Generic Drug Review User Fees
+$16,628,000

1. Why is this initiative necessary?

The number of generic drug applications submitted to FDA has been rising exponentially. During the past six years, applications increased by 186 percent, rising from 307 applications in FY 2001 to 880 applications in FY 2007. FDA estimates this dramatic trend will continue during FY 2008 and FY 2009. These statistics demonstrate the urgent need for increased resources for the Generic Drug Review Program. The proposed user fees for Generic Drug Review allow FDA to respond to the growing number applications.

Generic drugs often cost 20 to 70 percent less than their brand-name counterparts. The promise of significant savings makes timely review of generic drug applications a vital part of the Administration's strategy to reduce healthcare costs associated with prescription drugs.

The following table identifies FY 2009 proposed spending for Generic Drug Review User Fees.

Proposed Generic Drug User Fees

	FY 2009 Estimate
CDER	$12,242
Field Activities	$2,792
HQ/OC	$549
GSA and Other Rent Related	$1,045
Total	**$16,628**

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

This initiative supports HHS public health priorities for Transforming Healthcare. Specifically, the initiative supports the objective for rapidly approving safe new drugs, continually monitoring drug safety after approval, and proactively communicating new information to providers and patients. Improving generic drug review performance also supports other public health priorities:

- The initiative advances Medicare Rx objectives by promoting the availability of lower cost generic alternatives.
- The initiative advances Medicaid Modernization by enabling FDA to approve lower-cost generic drugs that generate savings to support a modernized Medicaid program.
- The initiative supports Pandemic Preparedness by allowing prompt review of generic drugs that support the HHS pandemic influenza response.

Furthermore, enhanced generic drug review ensures that American consumers have additional choices when buying drugs, which will produce a dramatic return on investment for the resources that FDA spends on generic drug review. The Congressional Budget Office estimates that generic drug use results in U.S. savings of $10 billion per year. One of the nation's largest pharmacy benefit management companies estimates that more extensive generic drug use could save an additional $20 billion per year. As $60-70 billion in brand name drugs lose patent protection in the next few years, Americans could substitute generic drugs for brand name drugs at a rate of 50 to 75 percent.

Enhanced generic drug review also directly supports the Secretary's vision for improving the human condition around the world. The FDA Generic Drug Review Program plays a significant role in the President's Emergency Plan for AIDS Relief (PEPFAR), by approving new generic treatments for HIV and AIDS. If FDA deems a generic drug safe and effective – but the brand name equivalent is still under patent in the United States – FDA can grant a tentative approval for the drug. The tentative approval allows the drug to be sold outside of the United States for HIV and AIDS treatment.

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

Not proceeding with user fees for Generic Drug Review program will result in the inability to capture significant savings from generic drug use. Generic drugs reduce the cost of pharmaceutical care and allow increased access to health care for many Americans. Generic drugs have the same quality, strength, purity, and stability as brand-name drugs.

Government programs rely on the availability of generic drugs to hold down costs. According to data from the National Association of Chain Drug Stores, in 2004 the average price of a brand prescription was approximately $96.01, while the average price of an available generic prescription was approximately $28.74. That is a difference of $67.27 per prescription.

Not funding this initiative limits the generic drugs available to treat diseases that are of major concern in the United States and abroad. The initiative also supports the availability of specialized drugs for foreign countries (under PEPFAR), and to assure availability of medical countermeasures to bioterrorism and natural disasters.

What activities will these funds support?

The addition of user fee resources for Generic Drug Review will allow FDA's Center for Drug Evaluation and Research (CDER) to ramp-up the Generic Drug program in FY 2008 and thereby begin to minimize the application backlog. CDER will hire staff to respond to the backlog. CDER will also enhance a range of operations, from establishing criteria for determining the bioequivalence of complex drugs and drugs with non-traditional dosage forms, to improving the information technology infrastructure that the generic drug program relies on to conduct application review.

5. What results will FDA achieve?

With the additional resources generated by the proposed Generic Drug User Fee, FDA will come closer to achieving generic drug review requirements. FDA is currently engaged with stakeholders to define a user fee program and associated performance. Later this year, the Administration will formally propose legislation to authorize user fees for the Generic Drug Review program.