

HUMAN DRUGS

The FY 2010 program level budget request for the FDA Human Drugs Program is \$908,013,000.

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

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	\$708,288,000	\$680,926,000	\$777,437,000	\$908,013,000	\$130,576,000
Center	\$600,366,000	\$587,551,000	\$659,221,000	\$763,076,000	\$103,855,000
FTE	2,551	2,396	2,791	2,996	205
Field	\$107,922,000	\$93,375,000	\$118,216,000	\$144,937,000	\$26,721,000
FTE	677	600	699	763	64
Program Level FTE	3,228	2,996	3,490	3,759	269
Budget Authority	\$381,288,000	\$353,909,000	\$413,482,000	\$457,814,000	\$44,332,000
Center	\$280,282,000	\$266,269,000	\$302,386,000	\$329,588,000	\$27,202,000
Field	\$101,006,000	\$87,640,000	\$111,096,000	\$128,226,000	\$17,130,000
<i>Pay Increase (non add)</i>				\$6,697,000	\$6,697,000
<i>Safer Medical Products (non-add)</i>				\$33,635,000	\$33,635,000
<i>Drug Importation (non-add)</i>				\$4,000,000	\$4,000,000
Budget Authority FTE	1,880	1,712	1,945	2,026	81
Center	1,243	1,144	1,286	1,342	56
Field	637	568	659	684	25
User Fees	\$327,000,000	\$327,017,000	\$363,955,000	\$450,199,000	\$86,244,000
Center PDUFA	\$320,084,000	\$321,282,000	\$356,835,000	\$406,984,000	\$50,149,000
FTE	1,308	1,252	1,505	1,598	93
Field PDUFA	\$6,916,000	\$5,735,000	\$7,120,000	\$8,306,000	\$1,186,000
FTE	40	32	40	49	9
Proposed User Fees	\$0	\$0	\$0	\$34,909,000	\$34,909,000
Center Generic Drugs				\$26,504,000	\$26,504,000
FTE				56	56
Field Generic Drugs				\$6,045,000	\$6,045,000
FTE				12	12
Field Reinspection				\$2,360,000	\$2,360,000
FTE				18	18
User Fees FTE	1,348	1,284	1,545	1,733	188

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 the 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 the CDER 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 Amendments Act (FDAAA) of 2007 increases the Center’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 premarket and postmarket inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMP). 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 Office of Information Management (OIM) provides FDA’s leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Drug Program by maintaining its legacy systems and databases used for managing and tracking its drug review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also works with the Drugs Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

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 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 FY2008, CDER approved a total of 79 new products, including 75 NDAs and 4 BLAs, 21 of which were new molecular entities (NMEs), unique new compounds that previously have not been approved by FDA. Significant approvals in 2008 included Raltegravir®, the first agent of the pharmacological class known as HIV integrase strand transfer inhibitor, an important new product for many HIV-infected patients whose infections are not being controlled by currently available medications; Xenazine®, the first product for treatment approved for any symptom of Huntington’s disease.

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 healthcare system. The trend to self-medicate has increased greatly in recent years as healthcare 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 the same, 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 ensure 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 2008, CDER issued 5 Written Requests to sponsors for on-patent drugs and 19 drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity represents early indications of the impact of a shift in Center policy.

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. The Center 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. For example, in 2008, CDER approved Levaquin (levofloxacin) tablets, injection, and oral solution for inhalational anthrax (post-exposure) to reduce the incidence or progression in pediatric patients; the drug previously was approved to treat adults after exposure to inhaled anthrax. In addition, FDA awarded a

contract to study the optimal dosing regimen to be used to protect pregnant women and children after they have been exposed to anthrax.

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 GMP regulations. In FY 2008, CDER met its goal of inspecting 500 foreign and domestic establishments identified as high-risk human drug manufacturers by inspecting 534 high-risk firms.

New Drug Safety and Effectiveness—Field Activities

The Food, Drug, and Cosmetic Act states that FDA may approve an NDA or an 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 firm's 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 GMP. 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 and CDER conducted 45 foreign inspections associated with AIDS product approval applications in FY 2008. 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.

