HUMAN DRUGS

Introduction

FDA's Human Drugs Program summarizes the budget program requirements that justify a $570,992,000 request for FY 2008. The Human Drugs program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Center for Drug Evaluation and Research and related Field support from the Office of Regulatory Affairs
- effects of the full year FY 2007 continuing resolution on the Human Drugs Program
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Human Drugs Program funding table shows a three-year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 budget request.

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget	Increase or Decrease
Program Level	**$508,905,000**	**$508,906,000**	**$552,579,000**	**$570,992,000**	**$18,413,000**
Center	*$423,071,000*	*$423,076,000*	*$466,103,000*	*$480,596,000*	*$14,493,000*
FTE	*2,286*	*2,203*	*2,308*	*2,369*	*61*
Field	*$85,834,000*	*$85,830,000*	*$86,476,000*	*$90,396,000*	*$3,920,000*
FTE	*661*	*622*	*656*	*662*	*6*
Total FTE	**2,947**	**2,825**	**2,964**	**3,031**	**67**
Budget Authority	**$297,715,000**	**$297,716,000**	**$305,003,000**	**$324,438,000**	**$19,435,000**
Center	*$217,792,000*	*$217,797,000*	*$225,209,000*	*$242,950,000*	*$17,741,000*
Field	*$79,923,000*	*$79,919,000*	*$79,794,000*	*$81,488,000*	*$1,694,000*
Pay Increase	--	--	--	*$4,914,000*	*$4,914,000*
Modernizing Drug Safety	--	--	--	*$8,960,000*	*$8,960,000*
Improving Generic Drug Review	--	--	--	*$5,661,000*	*$5,661,000*
Total FTE	**1,801**	**1,703**	**1,793**	**1,826**	**33**
User Fees	**$211,190,000**	**$211,190,000**	**$247,576,000**	**$232,358,000**	**($15,218,000)**
PDUFA - Center	*$205,279,000*	*$205,279,000*	*$240,894,000*	*$226,086,000*	*($14,808,000)*
PDUFA - Field	*$5,911,000*	*$5,911,000*	*$6,682,000*	*$6,272,000*	*($410,000)*
Proposed Generic Drugs – Center	--	--	--	*$11,560,000*	*$11,560,000*
Proposed Generic Drugs – Field	--	--	--	*$2,636,000*	*$2,636,000*
Total FTE	**1,146**	**1,122**	**1,171**	**1,205**	**34**

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2004 Actuals	$396,491,000	$229,372,000	$167,119,000	2,190
2005 Actuals	$482,134,000	$291,484,000	$190,650,000	2,918
2006 Actuals	$508,905,000	$297,715,000	$211,190,000	2,947
2007 Continuing Resolution	$508,906,000	$297,716,000	$211,190,000	2,825
2007 President's Budget	$552,579,000	$305,003,000	$247,576,000	2,964
2008 President's Budget	$570,992,000	$324,438,000	$232,358,000	3,031

Statement of Budget Request

The Human Drugs Program is requesting $570,992,000 in program level resources for its mission activities:

- ensuring that prescription, generic, and over-the-counter (OTC) drug products are adequately available to the public and are safe and effective
- monitoring marketed drug products for unexpected health risks
- monitoring and enforcing the quality of marketed drug products.

Program Description

The Human Drugs Program is responsible for ensuring that America’s supply of brand name, over the counter, and generic drugs is safe and effective and that the products are adequately available and of the highest quality. The vast majority of the Program resources, both budget authority and user fee funds, are devoted to the medical officers and the scientific experts who evaluate the safety, efficacy, and quality of drug products. Prescription Drug User Fee Act (PDUFA) funds support activities for evaluating new prescription drugs. The proposed generic drug user fees will support funding resources for the review of, and action on, generic drug applications.

The process for approving drug products begins with the companies, who must first conduct clinical research to test their products. CDER staff monitors their research to ensure the safety of people who volunteer for studies and to maintain the quality and integrity of scientific data. CDER assembles a team of physicians, statisticians, chemists, pharmacologists, and other scientists to review the company's data on the proposed use of the drug. If a drug is effective and if its health benefits outweigh its risks, FDA approves the drug for sale. CDER does not actually test the drug when reviewing the data. By setting clear standards for the evidence required to approve a drug, FDA helps bring new drugs to American consumers more rapidly.

After FDA approves a drug for sale in the United States and it enters the market, FDA continues to monitor the drug for unexpected health risks. A team of epidemiologists and safety evaluators collect and analyze data regarding drug usage and side effects. CDER collects and stores this data in the Adverse Event Reporting System (AERS). Safety evaluators use AERS data, combined with drug usage and population-based data, to monitor approved drugs and watch for any new, unanticipated risks associated with marketed products. If evaluators detect any new risks, FDA takes steps to inform the public and change how a drug is used or, if necessary, remove a drug from the market.

CDER also monitors the manufacturing process for approved drug products. In addition to setting standards for safety and effectiveness testing, CDER also sets guidelines for drug quality and manufacturing processes. The Center has a team of inspectors and quality management experts who ensure that any change to a manufacturing process does not adversely affect the safety or efficacy of the drug produced. CDER evaluates reports about suspected problems from manufacturers, health care professionals, and consumers. Throughout this process, FDA works closely with manufacturers to see where streamlining can cut red tape without compromising drug quality.

Because the pharmaceutical industry has become increasingly global, CDER is involved in international negotiations to harmonize standards for drug quality and the data required for drug approval. Harmonization reduces the number of redundant tests manufacturers perform and helps ensure drug quality for consumers at home and abroad.

The availability of accurate and complete information is vital to ensure the safe use of drugs. CDER staff includes risk communication experts, who help generate and publish drug information using media outlets such as print, radio, and the internet. CDER staff also oversees the advertising of prescription drugs to ensure that advertising and promotional materials are accurate, clear, and balanced (OTC drug advertising is regulated y the Federal Trade Commission). Historically, drug companies have promoted their products directly to physicians; however, they are now advertising more directly to consumers. CDER is responsible for ensuring that these advertisements meet FDA standards for consumer protection.

