HUMAN DRUGS

The FY 2009 program level budget request for the FDA Human Drugs Program is $738,723,000.

The following table shows a three-year funding history for the Human Drugs Program.

FDA Program Resources Table

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Program Level	**$543,565,000**	**$680,269,000**	**$738,723,000**	**$58,454,000**
Center	*$454,236,000*	*$586,215,000*	*$639,258,000*	*$53,043,000*
FTE	*2,288*	*2,537*	*2,820*	*283*
Field	*$89,329,000*	*$94,054,000*	*$99,465,000*	*$5,411,000*
FTE	*627*	*627*	*636*	*9*
Program Level FTE	**2,915**	**3,164**	**3,456**	***292***
Budget Authority	**$315,138,000**	**$353,269,000**	**$357,991,000**	**$4,722,000**
Center	*$230,760,000*	*$266,131,000*	*$268,234,000*	*$2,103,000*
Field	*$84,378,000*	*$87,138,000*	*$89,757,000*	*$2,619,000*
Med. Prod. Safety & Devel. (non-add)	*$315,318,000*	*$353,269,000*	*$360,281,000*	*$7,012,000*
Admin. Savings & Man. Efficiencies (non-add)			*-$2,290,000*	*-$2,290,000*
Budget Authority FTE	**1,772**	**1,816**	**1,855**	**39**
User Fees	**$228,427,000**	**$327,000,000**	**$380,732,000**	**$26,528,000**
Center PDUFA	*$223,476,000*	*$320,084,000*	*$346,612,000*	*$26,528,000*
Field PDUFA	*$4,951,000*	*$6,916,000*	*$6,916,000*	*$0*
Center DTC			*$12,170,000*	*$12,170,000*
Proposed User Fees	**$0**	**$0**	**$15,034,000**	**$15,034,000**
Center Generic Drugs			*$12,242,000*	*$12,242,000*
Field Generic Drugs			*$2,792,000*	*$2,792,000*
User Fee FTE	**1,143**	**1,348**	**1,601**	**253**
Mandatory User Fees:	**$0**	**$0**	**$2,126**	**$2,126**
Field Reinspection (non-add)	*$0*	*$0*	*$2,126*	*$2,126*
Mandatory User Fees FTE	**0**	**0**	**16**	**16**

The FDA Human Drugs Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act of 1944 (42 U.S.C. 201)
Federal Advisory Committee Act (FACA) of 1972 as amended
Orphan Drug Act of 1983 (21 U.S.C. 360ee)
Drug Price Competition and Patent Term Restoration Act of 1984 (Section 505(j) 21 U.S.C. 355(j)) (a.k.a. “Hatch Waxman Act”)
Prescription Drug Marketing Act (PDMA) of 1987 (21 U.S.C. 353)
Anti-Drug Abuse Act of 1988
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Orphan Drug Amendments of 1988

Generic Drug Enforcement Act of 1992
Prescription Drug User Fee Act (PDUFA) of 1992
FDA Export Reform and Enhancement Act of 1996
Food and Drug Administration Modernization Act (FDAMA)* of 1997
\Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Best Pharmaceuticals for Children Act (BPCA) of 2002
Freedom of Information Act (FOIA) as amended in 2002 (5 U.S.C. § 552)
Pediatric Research Equity Act (PREA) of 2003
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Food and Drug Administration Amendments Act (FDAAA) of 2007*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA Human Drugs Program is responsible for ensuring that prescription, generic, and over-the-counter (OTC) drug products are adequately available to the public and are safe and effective. The program is also responsible for monitoring marketed drug products for unexpected health risks, and for monitoring and enforcing the quality of marketed drug products.

Responsibilities and functions carried out by the Center for Drug Evaluation and Research (CDER) can be traced back to the earliest days of the Food and Drug Administration (FDA) and the 1906 Pure Food and Drugs Act. Largely in response to the deaths of 107 people who took Elixir Sulfanilamide, which contained diethylene glycol, Congress enacted the Food and Drug Cosmetic Act in 1938, legislation that required that new drugs be shown to be safe before marketing. That legislation and the Drug Amendments Act of 1962 (the "Kefauver-Harris Act"), which stipulated that a drug be "effective for its intended use," form the cornerstones of CDER's mission: to assure that safe and effective drugs are available to the American people.

In the 1990s, Congress focused on ensuring the timeliness of drug product application reviews and drug approvals for marketing. In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA) which essentially doubled FDA's resources to review applications. Most recently, the provisions of the Food and Drug Administration Amendments Act (FDAAA) of 2007 increases CDER's authorities for ensuring a more robust program for monitoring drug products after they have been approved for marketing.

The Human Drugs Program operates with funding from both appropriations and user fees. The PDUFA legislation of 1992 first authorized FDA to collect user fees from the pharmaceutical industry, and that authority was reauthorized by the Food and Drug Modernization Act (FDAMA) of 1997, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and most recently, by FDAAA.

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The Human Drugs Program conducts its activities with assistance from the Office of Regulatory Affairs (ORA). ORA provides FDA leadership on enforcement, import, inspection, and laboratory policies. Through its field offices nationwide, ORA supports the Drugs Program by conducting risk based domestic and foreign pre-market and post-market inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMPs). In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. ORA's Field Drugs program is funded by appropriated and user fee dollars.

The Human Drugs Program executes its regulatory responsibilities in three areas: new drug safety and effectiveness, generic drug review, and post-market safety and surveillance.

New Drug Safety and Effectiveness — Center Activities

The process for approving drug products by reviewing the product's safety and effectiveness begins with the drug 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. This area encompasses the activities CDER is responsible for prior to a drug being approved for marketing – otherwise known as "pre-market" activities.

