Current Law User Fees
($5,244,000) in User Fees

1. Why are these amounts necessary?

FDA user fee programs help bring safe and effective medical devices, human and animal drugs, biological products, and other FDA-regulated products to market. 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 2008 request and funding history for user fee programs:

Funding History of Current Law User Fees

Description	FY 2006 Enacted	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 Initiative	
				FY 2008 Total	+/- 07 PB
PDUFA	$305,332,000	$305,332,000	$352,200,000	$339,195,000	($13,005,000)
MDUFMA	$40,300,000	$0	$43,726,000	$47,500,000	+3,774,000
ADUFA	$11,318,000	$0	$11,604,000	$13,696,000	+2,092,000
MQSA	$17,173,000	$17,522,000	$17,522,000	$18,398,000	+876,000
Export Certification	$1,639,000	$2,300,000	$2,300,000	$2,500,000	+200,000
Color Certification	$6,001,000	$6,181,000	$6,181,000	$7,000,000	+819,000
Total	**$381,763,000**	**$331,335,000**	**$433,533,000**	**$428,289,000**	**($5,244,000)**

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

The user fees FDA collects support the vision of transforming health care and improving access to FDA-regulated products, both of which are important public health priorities. 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 enable 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:

- meeting the performance commitments for medical device (MDUFMA), human drug (PDUFA), and animal drug review (ADUFA)

- sustaining patient access to safe and effective new products by conducting rapid, transparent, and predictable review of medical product applications

- maximizing safe and effective use of medical products by communicating benefits and risks more effectively

- preventing harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response

- reducing product development time by increasing the availability of FDA experts to expand and improve outreach and consultation with industry.

4. What activities will these funds support?

PDUFA: ($13,005,000): In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to the collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007. FDA is engaged in a process to consult with the public about the terms of legislation to reauthorize PDUFA.

In FY 2007, FDA adjusted the PDUFA collections by +$31,600,000 for the one-time, final year adjustment under PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by PDUFA (+18,595,000). The increases and decreases net to ($13,005,000). However, the FY 2008 request assumes that authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget and establish new fee levels based on Administration recommendations and congressional action on PDUFA IV.

The following table identifies the FY 2008 fee request for PDUFA:

PDUFA User Fee Changes for FY 2008

Program	
CDER	($14,808,000)
CBER	($3,884,000)
Field Activities	($664,000)
Rent	$5,201,000
HQ and OC	$1,150,000
Total	**($13,005,000)**

PDUFA Program Reauthorization: $437,783,000 and 1,728 FTE
Direct-to-Consumer User Fee Program: $6,250,000 and 27 FTE
PDUFA III, which expires on September 30, 2007, improved FDA's ability to address postmarket risk management and develop industry guidance. A draft proposal for PDUFA IV printed in the Federal Register of January 16, 2007, continues to improve upon previous PDUFA authorizations by:

- upgrading and broadening FDA's drug safety program
- expanding guidances for industry and FDA reviewers
- modernizing FDA's human drug review information technology systems
- continuing to meet PDUFA performance commitments.

The following table identifies the proposed funding for the draft PDUFA IV proposal, including a separate direct-to-consumer television advertising:

Funding under the Prescription Drug User Fee Act Reauthorization (PDUFA IV)
($ Thousands)

Proposed Program Elements	$
PDUFA III FY 2007 baseline	305,455
Inflation adjustment (5.8%)	+17,716
Rent/Rent Related Adjustments	+11,721
IND/NDA increased work adjustments	+20,000
Adjusted PDUFA III baseline	**354,893**
PDUFA IV Program Increases	
Critical Path projects	*+4,600*
Increase Drug Safety	*+29,290*
Enhance IT Capabilities	*+4,000*
Total PDUFA IV Program Increases	**+37,890**
Estimated FY 2007 Workload Adjustment	**+45,000**
Total PDUFA IV FY 2008	**$437,783**
Separate DTC user fee	**$6,250**

The draft PDUFA IV proposal also recommends that FDA establish a separate program to collect user fees from companies that engage in Direct-to-Consumer (DTC) television advertising and seek FDA advisory reviews of their television advertisements. This new program will provide resources to support additional staff to complete timely review of DTC television advertisements.

The overall success of PDUFA provides FDA 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 approval.

MDUFMA: +$3,774,000: Enacted in 2002, MDUFMA improves 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. The authority to collect fees under MDUFMA expires on September 30, 2007. The terms of legislation to reauthorize MDUFMA are currently under discussion.

The FY 2008 increase of $3,774,000, for a total FY 2008 fee collection of $47,500,000, assumes that the authorities in effect for MDUFMA continue in FY 2008. FDA may need to amend its budget and establish new fee levels based on Administration recommendations and congressional action on MDUFMA. FDA bases the FY 2008 inflation increase on the current authorities in MDUFMA.

The following table identifies the FY 2008 fee request for MDUFMA:

MDUFMA Increase for FY 2008

Program	
CBER	$788,000
CDRH	$2,077,000
Field Activities	$111,000
Rent	$373,000
HQ and OC	$425,000
Total	**$3,774,000**

MDUFMA user fees allow FDA to improve the safety and efficacy of medical devices:

- to increase the safe and effective use of approved medical products, including new medical products for unmet public health needs, untreated conditions, emerging infectious diseases, and medical countermeasures

- to maximize medical product quality through improved manufacturing practices using new scientific and technical standards and systems.

ADUFA: +$2,092,000: Enacted in November 2003, 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 statute authorizes fee increases of $2,092,000 in FY 2008, for a total of $13,696,000, to support the new animal drug review program. FDA bases the FY 2008 increase on inflation factors for the new animal drug review program and the requirement to achieve three months of operating costs to carry over into FY 2009.

The following table identifies the FY 2008 fee request for ADUFA:

ADUFA Increase for FY 2008

Program	
CVM	$1,986,000
HQ and OC	$36,000
Rent	$70,000
Total	**$2,092,000**

MQSA: +$876,000: Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer death among American women. Experts estimate that one in eight women will contract breast cancer during their lifetime. MQSA addresses the public health need for safe and reliable mammography. MQSA requires FDA to certify mammography facilities and inspect facilities annually to ensure compliance with quality and safety standards. The $876,000 increase, for a total program of $18,398,000, covers program inflationary costs. The following table identifies the FY 2008 fee request for MQSA:

MQSA Increase for FY 2008

Program	
CDRH	$272,000
Field Activities	$593,000
HQ and OC	$11,000
Total	**$876,000**

Export Certification (Drugs/Devices): +$200,000: 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. The certification 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 $200,000 increase for FY 2008, for a total program of $2,500,000, covers program inflationary costs.

Color Certification: +$819,000: The Food, Drug, and Cosmetic Act requires the certification of color additives. FDA's Center for Food Safety and Applied Nutrition administers this program, which assesses the quality and safety of color additives used in foods, drugs, and cosmetics. Fees paid by commercial organizations entirely finance FDA's color certification program. The FY 2008 increase of $819,000 will result in a total program of $7,000,000. The increase will cover the program inflationary costs.

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.