide the needed infrastructure and to move the staff to the CDRH Engineering/ Physics Laboratory and a portion of FDA's shared use data center facilities.

Rent Costs

In prior years, FDA's rent costs were budgeted separately from the programs that used the space. To facilitate management improvement, FDA's FY 2006 budget proposes to move funding for rent to the program lines. This will place accountability for rental and other associated costs within the operating programs, and eliminate the need to transfer funds between budget lines when program space needs change. The FDA program lines include increases of $6.0 million to cover projected increases in rent charges; of this, $4.1 million is requested in budget authority and $1.9 million in user fees.

Buildings and Facilities

In FY 2005, FDA did not request funding to repair and maintain our building and facilities in order to fund other priority initiatives, but we are now challenged to continue to sustain these buildings, some of which are over 50 years old, in poor condition, and have severely deferred maintenance. The requested $7 million increase for buildings and facilities will help cover the cost of greatly needed repairs and improvements to existing owned or leased facilities that FDA occupies in 49 states and in the District of Columbia and Puerto Rico.

Management Efficiencies

FDA is continually working to create a stronger, more unified Agency. The increasing complexity of our regulatory mission requires that we look for new ways to create efficiency, standardize processes, enhance infrastructure and improve planning. FDA has made significant improvements to its business practices that support the agency's mission-critical activities

through the implementation of the President's Management Agenda. In FY 2006, proposed management savings will result in a $1.554 million reduction in administrative costs. In the area of Information Technology (IT), we are developing a roadmap to better align key technologies to our policy goals and objectives, which will better integrate enterprise architecture, capital planning and investment management, and project management into a more comprehensive investment review and governance process. We are consolidating IT functions across the Agency, which allows us to realize our goals and objectives while reducing spending. In FY 2006, we are expecting an IT savings of over $5.1 million.

FDA has redesigned the way we deliver various administrative and information technology services using the shared services model. This model aligns our administrative resources into a customer focused organization, providing more efficient services in a cost effective manner without jeopardizing our mission. This model also allows us to provide services in a way that maintains close ties to customers through negotiated service level agreements that specify the level of service to be delivered and the costs that will be charged to the customer. FDA has also competed and won all six of the commercial activities studied for competitive sourcing in FY 2003 and 2004, generating millions of dollars in efficiencies. FDA is pleased to announce it just won the seventh competition for clerical support services functions, which when implemented will result in a major change in the way we conduct our clerical support service functions.

In the area of financial management, we received our seventh consecutive "unqualified" or clean audit opinion in January 2005 on our financial statements from the Department's Office of

Inspector General. This achievement reflects our ability to produce credible financial statements in a timely manner despite the fact that our existing systems are not fully compliant with today's financial standards. We are pleased to announce that in April 2005 we implemented the new Unified Financial Management System, which will replace our old accounting system. This system used across the Department, will satisfy financial requirements, and provide timely financial information to executives and managers for better decision making. We have also integrated performance information into the traditional budget presentation, providing better linkages between the resource request and its performance goals.

User Fee Increases

We are also requesting an increase of $31.320 million for user fees that support prescription drug review, medical device review, animal drug review, mammography inspections, export certification, and color certification fees. All of these requested fee increases are authorized under current law.

Protecting the Homeland – Counterterrorism

Since September 11, 2001, public awareness of terrorist threats has changed and has underscored the importance of FDA's consumer protection mission. Because our regulatory authority and responsibility cut across critical elements of counterterrorism efforts, we must assess and respond to a broad range of terrorist related health and safety threats. One example of this coordinated effort is the establishment of the Food Emergency Response Network (FERN), which will enable us to test thousands of food samples within a matter of days in the event of an

act of terror or other emergency.

Additionally, I would like to highlight our progress in ensuring the safety of food imports as we continue to direct resources to where they are needed most. Import food field exams, along with laboratory analyses, were FDA's major tools to physically monitor imports prior to the Bioterrorism Act. One of the new approaches under the Act is the implementation of the risk based Prior Notice system as a basis for triaging and prioritizing the examination of imported food shipments that may pose the greatest risk to U.S. consumers. Our FY 2006 food defense request contains priorities (FERN, research, biosurveillance and crisis management) that Congress funded in FY 2005. This will allow us to take advantage of new authorities provided in the Bioterrorism Act to further our use of risk-based monitoring of food imports.