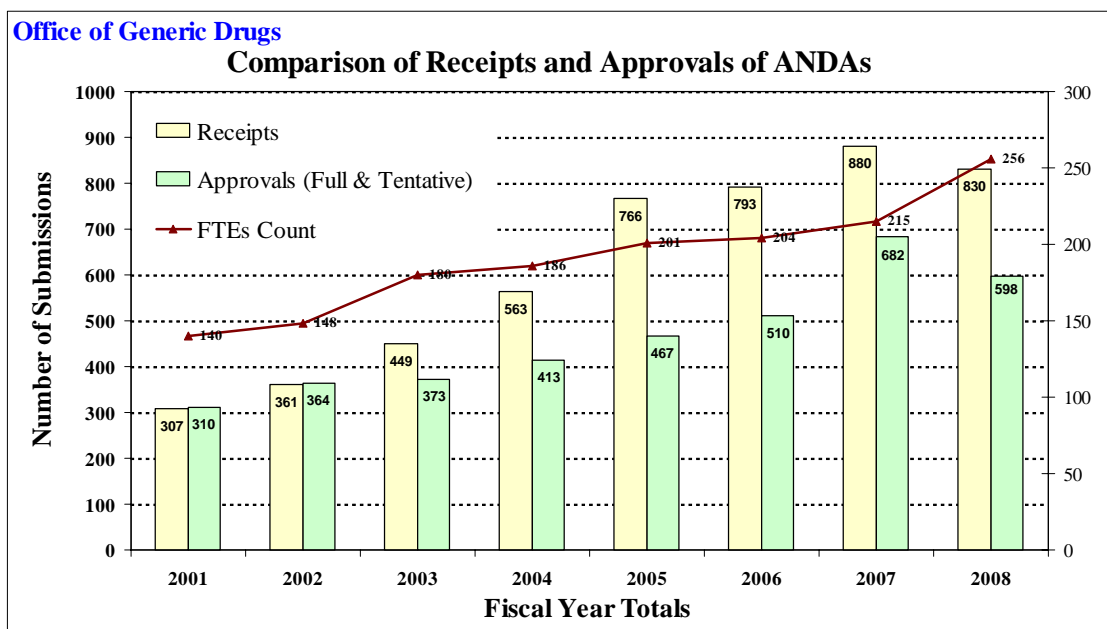
Generic Drug Review—Center Activities

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, generic drugs save consumers an estimated \$8 billion to \$10 billion a year compared to the price of trade-name products. The basic requirements for approval of generic and trade-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.

CDER has experienced a dramatic increase in workload with the number of generic drug applications or ANDAs almost doubling over the past 5 years at a time when staffing levels increased at a much lower rate. The following graph illustrates the increased workload demand and shows that in FY 2008, CDER approved or tentatively approved 598 applications, the equivalent of more than 2 approvals/tentative approvals made each business day of the year.



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 1934 actions in FY 2008 compared to 1779 in FY 2007.

Among the approvals in FY 2008 were a number of first-generics providing lower-cost alternatives to brand products including: Alendronate Tablets (generic competitor to Fosamax ®) for treatment of osteoporosis; Risperidone Tablets (generic competitor to Risperdal ®) for treatment of depression; Divalproex Sodium Delayed Release Tablets (generic competitor to Depakote ®) for seizure disorders; Ropinirole Tablets (generic competitor to Requip ®) – for treatment of restless leg syndrome; Galantamine Tablets (generic competitor to Razadyne ®) – for treatment of dementia associated with Alzheimer’s disease; Dorzolamide and Timolol Maleate Ophthalmic Solution (generic competitor to CoSopt ®) – for treatment of ocular hypertension.

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 GMP. In FY 2008, ORA conducted 132 domestic and 92 foreign site 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. As a result, 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. 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.

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). AERS houses millions of adverse event reports. The number of adverse events submitted to CDER annually reached over 522,871 in FY 2008 and is projected to be over 600,000 by FY 2010. 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, healthcare professionals, and consumers. Throughout this process, FDA works closely with manufacturers to see where streamlining can improve efficiency 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 FDAAA recognized 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. In FY 2008 CDER enhanced its capacity to oversee post-market drug safety

through increased staffing and the implementation of new post-market safety authorities under FDAAA. CDER's hiring efforts in this area are not complete but to date, there has been a 27 percent staffing increase in the Office of Surveillance and Epidemiology.

