Safer Medical Products:
Investments for Supply Chain Safety and Security
$166,433,000 / 346 FTE

1. Why is this initiative necessary?

A. Background

For FY 2010, FDA is proposing a budget increase of $166,433,000 to improve the safety of medical products. The funding for this initiative includes $36,000,000 in new user fees for generic drug review.

The FY 2010 Safer Medical Products Initiative contains strategic investments to improve the safety of medical products. The initiative also includes investments that will allow FDA to implement new approaches to effectively regulate the safety and security of the supply chain of medical products that American patients rely on to maintain and improve their health.

The resources in this initiative will allow FDA to measurably improve the safety of medical products: human drugs, vaccines, blood and other biological products, medical devices, animal drugs and medicated feed. The investments in this initiative will increase FDA's capacity to effectively monitor the safety of medical products. Moreover, these investments will provide better information about the safety profile of medical products at earlier stages of development.

B. Generic Drug User Fees

Ensuring the safety, quality, and comparability of lower cost generic drugs has never been more important to the American public. Generic drugs account for 70 percent of all prescriptions dispensed in the United States, up from 50 percent just four years ago. The number of generic drug application has nearly tripled since 2001. However, staffing has not kept pace with rising workload during much of this period.

With the globalization of the drug manufacturing, generic drugs or their ingredients are more likely to be produced in countries such as India and China. In India alone, the number of facilities named in generic drug applications grew from eight in 1992 to 963 in 2008. This dramatic growth imposes additional burdens on FDA. It is becoming increasingly difficult to conduct pre-approval inspections of all foreign facilities in a timely way.

In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. Not only will generic drug applications continue to grow, but companies will also be under increasing pressure to cut costs in response to competition. Yet, cost-cutting measures have the potential to comprise drug quality. It is imperative that FDA have the resources to ensure the safety, quality, and comparability of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs.

C. Cost of Living Increase for FDA 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 fulfill its responsibilities if it has sufficient resources to pay the scientific, professional, and technical staff required to conduct the operations of FDA medical product programs.

Delivering the FDA mission is a personnel-intensive effort. FDA performs its public health mission through a highly trained professional workforce. Personnel and related costs account for 78 percent of FDA's annual expenditures. To maintain its strong science and regulatory capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

This initiative includes funds for the annual cost of living increase for employees who conduct FDA medical product programs. If FDA does not receive the resources to pay these costs, FDA cannot adequately assure the safety of medical products or fulfill its fundamental responsibilities to the American public. Providing funds to meet the annual pay increase allows FDA to achieve performance commitments for medical product programs and ensures that FDA can anticipate and respond to public health emergencies.

D. Funding Table

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Dollars in Millions

Program	FY 2008 Enacted [1]	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
Budget Authority:				
Human Drugs	**$381.288**	**$413.482**	**$457.814**	**+44.332**
Center	$280.282	302.386	329.588	+27.202
Field Activities	$101.006	111.096	128.226	+17.130
Biologics	**$167.965**	**$183.451**	**$206.438**	**+22.987**
Center	$135.457	148.134	166.182	+18.048
Field Activities	$32.508	35.317	40.256	+4.939
Animal Drugs and Feeds	**$23.738**	**$27.325**	**$31.432**	**+4.107**
Center	$20.319	23.833	26.346	+2.513
Field Activities	$3.419	3.492	5.087	+1.595
Devices and Radiological Health	**$258.086**	**$280.587**	**$315.377**	**+34.790**
Center	$192.839	209.061	234.974	+25.913
Field Activities	$65.247	71.526	80.403	+8.877
National Center for Toxicological Research	**$42.079**	**43.828**	**48.369**	**+4.541**
Headquarters and Office of the Commissioner	**$71.576**	**75.722**	**84.816**	**+9.094**
Total, Budget Authority	**$944.732**	**$1,024.395**	**$1,144.247**	**+119.852**
Proposed Generic Drug User Fee:	**$0.000**	**$0.000**	**$36.000**	**+36.000**
Proposed Reinspection Fee	**$0.000**	**$0.000**	**$10.581**	**+10.581**
Total, Program Level	**$944.732**	**$1,024.395**	**$1,190.828**	**$166.433**

[1] *Amounts include June 30,2008 supplemental appropriation.*

2. What are the objectives of Supply Chain Safety and Security?

The globalization of the manufacturing and supply of medical products that FDA regulates and American patients rely on to maintain and improve their health poses unique and demanding challenges for FDA. In the complex and rapidly changing environment driven by globalization, FDA cannot rely on traditional approaches – inspection and sampling at the U.S. border – to protect Americans and ensure the safety of medical products. Rapid globalization requires that

FDA implement new approaches and conduct new activities to effectively regulate the supply chain. The priorities proposed in this initiative will assure the safety and security of foreign and domestic sources of ingredients, components, and finished products at all points in the supply chain, including their eventual use by American consumers.