FDA is also focusing its efforts on medical countermeasures to strengthen our preparedness and response capabilities and to help the Agency remain vigilant against potential threats to the public's health and security. FDA regulated products, such as human and animal drugs, vaccines, blood, and other products, will play a crucial role in countering the effects of a terrorist attack. We are working with industry to develop medical countermeasures using state-of-the-art science, and collaborating with other agencies and organizations to identify existing products that may be useful as medical countermeasures.

One example is Prussian Blue, which has been approved as Radiogardase™ for the treatment of contamination with radioactive cesium or non-radioactive thallium, released from a "dirty

bomb." The product has been used since the 1960s as an investigational drug to enhance excretion of cesium and thallium from the body. To encourage manufacturers to submit marketing applications for the approval of this important medical countermeasure, FDA carefully reviewed the available data and literature, determined that the product would be found safe and effective, and published this finding, along with draft labeling. In FY 2004, FDA approved two other drugs, pentetate calcium trisodium injection and pentetate zinc trisodium injection, for treating certain kinds of radiation contamination. And this February, FDA announced the approval of Vaccinia Immune Gobulin Intravenous, the first intravenous human plasma derived product available to treat certain rare complications of the smallpox vaccination. Approval of these countermeasure products was facilitated by FDA guidance documents as part of an ongoing effort to provide the public with the best available protection against nuclear accidents and terrorist threats.

We regularly collaborate with the Centers for Disease Control and Prevention, the Department of Homeland Security, the Department of Defense, and other government agencies to support the availability of essential products in case of a terrorist event. FDA helps to assure the safety and efficacy of the countermeasures held in the Strategic National Stockpile (SNS) that will be used in response to national emergencies. The SNS is a stockpile of critical medical products that includes antibiotics (to treat threats such as anthrax); antitoxins; vaccines (including enough smallpox vaccine for every person in the United States); medical supplies; medications; surgical items; and, other drugs (including treatments for radiation poisoning and chemical agent exposure). The Agency has also conducted vulnerability and needs assessments by reviewing information on available medical countermeasures as well as promising products under

development.

Patient and Consumer Safety and Protection

We continually strive to improve our mechanisms for assuring that patients and consumers are protected from product risks by improving our post-marketing monitoring, analysis, communication and regulatory activities. By partnering with healthcare providers, healthcare institutions and other government agencies, FDA will be able to quickly identify and understand the risks associated with FDA regulated products and effectively communicate concerns and prevention strategies. We also collaborate with foreign government counterparts to share vital information, coordinate enforcement actions, and to leverage our resources, so we can expand FDA's protective functions even more broadly.

FDA grants approval to medical products only after a sponsor demonstrates they are both safe and effective. Unfortunately, all approved products pose some level of risk. Unless a new product's demonstrated benefit outweighs its known risk for an intended population, FDA will not approve the product. However, the full scope of risks does not always emerge during the mandatory clinical trials conducted before approval. Occasionally, serious adverse effects are identified after approval either in post-marketing clinical trials being conducted for unapproved indications, or through spontaneous reporting of adverse events. Such reactions can range from a minor, unpleasant reaction to a product, to an event that is life-threatening or deadly. An adverse reaction may also result from errors in prescribing, dispensing or use. The issue of how to detect and limit adverse reactions is challenging. How to weigh the impact of an adverse reaction against the benefit of a product to a patient and the public health is multifaceted and complex,

involving scientific as well as public policy issues. FDA often relies on input from over thirty advisory committees to provide advice and guidance during and after the review process.

The number of serious adverse drug events reported to the FDA grew more than four-fold between 1992 and 2003. About 45 percent of these adverse events are caused by medication errors that occur in dispensing or administration. These troubling statistics demonstrates why Congress has supported FDA in creating a post-market safety program designed to assess these postmarket adverse events. This complements the pre-market safety reviews required for approval of medical products in the United States.

There is evidence that spontaneous reporting systems alone do not allow for adequate characterization of the true safety profile of a regulated product. We have been working with Federal, State and private organizations to identify useful sources of data using adverse event monitoring systems such as MedSun, which is a post-market reporting system that serves as an advance warning system and provides two-way communications to report adverse events associated medical devices. A primary focus involves identifying particular risks in specific populations such as children, elderly, and patients from particular demographic groups who may be associated with different risks.