CDER has also utilized new drug safety authorities under FDAAA. FDAAA provides FDA new authority to require drug sponsors to submit a Risk Evaluation and Mitigation Strategy (REMS) when a drug first comes on the market, or later if FDA becomes aware of new safety data about the drug. REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product and requires the sponsor to submit post-marketing studies, or clinical trials to address safety issues. In March 2008, CDER identified 25 drugs whose sponsors were required to submit safety plans by September 21, 2008. In addition, CDER have approved 13 REMS for new drugs.

In 2008 CDER took significant safety actions to manage a very diverse set of safety concerns and risks in products used to treat a wide range of diseases. For example, FDA issued a Public Health Advisory recommending that over-the-counter cough and cold products should not be used to treat infants and children less than 2 years of age because of serious and potentially life-threatening side effects.

Over the past few years, FDA has been leading an aggressive effort to improve the management of important drug safety issues. These activities, combined with additional resources provided both in appropriations and user fees, provide a foundation for CDER placing the necessary focus on post marketing drug surveillance. The 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 prior regulatory modernization initiatives such as PDUFA, CDER is now able to turn its attention to transform the post-market drug safety program.

Post-market safety and surveillance - Field Activities

ORA's role to reduce injuries and deaths associated with marketed products has several components. The first component involves the review of 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.

In particular, the Office of Criminal Investigations (OCI) is expanding its efforts to develop cases that address the marketing of counterfeit products. The increasing globalization of crime has created new challenges to law enforcement. In February 2007, FDA issued a press release warning consumers that a number of Americans who placed orders for specific drug products over the internet instead received haloperidol, a powerful anti-psychotic drug. Some consumers became ill and had to seek medical attention. In March - April 2008, a Greek and an Egyptian

national was arrested by OCI for illegally importing and distributing counterfeit, misbranded and unapproved medications into the United States. OCI determined that the Greek national was responsible for shipping the haloperidol tablets to United States consumers; and these two individuals supplied and distributed counterfeit, misbranded, and unapproved drugs for an international illegal pharmaceutical distribution ring.

In support of CDER's monitoring of the safety of drugs once they are on the market, ORA performed 534 domestic and foreign high-risk drug inspections in FY 2008.

Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Human Drugs Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	\$508,905,000	\$297,715,000	\$211,190,000	2,947
FY 2007 Actual	\$543,565,000	\$315,138,000	\$228,427,000	2,915
FY 2008 Actual	\$680,926,000	\$353,909,000	\$327,017,000	2,996
FY 2009 Omnibus	\$777,437,000	\$413,482,000	\$363,955,000	3,490
FY 2010 Estimate	\$908,013,000	\$457,814,000	\$450,199,000	3,759

Budget Request

The FY 2010 budget request for the Human Drugs Program is \$908,013,000. It is an increase of \$130,576,000 above the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009.

Human Drugs Increase

Base funding for human drug review and safety encompasses all of the 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 postmarket safety and effectiveness activities.

With the payroll funding increase, the Human Drugs program will sustain its performance for FY 2010. For 2009, 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 2010. In FY 2009 and FY 2010, CDER expects to sustain its generic drug approval performance from FY 2008. In FY 2009 and FY 2010, CDER will balance its focus on drug safety before and after drugs are approved for marketing.

Cost of Living Pay Increase

The Human Drug Program's portion of FDA's requested pay increase is \$6,697,000. Of this amount, CDER's portion of this increase is \$4,435,000 and the Field portion of this increase is \$2,262,000.

Prescription Drug User Fees

With the enactment of the FDAAA in September 2007, the collection of user fees for the regulatory review of prescription drug products was authorized for the fourth time. PDUFA IV enhances premarket 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 PDUFA IV include a change in the workload adjuster to better reflect the IND workload, an adjustment for rent activities, and the addition of fees for direct to consumer advertising. In addition PDUFA IV

changed the CPI fiscal year to the Federal fiscal year to correspond to FDA's budget process, and modified the inflation factor calculation to reflect a five-year average of FDA's salary and benefit costs.

PDUFA IV user fees help the Human Drugs Program 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, and conduct premarket inspections, including bioresearch monitoring inspections.