FDA conducts, and collaborates on, focused laboratory research and testing. Researchers use various analytical software tools and laboratory equipment to maintain and strengthen the scientific base of CDER's regulatory policy-making and decision-making. Most recently, CDER has supported FDA's Critical Path Initiative by focusing on new ways to review drug quality, safety, and performance; evaluating improved technologies; validating new approaches to drug development and review; and developing regulatory standards and consistency. With the funding increase proposed in this submission, CDER will continue the strategic activities associated with the Critical Path Initiative by acquiring additional scientists and by procuring contract support.

Field Human Drugs Activities

The Human Drugs Program also includes a Field component, which the Office of Regulatory Affairs (ORA) manages. ORA supports the Program by conducting risk-based domestic and foreign premarket and postmarket inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMPs). Besides overseeing regulated products on surveillance or "for cause" basis, ORA staff also respond to emergencies such as natural disasters and investigate incidents of product tampering and terrorist events. The Office of Criminal Investigations complements the regular Field force by investigating instances of criminal activity in FDA regulated industries.

Effects of Full Year FY 2007 Continuing Resolution

The analysis in this justification assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for the Human Drugs Program. For comparison purposes, FDA budget tables also include a column in the FDA budget tables that reflects an FY 2007 Continuing Resolution (CR) level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Human Drugs Program:

- limited funding for the Human Drugs program to the FY 2006 rate, which will result in the loss of more than 80 FTEs
- a 13 percent reduction in PDUFA user fees available to support human drug review, which will delay the approval of safe and effective new drugs and reduce the program's capacity to meet PDUFA review goals
- reduced ability to respond to the September 2006 Institute of Medicine (IOM) Report on Drug Safety
- reduced number of generic approvals and tentative approvals
- fewer Advisory Committee meetings

- reduced ability to identify and follow up on drug safety signals

- reduced pre-approval current good manufacturing practices (cGMP) inspections resulting in delays or elimination of critical information needed for approval decisions.

Field Human Drugs Program

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Field Human Drugs Program:

- ORA will reduce the number of Good Manufacturing Practice inspections by 277, reducing the inspection interval for moderate risk firms from every three years to every four years.

- ORA will reduce Foreign Pre-approval and Good Manufacturing Practice (GMP) inspections due to reduced numbers of investigators with the necessary specialized skills and the inability to fund inflationary increases in its foreign travel budget.

- ORA will continue to place a high priority on PEPFAR inspections for foreign establishments preparing to manufacture AIDS drugs for distribution outside the U.S. and will ensure that these inspections receive foreign inspection priority.

- "For Cause" and investigation activities will be limited to the highest risk situations where there is an ongoing risk to public health.

- Funding under the continuing resolution causes a loss of 39 FTE for the Field Human Drugs Program.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Human Drugs Program:

- diminished capacity to maintain adverse event reporting systems, identify and analyze medical product safety signals, and adequately communicate safety information to patients and the medical community

- decline in the number of generic drug reviews and approvals, while the backlog of generic drug applications continues to grow

- inability to implement its efforts to address key concerns raised by the September 2006 report on drug safety by the Institute of Medicine

- failure to keep pace with medical product advances when reviewing product applications. As science and technology advances, staff knowledge will lag behind these advances and reviewers will continue to rely on outdated scientific assumptions.

Field Human Drugs Program

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Field Human Drugs Program:

- Any new hires are unlikely to exceed 25 percent of typical productivity which means that FY 2008 inspection and laboratory analysis targets may not be met and ORA work will include a higher proportion of entry level tasks than in FY 2006.

- Despite ORA's desire to pursue risk based activities, newly hired employees will require intensive coaching and supervision and may need to assist an experienced ORA specialist for several months before assuming responsibility for complex risk based activities.

Program Resource Changes

Budget Authority

Pay Increase: +$4,914,000

The FDA request for pay inflationary costs is essential to accomplish our public health mission. Eighty percent of FDA's budget authority supports the FDA workforce. Of this, payroll costs account for almost sixty percent of our total budget authority. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. Maintaining the FDA workforce provides stability for the organization and allows FDA to maintain the current level of coverage for its premarket and postmarket activities. Without these funds, FDA must reduce FTE levels in order to have adequate resources to cover it payroll, which will lead to corresponding reductions in programs that protect public health. The total request for cost of living pay increases in FY 2008 is $21,773,000. The Human Drugs portion of this increase is $4,914,000.

Modernizing Drug Safety: +$8,960,000 and +20 FTE

The request would improve FDA's ability to resolve problems that challenge FDA's capacity to assure drug safety. Specific challenge areas include better post-market surveillance, the need for additional staff to closely monitor companies' annual reports of safety experience, and the need for rapid communication of drug safety information to health providers. The funds requested allow for high-priority drug safety activities:

- strengthen best practices for quantitative benefit-risk assessment
- conduct a pilot to review safety profiles of new molecular entities (NMEs) on a scheduled basis and establish whether FDA should initiate reviews for all NMEs
- access to additional databases for drug and biologic safety surveillance and analysis
- hire additional epidemiologists and programmers to evaluate drug databases

- upgrade the FDA Adverse Event Reporting System (AERS) by adding detection and tracking tools that allow reviewers to more efficiently and effectively identify and track safety signals from an ever-increasing number of adverse events reports
- identify, clarify, and define the purpose of each public communication tool FDA uses to disseminate drug safety information and streamline the use of tools to facilitate information flow
- publish a web-based newsletter with summaries of postmarketing drug reviews
- enlist experts in organizational improvement to identify additional opportunities for change and assist us with carrying out needed changes
- strengthen biologics adverse event databases and increase leveraging and information sharing with public health partners
- increase the ability of multidisciplinary biologics safety teams to detect adverse events and conduct analysis, risk management, and communication
- enhance involvement of safety experts throughout product lifecycle, including during the prelicensure identification of safety data needs and in the design of and continuing review of post-marketing safety studies.

Improving Generic Drug Review Performance: +$5,561,000 and +13 FTE
Submissions of Abbreviated New Drug Applications (ANDAs) for generic drug products continue to rise exponentially, from 307 in FY 2001 to 793 in FY 2006. Increased resources for the Generic Drug Review Program would enhance the review process for generic drug applications and respond to the growing number of these applications. The request keeps pace with the rising number of product submissions and the growing application backlog. The request allows CDER's Generics Drug Program to approve or tentatively approve as many as 550 generic products per year, by replenishing its staff losses due to attrition from previous years. More cost saving generic drug products would be available to the public.