Patient safety issues have surfaced for the drug Vioxx (rofecoxib), which illustrates the vital importance of both the ongoing assessment of the safety of an approved product once it is in widespread use and the effective communication of newly discovered risks to patients and medical providers. FDA has taken a number of steps to improve our drug safety system and

thereby better protect the public health. FDA is sponsoring an Institute of Medicine (IOM) study that will make an assessment of FDA's drug safety system and its effectiveness in safeguarding U.S. consumers. This study will focus on the postmarketing phase of FDA's oversight, and assess what additional steps can be taken to improve it. While this IOM process proceeds, FDA will institute a number of steps designed to foster greater independence and transparency in postmarketing safety deliberations.

On February 15, 2005, Health and Human Services Secretary Leavitt and I unveiled a new emboldened vision for FDA that will promote a culture of openness and enhanced oversight within the Agency. As part of this vision, FDA has created a new, independent, Drug Safety Oversight Board to oversee the management of drug safety issues, and will provide emerging information to health providers and patients about the risks and benefits of medicines. The Board will oversee the management of important drug safety issues within CDER. The Board is comprised of medical experts from FDA and other HHS agencies and government departments (e.g., Department of Veterans Affairs), and will consult with other medical experts and representatives of patient and consumer groups. I am pleased to announce that the Drug Safety Oversight Board had its inaugural meeting on June 17th.

FDA will also increase the transparency of our decision-making process by establishing new and expanding existing communication channels to provide targeted drug safety information to the public. These channels will help ensure that established and emerging drug safety data are quickly available in an easily accessible form. The increased openness will enable patients and their healthcare professionals to make better-informed decisions about individual treatment

options. The Agency is also proposing a new "Drug Watch" Web page for emerging data and risk information and increased use of consumer-friendly information written especially for healthcare professionals and patients.

As FDA develops these communications formats, we will solicit public input on how FDA should manage potential concerns associated with disseminating emerging information prior to regulatory action. The Agency will issue draft guidance on procedures and criteria for identifying drugs and information for the Drug Watch page. In addition, we will actively seek feedback from healthcare professionals and patients on how best to make this information available to them.

As one effort to help prevent medical administration errors, FDA has issued a rule requiring bar codes on the labels of thousands of human drugs and biological products. This measure will help protect patients from preventable medication errors, reduce the cost of healthcare and harness information technology to promote higher quality care. Monitoring the safety of marketed products requires close collaboration between our clinical reviewers and safety staff to evaluate and respond to adverse events identified in ongoing clinical trials or reported to us by physicians and their patients.

Children are a particularly vulnerable population. Until recently, they have not usually benefited from the knowledge that is gained by studying the products that are being used to treat them. Utilizing the tools Congress gave FDA in the Modernization Act, the Best Pharmaceuticals for Children Act (BPCA) and in the Pediatric Research Equity Act (PREA), we have made

enormous progress in obtaining information about the safety and efficacy on over 100 products that are prescribed to children. Of these, 87 have new labeling information for children. From these studies, it was determined that almost one in four of the products did not work, had a pediatric safety issue or required a change in dose. Almost all of the information that was developed concerning the safety of Selective Serotonin Reuptake Inhibitors (SSRIs) and their use in pediatrics came from studies FDA requested using these new tools.

BPCA contains important, new disclosure requirements. Under BPCA, a summary of FDA's medical and clinical pharmacology reviews of pediatric studies is publicly available regardless of the action taken on the application. Since 2002, FDA has posted the summaries of 41 product reviews on FDA's website at: *http://www.fda.gov/cder/pediatric/Summaryreview.htm*. This information provides a rich source of valuable safety information to allow pediatricians to make more informed decisions about whether and how to use these drugs in their patients.