CDER's new drug review process encompasses all activities associated with reviewing investigational new drugs (INDs), new drug applications (NDAs), biologics license applications (BLAs), supplements to new applications, and any amendments filed to application submissions. CDER evaluates NDAs while giving products for diseases such as cancer and Acquired Immune Deficiency Syndrome (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 has consistently met its performance target of reviewing and acting upon 90 percent of "priority" NDAs/BLAs within six months. In FY 2006, CDER met or exceeded all of the PDUFA review performance goals, including exceeding the goal for reviewing priority NMEs and new BLAs.

In 2007, CDER approved a total of 88 new products, including 87 NDAs and 1 BLA, 17 of which were new molecular entities (NMEs), unique new compounds that previously have not been approved by FDA. Significant approvals in 2007 included Aricept® (donepezil HCl), the first product for the treatment of all degrees of severity of Alzheimer's Disease; Lyrica® (pregabalin), the first drug approved to treat fibromyalgia; Selzentry® (maraviroc), the first member of a new class of drugs to treat HIV-1; Tykerb® (lapatinib), a new treatment option for patients with metastatic breast cancer; and Solaris® (eculizumab), the first drug approved to treat paroxysmal nocturnal hemoglobinuria, a rare blood disorder.

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. These drugs play an increasingly vital role in America's health care system. The trend to self-medicate has increased greatly in recent years as health care costs have risen and consumers want to be empowered to treat minor ailments with OTC drug products.

OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients and the dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet uniform criteria. CDER has maintained high performance by routinely exceeding its targets for completing review and action on 100 percent of applications to switch a prescription drug to OTC status and for making significant progress on developing new OTC monographs.

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. CDER has consistently exceeded its performance targets for increasing the number of drugs that are adequately labeled for children and ensuring the surveillance of adverse events in the pediatric population. One way CDER measures that performance is by tracking the number of written requests, or formal requests to drug sponsors to conduct pediatric studies for a drug product. In 2007, CDER issued a record 30 written requests, an unprecedented performance level.

CDER 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. CDER also works to ensure that terrorists do not use regulated drug and therapeutic biological products as vehicles of terrorism against Americans. CDER has consistently exceeded its performance target of increasing the number of medical countermeasures available. As an example, in 2007, CDER approved Cyanokit® (hydroxocobalamin), a new medical countermeasure for the treatment of known or suspected cyanide poisoning.

A large part of CDER's public health missions involves ensuring that companies market only the highest quality products. CDER ensures drug product quality by facilitating effective and efficient scientific assessment of relevant pharmaceutical and biotechnology information in regulatory applications submitted to FDA. CDER facilitates scientific and technological innovations that improve understanding of product performance, quality, and efficiency of development, manufacturing, and quality assurance processes. CDER uses a risk-based compliance inspection model for prioritizing inspections according to the risk to product quality. CDER evaluates its inspection findings for trends in deficiencies, focusing on product quality standards and manufacturers' compliance with good manufacturing practices (GMP) regulations. In FY 2007, CDER its goal of inspecting 500 foreign and domestic establishments identified as high-risk human drug manufacturers by inspecting 577 high-risk firms.

New Drug Safety and Effectiveness — Field Activities

The Food, Drug, and Cosmetic Act provides that FDA may approve a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) only if the methods and facilities used for the manufacture, processing, and testing of the drug are found adequate to ensure its strength, quality, and purity.

After CDER scientists review NDA and ANDA applications, ORA examines the adequacy of the firms' facilities to verify their ability to manufacture the product to the specifications stated in the application. ORA also confirms the authenticity of the data contained in the application and reports any other information which may impact on the firm's ability to manufacture the product in compliance with Current Good Manufacturing Practices. Inspectional coverage is necessary to assure that new drug applications are not approved if the applicant has not demonstrated an ability to operate with integrity and in compliance with all applicable requirements.

In support of the President's Emergency Plan for AIDS Relief (PEPFAR), ORA conducted 30 foreign inspections associated with AIDS product approval applications in FY 2007. These inspections supported an expedited review process to help ensure that those being served by the President's Plan would receive safe, effective, and quality manufactured antiretroviral drugs.

ORA also performs bioresearch monitoring inspections to verify that studies submitted in support of the safety and effectiveness of products being reviewed are properly conducted so that FDA can be assured that study results are scientifically valid. Inspections also help ensure that the rights and welfare of people participating in studies are protected.

Generic Drug Review — Center Activities

Generic drugs are widely known to be a cost-effective treatment alternative, costing consumers 20-70 percent less than brand-name drugs. According to the Congressional Budget Office, they save consumers an estimated $8 billion to $10 billion a year compared with the price of brand-name products. The basic requirements for approval of generic and brand-name drugs are the same as new drug approvals, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of the original product. Prior to approval, generic drug sponsors are required to demonstrate bioequivalence to the innovator drug product by showing that the active ingredient in their product is absorbed at a rate and extent similar to the innovator counterpart.

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. 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 Office of Generic Drugs (OGD) within CDER has experienced a dramatic increase in workload, with the number of generic drug applications (known as abbreviated new drug applications or ANDAs) almost doubling over the past 4 years at a time when staffing levels

have increased less than 20 percent. For example, in FY 2007, CDER approved or tentatively approved 682 applications.

To measure its performance, CDER tracks the number of total actions taken on ANDAs. The total number of actions includes approvals, tentative approvals, not approvable, and approvable actions on applications. CDER took 1779 actions in FY 2007, an over 20 percent increase in performance over the number actions taken in FY 2006.

