Prescription Drug User Fee Program Reauthorization

$437,783,000, 1,728 FTE

Direct-to-Consumer User Fee Program

$6,250,000, 27 FTE

The Prescription Drug User Fee Act (PDUFA) provides FDA 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.

PDUFA III expires in 2007. A draft proposal for PDUFA IV was printed in the Federal Register of January 16, 2007. PDUFA III contained changes that improved FDA's ability to address postmarket risk management and develop industry guidance. PDUFA IV continues to improve upon previous authorizations. The January 16 proposal recommends upgrading and broadening FDA's drug safety program, expanding guidances for industry and FDA reviewers, and investing in information technology that supports human drug review. The proposal facilitates more efficient development of safe and effective new drugs and a modernized drug safety system for the American public.

The following table identifies the proposed funding for the PDUFA IV proposal, including a separate user fee program to support advisory review of 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**

This initiative advances the HHS 500-day plan for Transforming Healthcare. Specifically, it supports the Secretary's objective for rapidly approving safe, new drugs, continually monitoring drug safety after approval, and proactively communicating new information to providers and patients.

The draft proposal for PDUFA IV has four important components that will facilitate premarket review and postmarket safety of drugs.

Modernizing and Transforming Postmarket Drug Safety

The January 16 proposal recommends an increase the number of staff dedicated to monitoring and ensuring the safety of drugs on the market. This includes improving collection and management of adverse events data, developing guidance for epidemiological best practices, enhancing drug safety IT tools, accessing externally linked databases, and developing a safety workflow tracking system.

Enhancing Premarket Review

The January 16 proposal recommends enhancing premarket drug review by expanding Good Review Management Principles (GRMPs). The enhancing premarket review component will also promote earlier discussions between FDA and industry about product labeling and postmarketing study commitments. The result will be clearer product labels and a greater likelihood of completing postmarket study commitments on time. FDA will also provide more guidance to industry on topics on a variety of innovative clinical trial designs, which will help to increase drug safety and expedite new drug development.

Improving IT infrastructure

The January 16 proposal recommends additional resources to improve information technology and move FDA towards an all-electronic environment. This will increase efficiency in the application submission and drug review process, and allow for more reliable management of drug applications and other drug submissions. FDA will also be able to move away from costly maintenance of legacy systems and toward the development of better-coordinated and more flexible IT systems.

Direct-To-Consumer User Fee Program

The January 16 proposal recommends that FDA to establish a separate program to collect user fees from companies that engage in 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.