After a year of hard work by our dedicated staff, I am pleased to report that we have made significant progress in achieving our goals for protecting and advancing America's health and safety. We have empowered consumers to improve their own health through better information about the foods they eat and the medicines they consume. The Agency introduced a national education campaign to give consumers advice on how to safely use over-the-counter pain relief products like non-steroidal anti-inflammatory drugs (including aspirin and ibuprofen) and acetaminophen. In addition, FDA, FDA is asking the manufacturers of all OTC non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labels to include more specific information about potential cardiovascular and gastrointestinal risks as well as information to assist

consumers in the safe use of such drugs. This effort on OTC NSAIDs is consistent with FDA's efforts to address similar concerns about prescription NSAIDs.

I am also proud to report that one of FDA's top priorities is the implementation of the Food Allergen Labeling and Consumer Protection Act. Beginning in 2006, the Agency plans to ensure that manufacturers provide improved food labeling information that will help the millions of consumers who suffer from food allergies. The act specifically requires food labels to identify in plain English if the product contains any of the eight major food allergens - milk, eggs, fish, crustacean shellfish, peanuts, tree nuts, wheat and soybeans. The new labeling will be especially helpful in teaching children who suffer from food allergies to recognize the presence of substances they need to avoid.

The final rule prohibiting the sale of dietary supplements that contain ephedra, went into effect in April 2004, paving the way for greater consumer protection and removal of risky products from the market. FDA has developed a four-pronged approach for ensuring the safety of dietary supplements, including supplements promoted for weight loss. This approach includes guidance on assuring the safety of new dietary ingredients, development of good manufacturing practices guidelines for dietary supplements, guidance on the scientific evidence needed to substantiate label claims on dietary supplements, and diligent enforcement.

We are also working collaboratively with federal and other partners to develop the scientific evidentiary base FDA will use to make safety and enforcement decisions on dietary supplements that contain ephedra. Partners in this effort include FDA's Center for Food Safety and Applied

Nutrition, National Center for Toxicological Research, the National Institutes of Health's Office of Dietary Supplements and National Center for Complementary and Alternative Medicine and the National Toxicology Program in the Department of Health and Human Services. We are also partnering with the University of Mississippi's National Center for Natural Products Research, as well as others, on dietary supplement issues.

I am also pleased to report that a training program was also developed for health educators to help teach food safety to pregnant women and women who might become pregnant. In January of this year the HHS, in conjunction with USDA released the "Dietary Guidelines for Americans 2005," an update of the Federal Government's science-based advice to promote health and reduce risk of chronic diseases through nutrition and physical activity. FDA was instrumental in developing the Dietary Guidelines. However, FDA will continue to confront complex challenges in FY 2006.

As you can see, FDA is further protecting the public health by constantly exploring new ideas, modernizing our rules, streamlining our procedures and carrying out ground-breaking reforms, which began with the FDA Modernization Act. We are experiencing one of our greatest periods of innovation. The strategies we are putting to work are designed to deliver optimum health gains for each tax dollar while easing regulatory burden on industry and removing obstacles in the path of product innovation across all industries in the FDA's purview.

The FDA strives to be a respected steward of the public's trust and ensures that benefits outweigh the risks of regulated products. We will keep the promise of the FDA mission by

putting in place more rigorous oversight and by collecting and sharing important and emerging information about product safety and effectiveness. The 21st Century has brought unprecedented new challenges to patient and consumer safety and FDA is aggressively moving ahead on a number of important protections, old and new.

Using Risk Based Management Practices

Our mission has become much more complicated as public health protection continues to entail a wide range of unprecedented challenges and threats. The number of medical products that we regulate now exceeds 150,000, and the products are becoming increasingly more complex. Access to this rapidly growing range of products offers opportunities for improving health, improving lives, and enhancing lifestyles, but it also creates new kinds of vulnerabilities and risks to the public health.

FDA has identified efficient risk management as the primary way to make the most effective use of resources to address the growing number of FDA regulated products on the market and the increased complexity of many of these products. The Agency has initiated a critical, comprehensive review of its practices related to planning and prioritizing its inspections, conducting inspections as effectively and efficiently as possible, and, achieving compliance with the Federal Food, Drug and Cosmetics Act.