In FY 2007, CDER approved or tentatively approved 682 new generic drugs, a 33 percent increase over the previous year. Among those approvals were a number of first-generics providing lower-cost alternatives to brand products including: Metoprolol Extended Release Tablets (generic competitor to Toprol-XL®), Zolpidem (Ambien®); Albuterol and Ipratropium Inhalation Solution (Duoneb®); Ondansetron (Zofran®); Oxybutynin Extended Release Tablets (Ditropan XL®) and Terbinafine (Lamisil®). The approved generic total also included nevirapine, the 51st anti-retroviral drug approved as part of the President's Emergency Fund for AIDS Relief (PEPFAR), a five-year, $15 billion program for combating the disease in the most affected countries.

Generic Drug Review — Field 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. In FY 2007, ORA conducted 83 domestic and 140 foreign Pre-approval Inspections intended to ensure that FDA-regulated generic drugs meet requirements outlined in the Federal Food, Drug, and Cosmetic Act as to the safety, quality, and purity of the product. This supports the availability of high-quality generic drug products and provides consumers an additional option to save money on their prescription drug needs.

Post-market safety and surveillance — Center Activities

FDA must be vigilant to protect Americans from injuries and deaths caused by unsafe, illegal, fraudulent, substandard, or improperly used products. 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; therefore, a degree of uncertainty always exists about the risks of drugs. If FDA detects any new and unexpected health risks, CDER takes steps to inform the public and change how a drug is used, and when necessary, remove a drug from the market. FDA also monitors the promotion of drug and biologic products to assure the public that information provided presents a fair balance of risks and benefits and is not false or misleading. A primary function of post-market drug surveillance involves a team of epidemiologists and safety evaluators who collect and analyze data regarding drug usage and side effects. CDER collects and stores this data in its Adverse Event Reporting System (AERS), which houses millions of adverse event reports. The number of Adverse Events (AEs) submitted to CDER annually reached over 450,000 in FY 2007 and is projected to be over 600,000 by FY 2009. 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. CDER 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. CDER monitors potentially fraudulent Internet sites to identify targets for investigation and sampling of products. CDER consults with industry and coordinates FDA program activities to alleviate drug shortages in the U.S. market. 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.

The Food and Drug Administration Amendments Act (FDAAA) of 2007 for the first time recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is moving toward establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way that pre-market issues are tracked according to PDUFA requirements.

Over the past few years, FDA has been leading an aggressive effort to improve the management of important drug safety issues. FDA has implemented significant reforms that have improved how it manages safety issues and communicates information about the benefits and risks of drugs to physicians and patients. Examples of these efforts are many. FDA created the Drug Safety Oversight Board (DSOB) in FY 2005 to provide oversight and advice to the CDER Center Director on the management of important drug safety issues. FDA revised the format of prescription drug information, commonly called the package insert, to give healthcare professionals clear and concise prescribing information. CDER has conducted extensive process improvement efforts to ensure standards and consistency for post-marketing safety monitoring across its Office of New Drugs (OND) and to strengthen collaboration between OND and CDER's Office of Surveillance and Epidemiology. CDER launched a new *Drug Safety Newsletter* that provides information for healthcare professionals about the findings of selected post-marketing drug safety reviews, important emerging drug safety issues, and recently approved new drugs. CDER developed a safety tracking system to provide a platform to manage assignments, requests for information, consult requests, and due dates related to safety issues.

These recent activities, combined with additional resources provided both in appropriations and user fees, provide a foundation for and position CDER for putting a necessary focus on post-marketing drug surveillance. The original 1992 PDUFA legislation began a period of unprecedented accountability for the new drug review program by calling for institutionalizing regulatory project management and prioritizing and tracking pre-market review activities.

Drawing from lessons learned from previous regulatory modernization initiatives such as PDUFA, CDER is now able to turn its attention to transforming the post-market drug safety program.

Post-market safety and surveillance – Field Activities

ORA's role in reducing injuries and deaths associated with marketed products has several components. The first component involves reviewing adverse event and complaint files at manufacturers during inspections to determine if the firm is submitting all adverse drug event reports to FDA in accordance with regulatory time frames.

ORA also conducts follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. The final component involves 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.

At present, there is an accelerating growth in the number of new Web sites marketing FDA-regulated products to the U.S. consumer and medical professionals. The Office of Criminal Investigations (OCI) is expanding its efforts to develop cases that address the marketing of counterfeit products. OCI activities include monitoring potentially fraudulent Web sites to identify targets for investigation and sampling of products; conducting "undercover only" purchases of prescription drugs from Web sites suspected of engaging in illicit drug sales, distribution, and/or marketing; and, providing oversight of mail and courier packages entering the U.S. from foreign sources.

In addition, ORA and the Federal Trade Commission (FTC), working with government agencies in Mexico and Canada, conducted a joint enforcement campaign to stop deceptive Internet promotions of fraudulent products to treat or cure diabetes. Over 180 Warning Letters and other advisories were sent to online outlets in the three countries. FTC issued Warning Letters to 84 domestic sites and ORA followed with Warning Letters to 24 sites. Most of the firms warned by FDA removed the violative claims or products. Follow-up enforcement activities with the few noncompliant sites continue. The initiative included a new consumer education campaign to teach consumers how to recognize and avoid phony diabetes cures and to check with their doctor, nurse or pharmacist before trying any new health product.

In support of CDER's monitoring of the safety of drugs once they are on the market, ORA performed 583 domestic and foreign high-risk drug inspections in FY 2007.

