Current Law User Fees
+ $57,534,000

1. Why are these amounts necessary?

FDA user fee programs facilitate enhanced premarket review performance and the timely availability of safe and effective medical devices, human and animal drugs, biological products, and other FDA-regulated products. The budget request includes increases for existing user fee programs as authorized by statute. The increases expand the available options for treating and curing diseases and other health problems.

The following table identifies the FY 2009 request and funding history for user fee programs:

Funding History of Current Law User Fees

Description	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
PDUFA	$320,430,000	$459,412,000	$511,108,000	+ 51,696,000
MDUFA	$35,202,000	$48,431,000	$52,547,000	+ 4,116,000
ADUFA	$12,270,000	$13,696,000	$13,698,000	+ 2,000
MQSA	$13,838,000	$18,398,000	$19,318,000	+ 920,000
Export Certification	$2,732,000	$2,500,000	$2,600,000	+ 100,000
Color Certification	$6,954,000	$7,000,000	$7,700,000	+ 700,000
Total	**$391,426,000**	**$549,437,000**	**$606,971,000**	**+ 57,534,000**

2. How does this initiative support important public health priorities?

The currently authorized user fees that FDA collects support two important public health priorities: transforming health care and improving access to FDA-regulated products. The fees allow FDA to improve product review performance, which reduces the time it takes for safe and effective human and animal drugs, medical devices, and other FDA-regulated products to reach the market. User fees supplement appropriated dollars and allow FDA medical product programs to hire additional scientific review staff and review process managers, improve the review process, reduce review time, and provide essential information technology to support product review.

3. What are the risks of not funding this initiative?

Without additional resources, FDA will not be able to perform the following critical work that advances public health:

- Meet the performance commitments for faster medical device review (MDUFA) and faster human drug (PDUFA) and animal drug review (ADUFA). The performance commitments are designed to ensure that FDA provides the public with earlier access to safe and effective medical products, thereby saving lives, relieving suffering, and improving the quality of life.
- Sustain patient access to safe and effective new products by providing rapid, transparent, and predictable review of marketing applications.
- Maximize safe and effective use of medical products by communicating benefits and risks more effectively.
- Prevent harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response.
- Increase availability of FDA experts to expand and improve consultation and outreach to industry, thereby reducing medical product development time.

4. What activities will these funds support?

PDUFA: + $51,696,000

In the FDA Amendments Act of 2007 (FDAAA), Congress renewed FDA's authority to the collect Prescription Drug User Fee Act (PDUFA) user fees. Known as PDUFA IV, this authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2012.

PDUFA IV continues to improve upon previous authorizations. PDUFA IV upgrades and broadens FDA's drug safety program and expands guidance for industry and FDA reviewers. The funds in this initiative allow FDA to invest in information technology that supports human drug review. The funds in this initiative will also facilitate more efficient development of safe and effective new drugs and support FDA efforts to modernize the drug safety system for the American public.

Based on current information and established PDUFA formulas, the statute authorizes fee increases of $37,696,000 in FY 2009 to support drug review. This increase is based on inflation and workload factors associated with the FDA drug review program.

The FY 2009 also includes an increase of $14,000,000 for the Direct-to-Consumer (DTC) television advertising review program. This increase supports the program authorized by FDAAA to collect user fees from companies that seek FDA advisory reviews of their DTC television advertising. This new program will provide resources to support additional staff to

complete timely review of DTC television advertisements. FDA will work with Congress to enact technical changes to ensure that FDA can commence this program during FY 2009.

The following table identifies the FY 2009 increase for PDUFA:

PDUFA Increase for FY 2009

Program	
CDER	$38,698,000
CBER	$5,685,000
Field Activities	$0
GSA Rent, Rent Related and White Oak	$4,641,000
HQ/OC	$2,672,000
Total	**+$51,696,000**

The overall success of PDUFA provides FDA with the revenue to hire additional reviewers and support staff and upgrade FDA information technology systems to speed the application review process for new drugs and biological products. FDA accomplishes its PDUFA responsibilities without compromising FDA's high standards for drug approval.

MDUFMA: +$4,116,000

In the FDAAA, Congress renewed FDA's authority to collect user fees under the Medical Device User Fee and Modernization Act (MDUFMA). This authority is effective for five years and directs FDA to improve the quality and timeliness of the medical device review. MDUFMA authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications and annual registration fees from certain device establishments. The authority to collect fees under MDUFMA expires on September 30, 2012.

The Medical Device User Fee Amendments enacted in FDAAA also ensured a sound financial footing for medical device review, enhanced the process for premarket review, and modified the third party inspection program.

The following table identifies the FY 2009 increase for MDUFMA:

MDUFMA Increase for FY 2009

Program	Dollars
CBER	$859,000
CDRH	$2,264,000
Field Activities	$122,000
GSA Rent and Rent Related	$407,000
HQ/OC	$464,000
Total	**+$4,116,000**

ADUFA: +$2,000

Enacted in November 2003, Animal Drug User Fee Act (ADUFA) helps FDA strengthen animal drug pre-market review program and provide greater public health protection. ADUFA fees help ensure that animal drug products subject to FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption. ADUFA provides a cost-efficient, high quality animal drug review process that is predictable and performance driven. The ability to collect ADUFA user fees expires on September 30, 2008. The FY 2009 budget proposes to reauthorize ADUFA for five years, and reflects a placeholder fee revenue level for FY 2009, consistent with an extension of the current ADUFA statute. Later this year, the Administration will formally propose legislation to reauthorize ADUFA.

For FY 2009, FDA adjusted for increases due to inflation, resulting in an increase of $2,000 for the Center for Veterinary Medicine.

The following table identifies the FY 2009 increase for ADUFA:

ADUFA Increase for FY 2009

Program	
CVM	$2,000
HQ/OC	$0
Rent	$0
Total	**+$2,000**

MQSA: +$920,000

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 women will contract breast cancer during their lifetime. Mammography Quality Standards Act (MQSA), which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography. MQSA required that FDA certify mammography facilities by October 1994, and inspected facilities annually to ensure compliance with national quality and safety standards.

The statute directs the assessment, collection, and use of fees to cover the costs of MQSA inspections, record keeping and development of annual reports. In FY 2009, FDA is requesting a $920,000 increase. This increase is based on inflation for the Mammography Quality Standards Act.

The following table identifies the FY 2009 increase for MQSA:

MQSA Increase for FY 2009

Program	
CDRH	$286,000
Field Activities	$623,000
HQ/OC	$11,000
Total	**+$920,000**

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/Biologics/Devices): +$100,000

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device. These certificates state that the product meets certain requirements of 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 FY 2009 increase of $100,000 will cover program inflationary costs.

Color Certification: +$700,000

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 increase of $700,000 will cover the anticipated increase in color certifications in FY 2009.

5. What results will FDA achieve from the current law user fee increases?

The current law user fee increases allows FDA to meet performance commitments that provide for faster medical device review (under MDUFMA), human drug review (under PDUFA), and animal drug review (under ADUFA). These programs provide earlier access to safe and effective medical products, thereby saving lives, relieving suffering, and improving the quality of life.