Medical Product Safety and Development
$17,395,000 / 8 FTE

1. Why is this funding necessary?

A. Medical Product Program Increases

The Medical Product Safety and Development Initiative advances core FDA responsibility to protect the public health. The initiative allows FDA to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, and animal drugs and medicated feed. The investments in this initiative will increase FDA's ability to effectively monitor the safety of medical products, including imported products.

At the same time, the FDA mission to promote public health requires that we assist medical product manufacturers as they develop new products to treat life-threatening diseases and conditions. The investments in this initiative allow FDA to help innovators overcome product development challenges and maintain America's world leadership in medical innovation.

This initiative also supports FDA responsibilities under the Import Safety Action Plan that the Administration announced on November 6, 2007. The Action Plan includes steps to improve the safety of imports entering the United States, including imports of medical products. Implementing the recommendations in the Action Plan will build safety into medical product imports every step of the way.

B. Cost of Living Pay Increase for Medical Product Programs

FDA regulates a diverse and complex portfolio of products that account for 20 percent of U.S. consumer spending. FDA can only accomplish these responsibilities if it has sufficient resources to pay the scientific, technical, and technical staff that is essential to FDA operations.

The FDA mission of protecting public health is a personnel-intensive activity. FDA delivers its public health mission through a highly trained professional workforce. Personnel and related costs account for 80 percent of FDA's annual expenditures. To maintain a strong scientific capability, FDA must employ, train, develop, and retain highly trained professionals.

The Medical Product Safety and Development Initiative includes funds for the cost of living pay increase for employees who contribute to FDA's medical product programs. If FDA does not receive the resources to pay these costs, FDA cannot fulfill its fundamental mission to the American public. Providing the funds for FDA to meet the annual pay increase allows FDA to achieve performance commitments and ensures that FDA can anticipate and respond to public health emergencies.

2. What activities will these funds support?

A. Funding Table

The table below displays the distribution of funds for this initiative across FDA programs.

Modernizing Medical Product Development

Dollars in Millions

Program	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	+/- FY 2008
Budget Authority:				
Human Drugs	**$315.138**	**$353.269**	**$360.281**	**+7.012**
Center	$230.760	$266.131	269.999	+3.868
Field Activities	$84.378	$87.138	90.282	+3.144
Biologics	**$146.328**	**$155.229**	**$159.295**	**+4.066**
Center	$117.774	$125.834	129.292	+3.458
Field Activities	$28.554	$29.395	30.003	+0.608
Animal Drugs and Feeds	**$19.916**	**$20.384**	**$21.384**	**+1.000**
Center	$18.097	$18.519	19.519	+1.000
Field Activities	$1.819	$1.865	1.865	0
Devices and Radiological Health	**$230.682**	**$237.992**	**$242.921**	**+4.929**
Center	$172.257	$177.839	180.856	+3.017
Field Activities	$58.425	$60.153	62.065	+1.912
National Center for Toxicological Research	**$38.615**	**$39.683**	**$40.071**	**+0.388**
Headquarters and Office of the Commissioner	**$59.654**	**$63.370**	**$63.370**	**0**
Total, Budget Authority	**$810.333**	**$869.927**	**$887.322**	**+17.395**
Proposed Generic Drug User Fee:			**$16.628**	**+16.628**
Proposed Animal Generic Drug User Fee:			**$4.831**	**+4.831**
Total, User Fee			**$21.459**	**+21.459**
Total, Program Level	**$810.333**	**$869.927**	**$908.781**	**+38.854**

B. Activities that the Initiative Supports

i. Medical Product Program Increases

FDA's FY 2009 budget proposes the following investments to modernize medical product safety and development:

- In the Biologics Program, the resources in this initiative will allow FDA to strengthen essential infrastructure, including laboratory capacity and review expertise to prevent, detect, and respond to emerging safety threats in blood and blood products.

- In the Biologics Program, the resources in this initiative will allow FDA to strengthen medical and microbiologic review and acquire greater epidemiologic expertise to conduct adverse event analysis and safety investigations. FDA will also improve tissue safety by conducting workshops to educate industry about tissue processing and tissue safety technologies.

- In the Human Drugs Program, the resources in this initiative will permit FDA to improve import safety by allowing FDA to hire three new agents in the ORA field operations to conduct import investigations of criminal drug activity.

- In the Device and Radiological Health Program, FDA will strengthen import safety by improving the ability of the ORA field operations to work on import issues with Customs and Border Protection and other agencies. FDA will also leverage information from other sources to conduct stronger risk-based entry review of medical devices.

- In the Animal Drugs and Feed Program, the resources in this initiative will allow FDA to provide grants to stimulate development of new animal drugs under the Minor Use and Minor Species Animal Health Act of 2004.

ii. Cost of Living Pay Increase for Medical Product Programs

Funding the cost of living pay increase allows FDA to retain its professional workforce by paying salary increases that track the cost of living. Without these funds, FDA must reduce the number of inspectors, medical and consumer safety officers, medical product reviewers, postmarket safety specialists, and other health experts that perform essential functions in FDA's mission to protect and promote public health.

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

Not funding the Medical Product Safety and Development Initiative will impair FDA's ability to perform its core responsibility to protect the public health. FDA will not be able to commence or strengthen activities to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, animal drugs and medicated feed. Finally,

FDA will not be able to implement expanded responsibilities under the Import Safety Action Plan and build safety into medical product imports every step of the way.