Five Year Funding Table with FTE Totals

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2005 Actual	$482,134,000	$291,484,000	$190,650,000	2,918
2006 Actual	$508,905,000	$297,715,000	$211,190,000	2,947
2007 Actual	$543,565,000	$315,138,000	$228,427,000	2,915
2008 Enacted	$680,269,000	$353,269,000	$327,000,000	3,164
2009 Estimate	$738,723,000	$357,991,000	$380,732,000	3,456

Budget Request

The FY 2009 President's Budget requests $738,723,000 in program level funding for the Human Drugs Program, including the support of 3,456 FTE. The Field portion of the request is $99,465,000, supporting 636 FTE. The request represents an increase of $58,454,000 (or 8.6 percent) over the FY 2008 enacted level in budget authority and user fee amounts. The overall increase provides additional budget authority to cover a cost of living pay increase for the Human Drugs Program.

Modernizing Medical Product Safety and Development Initiative

The FY 2009 budget request for the Medical Product Safety and Development Initiative is $360,281,000, an increase of $7,012,000 over the FY2008 enacted level. Base funding for human drug review and safety encompasses the entire Human Drug program for ensuring the safety and effectiveness of America's drug supply. Critical activities are focused in three areas: new drug safety and effectiveness, generic drug review, and post-market safety and effectiveness activities.

The FY 2009 budget requests $7,012,000 for the Medical Product Safety and Development Initiative. Of this amount, $5,756,000 is for the pay raise and $1,256,000 is the Human Drugs program portion of the initiative that will fund implementation of the President's Import Products Safety Action Plan. The CDER portion of the pay raise is $3,868,000 and the Field portion of the pay raise is $1,888,000. The cost of living pay raise will contribute to maintaining the Results Act performance targets and other workload outputs at the FY 2008 levels.

With the payroll funding increase, the Human Drugs program will sustain its performance for FY 2009. For 2008, CDER will continue to review and act upon standard and priority applications within the PDUFA-required timelines. CDER expects to continue that performance in FY 2009. In FY 2008 and FY 2009, CDER expects to sustain its new generic drug approval performance from FY 2007 when CDER approved 682 new generic drugs, a 33% increase over FY 2006.

Within the generics program, CDER expects to hire additional staff in FY 2008; therefore, by FY 2009, when CDER realizes the full performance level of the increased staff, the generic drug review program is targeting an FY 2009 increase in ANDA actions (which can include approvals, tentative approvals, and non-approvals). In FY 2008 and FY 2009, CDER will work to balance its focus on drug safety before and after drugs are approved for marketing. With increased resources both in appropriations and user fees in FY 2008, CDER will work to establish procedures and tools to manage safety post-market safety issues in ways similar to how pre-market issues are tracked according to PDUFA requirements.

The funding for pay will allow ORA to maintain new investigative FTE hired during the FY 2007 hiring initiative. These FTE will perform an additional 23 domestic drug Good Manufacturing Practice (GMP) inspections, 50 foreign pre-approval inspections, 11 foreign bioresearch monitoring inspections, and 64 foreign GMP inspections.

The Modernizing Medical Product and Safety initiative allocated an increase of $1,256,000 to the Field Drugs Program. This increase will allow the Field to support three new agents to strengthen the Office of Criminal Investigations (OCI) ability to investigate criminal drug import violations and the necessary support equipment. The volume of drugs imported into the United States is estimated to increase by 12 percent in FY 2009, heightening the need for import surveillance activities. The funds strengthen FDA's ability to regulate foreign drugs and decrease the probability of unsafe or counterfeit drug products entering the U.S. marketplace that could adversely affect the health of the American consumer.

Administrative Savings and Management Efficiencies

In FY 2008, CDER will move another significant segment of the Center to the White Oak campus. With that move, CDER will have consolidated nearly 85 percent of the Center's staff at White Oak and will have reduced the number of buildings once occupied by CDER employees from 17 to 6. As a result of that consolidation, CDER expects to achieve by FY 2009 an administrative savings of -$1,765,000 in reduced operating costs to the Center as a result of having staff consolidated primarily in one location, and of having brand new state-of-the-art equipment and facilities.

Recent hires of administrative and support staff allow ORA to increase inspectional time previously lost to administrative duties and increase the efficiency in performing administrative tasks. Additionally, ORA will realize management efficiencies through a more streamlined laboratory approach that will improve the productivity of existing FTE within ORA labs. Increases in efficiency as a result of these recent hires and new laboratory methods will allow the Field Drugs program to reallocate -$525,000 in savings to activities of a higher priority.

User Fees Increase

In September 2007, the President signed into law the FDA Amendments Act of 2007. The collection of user fees for the regulatory review of prescription drug products was authorized for the fourth time by that legislation. PDUFA IV enhances pre-market review and gives FDA more resources to create a modern post-market drug safety system that follows products across their full life cycle. Changes in the PDUFA IV package include a change in the workload adjuster to better reflect the IND workload, an adjustment for rent activities and the addition of $12,170,000

in fees and 22 FTE for review of direct-to-consumer television advertisements.. Additionally, the proposal contains a change in the CPI factor to October to better correspond to our budgeting process and the addition of an inflation factor to reflect the five-year average of FDA's salary and benefit costs.

PDUFA user fees help the Human Drug Program speed review of applications for new drug products. The Human Drug Program speeds product development by publishing industry guidance to improve the quality of applications and improve procedures and standards so that reviews are more rigorous, consistent, and predictable. This makes innovative medical treatments available to patients faster with greater assurance of safety, effectiveness, and quality. User fees also enable the Human Drug Program to conduct pre-market inspections, including bioresearch monitoring inspections.

