Improving Generic Drug Review Performance
Generic Drug Budget Authority: +5,561,000; 13 FTE
Generic Drug User Fees: +$15,701,000; 34 FTE (First Year)

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 158 percent, rising from 307 applications in FY 2002 to 793 applications in FY 2006. FDA estimates it will receive 857 applications in FY 2008. These statistics demonstrate the urgent need for increased resources for the Generic Drug Review Program. The additional budget authority and proposed user fees in the Improving Generic Drug Review Initiative 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 the funding history for the Generic Drug Review Program and the FY 2008 levels, including the increased generic drug budget authority and proposed user fees:

Funding History for the Generic Drug Review Program

Program	FY 2006 Actuals	FY 2007 President Budget	FY 2008 Initiative	
			FY 2008 Total[1]	+/- 07 President Budget
Budget Authority				
Human Drugs	**$62,567,000**	**$64,600,000**	**$70,161,000**	**$5,561,000**
Center	$55,437,000	$58,000,000	$63,561,000	$5,561,000
Field	$7,130,000	$6,600,000	$6,600,000	-
User Fees				
Generic Drug User Fee	**0**	**0**	**$15,701,000**	**$15,701,000**
Program Total	**$62,567,000**	**$64,600,000**	**$85,862,000**	**$21,262,000**

[1] The FY 2008 Generic Drug total is $87,102,000. This includes generic drug funds and pay increase.

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

This initiative supports the public health priorities of the HHS 500-day plan for Transforming Healthcare. Specifically, the initiative 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. 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 the Improving Generic Drug Review Initiative 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.

4. What activities will these funds support?

Budget Authority: The budget authority increase in the Improving Generic Drug Review Initiative directly supports core review functions in the Generic Drugs Program and allows CDER to sustain performance in a number of important areas:

- managing the existing generic drug application backlog as quickly and efficiently as possible
- increasing efficiency and improving generic drug review times by evaluating ways to improve communication with industry and improve the quality of applications
- assuring that generic drugs conform to manufacturing standards equal to the standard for brand name drugs
- providing medical and scientific expertise necessary to fulfill the President's commitment to ensuring the quality of HIV/AIDS drugs purchased by the United States for developing countries.

User Fees: The addition of fee resources under the Improving Generic Drug Review Initiative 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.

Following the first full year of implementing this initiative, FDA will achieve a 50 percent increase in approvals. FDA currently performs an average of 40 approvals or tentative approvals per month. FDA will achieve the 50 percent increase after one full year because FDA must first hire and train the new generic drug review staff before it can achieve the additional approvals. During the next five years, the goal is to meet the statutory requirement for generic drug review by acting on 90 percent of original generic drug applications and amendments to unapproved applications within 180 days.

The funds in this initiative will support all activities associated with the review of generic drugs. FDA will achieve increased outputs from FY 2007 to FY 2008 in four measures:

- First cycle approvals will increase from two percent of applications approved or tentatively approved to five percent of applications approved or tentatively approved.
- FDA will reduce the time it takes to approve 40 percent of first generic applications without patent or exclusivity protection from 12 months to four months. FDA will also reduce the time it takes to approve 80 percent of first generic applications without patent protection from 14 months to six months.

This improvement depends on receiving the authority to formally expedite these applications.

- The number of domestic pre-approval generic drug inspections will increase from 110 to 155.
- The number of foreign pre-approval generic drug inspections will increase from 42 to 87.

5. What results will FDA achieve?

Budget Authority: With additional base resources for the Generics Drug Program, CDER will be able to approve or tentatively approve as many as 550 generic drugs per year. The American public will enjoy more cost saving from generic drugs.

User Fees: With the additional resources generated by the proposed Generic Drug User Fee, FDA will come closer to achieving generic drug review requirements. The statutory requirement for generic drug review is to act on original generic drug applications within 180 days. Currently, FDA estimates that performance toward this requirement with existing resources in FY 2006 and FY 2007 is near 55-60 percent percent. Although the number of generic drug applications that FDA receives will continue to rise, FDA expects that it can achieve the following performance toward meeting the statutory requirement:

- 70 percent by the end of FY 2008
- 72 percent by the end of FY 2009
- 73 percent by the end of FY 2010
- 75 percent by the end of FY 2011
- 80 percent by the end of FY 2012
- 85 percent by the end of FY 2013
- 90 percent by the end of FY 2014.

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