Generic Drugs Proposed User Fees +\$32,549,000 and 68 FTEs

The proposed Generic Drugs User Fee program will modify the Food, Drug, and Cosmetic Act to permit the establishment of user fees for applications to market generic drugs (ANDAs), and to establish annual fees for approved generic products. The proposal will provide an initial investment in the generic drug review program by building an expanded capacity to protect the public health, promote public confidence in generic drugs thus sustaining the viability of the generic industry. The additional fees will enhance FDA's ability to conduct timely and complete reviews of generic drug applications with quality standards equivalent to the brand industry, and support the development of regulatory scientific standards for equivalence thus encouraging the further expansion of new generic drug alternatives in more complex dosage forms resulting in the lowering public and private spending on pharmaceuticals

Human Drugs Performance Measures Table

Long Term Objective: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

Measure	FY	Target	Result
<u>223201</u> : Percentage of Standard NDAs/BLAs within 10 months. (Output)	2010	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	88% (Target Not Met)
	2006	90%	95% (Target Exceeded)
	2005	90%	99% (Target Exceeded)
<u>223202</u> : Percentage of Priority NDAs/BLAs within 6 months. (Output)	2010	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	90% (Target Met)
	2006	90%	97% (Target Exceeded)
	2005	90%	88% (Target Not Met)
<u>223101</u> : 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. (Output)	2010	7/7	Nov 30, 2010
	2009	5/7	Nov 30, 2009
	2008	8/8	5/19 (Target Not Met)
	2007	7/7	30/13 (Target Met)
	2006	N/A	18/12 (Historical Actual)
	2005	N/A	12/14 (Historical Actual)
<u>223205</u> : The total number of actions taken on abbreviated new drug applications in a fiscal year. (Output)	2010	1900	Nov 30, 2010
	2009	1900	Nov 30, 2009
	2008	1780	1934 (Target Exceeded)
	2007	N/A	1779 (Historical Actual)
	2006	N/A	1456 (Historical Actual)
	2005	N/A	1496 (Historical Actual)

Measure	FY	Target	Result
<u>223206</u> : Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. <i>(Output)</i>	2010	100%/5	Nov 30, 2010
	2009	100%/5	Nov 30, 2009
	2008	100%/5	100%/9 (Target Met)
	2007	100%/5	100%/9 (Target Met)
	2006	NA	100%/8 (Historical Actual)
	2005	NA	100%/17 (Historical Actual)
<u>223207</u> : 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. <i>(Outcome)</i>	2007	514 Days	May 31, 2011
	2006	N/A	May 31, 2010
	2005	N/A	May 31, 2009
<u>223208</u> : 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. <i>(Outcome)</i>	2007	16.4 months	May 31, 2010
	2006	N/A	May 31, 2009
	2005	N/A	17.8 months (Historical Actual)
<u>223102</u> : Number of medical countermeasures in which there has been coordination and facilitation in development. <i>(Output)</i>	2010	4	Nov 30, 2010
	2009	4	Nov 30, 2009
	2008	5	6 (Target Exceeded)
	2007	4	4 (Target Met)
	2006	N/A	6 (Historical Actual)
	2005	N/A	11 (Historical Actual)

Long Term Objective: Improve information systems for problem detection and public communication about product safety.

Measure	FY	Target	Result
<u>222301</u> : Improve the Safe Use of Drugs in Patients and Consumers. <i>(Output)</i>	2010	Act upon 55% of issues within timelines	Nov 30, 2010
	2009	Act upon 50% of issues within timelines	Nov 30, 2009

Measure	FY	Target	Result
	2008	Conduct pilot and act upon 50% of issues within timelines	Conducted pilot and acted upon 50% of issues within timelines (Target Met)
	2007	Implement safety issue tracking system	Implemented (Target Met)
	2006	N/A	Standardized communication processes (Target Met)
	2005	N/A	Reviewed and provided comments on 100% of RiskMAPs for NMEs or products FDA or sponsor initiated discussions (Target Met)
<u>222201</u> : Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (Efficiency)	2010	\$12 per report	Nov 30, 2010
	2009	\$12 per report	Nov 30, 2009
	2008	\$13 per report	\$10.59 per report (Target Exceeded)
	2007	\$15 per report	\$13.64 per report (Target Exceeded)
	2006	N/A	\$16.47 per report (Historical Actual)
	2005	N/A	\$17.35 per report (Historical Actual)
<u>222202</u> : Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (Outcome)	2007	12.5%	19.6% (Target Exceeded)
	2006	N/A	13.2% (Historical Actual)
	2005	N/A	9.4% (Historical Actual)