Supply Chain Safety and Security relies on risk-based prevention with a verification-focused approach to hold all segments of industry accountable for ensuring that their products meet U.S. safety standards, with FDA verifying compliance with standards. Supply Chain Safety and Security also extends FDA's reach by supporting and leveraging the activities of, and benefiting from information generated by, trusted State, local and foreign regulatory partners.

The following are some of the key principles of FDA Supply Chain Safety and Security that this FY 2010 initiative will support:

Oversight of the Supply Chain – FDA will increase medical product safety and security by enhancing oversight of entities in the supply chain. FDA will use traditional and innovative mechanisms that include FDA inspections and field exams, integrated federal-state oversight, and greater access to inspection data and results acquired from trusted foreign regulatory authorities. These activities will prevent harm by achieving greater compliance with FDA safety standards and detecting and correcting safety risks.

Response – When problems occur, FDA will respond more effectively with rapid and targeted product tracing using to more accurately identify firms that are responsible for the problem. FDA will also better identify firms that are not associated with the safety problem. FDA will better coordinate its response with state and local authorities and strengthen its laboratory analysis capability and capacity, including greater electronic connectivity with other federal, state, and local laboratories.

Targeting Areas of Greatest Risk – FDA will allocate resources based on data-driven risk analysis. FDA will achieve this objective by increased the quality and quantity of relevant data it analyzes on products and manufacturers that are part of the supply chain. FDA's success will increasingly depend on modern information technology systems, better analytic tools, and better recruiting and training of personnel in statistical and decision sciences, informatics, and operations research, as well as the traditional fields of natural sciences and engineering. The result will be a stronger ability to target products or firms that violate FDA safety standards.

Risk Communication – FDA will improve safety through better risk communication. Better risk communication will ensure that patients understand what to do – and not do – in response to safety problems.

3. What will FDA achieve with this investment?

A. Specific activities that the funds in this initiative support

The following are examples of investments in FDA's Safer Medical Products Initiative:

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Safety of biological products –

FDA will hire experts to bring additional expertise to blood, tissue and vaccine safety teams, which will strengthen the ability of these teams to analyze adverse events. FDA will also modernize blood, tissue, and vaccine standards to enhance product development, safety and quality.

FDA will strengthen the safety of the supply chain for biological products by providing increased support for inspection teams and by working with biological manufacturers to establish quality systems focused on product safety and quality. CBER will also develop new screening tests for emerging blood-borne diseases.

Safety of medical devices –

FDA will strengthen the safety of the supply chain for medical devices by employing a global medical device nomenclature to improve postmarket surveillance and facilitate our ability to share and analyze adverse event reports with other regulators.

FDA will hire and train staff to provide technical assistance to domestic and foreign inspections of medical device manufacturers and to provide support to the device activities of FDA foreign offices.

FDA will strengthen the safety of the supply chain for medical devices by delivering training to field offices on the technical aspects of conducting device inspections. FDA will also conduct audits of inspection reports issues by other countries.

FDA will more rapidly identify product defects in medical devices by developing web-based tools to gather unique device information.

FDA will hire staff to develop new tests and strengthen safety reviews of ophthalmic medical devices.

Safety of human drugs –

FDA will identify internet sites that expose consumers to drug fraud. This effort will improve FDA's ability to conduct enforcement against those who sell and promote fraudulently marketed products.

FDA will perform research to establish generic bioequivalence standards for novel products. FDA will also expand generic drug education that informs patients of the value of generic drugs and strengthens the confidence of health care providers in prescribing and treating patients with generics.

FDA will evaluate how we use of Risk Evaluation and Mitigation Strategies to minimizing drug risks and promoting save drug use.

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FDA will develop policies to implement the Administration's policy of allowing Americans to buy safe and effective drugs from other countries. The request includes funds to allow FDA to begin working with stakeholders to develop policy options related to drug importation. In addition, the Administration will work with Congress on legislation to support the infrastructure required to ensure the safety of these medicines.

Safety of veterinary drugs and feeds –

FDA will strengthen the supply chain by improving the sampling of imported animal drugs and feeds for chemical and microbiological contamination and for BSE.

