USER FEES -- $31,320,000

User Fee Overview

This budget requests a $31,320,000 increase. This increase is based on a current service estimate and does not account for workload adjustments or payroll adjustments. The increase includes $20,938,000 for Prescription Drug User Fee Act (PDUFA) fees, $6,362,000 for Medical Device User Fee Modernization Act (MDUFMA) fees, $2,964,000 for the recently enacted Animal Drug User Fee Act (ADUFA) fees, $254,000 for Mammography Quality Standards Act (MQSA), $24,000 for Drugs/Devices Export Certification and $778,000 for Color Certification.

The user fees FDA collects support the following FDA strategic goals:

- Enhance public health and reduce suffering by providing quicker access to important lifesaving, safe, and effective drugs and devices; and,

- Prevent unnecessary injury and death caused by adverse drug reactions, injuries, medication errors, and product problems.

User Fee Increases for FY 2006
(Dollars in $000)

Program	
PDUFA Total	**$20,938**
MDUFMA	**$6,362**
ADUFA	**$2,964**
MQSA	**$254**
Export Certification	**$24**
Color Certification	**$778**
Total	**$31,320**

PDUFA: + $20,938,000

The Bioterrorism Act of 2002 reauthorized the collection of PDUFA user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. This authority is effective for five years and directs FDA to strengthen and improve the review and monitoring of drug safety, consider greater interaction with sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases, and develop principles for improving first-cycle reviews.

For FY 2006, FDA requests an increase of $20,938,000 for a total of $305,332,000 in PDUFA user fees. This increase is based on inflation and workload factors for the FDA drug review program.

PDUFA Increase for FY 2006
(Dollars in $000)

Program	
Human Drugs	$14,356
Biologics	$6,624
Field Activities	$1,550
Other Activities	$1,408
White Oak	($3,000)
Total	**$20,938**

Fees collected support the following FDA performance goals:

- Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available;

- Review and approve 90 percent of standard original PDUFA NDA/BLA submissions within ten months; and review and act on 90 percent of priority original PDUFA NDA/BLA submissions within six months of receipt; and,

- Review and approve 90 percent of standard PDUFA efficacy supplements within ten months; and review and act on 90 percent of priority PDUFA efficacy supplements within six months of receipt.

MDUFMA: + $6,362,000

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002 is patterned after the successful Prescription Drug User Fee Act that has enabled FDA to add over 1,000 employees to the drug review process over the last decade.

This multi-year effort is designed to improve the quality and timeliness of the medical device review process. It authorizes the collection of user fees to supplement the appropriated portion of the medical device review program for the review of medical device applications. The fee is collected from device manufacturers that submit premarket applications, certain supplements to those applications, and premarket notifications.

Implementation of MDUFMA makes available new revenue for completing more timely and complete device reviews, by reducing the cumulative approval time, reducing the number of review cycles, encouraging and supporting high quality applications, and providing a more efficient resolution of outstanding issues.

For FY 2006, FDA is requesting an increase of $6,362,000 for a total of $40,300,000 in MDUFMA fees. This increase is based on inflation for the medical device review program.

MDUFMA Increase for FY 2006
(Dollars in $000)

Program	
Biologics	$673
Devices	$4,886
Field Activities	$308
Other Activities	$495
Total	**$6,362**

Fees collected support the following FDA performance goals:

- Complete review and decision on 80 percent of expedited PMAs within 300 days;

- Complete review and decision on 80 percent of 180 day PMA supplements within 180 days; and,

- Complete review and decision on 75 percent of 510(k)s (Premarket notifications) within 90 days.

ADUFA: + $2,964,000

The Animal Drug User Fee Act (ADUFA) was enacted on November 18, 2003 through the Consolidated Appropriations Act of 2004. This legislation provides a cost-efficient, high quality animal drug review process that is predictable and performance driven, to ensure the safe and effective animal drugs are available on the market The program requires new animal drug

applicants, sponsors, and establishments to incur a fee to expedite their respective applications.

The availability of safe and effective animal drugs allows food animal producers to maintain healthy animals with the assurance that resulting food products will be safe, wholesome, and free of drug residue. A safe and effective drug supply also ensures companion, service animals that assist the disabled, and other animals such as zoo animals will live healthier and longer lives.

ADUFA Increase for FY 2006
(Dollars in $000)

Program	
ADUFA	
Veterinary Medicine	$2,462
Other Activities	$502
Total	**$2,964**

The fees collected support the following FDA performance goal:

- Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. This goal is dependent upon a sustained level of base and user fee resources.

MQSA: + $254,000

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight American women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which was reauthorized in October 2004, addresses the public health need for safe and reliable mammography. The Act required that mammography facilities be certified by October 1994, and inspected annually to ensure compliance with national quality and safety standards.

The reauthorization codified existing certification practices for mammography facilities and laid the groundwork for further study of key issues that include ways to improve physicians' ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms.

FDA is authorized to collect fees to pay for the costs of the annual inspections. In FY 2006, FDA is requesting a $254,000 increase for a total of $17,173,000 in MQSA fees. This increase is based on inflation and workload factors for the medical device review program.

MQSA Increase for FY 2006
(Dollars in $000)

Program	
MQSA	
Medical Devices	$163
Field Activities	$81
Other Activities	$10
Total	**$254**

This program supports FDA's strategic goal of reducing the risk of medical devices and radiation emitting products on the market by assuring product quality and correcting problems associated with their production and use.

Export Certification (Drugs/Devices):

+ $24,000

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device, that the product to be exported meets certain requirement of the law. This applies to products approved for sale in the U.S., as well as unapproved products. The purpose of these certificates is to promote the export of products made in the U.S. The $24,000 increase will cover the programs' inflationary costs.

Color Certification: + $778,000

The Federal Food, Drug and Cosmetic Act (FFD&C) requires the certification of color additives. This function, which is administered by FDA's Center for Food Safety and Applied Nutrition, involves assessing the quality and safety of color additives used in foods, drugs and cosmetics. Employee salaries and expenses are funded directly by FDA's Revolving Fund for Certification and Other Services which is financed entirely by fees paid by commercial organizations. The FY 2005 increase of $778,000 will cover the programs inflationary costs and covers a anticipated fee increase with industry.

Requested Certification Increases for FY 2006
(Dollars in $000)

Program	Center	Field	Total
Export Cert.	$24	$0	$24
Color Cert.	$778	$0	$778
Total	**$802**	**$0**	**$802**