A. Medical Product Program Funding Increases

Not funding this initiative will have the following consequences for FDA's programs:

- In the Biologics Program, FDA will not strengthen essential infrastructure, laboratory capacity, and review expertise to prevent, detect, and respond to emerging safety threats in blood and blood products. As a result, Americans will face new risks due to threats such as malaria, babesiosis, vCJD, dengue fever, and other diseases that can be communicated through blood and in plasma-derivatives.

- In the Biologics Program, FDA will not have the resources to strengthen the review of adverse events and conduct additional safety investigations for tissues. FDA will lose an opportunity to better educate industry and practitioners about tissue processing and tissue safety technologies[1].

- In the Human Drugs Program, FDA will not be able to strengthen its ability to protect Americans from the growing risk of unsafe or counterfeit drug products entering the U.S. marketplace. The volume of drugs imported into the United States will likely increase by 12 percent during FY 2008.

- In the Device and Radiological Health Field Program, FDA will delay implementation of the Import Safety Action Plan recommendation to develop strategic information-sharing agreements to respond to import safety concerns. As the volume of imported medical devices continues to grow, American consumers face greater risk from unsafe medical devices entering the U.S. market.

- In the Animal Drugs and Feeds Program, FDA will not commence a grants program to stimulate development of new animal drugs under the Minor Use and Minor Species Animal Health Act of 2004. As a result, FDA will not provide additional public health protection from animal diseases that can be transferred to humans.

B. Cost of Living Pay Increase for Medical Product Programs

Failing to fund this initiative means that FDA must reduce core public health programs, including professional staff that performs the FDA mission. Failing to fund the cost of living pay increase will result in an FDA-wide loss of 98 FTEs. This total includes 27 Field FTEs who perform work in medical product program areas.

[1] There are more than 1.6 million tissue transplants each year in the U.S. These transplants have the potential to transmit bacterial infections, fungi, Creutzfeldt-Jakob disease, HIV, hepatitis C, and other viral infections. Because more than 100 transplants may come from a single donor, many individuals are at risk if communicable disease risk assessment and control or manufacturing practices are inadequate.

If FDA does not receive these funds, FDA must reduce staff so that FDA can pay mandatory cost of living increases for the remaining staff. The loss of these scientific and technical experts will impair FDA's ability to fulfill its public health responsibilities and to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to ensure the safety and effectives of medical products, secure the homeland, and protect the health and security of the American people.

Not funding this initiative will have far-reaching public health consequences for FDA's ability to prevent and respond to safety events related to human and animal drugs, vaccines, blood, blood products, tissues, and medical devices:

- FDA will face a diminished capacity to maintain adverse event reporting systems, identify and analyze medical product safety signals, and adequately communicate safety information to patients and the medical community.

- Preventable injuries and deaths due to adverse events, medical errors, and product defects will occur at unnecessarily high rates.

- FDA will have limited ability to implement improvements that address key concerns raised by the Institute of Medicine's September 2006 report on drug safety.

- FDA will not be able to fully implement its adolescent drug safety responsibilities, as mandated by the Best Pharmaceuticals for Children Act.

- FDA will not be able to keep pace with medical product advances when reviewing product applications, particularly in non-user fee supported areas.

- FDA will have limited capacity to strengthen the science of medical product safety and identify risks to patients at the earliest stage of medical product development or avoid safety problems before medical products reach the market.

- FDA will not be able to provide the advice and consultation that is critical to ensuring that Americans will have an adequate supply of safe, approved antivirals, or tests to detect illegal use of human antivirals in poultry.

Maintaining workforce levels means that FDA can safeguard the health of millions of Americans who consume FDA-regulated medical products on a regular basis. This investment will produce tangible benefits for the Nation's health, security, and economy.

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

The Medical Product Safety and Development initiative will promote the safety of medical products used to prevent, treat, and cure serious diseases and conditions. The initiative will allow FDA to meet the priorities for the Import Safety Action Plan, Project Bioshield, and the President's Emergency Plan for AIDS Relief.

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Through this initiative, FDA will also meet priorities for personalized healthcare, pandemic preparedness, and emergency response. Finally, the initiative also advances HHS 500-day priorities for Transforming the Healthcare System, Securing the Homeland, and Improving the Human Condition Around the World.

5. What results will FDA achieve?

A. Medical Product Programs

FDA will achieve the following results with the investments in medical product programs:

- In the Biologics Program, FDA will publish guidance on developing and implementing pathogen detection technologies for blood components.

- In the Biologics Program, FDA will review data and applications from U.S. cord blood establishments to ensure the safety and effectiveness of allogeneic cord blood products and compliance with best practices.[2]

- In the Human Drugs Program, FDA will strengthen the capacity of ORA field operations to investigate criminal import violations. Such investigations will improve import safety and protect the public health by preventing potentially dangerous counterfeit and other illegal drugs from entering the United States.

- In the Device and Radiological Health Program, FDA will improve import safety through risk-based targeting of imports using information technology enhancements that allow FDA to integrate with the Standard Establishment Data Service hosted by Customs and Border Protection.

- In the Animal Drugs and Feed Program, FDA will increase in availability of safe and effective drugs to treat minor species and uncommon diseases in major animal species. As a result, Americans will have less exposure to animal diseases that can be transferred to humans. Americans will also have less exposure to illegal drug residues in food derived from treated animals.

B. Cost of Living Pay Increase for Medical Product Programs

Funding the annual cost of living increase allows FDA to extend through FY 2009 the FDA performance for FY 2008. In contrast, failing to fund the cost of living pay increase will result in deterioration of performance across all FDA program areas.

[2] Allogeneic cord blood is from a donor of the same species, yet is genetically different, which presents a risk of an immunological response in a recipient. More than 83,000 allogeneic cord blood products are collected annually in the United States.