User Fees

Current Law User Fees

Prescription Drug User Fee Act: -$15,218,000
In FY 2007, PDUFA collections included a one-time increase of $31,600,000 for the final year adjustment under PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by the PDUFA statute. The net decrease in FY 2008 for the Drugs program is due to this one-time, non-recurring FY 2007 Final Year adjustment. Because FDA has not completed the public comment period regarding FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments.

In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to the collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007.

Proposals to reauthorize PDUFA are currently under discussion. The PDUFA user fee is expected to bring in $339,195,000 in collections in FY 2008, with the Human Drug Program totaling $232,358,000. These FY 2008 amounts assume that the current authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes PDUFA IV and establishes new performance goals and fee levels.

PDUFA user fees help the Human Drug Program perform four activities:

- speed review of applications for new drug products
- speed the development of products by publishing industry guidance to improve the quality of applications and improve procedures and standards so that reviews are more rigorous, consistent, and predictable
- make innovative, new medical treatments available to patients faster with greater assurance of safety, effectiveness, and quality
- conduct premarket inspections, including bio-research monitoring inspections.

Proposed User Fees

Generic Drugs: +$14,196,000 and +34 FTE
Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering federal spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled.

This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional resources generated by the proposed generic drug user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Reinspection User Fee: $2,126,000 and 16 FTE (Non-Add)
The FY 2008 budget includes $23,276,000 in budget authority for reinspection related activities. The Budget also proposes a new mandatory user fee to support reinspection activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. Under this proposal, FDA reclassifies these activities as mandatory user fees in FY 2008. The total proposed collections for the Agency in FY 2008 are $23,276,000, with $2,126,000 of the collections being allocated to the Field component of the Human Drugs program.

Justification of Base

The mission of the Human Drugs Program is to ensure the availability, safety, and efficacy of human drug products for the American people. There are five primary functional areas within the Human Drugs Program:

- reviewing applications for new and generic drug products and new treatment uses for existing products to ensure safety and efficacy prior to market approval
- continuing to monitor those products after marketing to ensure on-going safety
- communicating the risks associated with use of drug products with consumers and healthcare providers
- enforcing regulations for product manufacturing and marketing compliance
- increasing the number of products available as medical countermeasures in the event of a terrorist attack.

Functions within the Human Drugs Program fundamentally align with the FDA Strategic Goals. Throughout the pre-market application review process for both new and generic drug products, including new medical countermeasures, reviewers are concerned about identifying the proper information to convey to consumers and healthcare providers in the product label, advertisements, and other marketing materials about the safe and proper use of products. After market approval, CDER monitors the use of drug products and modifies communication materials to alert consumers and healthcare providers to any new risks or changes to the safety profile of products as necessary. Moreover, the functions of reviewing applications for new and generic drug products include activities to increase CDER's science base to ensure that our medical experts are up-to-date on the latest technologies and drug development methodologies so that safe and effective new products to improve consumers' health are available on the market. All of the functional areas of the Human Drugs Program touch on ensuring quality of products available on the market. However, enforcing regulations for product manufacturing and marketing compliance fundamentally addresses FDA strategic goals for better manufacturing and production oversight of drug products. The table below

provides a mapping of the Human Drugs Program functions to the FDA Strategic Goals:

	FDA Strategic Goals		
	Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products	Increase Access to Innovative Products and Technologies to Improve Health	Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight
Program Area			
New Drug Review	X	X	X
Generic Drug Review	X	X	X
Postmarketing Surveillance/Drug Safety	X		X
Risk Communication	X		X
Drug Regulatory Enforcement and Compliance			X
Medical Countermeasures	X	X	X

New Drug Review

CDER's new drug review process encompasses all activities associated with reviewing investigational new drugs (INDs), new drug applications (NDAs), supplements to new applications, and any amendments filed to application submissions. In the process of reviewing applications, CDER reviewers are involved in activities that directly support all three of FDA's strategic goals. Reviewers are seeking answers to questions that would provide the best information about drug products in labeling, advertising, and other material. Medical officers and specialists are applying their scientific expertise to evaluating products developed with state-of-the-art technology and methodologies. New drug reviewers are involved in evaluating the proposed manufacturing and production for new products. As a result of the efforts of the New Drug Review program, Americans have access to the safest and most effective drug supply in the world. CDER's New Drug Review Program directly supports the President's initiative to ensure consumers have quality healthcare by expanding consumers' choices for new, innovative treatment options. Likewise, the New Drug Review Program supports the Departments' priorities for ensuring consumers have the information they need to make informed decisions about the treatment options for their personal needs. The New Drug Review Program performs a number of activities to make more new drugs available to the public:

- CDER evaluates NDAs while giving products for diseases such as cancer and AIDS priority status, assessing them by an accelerated evaluation process that makes promising products for serious or life-threatening diseases available earlier in the development process.
- CDER reviews and evaluates biological therapeutic products, including establishing standards, conducting mission-related research, participating in

inspections, developing policy and procedures, and evaluating trial results and reports of adverse events.

- CDER reviews and evaluates over-the-counter (OTC) drugs to ensure that they are safe, effective, and high quality while also assisting consumers on how to best use OTC products by providing clear, easy-to-read drug information;
- CDER protects children who need prescription or OTC drug products by working with manufacturers to encourage studies in children so that age-appropriate labeling and dosing is available for products.
- The Office of Orphan Products Development (OOPD) promotes development of products that demonstrate promise for diagnosis and/or treatment of rare diseases or conditions by administering a grant program that provides funding for clinical research in rare diseases.

Field Human Drugs Activities

ORA conducts premarket activities such as bioresearch monitoring of clinical research, pre-approval inspections, and laboratory method validations needed for application decisions, and inspects facilities to ensure their ability to manufacture the product to the specifications stated in their application. Specifically, these activities include conducting pre-approval inspections and pre-operational visits in support of the Presidential Emergency Plan for Aids Relief and conducting bioresearch monitoring inspections to support the drugs pre-approval programs.