Generic Drugs Proposed User Fees

FDA is requesting $15,034,000 and 34 FTE to support CDER's review of generic drug applications. Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering public and private 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 by the proposed generic user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Human Drugs Outputs / Outcomes Table

#	Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.									
1.1	Percentage of Standard NDAs/BLAs within 10 months. (223201) (Output)	97% of 94	99% of 73	90%	95% of 90	90%	11/08	90%	90%
1.2	Percentage of Priority NDAs/BLAs within 6 months (223202) (Output)	96% of 28	88% of 32	90%	97% of 29	90%	11/08	90%	90%
2	Number of Written Requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. (223101) (Output)	NA	12/14	8/8	18/12	7/7	30/13	8/8	7/7
3	The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205) (Output)	1361	1496	NA	1456	NA	1779	1780[†]	1900
4	Percentage of Rx-to-OTC Switch applications within 10 months receipt in which there was a complete review action. (223206) (Output)	100%/8	100%/17	100%/6	100%8	100%/5	100%/9	100%/5	100%/5
5	Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007. (223207) (Outcome)	2/08	2/09	NA	2/10	514 Days	2/11	NA	NA
6	Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007. (223208) (Outcome)	16.0 months	17.8* months	NA	5/09	16.4* months	5/10	NA	NA

[†] New measure for FY 2008 to better reflect FDA's current program management challenge to increase throughput and productivity to address the higher workload while maintaining standards of quality and safety.

Long-Term Objective 2: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.									
7	Number of medical countermeasures in which there has been coordination and facilitation in development (223102) (Output)	NA	11	5	6	4	4	5	4
Long-Term Objective 3: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
8	Improve the Safe Use of Drugs in Patients and Consumers (222301) (Output)	NA	Reviewed and provided comments on 100% of RiskMAPs for NMEs or products FDA or sponsor initiated discussions	Stand-ardize Agency processes and criteria for commun-icating risk inform-ation.	Stand-ardized communi-cation processes.	Imple-ment safety issue tracking system.	Imple-mented.	Conduct pilot and act upon 50% of issues within timelines‡	Act upon 60% of issues within timelines
9	Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201) (efficiency goal)	$19.30 per report	$17.35 per report	NA	$16.47 per report	$15 per report	2/08	$13/per report	$13/per report
10	Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202) (Outcome)	4.4%	9.4%	NA	13.2%	12.5%	8/08	NA	NA
11	Number of foreign and domestic high-risk human drug inspections. (224201) (output)	481	600	483	510	500	583	500	600

*The reported results represent a three year average calculated using cohort data from the reported year and the two prior years.

1. Percentage of Standard NDAs/BLAs and Priority NDAs/BLAs within 10 months.
(223201 and 223202)

Context: This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes new drug and biologics licensing applications. Central to that focus is FDA's commitment to meeting PDUFA goals and requirements. The Food and Drug Administration Amendments Act of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. A key determinant in knowing if CDER is effective and efficient is to measure the time to "first action." The first action is the first regulatory action CDER takes (complete response, approvable, not approvable, or approval letter) at the end of the review of the original NDA/BLA submission (the first review cycle).

‡ FY 2008 target revised. CDER has standardized communication processes. FDAAA gives FDA substantial new resources for medical product safety so CDER is increasing its staff resources for tracking, managing, and monitoring safety issues.

The "first action time" refers to the time it takes to review and take an action on the original submission. This statistic is different from "total approval time" which is the time it takes from the original receipt of the application until it is approved, which may take more than one review cycle. "Total approval time" includes time spent reviewing an application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the complete response or approvable/not approvable letter(s) and to re-submit the application for review. CDER's featured targets under this performance goal are to measure time to first action for "priority" submissions and "standard" submissions. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: CDER will not have the final performance numbers for the FY 2007 submission cohort until November 2008. The latest information on CDER's performance toward the targets for this performance goal is from FY 2006. In FY 2006, CDER met or exceeded all of the PDUFA review performance goals, including exceeding the goals for reviewing priority and standard NMEs and new BLAs.

2. Number of Written Requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. (223101)

Context: The context of the Pediatric Program's performance goal in CDER covers the activities and requirements of the various laws passed to ensure safe and effective drug products are available for children, including the Best Pharmaceuticals for Children Act (BPCA), which provides incentives to manufacturers who conduct studies in children including a 6-month extension of marketing exclusivity for conducting pediatric studies requested by FDA, and the Pediatric Research Equity Act (PREA) which provides FDA the authority to require pediatrics studies for certain new and already marketed drug and biological products.

Performance: The target for FY 2007 performance was to issue at least 7 written requests to drug sponsors for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for 7 drugs that receive pediatric exclusivity. CDER issued 30 Written Requests to sponsors: 28 for on-patent drugs and 2 for drugs on NIH's annual Priority List, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committee meetings on adverse events for 13 drugs that received pediatric exclusivity.

3. The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205)

Context: The Office of Generic Drugs (OGD) has experienced a dramatic increase in workload, with the number of generic drug applications almost doubling over the past 4 years at a time when staffing levels have increased less than 20%. Consequently, the previous measure (the percentage of new applications for which first action is taken within 180 days) no longer reflects FDA's current program management challenge to increase throughput and productivity to

address the higher workload while maintaining standards of quality and safety. Therefore, FDA has determined that a more meaningful performance goal for the generic drug program is the number of total actions taken on abbreviated new drug applications. The total number of actions includes approvals, tentative approvals, not approvable, and approvable actions on applications.