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers

Measure	FY	Target	Result
<u>224201</u> : Number of foreign and domestic high-risk human drug inspections. (Output)	2010	700	December 31, 2010
	2009	600	December 31, 2009
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)
	2006	N/A	510 (Historical Actual)
	2005	N/A	600 (Historical Actual)

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). 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 2008 submission cohort until November 2009. The latest information on CDER's performance toward the targets for this performance goal is from FY 2007. In FY 2007, CDER met the PDUFA review performance goals for reviewing priority NDAs and BLAs, including meeting the goal for reviewing priority NMEs and new BLAs, but did not meet the PDUFA review performance goals for reviewing standard NDAs and BLAs, including not meeting the goal for reviewing standard NMEs and new BLAs. CDER met its FY 2007 performance target for priority reviews. However, CDER narrowly missed its target of 90% review of standard applications. CDER's 88% performance on standard applications represents early indications of the impact of a shift in Center policy to put equal emphasis on post-market safety review decisions as on pre-market review decisions.

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. In FY 2009, the targets are five written requests and seven drugs reported to the pediatric advisory committee.

Performance: The target for FY 2008 performance was to issue at least 8 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 8 drugs that receive pediatric exclusivity. CDER issued 5 Written Requests to sponsors for on-patent drugs, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committee meetings on adverse events for 19 drugs that received pediatric exclusivity. CDER's 5 Written Requests (WRs) issued for drugs and 19 drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity represents early indications of the impact of a shift in Center policy.

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, the Office of Generic Drugs exceeded its goal by more than 150 actions, while also exceeding the number of actions in FY 2007. In FY 2009, the target is 1900 actions, an increase of almost 7% over the FY 2008 target. This reflects the estimated increase in performance as new staff, hired in FY 2008, are trained and achieve full performance levels.

4. Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. (223206)

Context: OTC drug products can be legally marketed in the United States under an approved new drug application (NDA) or pursuant to an OTC drug monograph. OTC drugs can be approved under an NDA through an Rx-to-OTC switch or by direct to OTC. OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients, 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). FDA is working to review OTC monographs for 29 categories of drug

products to eliminate unsafe and ineffective products from the OTC market. The ability to reach these goals is contingent upon the addition of experienced staff in all facets of rulemaking development as well as improvement in the efficiency of the FDA document clearance process.

Performance: FDA exceeded its FY 2008 target by completing review and action on 100% of Rx-to-OTC switch and direct to OTC applications within 10 months of receipt. All Rx-to-OTC switch applications received in FY 2008 with action goal dates in FY 2008 were acted on within 10 months of receipt. There were 4 approval actions encompassing a total 7 switch products.

FDA made significant progress on the following 9 monographs: (1) Internal Analgesic, Antipyretic, and Antirheumatic Drug Products - Organ Specific Warnings, Final Rule (proposed rule published 12/06); (2) Pediatric Dosing for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products - Amendment of the Final Rule (Advisory Committee meeting held 10/18/07 ; Part 15 Hearing held 10/2/08) ; (3) UVA Testing and Labeling for OTC Sunscreen Drug Products, Final Rule (proposed rule published 8/07); (4) OTC Topical Acne Drug Products Containing Benzoyl Peroxide, Final Rule; (5) Vaginal Contraceptive Drug Products – Proposed Amendment to the Proposed Rule ; (6) Laxative Professional Labeling, Proposed Rule; (7) Topical Antimicrobial Drug Products - Consumer Antiseptics; (8) Labeling for OTC Drug Product - Convenience Size Labeling Rule (proposed rule published 12/06); and (9) Cold Cough Allergy, Bronchodilator and Antiasthmatic Drug Products – Labeling for Bronchodilators to Treat Asthma (Ephedrine Single Ingredient) Final Rule.

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. Performance for the FY 2004 submission cohort was 547 days.

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. In the last several years, submissions of abbreviated new drug applications have increased exponentially.

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. 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 medical countermeasures that reside in the SNS. For example, although ciprofloxacin and doxycycline are FDA approved for post-exposure prophylaxis of anthrax, these drugs are not recommended for use in children and pregnant women unless no other drug is available. Amoxicillin may be recommended as an alternative for these special populations, but it is not FDA approved and the optimal dose and dosing frequency are unknown. Hollow fiber studies with amoxicillin may provide data to develop appropriate dosing regimens. FDA is also active in department and agency efforts to prepare for other emergencies, such as natural disasters and pandemics. In FY 2009, the target remains at 4 countermeasures.