Generic Drug Review

Generic drugs save consumers billions of dollars each year. Every year, FDA expands the availability of high-quality generic drug products and provides consumers and healthcare providers with information on their safety and effectiveness. The Generic Drug Review Program represents a fundamental component of both the President's and the Department Secretary's priorities for empowering consumers to save money on quality health care. With each new generic version of a brand-name drug the FDA approves, consumers have an additional option to save money on their prescription drug needs. The Generic Drug Review Program performs a number of activities to make more generic drugs available to the public:

- conducts traditional drug product review activities for generic forms of existing products to ensure safety and effectiveness by assuring generic products conform to manufacturing standards equal to the standards of the brand name pharmaceuticals
- increases efficiency and improving generic drug review times by evaluating ways to improve communications with industry
- manages the existing generic drug application backlog as quickly and efficiently as possible

- provides medical and scientific expertise necessary to fulfill the President's commitment to ensuring the quality of HIV/AIDS drugs purchased by the US for developing countries
- performs outreach to pharmaceutical firms, including many foreign firms who are unfamiliar with FDA's regulatory processes.

Field Human Drugs Activities

ORA supports the generic drug program through pre-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with Current Good Manufacturing Practices.

Postmarketing Surveillance/Drug Safety

FDA's public health responsibility to ensure the safety and efficacy of drug products continues after FDA approves drugs for marketing. This program supports the President's and the Department's priorities for ensuring consumers have access to quality healthcare. The relatively small size required to make pre-marketing clinical trials practical means that CDER cannot learn everything about the safety of a drug before its approval. As a result, a degree of uncertainty always exists about the risks of drugs. FDA must be vigilant to protect Americans from injuries and deaths caused by unsafe, illegal, fraudulent, substandard, or improperly used products. If FDA detects any new and unexpected health risks, CDER takes steps to inform the public and change how a drug is used. When necessary, FDA will remove a drug from the market. In addition, FDA monitors the promotion of drug and biologic products to assure the American public that information provided presents a fair balance of risks and benefits and is not false or misleading. The Postmarketing Safety/Drug Surveillance program performs a number of activities to ensure the safety and efficacy of drug products after FDA approves drugs for marketing:

- CDER monitors the quality of marketed drugs and their promotional materials through product testing and surveillance.
- CDER develops policies, guidance and standards for drug labeling, current good manufacturing practices, clinical and good laboratory practices, and industry practices to demonstrate the safety and effectiveness of drugs.
- CDER conducts investigations of reported errors to collect information needed to assess the error and develop error reduction strategies with manufacturers and the medical community.
- During inspections CDER reviews manufacturers' files for compliance with FDA reporting regulations and conducts follow-up inspections on adverse event reports when inspectors need information from the manufacturer to evaluate the risks involved.
- CDER operates the MedWatch Program, which permits health care professionals to voluntarily report observed or suspected defects and quality problems associated with marketed drug products.

- CDER identifies health hazards associated with the manufacturing, labeling, and packaging of pharmaceuticals and biologics and removes unsafe and ineffective products from the marketplace.

Field Human Drugs Activities

FDA believes that roughly half of the deaths and injuries associated with medical errors can be avoided by fully implementing its strategies. ORA's role in reducing these injuries and deaths has three components:

- reviewing adverse event and complaint files at manufacturers during inspections for compliance with FDA reporting regulations

- conducting follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved

- conducting investigations of reported errors and product recalls so that program managers can collect information and develop error reduction strategies with manufacturers and the medical community.

Risk Communication

FDA is committed to enhancing CDER's communication with consumers to prevent any harm from occurring due to a lack of accurate and timely information about a drug product. FDA's human drug program is engaged in a variety of activities designed to enable consumers to make informed decisions while weighing benefits and risks of FDA-regulated products, activities that fundamentally support the President's and Secretary's priorities for empowering individuals to be responsible for their own healthcare decisions:

- CDER is responsible for providing clear, timely, and accurate drug information to consumers and healthcare providers so that they can base their medical decisions on the best-available information.

- CDER develops education campaigns to disseminate consumer-friendly information to promote the safety and quality of drug products.

- CDER develops press releases and public health advisories to warn the public about potential hazards associated with using or purchasing particular products from stores or over the Internet.

Drug Regulatory Enforcement and Compliance

A large part of CDER's public health mission is ensuring that companies market only the highest possible quality products. In direct support of the President's and Department's priorities for ensuring quality healthcare for consumers, CDER ensures drug product quality by facilitating effective and efficient scientific assessment of

relevant pharmaceutical and biotechnology information in regulatory applications to FDA. CDER facilitates scientific and technological innovations that improve understanding of product performance, quality, and efficiency of development, manufacturing, and quality assurance processes. Further, CDER monitors potentially fraudulent Internet sites to identify targets for investigation and sampling of products. CDER performs a number of enforcement and compliance activities to ensure that companies market only the highest possible quality products:

- CDER develops, deploys, and maintains risk-based compliance inspection models for prioritizing GMP inspections by risks to product quality.
- CDER evaluates and analyzes inspection findings for trends in deficiencies, focusing on product quality standards and manufacturers' compliance with GMP regulations.
- FDA operates a comprehensive program to guide, assist, and manage industry self-compliance with manufacturing quality objectives of the Federal Food, Drug and Cosmetic Act.
- CDER assists industry in voluntary product recalls and assists in the investigation, evaluation, and correction of the conditions and practices that led to the recalls.
- CDER certifies conformance with current good manufacturing practice by industry for use in facilitating export of U.S. pharmaceutical production to countries with limited regulatory systems.
- CDER consults with industry and coordinates FDA program activities to alleviate drug shortages in the U.S. market.
- CDER takes necessary enforcement action when pharmacies compound drugs that are contaminated or are dangerously subpotent or superpotent, and works with state regulatory authorities to provide support for their regulation of pharmacy compounders.

Field Human Drugs Activities

At present, there is an accelerating growth in the number of new websites marketing FDA-regulated products to the U.S. consumer and medical professionals. FDA currently conducts only minimal levels of web-based oversight. The Office of Criminal Investigations is expanding its efforts to develop cases that address the marketing of counterfeit products:

- monitoring potentially fraudulent websites to identify targets for investigation and sampling of products
- conducting "undercover only" purchases of prescription drugs from websites suspected of engaging in illicit drug sales, distribution, and/or marketing

- providing oversight of mail and courier packages entering the U.S. from foreign sources.