FDA accomplishes these goals through rigorous analysis to consistently identify the most important risks and the use of a quality system approach to designing and conducting our core business processes. Another integral component in the risk-based management strategy is the

use of risk-based Current Good Manufacturing Practices (cGMP), to provide a greater focus on product quality. This was initiated under FDA's Good Manufacturing Practices for the 21st Century initiative. The objectives of risk-based GMPs will encourage industry to adopt new technological advances early in the process; to facilitate application of modern quality management techniques, including implementation of quality systems approaches, to all aspects of pharmaceutical production and quality assurance; and, to implement risk-based approaches that focus industry and Agency attention on critical areas. This new approach will also ensure that regulatory review and inspection policies are based on state-of-the-art pharmaceutical science and will also enhance the consistency and coordination of FDA's drug quality regulatory programs, in part, by integrating enhanced quality systems approaches into our business processes and regulatory policies concerning review and inspection activities.

These strategies have resulted in an inspection and enforcement program that provides the foundation for a strong, robust Agency centered on the protection of public health. An example of an innovation stemming from the FDA's recent GMP initiative is the Pharmaceutical Inspectorate, which created a cadre of highly-trained field investigators that focuses on conducting inspections of highly complex or high-risk drug products and processes. Given the environment of fiscal restraint, the Agency must make informed decisions on how the workload can be best accomplished, while still safely monitoring regulated products. This is being accomplished by covering the highest risks in regulated products.

An example of efficient and effective use of risk management in our operations is the Prior-

Notice Import Security Reviews conducted at the Prior Notice Center. These reviews are just one example of the expanded targeting and follow through on potentially high-risk import entries that FDA is developing to complement the import field exam. Nearly 20 percent of all imports into the U.S. are food and food products consumed daily by the public, making imported foods potential vehicles to carry out terrorist attacks in the U.S. by contamination of our food supply. The Prior-Notice system requires food importers to provide the FDA with advance notice of human and animal food shipments imported or offered for import into the U.S.

By requiring advance notice for imported foods, we gain critical new tools that could help identify shipments containing potentially dangerous foods and prevent them from entering the country. For example, FDA would know in advance, when and where specific food shipments will enter the U.S., what those shipments will contain, from where and from whom they are imported, and the facility where the food was manufactured. This advance information, along with other information from the intelligence community, allows FDA to more effectively target inspections and ensure the safety of imported foods.

FDA receives on average, 27,000 notifications about incoming food shipments each day, and works closely with the Customs and Border Protection (CBP) at the prior-notice Center which is co-located with CBP's National Targeting Center to ensure that the Prior-Notice regulations promote a coordinated strategy for border protection. Using the electronic data required under those regulations, the science-based knowledge of the Agency, and a sophisticated automated targeting system, FDA works side-by-side with CBP while making decisions about food shipments that could pose a potential threat to the United States. Those identified as potential

threats will be subject to thorough inspections upon arrival at our ports. This integrated risk-management process increases our security and facilitates the movement of legitimate commerce.

FDA is also helping vaccine manufacturers overcome challenges such as the problems Chiron is experiencing. Under the Good Manufacturing Practices for the 21st Century Initiative, we are working with industry to encourage use of advanced technologies as well as quality systems and risk-based approaches that build quality into the manufacturing process. We are also increasing our surveillance of influenza vaccine manufacturers and have expanded our ability to communicate with our foreign regulatory counterparts on critical public health issues.

Closing

We at the Food and Drug Administration are working hard to address key challenges in fulfilling our public health mission. Our goal is to maximize the benefits and minimize the risks from the products we regulate. We work to provide high quality and consistent oversight in an environment of changing public health risks, new technologies and global market dynamics. We recognize that our responsibilities are growing in scope and complexity, and we are responding by focusing on our core public health mission, by making high-yield investments and by seeking effective collaborations and partnerships.

Our vision for the future of FDA is one of transformation, requiring the broad use of new technology and new ways of thinking, developed in collaboration with a broad network of partners—public and private, U.S. and international. By capitalizing on 21st century information technology and regulatory process innovation, we will leverage public investment in FDA to yield an even greater level of public health protection, and lower barriers on the critical path to medical innovation. This will allow us to further implement a quality systems approach in all of our operations, improving regulatory business processes, increasing productivity, and promoting better health outcomes. We are committed to fostering increased predictability and transparency in every aspect of what we do.

We would like to thank you for your continued support of the agency and its public health mission. This year is expected to be another exciting one for the Agency and we look forward to working with you throughout the 109th Congress.