Performance: In FY 2008, CDER facilitated the development of and access to medical countermeasures for counterterrorism and emerging infections through these actions:

- FDA extended the expiry of **Tamiflu (oseltamivir)** capsules from 5 years to 7 years.
- FDA assisted the HHS/PHEMCE Radiological/Nuclear Integrated Program Team (R/N IPT) in preparing a White Paper for the Enterprise Executive Committee: “**Neupogen** in the Strategic National Stockpile to Address Neutropenia Associated with Acute Radiation Syndrome -- Issues Regarding Potential Use in an Emergency.”
- FDA provided comments to the Department of Health and Human Services (HHS) regarding a plan for anticipated information needs to support submission of an NDA for approval of a “**home MedKit**” containing antiviral drugs as a mitigation strategy for a potential influenza pandemic.
- **Levaquin (levofloxacin)** tablets, injection, and oral solution were approved for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis* in pediatric patients. The drug previously was approved to treat adults after exposure to inhaled anthrax.
- To prepare the American population for an anthrax attack, FDA posted on its internet site revised home preparation instructions for **doxycycline** dosing for children and adults who are not able to swallow pills, at: http://www.fda.gov/cder/drug/infopage/penG_doxy/home_prep.htm.
- FDA awarded a contract for hollow fiber studies and mathematical modeling to determine the optimal dosing regimen for **amoxicillin** for anthrax post-exposure prophylaxis for pregnant women and children.

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

Context: CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. The FDA Amendments Act of 2007 (FDAAA) 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 establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way CDER tracks pre-market issues 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. In FY 2009 the target is to act on 50% of the issues within timelines.

Performance: In FY 2008, CDER met its target of acting upon at least 50 percent of the identified priority postmarket safety issues within an established timeframe. During the first year of this new process, CDER focused its efforts on increasing its staff resources for tracking, managing, and monitoring postmarket safety issues. CDER conducted a pilot for prioritizing postmarket safety issues, developing action plans and timelines for those issues, and monitoring and managing progress toward those plans.

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. In FY 2007, the cost per report was \$13.64/per report. In FY 2008, the actual cost per report was \$10.59/per report. The proposed FY 2009 target of \$12 per report is an increase over the FY 2008 value due to the expected addition of periodic reports that have not been previously entered in the past. The cost decrease for the FY 2008 actual of \$10.59 per report as compared to the target value of \$13 per report is due mainly to the high volume of electronic submissions, thereby offsetting the cost per report. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports. In the absence of electronic submissions, the program costs for manual data entry would be nearly double what they are today.

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. 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) national survey of pharmacy practice in hospital settings: prescribing and transcribing-2007 were published in 2008. Over the last few years the adoption rate of bar code medication administration technology has grown each year, up to 19.6% overall in 2007.

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 2010. 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. For FY 2010, the target has been increased to 700 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 high-risk foreign and domestic drug manufacturers.

CDER Program Activity Data (PAD)

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
New Drug Review				
<i>Workload – Submissions/Filings/Requests</i>				
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	104	135	110	110
Efficacy Supplements	176	132	185	185
Manufacturing Supplements	2031	1784	2220	2350
Active INDs (Drugs and Biologics—Commercial and Research)	14,820	15,745	15,270	15,500
Sponsor Requests: IND-Phase Formal Meetings	2502	2059	2575	2600
Sponsor Requests: Review of Special Study Protocols	456	347	485	500
Submissions of Promotional Materials	68,288	70,509	72,500	75,000
<i>Outputs – Reviews/Approvals</i>				
Reviews: Priority NDA/BLA	31	31	32	30
Reviews: Standard NDA/BLA	140	118	140	135
Approvals: Priority NDA/BLA	21	20	22	22
Approvals: Standard NDA/BLA	67	60	70	70
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	9.9	10.4	10.0	10.0
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	15.3	23.3	15.0	15.0
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	6.0	6.0	6.0	6.0
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10.0	16.1	10.0	10.0
Reviews: NDA Supplementals	3,147	3,167	3,250	3,250
Reviews: Clinical Pharmacology/Bio-Pharmaceutic	1,730	1,880	1,780	1,780
Biologic Therapeutics Review				
<i>Workload – Submissions/Filings/Requests</i>				
Receipts: Commercial IND/IDE (Biologics Only)	98	100	99	100
Receipts: IND/IDE Amendments (Biologics Only)	8,325	13,727	14,023	14,023
<i>Outputs – Reviews/Approvals</i>				
Reviews: Total Original License Application (PLA/ELA/BLA)	5	7	7	7
Approvals: PLA/BLA	1	5	2	2
Reviews: License Supplement (PLA/ELA/BLA)	232	240	250	250
Generic Drug Review				
<i>Workload – Submissions/Filings/Requests</i>				