Medical Countermeasures

The Human Drugs Program provides medical and scientific expertise and information to federal and state agencies, healthcare providers, and consumers regarding the safety, efficacy, and availability of drug products in case of natural disaster, terrorist event, or other emergency. FDA is also working to ensure that terrorists do not use regulated drug and therapeutic biological products as vehicles of terrorism against Americans. CDER's capabilities to identify, prepare for, and respond to biological, chemical, and radiological/nuclear threats and incidents fundamentally supports the President's Bioshield initiative and the Secretary's priority for emergency preparedness and response. CDER performs a number of activities to ensure the availability of medical countermeasures:

- CDER encourages early and frequent interactions with sponsors, whether they are developing a novel compound or a new indication for a previously approved product.
- CDER expands the availability of safe and effective countermeasures for special populations (e.g., pregnant women, infants, elderly) through funding pharmacokinetic and safety studies for antibiotics likely to be used to prevent or treat illness following a terrorist attack.
- CDER assures processes are in place if an unapproved product is required in response to an event.
- CDER collaborates with other agencies on the development of INDs to allow access to investigational medical countermeasures.
- CDER interacts frequently with the Strategic National Stockpile to support the development, availability, maintenance, and deployment of medical countermeasures.

<u>Research, Development and Evaluation (RD&E) Activities</u>

The Human Drugs Program is responsible for ensuring that the American public has adequate access to safe, effective, and high quality drug and therapeutic biologic products. CDER models studies in animals to ensure that products are safe to study in humans:

- CDER analyzes specific immune deficiencies in animal models of bioterrorism-related radiation injury to clarify clinical problems potentially treatable with therapeutic proteins.
- CDER studies broadly acting stimulators of the immune system in animal models to assess protective effects against various infectious agents potentially used in bioterrorist attacks.

- CDER develops new assays for anthrax toxin that more closely model toxin activity in humans than current mouse cell assays, and provide biomarkers for assessing anthrax toxin effects in vivo.
- CDER clarifies normal function of novel proteins proposed as targets for cancer therapy, in order to predict adverse effects due to inhibition of these proteins in normal cells.

CDER also performs research to develop regulatory standards and risk assessment criteria to reach sound, science-based public health decisions when evaluating the safety and effectiveness of drug products:

- CDER clarifies mechanisms of cell death induced by cancer drugs in order to enable better bioassays to serve as markers for safety and efficacy of novel cancer drugs.
- CDER identifies biomarkers of cancer development and progression to facilitate diagnosis and monitoring of treatment efficacy.

Selected FY 2006 Accomplishments

New Drug Review

The following table, based on the latest complete performance data available, shows that in FY 2005, CDER exceeded its PDUFA performance goals for priority and standard new molecular entities/new biologic licensing applications.

Fiscal Year 2005 First Action Review Performance
(Performance data as of September 30, 2006)

	Number Filed	2005 Performance Goal	Final Performance
NMEs/New BLAs			
Standard	15	90% in 10 mo.	93%
Priority	18	90% in 6 mo.	94%

CDER issued new guidance titled "*Exploratory IND Studies and INDs --Approaches to Complying with CGMP During Phase 1*" that provides specific approaches for researchers conducting early clinical trials in people, performing safe testing, and producing small amounts of drugs. Specific advice from the FDA on safely producing drugs will expedite bringing safe drugs for life-threatening illnesses to market.

CDER completed a study that demonstrated the benefits of earlier Industry meetings with FDA in making the drug review process more efficient. CDER released a report titled "*Independent Evaluation of FDA's First Cycle Review Performance -- Retrospective Analysis*" that showed the importance of communication with the FDA in the development process of drugs. As a result, FDA approves safe and effective drugs more efficiently so that the public has access to them earlier.

CDER launched an internal assessment of its Advisory Committee Meeting system to ensure the process applies best practices. This assessment will identify the strengths of advisory committees and apply them center-wide. Improved advisory committee processes and procedures will result in improved regulatory decision-making and increased credibility of the FDA decision-making process.

FDA Approved First Ever Inhaled Insulin Combination Product for Treatment of Diabetes

FDA approved the first inhaled insulin for treatment of adults with type 1 and type 2 diabetes. Exubera® is the first new insulin option developed since its initial discovery in the 1920s. Until this approval, patients with diabetes who need insulin to manage their disease had only one way to treat their condition. Inhaled insulin will offer patients more means to control their blood sugars.

FDA approved several significant new drugs. Eight examples are listed below:

- *Nexavar® is a New Treatment for Advanced Kidney Cancer* – Nexavar is a new anti-cancer medicine for adults with advanced kidney cancer (renal cell carcinoma). Currently in the US, there are 32,000 new cases of kidney cancer and 12,000 deaths from the disease per year. Studies showed that patients with advanced kidney cancer showed more time before tumor progression or death when treated with Nexavar.

- *Revlimid® is a New Treatment for Myelodysplastic Syndrome (MDS)* -- This drug will offer a new option for patients with this rare illness that can progress to life-threatening leukemia.

- *Sutent® is a New Treatment for Gastrointestinal and Kidney Cancer* – Sutent is approved for rare stomach cancer, gastrointestinal stromal tumors, as well as advanced kidney cancer – diseases that are difficult to treat. This is the only time a new oncology product has been approved for two purposes simultaneously.

- *Emsam® Approved as First Drug Patch for Depression* -- The drug Emsam, a patch that delivers selegiline through the skin and into the bloodstream, offers an alternative treatment to patients in need of an antidepressant.

- *Erbitux® Approved as First Head and Neck Cancer Treatment in 45 Years* -- Erbitux was approved to treat patients with squamous cell cancer of the head and neck, for use in combination with radiation therapy. This new drug is the first head and neck cancer treatment approved since methotrexate was approved in the 1950s. Erbitux will offer patients another effective treatment options that may help prolong their life in the fight against cancer.

- *Myozyme® Approved as First Treatment for Pompe Disease* -- Myozyme, an orphan drug for the treatment of Pompe's disease, demonstrates the benefits of the Orphan Drug Program, which provides incentive to develop orphan drugs to benefit patients who suffer from rare diseases.

- *Exelon® Approved as First Treatment for Dementia of Parkinson's Disease* – Previously approved for treatment of dementia associated with Alzheimer's, Exelon is the first drug approved to treat dementia for Parkinson's patients and will help the 0.2% to 0.5% over the age of 65 who suffer from this disease.