Performance: In FY 2008, we hope to remain near the FY 2007 performance level with a target of 1780 actions. During this time, OGD will move to the FDA White Oak campus, which is expected to cause a disruption in productivity. Also, OGD operated under a Continuing Resolution during the first quarter of FY 2008, which has also caused a delay in hiring and training new staff for the program. In FY 2009, the target is 1900 actions, an increase of almost 7%. This reflects both the estimated increase in performance as new staff that are expected to be hired in FY 2008 are trained and achieve full performance levels, as well as the estimated increase in performance due to increased staffing levels proposed for FY 2009. At the time this budget was developed, FDA and industry are in discussions about the terms of a generic drug user fee program that could begin in FY 2009.

4. Percentage of Rx-to-OTC Switch applications within 10 months receipt in which there was a complete review action. (223206)

Context: OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients and the dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet the same, uniform criteria. Final monographs (agency final rules) need to be completed for a number of large product categories (e.g., external analgesics, internal analgesics, antimicrobials, oral health care products, laxatives). In the next 5 years, FDA plans to complete the initial review of OTC monographs for 29 categories of drug products, thereby eliminating all unsafe and ineffective products from the OTC market. The ability to reach these goals will depend on maintaining experienced staff in all facets of rulemaking development and improvement in the efficiency of the FDA document clearance process.

Performance: FDA exceeded its 2007 target by completing review and action on 100% of Rx-to-OTC switch and direct to OTC applications within 10 months of receipt and making significant progress on 9 OTC monographs: (1) Internal Analgesic, Antipyretic, and Antirheumatic Drug Products - Organ Specific Warnings (proposed rule published 12/06); (2) OTC Vaginal Contraceptive Products Containing N9 - Required Labeling; (3) Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products - Nasal; Decongestants, Phenylephrine (subject of Advisory Committee discussion 12/07); (4) Insect Repellant-Sunscreen Drug Products (request for data published 2/07); (5) Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products (final rule published 3/07); (6) Sunscreen Drug Products (proposed rule published 8/07); (7) Topical Antimicrobial Drug Products - Healthcare and Consumer Antiseptics; (8) Labeling for OTC Drug Product - Convenience Size Labeling Rule (proposed rule published 12/06); and (9) Laxative Drug Products, Granular Psyllium Warning (final rule published 3/07).

5. Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007. (223207)

Context: Reducing unnecessary delays in the approval time for safe and effective drugs that truly represent new therapies [i.e., new molecular entities (NMEs) and biologics] means earlier patient access for these medicines. Reducing unnecessary delays in drug approval also helps to both control the cost of new drug development, cited as a factor affecting the cost to consumers, and supports market competition among innovators. This is both good for the drug industry and good for consumers. New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition both from new drugs with therapeutic value – but not blockbuster potential, and new innovators that don't have access to the capital available to more established pharmaceutical companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated, helping speed patient access to new drugs, and reducing the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty. The targeted reductions in this FDA outcome goal represent approximately 10.5 percent reductions in total FDA review times for priority and standard NMEs and BLAs. Using Tufts estimates of potential cost reductions by phase of drug development, a 10 percent reduction in regulatory review time yields a 1.6 percent reduction in total capital costs, now estimated at $802 million, translating to a savings of $12.8 million per NME approved.

Performance: The FDA approval time for the fastest 50 percent of standard NME and biologics licensing applications (BLAs) approved in CDER and CBER for the FY 2001-2003 cohort is 523 days as compared to 575 days for the baseline FY 1999-2001 submission cohort. This is a reduction of 52 days versus the FY 2005-2007 target of a reduction of 61 days. An update of progress on this goal for the FY 2004 submission cohort is not expected until January 2008.

6. Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007. (223208)

Context: FDA achievement of this goal will create earlier access to lower cost drug alternatives for patients. The high cost of drugs limits patient access to treatment. The lower income and uninsured populations are particularly affected. Research has shown that 42 percent of the uninsured do not fill prescriptions because of financial reasons. The Center for Medicaid and Medicare Services has stated that the new Medicaid prescription drug coverage has come in under budget and points to the availability of more generic products as a factor in this outcome. Increasing the availability of generic drugs will make many important treatments more affordable to the poor and the elderly and significantly improve access to treatment. Optimal access and use of generic drugs will enable policy decision makers to contain costs in both the Medicare and Medicaid programs. This will only become more important as more of the top selling brand name drugs go off patent over the next few years.

Performance: The FDA approval time for the fastest 70 percent of original generic drug applications approved for the FY 2003-2005 cohort is 17.8 months as compared to 17.9 months

for the baseline FY 1998-2000 submission cohort. This is an increase from the FY 2002-2004 cohort of 16.0 months. Despite the exponential increase in receipts, new resources to manage the increased workload have increased only marginally.

7. Number of medical countermeasures in which there has been coordination and facilitation in development. (223102)

Context: In the Federal Government's response to a biological, chemical, or radiological/nuclear attack or to a natural disaster, drugs will be mobilized from the CDC's Strategic National Stockpile (SNS). However, not all drugs in the SNS are FDA-approved as countermeasures against threat agents or emerging infections. FDA has been taking an aggressive and proactive approach to identify and facilitate development of new therapeutic options as well as to obtain information on existing approved drugs that may be used for an unapproved indication. For example, although gentamicin has not been FDA-approved for treatment of plague, it is widely recommended as a preferred therapy by experts. Human clinical trial data and animal efficacy data have been generated to determine the safety and efficacy of gentamicin for specific plague treatments. Identification of gaps in the therapeutic armamentarium and development of a plan to address these gaps will move the FDA closer to a goal of labeling all drugs that reside in the SNS for counterterrorism uses. FDA is also active in department and agency efforts to prepare for other emergencies, such as natural disasters and pandemics.