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Receipts: Abbreviated New Drug Applications (ANDA)	882	830	850	800
<i>Outputs – Reviews/Approvals</i>				
Actions – ANDA	1779	1934	1900	1900
Approval Actions - ANDA (both Tentative and Full Approvals)	682	598	650	700
Median Review Time from ANDA Receipt to Approval (months)	18.89	21.65	17.5	17.5
Actions - ANDA Supplementals (Labeling and Manufacturing)	3720	5562	3000	3000
Over-the-Counter Drug Review				
OTC Monographs Under Development*	15	12	12	12
OTC Monographs Published*	5	3	5	5
*Category includes Proposed Rules and Final Rules				
Best Pharmaceuticals for Children Act				
Labels Approved with New Pediatric Information	17	16	22	20
New Written Requests Issued	30	5	5	5
Pediatric Exclusivity Determinations made	14	18	22	20
Post Exclusivity Safety Report	13 drugs (2 A/Cs)	19 drugs (2 A/Cs)	12	12
Patient Safety				
<i>Workload – Submissions/Filings/Requests</i>				
Submissions: Adverse Event Reports	486,882	522,871	600,000	650,000
Electronic Submissions: % of Total Adverse Drug Reaction Reports	43%	58%	60%	65%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	70%	77%	85%	85%
Submissions: Drug Quality Reports	3371	5390	5900	6400
<i>Outputs – Reviews/Approvals</i>				
Safety reviews completed by Office of Surveillance & Epidemiology	1863	1,900	2,000	2,000
Number of drugs with Risk Communications	63	104	60-80	70-90
Administrative/Management Support				
<i>Workload</i>				
Number of Advisory Committee Meetings	25	28	35	35
Number of FOI Requests	2,984	2431	3,200	3,200
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	83	75	100	100
Number of Citizen Petitions Pending	217	237	277	317

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)				
<i>Outputs</i>				
Number of FOI Requests Processed	3676	3588	3,900	3,900
Number of Citizen Petitions Completed ¹ (excluding suitability petitions and OTC monograph-related petitions)	48	55	60	60

¹ Citizen Petitions completed may include petitions filed in prior years.

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	1,774	1,960	1,960
Pre-Approval Inspections (NDA)	138	120	120
Pre-Approval Inspections (ANDA)	95	51	51
Bioresearch Monitoring Program Inspections	526	490	490
Drug Processing (GMP) Program Inspections	972	1,085	1,085
Compressed Medical Gas Manufacturers Inspections	46	159	159
Adverse Drug Events Project Inspections	88	144	144
OTC Monograph Project and Health Fraud Project Inspections	33	48	48
Domestic Laboratory Samples Analyzed	1,769	951	951
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	452	566	566
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	174	192	192
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	117	69	69
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	129	210	210
Foreign Drug Processing (GMP) Program Inspections	268	382	382
Foreign Adverse Drug Events Project Inspections	6	16	16
IMPORTS			
Import Field Exams/Tests	2,863	2,870	6,197
Import Laboratory Samples Analyzed	346	586	586
Import Physical Exam Subtotal	3,209	3,456	6,783
Import Line Decisions	321,205	330,267	339,584
Percent of Import Lines Physically Examined	1.00%	1.05%	2.00%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	166	166	166
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	135	110	110
State Partnership Inspections: GMP Inspections	25	50	50
TOTAL HUMAN DRUG INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	2,392	2,692	2,692

Estimates for FY10 Generic Drugs User Fee Inspections not reflected in the table.
Estimated timeframe for these inspections is FY 2012 and FY 2013.