- *Sprycel® Given Rapid Approval as a New Treatment For a Rare Type of Leukemia* -- Given accelerated approval, Sprycel can be used to treat chronic myeloid leukemia. Sprycel has shown the ability to reduce or eliminate detectable leukemia cells in blood or bone marrow. Patients with CML will

now have an alternative option to treat their disease if it has stopped responding to other treatment options.

New Drug Review – Field Activities

President's Emergency Plan for AIDS Relief (PEPFAR): ORA conducts pre-approval inspections and pre-operational visits (when necessary) in support of PEPFAR. These inspections help ensure the safety, efficacy and availability of critical AIDS medications in the developing world.

Generic Drug Review

CDER approved or tentatively approved 13 generic applications for AIDS drugs in association with the President's Emergency Plan for AIDS Relief (PEPFAR). These include pediatric formulations for lamivudine, nevirapine, stavudine and abacavir. These approvals will contribute significantly to the care of vulnerable children. A combination lamivudine/zidovudine tablet was also tentatively approved which will make treatment less complicated for some patients.

CDER made several significant generic approvals. Each of these approvals as well as the dozens of other generic approvals made in FY 2006 represent steps in countering the rising costs of health-care to provide the public with lower-costing drug options to brand name drugs:

- CDER approved a generic Pravastatin, which is the first generic version of Bristol-Myers Squibb's Pravachol®; pravastatin is a treatment for hyperlipidemia or for those who are at higher risk for heart attack or stroke.

- CDER approved a generic sertraline, the first generic version of Zoloft®, which will treat major depressive disorder in adults and some anxiety related disorders.

FDA Approves Generic Version of Zocor®

CDER approved the first generic Simvastatin, the first generic version of Zocor®. This drug will treat hypercholesterolemia along with a restricted diet. Simvastatin should be used along with a diet restricted in saturated fat and cholesterol to treat hypercholesterolemia (high cholesterol) and to reduce the amount of certain fatty substances in the blood such as triglycerides and other lipids. According to the research firm, IMS Health, statins accounted for $16 billion in U.S. sales in 2005. Zocor® was the second most widely prescribed statin.

- CDER approved a generic meloxicam, the first generic version of Boehringer Ingelheim's Mobic® Tablets; this drug is a treatment for osteoarthritis.

- The FDA has approved several versions of Ciprofloxacin Injection, USP- the first generic versions of Bayer Corporation Pharmaceutical Division's CIPRO I.V; this drug is a treatment for bacterial infections.

Postmarketing Surveillance/Drug Safety

FDA selected Gerald J. DalPan, M.D, M.H.S as director of the Office of Drug Safety. Dr. DalPan's extensive training, practical experience, and strong leadership will be an invaluable asset to FDA's commitment to drug safety and risk communication. Dr. DalPan will work closely with stakeholders, consumers, the healthcare community, and Congress to improve matters relating to adverse drug events and represent CDER in matter relating to drug safety.

FDA marked a historic milestone for pediatric drugs in FY 2006: Trileptal became the 100^{th} drug to include labeling information on safety, efficacy, dosing, and unique risks for children and teenagers. Under the Federal Food, Drug and Cosmetic Act and the 2002 Best Pharmaceuticals for Children Act, the FDA has worked with the pediatric community to decide which drugs should be studied based on the public health needs of children. These drugs were studied for a wide range of needs, including asthma, HIV, seizures, diabetes, high blood pressure, attention deficit hyperactivity disorder, brain tumors, and leukemia.

FDA announced a new prescription drug information format to improve patient safety. FDA revised the format of the package insert with a new design that will provide up-to-date information in an easy-to-read format. About 300,000 preventable adverse events occur due to confusing medical information. Clear and concise information will facilitate safe use of drugs and increase the ease of explaining benefits and risks of medications for healthcare providers.

FDA published two final and two draft guidances for industry. This series of guidance documents will assist applicants in complying with the new requirements in the final rule on the content and format of labeling for human prescription drug and biological products:

- Final: *Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products – Content and Format*

- Final: *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products – Content and Format*

- Draft: *Labeling for Human Prescription Drug and Biological Products-- Implementing the New Content and Format Requirements*

- Draft: *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products--Content and Format.*

CDER is implementing process improvements to ensure standards and consistency for postmarketing safety monitoring across its Office of New Drugs (OND). CDER has formed a Postmarketing Safety Process Improvement Team that works with the CDER Office of Surveillance and Epidemiology (OSE) to develop standards. The Team is documenting roles and responsibilities for OND and OSE, and is working closely with the Center to develop an overall integrated system for tracking postmarketing safety activities. Each review division has medical leads and regulatory project managers to oversee and coordinate postmarket safety issues and conducts regular meetings between the division medical staff and OSE.

FDA awarded a contract to evaluate the postmarketing study commitment process for collecting medical information. The goal of this in-depth examination is greater internal consistency across the medical product Centers at FDA for requiring, requesting, facilitating, and reviewing postmarketing study commitments for human drugs, biologic products, and medical devices. By strengthening the process for postmarketing study commitments, FDA is continuing to improve its regulation of new medical products by using the best management approaches, the best information technology, and the best quality systems and review processes. The evaluation began in April, 2006 and is expected to take approximately 12 months to complete.

Postmarketing Surveillance – Field Activities

Seizure of Dried Eggs: On April 25, 2006, 49,500 pounds of "hyperimmune" dried eggs worth at least $129,000 were seized at Allegheny Cold Storage in Pittsburgh, PA. The firm responsible for the eggs, OvImmue, had arranged to get the eggs from specially vaccinated chickens which the firm claimed gave the eggs special “hyperimmune” properties which would cure and/or prevent a wide variety of diseases when consumed by humans. The dried eggs were seized as a misbranded and unapproved new drug due to the product’s intended use as a drug, with unsubstantiated claims to treat diseases.

Risk Communication

CDER named its first Associate Center Director for Safety Policy and Communication in the Center for Drug Evaluation and Research. CDER appointed Capt. Paul Seligman, M.D., to oversee drug safety issues as well as staff who distribute safety information to patients and professionals on the FDA Website. This position will help standardize drug safety approaches and improve the timeliness of information reaching the public.