Performance: CDER facilitated the development of and access to medical countermeasures for counterterrorism and emerging infections through these actions:

- **Cyanokit** (hydroxocobalamin) was approved as an antidote to cyanide poisoning. The kit contains the drug hydroxocobalamin, intravenous tubing, and a sterile spike for reconstituting the drug product with saline. Approval of this product improves the nation's ability to respond to emergencies, including potential terrorist attacks.
- A supplement for **Tamiflu** (oseltamivir phosphate) was approved to provide instructions for pharmacists for the preparation of a suspension using the contents of Tamiflu capsules in an emergency setting, when the commercially manufactured oral suspension is not available. CDER also approved Tamiflu 30 mg and 45 mg capsules for the treatment of influenza. Previously, Tamiflu was available in 75 mg capsules and in an oral suspension for pediatric patients. These supplements for the lower dosage strengths also provide for carton and container labeling for the marketed product, Department of Defense stockpiles, state stockpiles, and the Strategic National Stockpile.
- Updated Home Preparation Instructions for **doxycycline** have been finalized and will be available for use by emergency response planners and public health personnel. In a terrorism event, if pediatric dosage forms are not available, tablets or capsules can be crushed with food.
- Enrollment for the third and final year of the CDER/CDC collaboration on human trials of **gentamicin** in plague in Africa has been completed. Efforts continue with NIH/NIAID and USAMRIID on monkey studies of gentamicin, ciprofloxacin, levofloxacin, ceftriaxone, and doxycycline in pneumonic plague.

8. Improve the Safe Use of Drugs in Patients and Consumers. (222301)

Context: CDER is working toward a policy of more transparency to ensure that patients and physicians have the most up-to-date and complete information necessary to make their treatment decisions. The Food and Drug Amendments Act (FDAAA), sweeping new legislation signed by the President in September 2007, for the first time recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is moving toward establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way that pre-market issues are tracked according to PDUFA requirements. Activities in FY 2006 and FY 2007 to standardize communications policies and procedures and to develop a tracking system to capture information about known and emerging safety issues established a foundation upon which CDER can now begin to build the capacity and capability to more effectively manage safety issues in a timely fashion.

Performance: In FY 2007, CDER met its target of establishing a tracking system for postmarketing safety issues. The safety application functions to track postmarketing safety issues as well as archive reviews, forms, and correspondence pertaining to the tracked issues. The system also has a report generating function so that managers can monitor active issues. CDER will be focusing its efforts in FY 2008 on increasing its staff resources for tracking, managing, and monitoring safety issues. The Center will be conducting a pilot for prioritizing safety issues, developing action plans and timelines for those issues, and monitoring and managing progress toward those plans. During the first year of this new process, CDER is targeting acting upon at least 50 percent of the identified priority safety issues within an established timeframe.

9. Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201)

Context: The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product to identify unexpected safety risks associated with the use of a human drug that could not have been predicted by clinical trials and biostatistical analysis. Reports of these unexpected safety problems, called adverse events, are captured in the Adverse Event Reporting System (AERS), a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. Information captured in AERS allows FDA scientists and statisticians to search for patterns that may indicate an emerging safety hazard, which is the first step in analyzing the potential causes and formulating an effective risk management response. FDA is working to make AERS more efficient by improving the data entry work processes and reengineering the system to increase the percentage of electronic submissions, to reduce the amount of manual re-keying, along with other efficiencies. These system improvements will allow the FDA to reduce the average cost and time associated with turning a

submitted Adverse Event Report into a verified record in the database. This improvement in efficiency will allow scientists and statisticians to access safety information sooner, and will free up resources that can be redirected to risk analysis activities that directly improve our ability to recognize and respond to drug safety problems.

Performance: The average cost associated with turning a submitted Adverse Event Report into a verified record in the database has been decreasing since FY 2003 due to FDA efforts to streamline its business processes and improve the information systems that are used to process records. In FY 2003, the cost per report was $21.91/per report. In FY 2004, the cost per report was $19.30/per report. In FY 2005, the cost per report was $17.35/per report. In FY 2006, the cost per report was $16.47/per report. FDA expects to achieve further improvements in efficiencies due to improved automation of the submission and validation processes, and outreach to improve adoption of electronic submissions. The proposed FY 2007 target of $15 per report represents almost a 32% reduction in cost per adverse event report compared to the FY 2003 level, not including inflationary impacts.

10. Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202)

Context: In November 1999, the Institute of Medicine released a report estimating that as many as 98,000 patients die from medical errors in hospitals alone. Many of these deaths, as well as additional non-fatal illnesses, are associated with errors involving FDA regulated medical products, especially medications. A significant percentage of drug related mortality and morbidity results from errors that are preventable. In addition to their human cost, these errors impose significant economic costs on the U.S. health care system. The total cost of preventable adverse events has been estimated at $17 Billion. Preventing some of the adverse drug events related to medication errors in U.S. hospitals will significantly reduce related morbidity, mortality and health care costs.

The Secretary of Health and Human Services directed FDA to promulgate the bar coding regulation to reduce preventable errors from medical products. This rule is expected to enable the uptake and use of bar code scanners that will allow a health professional to compare the bar code on a human drug product to a specific patient's drug regimen and then verify that the right patient is receiving the right drug, at the right dose, via the right route, at the right time. Research to date has demonstrated the ability of bar code scanners at the point of care to intercept errors in dispensing and administration of medications and thereby prevent related adverse events. Consequently, this measure tracks the adoption rate of bar code medication administration technology in hospitals, with the expectation that increased adoption rates will be directly related to decreased medication error-related adverse events.

Performance: The results of the American Society of Health-System Pharmacists (ASHP) 2006 annual survey of pharmacy practice in hospital settings (dispensing and administration) were published in 2007. Over the last few years the adoption rate of bar code medication administration technology has grown each year, up to 13.2% overall in 2006, with a slightly higher rate of adoption in larger hospitals. The differentiation between small and large hospitals is becoming less each year.

