Modernizing Drug Safety
+$11,200,000, 25 FTE

1. Why is this initiative necessary?

The Modernizing Drug Safety Initiative will revolutionize FDA's ability to identify safety issues and rapidly and effectively communicate known and emerging safety concerns to health professionals, patients, and the public. The initiative will improve drug safety before FDA grants approval and after drugs reach the market. To accomplish these goals, the initiative proposes a significant additional investment to modernize the process for ensuring drug safety.

The following table identifies funding for the Modernizing Drug Safety Initiative and the history of funding for the activities in this initiative:

Funding for Modernize Drug Safety

Program	FY 2006 Actuals	FY 2007 President's Budget	FY 2008 Initiative	
			FY 2008 Total [1]	+/- 07 President's Budget
Human Drugs	$108,896,000	$112,605,000	$121,565,000	$8,960,000
Biologics	$9,380,000	$10,620,000	$12,860,000	$2,240,000
Total	$118,276,000	$123,225,000	$134,425,000	$11,200,000

[1] FY 2008 Drug Safety total is $138.815 million. This total includes drug safety funds and pay increase.

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

This initiative includes high priority public health activities that are the foundation of the President's and the Secretary's vision for transforming healthcare. The Modernizing Drug Safety Initiative directly supports their vision by providing better information and more drug choices to consumers. The initiative also ensures that FDA continually monitors the safety of drugs and that FDA proactively communicates important new safety information to health care providers and patients.

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

If FDA does not receive the funds in this initiative, FDA risks continued decline in public confidence in the agency's ability to ensure the safety of drugs. The recent Institute of Medicine (IOM) report, "The Future of Drug Safety," and media reports highlights this concern. FDA recognizes the need to improve drug safety, and the Modernizing Drug Safety Initiative responds with an aggressive steps to improve FDA's ability to detect and manage important safety issues.

This initiative is vitally important to FDA and its staff, to medical experts interested in drug and biologic safety, and most importantly to U.S. patents and consumers. In response to their concerns, FDA is working to achieve greater transparency in its process for analyzing safety issues. FDA is also working to ensure that patients and physicians have the most up-to-date and complete information to inform their treatment decisions.

However, as we recognize, and as studies conducted by the IOM and the Government Accountability Office (GAO) have validated, FDA needs additional resources for safety. Without these resources, FDA will not be able to address many of the concerns raised in the IOM and GAO studies – concerns shared by members of Congress, the public, and our own leadership – as quickly and as thoroughly as we believe is necessary.

Moreover, it is imperative that FDA continue to keep pace with the rapidly changing drug and biologic technology. FDA needs to modernize the tools it uses to collect and analyze safety data. Without the funds in the Modernizing Drug Safety Initiative, FDA will continue to use the existing, outdated version of our drug and biologic surveillance monitoring tool, the Adverse Event Reporting System (AERS). Further, FDA needs to expand its capability and capacity to identify, investigate, and assess safety by accessing additional sources of drug safety data, beyond the data collected in AERS. Without additional funds, FDA will continue to depend on the AERS data as the primary data source for identifying drug safety signals.

4. What activities will these funds support?

The funding in this initiative allows FDA to make essential progress on multiple paths to modernize drug safety:

- strengthen best practices for conducting quantitative benefit-risk assessment
- conduct a pilot to review safety profiles of new molecular entities (NMEs) on a scheduled basis and establish whether FDA should initiate reviews for all NMEs
- access additional databases for drug and biologic safety surveillance and analysis
- hire additional epidemiologists and programmers to evaluate drug databases
- upgrade the FDA Adverse Event Reporting System (AERS) by adding detection and tracking tools that allow reviewers to more efficiently and effectively identify and track safety signals from an ever-increasing number of adverse events reports
- identify, clarify, and define the purpose of each public communication tool that FDA uses to disseminate drug safety information and streamline the use of tools to facilitate information flow
- publish a web-based newsletter with summaries of postmarketing drug reviews

- enlist experts in organizational improvement to identify additional opportunities for change and assist FDA to carry out needed changes

- strengthen biologics adverse event databases and increase leveraging and information sharing with public health partners

- increase the ability of multidisciplinary biologics safety teams to detect adverse events and conduct analysis, risk management, and communication

- strengthen the involvement of safety experts throughout the drug lifecycle, by having these experts identify safety data needs prior to approval and during the design and review of post-marketing safety studies.

5. What results will FDA achieve?

FDA will achieve significant results in areas that contribute to the U.S. drug and biologic safety system:

- strengthen science and tools that support the drug safety system at every stage of the drug life-cycle, from premarket testing and development through postmarket surveillance and risk management
- improve communication and information flow among all stakeholders engaged in promoting the safe use of drugs
- improve operations and management to ensure that FDA implements the review, analysis, consultation, and communication processes needed to strengthen the U.S. drug safety system.

In summary, these resources will support FDA's ability to effectively detect, communicate, and act on important safety issues. This will improve patient safety and public confidence in FDA drug safety efforts.