CDER issued a public health advisory on the use of NeutroSpec, [Technetium (99m TC) Fanolesomab], an imaging agent for the diagnosis of appendicitis. The Public

Health Advisory alerted the public to the withdrawal of NeutroSpec until further investigation can take place of reported deaths and serious adverse events linked to use of the product. Palatin Technologies Inc. and Mallinckrodt, NeutroSpec's manufacturer and marketer respectively, agreed to instant voluntary market suspension. Adverse events included shortness of breath and drops in blood pressure that led to the death of two patients.

CDER updated the labeling for the Ortho Evra Contraceptive Patch. CDER approved updated labeling to warn consumers about the higher levels of estrogen associated with Ortho Evra compared to most birth control pills. The new labeling encourages women to talk to their healthcare provider to ensure whether Ortho Evra is the right method of birth control for them.

CDER approved updated labeling with a boxed warning and a medication guide for two Eczema Drugs, Elidel® and Protopic®. The new label warns about the possible risk of cancer, includes a Medication Guide, and recommends use of these products as second-hand treatments. New labeling will ensure healthcare providers and patients are fully aware of the risks associated with these products so that an appropriate decision can be made as to whether to use it for treatment.

CDER issued a public health advisory for Trasylol®, a drug linked to serious side effects such as kidney problems, heart attacks, and strokes in patients having artery bypass graft surgery. Trasylol is the only FDA approved product to prevent blood loss during artery bypass graft surgery. While CDER further investigates the adverse events, it recommends doctors monitor toxicity levels, limit Trasylol use, and weigh risks and benefits of Trasylol use for the protection of patients.

CDER announced new labeling changes for the antibiotic Tequin®, a treatment for pneumonia, bronchitis, uncomplicated gonorrhea, and other infections. The new labeling reflects continued reports of hypoglycemia and hyperglycemia. This addition to the "Warning" sections of the label will help patients determine if the benefits outweigh the risks from taking this drug.

CDER warns consumers against drinking high strength hydrogen peroxide for medicinal use. Ingestion of high-strength hydrogen peroxide can be incredibly harmful and even fatal. This action is significant contribution to the FDA's fight against companies making illegal claims about their products.

Drug Regulatory Enforcement and Compliance

CDER sent 16 warning letters to marketers who were promoting dietary supplements and hormone creams that claimed to prevent or treat diseases such as cancer, heart disease, and osteoporosis. By selling unapproved new drugs that have not been proven safe and effective for this purpose, patients with these life-threatening conditions have false hope of treatment.

FDA seized Ephedra-Containing dietary supplements. FDA requested that Complaints of Forfeiture be filed against Nature's Treat Energy Plus #1 that contained 46.8 mg of ephedrine alkaloids, a component of ephedra. Given ephedrine alkaloids' adrenaline-like stimulants, they potentially cause adverse effects on the heart. This includes raised blood pressure that is linked to heart attacks and strokes. The confiscation of these supplements is part of FDA's continued initiative to warn consumers against the consumption of dietary supplements containing ephedrine alkaloids.

CDER issued a new guidance titled "Marketed Unapproved Drugs—Compliance Policy Guide" to strengthen efforts against unapproved drugs. The first focus will be on products containing antihistamine carbinoxamine due to the possible adverse events in children under the age of two. Currently, unapproved drugs pose a risk in that they mislead the public into thinking they these products have been determined safe and effective.

FDA announced new measures to protect Americans from counterfeit drugs. FDA collaborated with a counterfeit drug task force on a report that emphasizes certain regulatory actions and new technologies to ensure the safety of the U.S. drug supply. Such actions will help to reduce the dangerous risk that counterfeit products will reach patients.

FDA issued proposed rule-making automate Drug Registration and Listing. FDA is proposing an Electronic Drug Registration and Listing System that would make a complete list of drugs available electronically. This system will increase the efficiency of the registration and listing process. Drug makers will be able to submit all drug information electronically which will give the FDA accurate and up-to-date information. As a result, FDA will have an easier time responding to drug emergencies such as recalls and shortages.

Drug Regulatory Enforcement and Compliance – Field Activities

Counterfeit Drugs from Canadian Websites: In August 2006, FDA advised consumers not to purchase prescription drugs from websites that used two pharmacies in Manitoba, Canada to fill their orders after it was reported that the pharmacies had filled some orders with counterfeit prescription drugs. FDA investigated these reports and coordinated its investigation with international law enforcement authorities. Combating counterfeit drugs is a high priority in FDA enforcement initiatives.

Permanent Injunction Halts Illegal Importation of Drugs: On March 9, 2006, FDA obtained a Permanent Injunction against Canada Care Drugs, Inc., and two individuals thus preventing the defendants from illegally importing prescription drugs. This injunction is an example of FDA's continued efforts to stop the illegal importation of drugs. Drugs purchased under these conditions are more likely to be contaminated, counterfeit, ineffective, or contain different amounts of active ingredients than similar drugs.

Medical Countermeasures

FDA Approves Treatment for Nerve-Poisoning Agents for Use by Trained Emergency Medical Services Personnel

CDER approved Duodote, an atropine and pralidoxime chloride injection to treat organophosphorus-containing nerve agents. Now with an approval, Duodote will be a product distributed directly to emergency medical service organizations for civilian use. The FDA previously approved such an injection called Antidote Treatment - Nerve Agent Auto-Injector (ATNAA) for military use. This approval will allow stockpiling of the product for treating civilians in case of an emergency.

FDA approved five abbreviated new drug applications (ANDA) for generic versions of Bayer Corporation Pharmaceutical Division's Cipro® I.V., a drug used to treat certain bacterial infections. Ciprofloxacin is approved for inhalational anthrax (after exposure). The additional ANDA approvals will provide redundancy if mass prophylaxis and treatment is needed for an anthrax event.

FDA continued to collaborate with the Centers for Disease Control (CDC) on the development of the Home MedKit study designed to evaluate whether participants and members of their households follow instructions about proper storage, use, and maintenance of the MedKit, which contain two antimicrobials as countermeasures for a bio-terrorism threat. FDA is recruiting approximately 5000 volunteer households in the St. Louis area to store these MedKits and reserve them for emergency use.

