Medical Device Safety and Review
+$7,164,000, +3 FTE

1. Why is this initiative necessary?

This initiative will improve the safety of medical devices. With these funds, FDA can strengthen medical device safety and improve FDA's ability to identify, analyze, and act on postmarket safety information. The Device Safety and Review Initiative also allows FDA to use postmarket safety information to improve the quality of new devices coming to market, ensure the safety of products currently on the market, and provide timely device safety information to consumers.

The initiative is also necessary for FDA to maintain medical device review performance and thereby allow Americans to enjoy the benefits of lifesaving medical devices. In addition, the funding in the initiative insures that FDA meets statutory requirements, known as triggers. If FDA does not meet the statutory requirements, the agency cannot continue to collect medical device user fees in FY 2008.

The following table identifies the distribution of funds under the Device Safety and Review Initiative to FDA's Center for Devices and Radiological Health (CDRH) and FDA Field operations:

Distribution of FY 2008 Budget Authority for Device Safety and Review

Program	FY 2008 Initiative	
	+/- FY 2007 PB	FY 2008 Total
Center (Safety and Review)	+ $4,743,000	$178,265,000
Field	+$2,421,000	$61,857,000
Total Medical Devices and Radiological Health	+$7,164,000	$240,122,000

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

Improving medical device safety and performing timely and consistent device review contributes to the Administration's goal of advancing medical research through timely review of safe and effective medical devices. The initiative also supports the President's Health Information Technology goal and the Secretary's vision for transforming the health system by improving processes to identify medical errors and by communicating risk and benefit information to consumers in a timely manner.

The initiative also contributes to securing the homeland by ensuring timely review of medical countermeasure devices used to respond to bioterrorism, chemical, or radiological incidents. Finally, the initiative supports three FDA strategic goals:

- enhancing patient and consumer protection, and empower them with better information about regulated products
- increasing access to innovative products and technologies to improve health

- improving product quality, safety, and availability through better manufacturing and product oversight.

3. What are the risks of not proceeding with the initiative?

If FDA does not receive the funds for the Device Safety and Review Initiative, FDA will fail to meet a statutory trigger under the Medical Device User Fee and Modernization Act (MDUFMA). Failing to meet the trigger means that FDA cannot collect and spend $47,500,000 in medical device user fees. This will force FDA to execute significant personnel reductions of nearly 200 FTE paid for by device user fees. The loss of experienced device reviewers will cause review performance to plummet and significantly delay critical work that supports the President's vision of a healthier America. MDUFMA user fee revenue also supports more than 85 percent of the pre-approval inspections conducted by the FDA Field staff in the Office of Regulatory Affairs (ORA). Without user fees, ORA must cut approximately 100 pre-approval device inspections.

The loss of device user fees will have direct consequences for patients who rely on safe and effective medical devices, often to treat life-threatening conditions. The loss of user fees will dramatically slow the flow of new potentially life saving medical devices that are available to patients who need them. In addition to this public health impact, the U.S. medical device industry will suffer significant economic disruption.

4. What specific activities will these funds support?

With these funds, FDA will maintain a strong premarket review process, supported by user fees. These funds will also increase FDA's ability to identify, analyze, and act on postmarket device safety information.

Because the Device Safety and Review Initiative allows FDA to meet the statutory trigger under MDUFMA, the initiative permits FDA to maintain or strengthen a broad spectrum of premarket and postmarket device activities:

- meeting the performance goals for medical device review
- conducting approximately 100 additional Good Manufacturing Practice (GMP) inspections
- improving adverse event reporting and reducing the time it takes to conduct device recalls
- strengthening the skills of FDA's device workforce in the areas of risk management and risk communication
- ensuring that FDA's device staff has the skills to keep pace with rapid advances in device technology
- expanding the Medical Device Surveillance Network (MedSun), and thereby improving CDRH's ability to identify, verify, and validate device problems

- modernizing the information technology infrastructure that supports device review and postmarket device safety

- developing new guidances for industry, maintaining the small business assistance program, and increasing training for industry on ways to reduce manufacturing errors and omissions.

5. What results will FDA achieve?

In addition to achieving the ambitious performance commitments for device review established by MDUFMA and meeting the third party inspection requirement, FDA will achieve important device safety results in seven priority areas:

- increase the number of children's hospitals and neonatal and pediatric intensive care units that participate in the MedSun program by 22 percent (5 locations), to achieve active, real-time, in-hospital surveillance for device problems

- increase the number of hospitals under the MedSun program by seven percent (25 locations) for active surveillance of device problems

- increase MedSun reports by ten percent (45 reports) on problems associated with the use of devices in pediatric populations

- increase MedSun special studies by 30 percent (6 studies) to verify, understand, and validate device problems and problem solutions

- increase electronic reporting by industry of Radiation Safety Product Reports and accidental radiation occurrences by 50 percent (3,000 reports)

- increase guidances for industry by 10 percent

- reduce the time to process Class 2 and 3 recall actions by 15 percent from 2005 levels.