11. Number of foreign and domestic high-risk human drug inspections. (224201)

Context: FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2009. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way.

Performance: FDA exceeded the FY 2007 goal of 500 by inspecting 583 high-risk foreign and domestic drug manufacturers.

CDER Program Activity Data (PAD)

CDER Workload and Outputs	FY 2006 Actual	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
New Drug Review				
Priority New Drug Application (NDA/BLA) Reviews	42	31	32	32
Standard NDA/BLA Reviews	129	140	140	140
Priority NDA/BLAs Approved	27	21	22	22
Standard NDA/BLAs Approved	64	67	69	70
Time from Receipt to Approval (mos.)(mean)-Priority NDA/BLAs	7.4	9.9	10.0	10.0
Time from Receipt to Approval (mos.)(mean)-Standard NDA/BLAs	26.2	15.3	15.0	15.0
Time from Receipt to Approval (mos.)(median)-Priority NDA/BLAs	6.0	6.0	6.0	6.0
Time from Receipt to Approval (mos.)(median)-Standard NDA/BLAs	16.2	10.0	10.0	10.0
NDA Supplemental Reviews (NDAs only)	2,872	3,147	3,200	3,250
INDs (Active) (Drugs and Biologics—Commercial and Research)	13,881	14,820	15,020	15,270
Clinical Pharmacology/ Bio-Pharmaceutic Reviews	1,584	1,730	1,760	1,790
Biologic Therapeutics Review				
Total Original License Application (PLA/ELA/BLA) Reviews	5	5	7	7
PLA/BLA Approvals	5	1	2	2
License Supplement (PLA/ELA/BLA) Reviews	249	232	240	250
Commercial IND/IDE Receipts (Biologics Only)	114	98	99	99
IND/IDE Amendments Receipts (Biologics Only)	11,249	8,325	8,400	8,500
Generic Drug Review				
Abbreviated New Drug Application (ANDA) Receipts	79	880	800	800
ANDA Actions	1,456*	1779	1618	1
ANDA Approval Actions (both Tentative and Full Approvals)	510	682	700	700
Median Review Time from ANDA Receipt to Approval (months)	16.6	18.89	17.5[§]	17.5
ANDA Supplemental Actions (Labeling and Manufacturing)	4,577*	3720	3500	3000
* = administrative actions not counted				
Over-the-Counter Drug Review				
*OTC Monographs Under Development	28	15	12	12
*OTC Monographs Published	5	5	5	5

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

CDER Workload and Outputs	FY 2006 Actual	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
* Category includes Proposed Rules and Final Rules				
Best Pharmaceuticals for Children Act				
Approved Labels with New Pediatric Information	12	17	26	22
New Written Requests Issued	20	30	22	20
Pediatric Exclusivity Determinations made	14	14	20	22
Post Exclusivity Safety Report	12 drugs (2 A/Cs)	13 drugs (2 A/Cs)	12 drugs (2 A/Cs)	12
Patient Safety				
Adverse Event Reports	448,837	486,882	552,967	608,300
Percentage of Adverse Drug Reaction Reports Submitted Electronically (% of total)	35%	43%	55%	60%
Percentage of Serious/Unexpected Adverse Drug Reaction Reports Submitted Electronically	56%	70%	80%	85%
Drug Quality Reporting System Report	1,387	3371	3,600	3,600
Safety reviews completed by Office of Surveillance & Epidemiology	1,760	1863	1,900	2,000
Number of drugs with sheets (this combines HCP and PI sheets)	45	63	60-80	60-80
Administrative/Management Support				
Number of Advisory Committee Meetings	26	25	25	23
Number of FOI Requests	3,562	2984	3,600	3,200
Number of FOI Requests Processed	4,052	3676	4,200	3,900
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	92	83	100	120
Number of Citizen Petitions Completed** (excluding suitability petitions and OTC monograph-related petitions)	57	48	60	58
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	182	217	262	300

** Citizen Petitions completed may include petitions filed in prior years.

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
DOMESTIC INSPECTIONS			
Pre-Approval Inspections (NDA)	133	120	120
Pre-Approval Inspections (ANDA)	83	132	177
Bioresearch Monitoring Program Inspections	494	511	511
Drug Processing (GMP) Program Inspections	1,073	1,400	1,423
Compressed Medical Gas Manufacturers Inspections	74	127	127
Adverse Drug Events Project Inspections	89	122	122
OTC Monograph Project and Health Fraud Project Inspections	32	48	48
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	21	110	110
State Partnership Inspections: GMP Inspections	15	50	50
Total Above FDA and State Partnership Inspections	2,014	2,620	2,688
Domestic Laboratory Samples Analyzed	1,368	1,144	1,144
PROGRAM OUTPUTS-			
IMPORT/FOREIGN INSPECTIONS			
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	167	192	192
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	140	92	187
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	152	46	57 [1]
Foreign Drug Processing (GMP) Program Inspections	282	221	281
Foreign Adverse Drug Events Project Inspections	9	16	16
Total Above Foreign FDA Inspections	750	567	733
Import Field Exams/Tests	2,329	4,400	4,400
Import Laboratory Samples Analyzed	324	260	260
Import Physical Exam Subtotal	2,653	4,660	4,660
Import Line Decisions	312,392	348,953	389,792
Percent of Import Lines Physically Examined	0.85%	1.34%	1.20%

1. The estimate for FY09 Human Drugs ANDA inspections include Proposed Generic Drug User Fee inspections.