Human Drugs Program
Program Activity Data (PAD)

CDER WORKLOAD AND OUTPUTS	FY2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget
New Drug Review				
Priority New Drug Application (NDA/BLA) Reviews	42	38	40	40
Standard NDA/BLA Reviews	129	130	135	135
Priority NDA/BLAs Approved	27	25	25	25
Standard NDA/BLAs Approved	64	75	75	80
Time from Receipt to Approval (mo.s)(mean)-Priority NDA/BLAs	7.4	8.5	8.5	8.5
Time from Receipt to Approval (mo.s)(mean)-Standard NDA/BLAs	26.2	20.0	20.0	19.0
Time from Receipt to Approval (mo.s)(median)-Priority NDA/BLAs	6.0	6.0	6.0	6.0
Time from Receipt to Approval (mo.s)(median)-Standard NDA/BLAs	16.2	15	15	13
NDA Supplemental Reviews (NDAs only)	2,872	3,300	3,300	3,300
INDs (Active) (Drugs and Biologics—Commercial+Research)	13,881	13,800	13,800	14,000
Clinical Pharmacology/ BioPharmaceutic Reviews	1,584	1,600	1,600	1,700
Total number of Promotional Material Submitted using FDA Form 2253 - Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use	59,198	64,100	64,100	69,400
Biologic Therapeutics Review				
Total Original License Application (PLA/ELA/BLA) Reviews	5	4	4	4
PLA/BLA Approvals	5	4	4	4
License Supplement (PLA/ELA/BLA) Reviews	249	280	280	300
Commercial IND/IDE Receipts (Biologics Only)	114	105	105	110
IND/IDE Amendments Receipts (Biologics Only)	11,249	8,800	8,800	8,800

CDER WORKLOAD AND OUTPUTS	FY2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget
Generic Drug Review				
Abbreviated New Drug Application (ANDA) Receipts	793	800	800	857
ANDA Actions	1456 *	1400	1500	1500
ANDA Approval Actions (both Tentative and Full Approvals)	510	485	500	550
Median Review Time from ANDA Receipt to Approval (months)	16.6	18	18	17.5[1]
ANDA Supplemental Actions (Labeling and Manufacturing)	4577 *	4400	4500	4000[2]
* = administrative actions not counted				
Over-the-Counter Drug Review				
*OTC Monographs Under Development	28	15	15	15
*OTC Monographs Published	5	5	5	5
* Category includes Proposed Rules and Final Rules				
Best Pharmaceuticals for Children Act				
Approved Labels with New Pediatric Information	12	26	26	26
New Written Requests Issued	20	22	22	22
Pediatric Exclusivity Determinations made	14	20	20	20
Post Exclusivity Safety Report	12 drugs (2 A/Cs)	12 drugs (2 A/Cs)	12 drugs (2 A/Cs)	12 drugs (2 A/Cs)
Patient Safety				
Adverse Event Reports	448,837	493,721	493,721	552,967

[1] The increase in the Human Drugs ANDA activities for FY08 above FY07 are due to the Proposed Generic Drugs User Fee.

[2] The basis for the decrease in FY08 is a projected decrease in chemistry supplements. With the new Question-based Review format, sponsors are required to submit more information to demonstrate their knowledge of the product and the science basis for the development of the product. Because of the quality of content of the applications submitted in this format, firms will be able to submit information about more changes in the annual report reducing the need for supplements, which results in a projected decrease in supplement actions.

CDER WORKLOAD AND OUTPUTS	FY2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget
Percentage of Adverse Drug Reaction Reports Submitted Electronically (% of total)	35%	45%	45%	55%
Percentage of Serious/Unexpected Adverse Drug Reaction Reports Submitted Electronically	56%	70%	70%	80%
Drug Quality Reporting System Report	1,387	3,500	3,500	3,600
Safety reviews completed by Office of Surveillance & Epidemiology	1,760	1,800	1,880	1,900
Number of drugs with sheets (this combines HCP and PI sheets)	45	60-70	60-70	60-80
Administrative/Management Support				
Number of Advisory Committee Meetings	26	20	25	25
Number of FOI Requests	3,562	3,600	3,600	3,600
Number of FOI Requests Processed	4,052	4,000	4,200	4,200
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	92	100	100	100
Number of Citizen Petitions Completed* (excluding suitability petitions and OTC monograph-related petitions)	57	55	60	60
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	182	240	222	262
* Citizen Petitions completed may include petitions filed in prior years.				
Stakeholder (consumers, health care professionals, industry, government, etc) information requests processed				
Telephones	31373	35,000	35,000	39,000
Emails	55,846	40,000	45,000	55,000
Letters	884	750	800	1000

DRUGS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY 2006 Actuals	FY2007 Continuing Resolution	FY2007 President's Budget	FY2008 President's Budget
Pre-Approval Inspections (NDA)	139	112	112	112
Pre-Approval Inspections (ANDA)	80	110	110	155 [1]
Bioresearch Monitoring Program Inspections	498	555	555	555
Drug Processing (GMP) Program Inspections	1,222	1,100	1,377	1,377
Compressed Medical Gas Manufacturers Inspections	106	158	158	158
Adverse Drug Events Project Inspections	105	133	133	133
OTC Monograph Project and Health Fraud Project Inspections	28	32	32	32
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	63	110	110	110
State Partnership Inspections: GMP Inspections	50	50	50	50
Total Above FDA and State Partnership Inspections	**2,291**	**2,360**	**2,637**	**2,682**
Domestic Laboratory Samples Analyzed	1,706	1,587	1,587	1,587
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	123	125	190	190
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	79	42	42	87 [1]
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	124	44	44	44
Foreign Drug Processing (GMP) Program Inspections	164	134	174	209
Foreign Adverse Drug Events Project Inspections	10	16	16	16
Total Above Foreign FDA Inspections	**500**	**361**	**466**	**546**
Import Field Exams/Tests	3,525	4,400	4,400	4,400
Import Laboratory Samples Analyzed	277	275	275	275
Import Physical Exam Subtotal	3,802	4,675	4,675	4,675
Import Line Decisions	279,662	295,627	295,627	312,504
Percent of Import Lines Physically Examined	1.36%	1.58%	1.58%	1.50%

Note:

[1] The increase in Human Drugs ANDA inspections for FY08 above FY07 are attributed to the Proposed Generic Drugs User Fee.

Performance Analysis

During the latest performance period (FY 2006), the Human Drugs program successfully met four of its Center performance measures, expects to meet the three other measures when it reports complete data, and met its one field performance goal. For more information about these performance goals and results, please see the Performance Detail section. For more information about these performance goals and results, please see the Performance Detail section.