FDA will conduct scientific and risk evaluation of animal biotechnology products. FDA will also review of new animal biotechnology products and coordinate U.S. and foreign regulation on animal health issues within FDA's jurisdiction.

FDA will hire cross-disciplinary staff to provide technical and laboratory support to develop and improve methods to detect pathogens.

FDA will strengthen the supply chain by partnering with states to conduct targeted sample analysis of animal feeds. FDA will also expand laboratory capacity to accommodate increased levels of feed sampling.

Safety of pediatric medical products –

FDA will collect adverse event information related to medical devices from pediatric hospitals and will conduct a pediatric medical trials workshop to address unmet pediatric device needs.

FDA will support additional pediatric medical device research, increase technical assistance for orphan product development, and expand the amount of information that it disseminates related to foreign pediatric clinical trials.

B. Generic Drug User Fees

The FY 2010 budget for Generic Drug User Fees represents the first year of a multi-year program to expand FDA's capacity to ensure the safety, quality, and comparability of lower cost generic drugs. In the short-term, the results of this initiative will include hiring and training of additional staff so that new staff gains the technical expertise that allows FDA to expand its ability to conduct generic drug application reviews.

These funds will support the hiring and training of the expert staff necessary for a modernized and effective generic drug review and oversight program. FDA will also enhance a range of operations related to generic drugs. This effort will include scientific work on generic bioequivalence standards, process improvements to modernize the generic drug review process, a more effective electronic review process, greater capacity to conduct pre-approval inspections,

and more oversight of foreign manufacturing sites. Many of these operations are essential to the safety and security of the supply chain for generic drugs.

Once these building blocks are in place, FDA will be better able to conduct timely, efficient, and effective reviews of a significantly greater number of generic drug applications. FDA will also be able to provide appropriate oversight of manufacturing facilities across the globe to ensure the safety and security of the supply chain of generic drugs. Ultimately, FDA will be able to ensure greater access to generic drugs and maintain confidence that generic drugs that are safe, of high quality, and comparable to their brand competitors. This will ensure the viability of the generic industry and its ability to provide lower cost drugs to the American public.

C. Information Technology

Modernizing and enhancing information technology (IT) at FDA will allow FDA to collect, store and analyze large volumes of regulatory, scientific, and risk-based data. Efficiently analyzing this data through IT improvements will help ensure that FDA achieves its mission of protecting the public health by assuring the safety and security of the drugs, devices, vaccines, and other medical products that patients rely on to protect or improve their health.

Through the FY 2010 IT investments in the Harmonized Inventory Initiative, FDA will develop and validate a database with a complete and reliable inventory of firms, facilities, products, components and ingredients. The database will also identify relationships between firms and points of contact for all FDA regulated products, whether imported or domestic. FDA will also upgrade and integrate the IT systems it uses to receive, analyze, and assess quality and safety reports for medical products. These IT improvements will measurably improve FDA's ability to assure the safety and effectiveness of imported and domestic medical products and thereby protect the safety of American patients.

D. Cost of Living Pay Increase for FDA Medical Product Programs

Funding the annual cost of living increase allows FDA to sustain ongoing performance in the medical product programs that are essential to allowing American patients to enjoy the benefits of safe and effective drugs. In contrast, failing to fund the annual cost of living increase will cause performance to deteriorate across all FDA medical product programs.

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

A. Safer Medical Products

Not funding this initiative will threaten the health of the American Public. FDA will face a significantly diminished capacity to address adverse events, identify and analyze medical product safety signals, and communicate safety information to patients and the medical community. This will lead to preventable injuries and deaths due to adverse events, medical errors, and product defects, with increased health care costs for patients, insurers, and federal and state governments.

B. Generic Drug User Fees

The failure to approve generic drug user fees will result in continued understaffing of generic drug review, gaps in science-based quality standards for generic drugs, and insufficient pre-approval inspections to support the growth in generic applications. This will place serious constraints on FDA's ability to provide proper oversight of the growing number of increasingly complex applications for generic drugs being manufactured in distant foreign facilities with little prior regulatory oversight. This invites a greater opportunity for the public to question the safety, quality and comparability of generic drugs. A loss of confidence in generic drug alternatives will hurt the generic industry and erode the public benefits and health care cost savings provided by lower-cost generic drugs.

C. Information Technology

FDA will have an inadequate ability to collect, store and analyze large volumes of regulatory, scientific, and risk-based information. Without these IT investments, FDA cannot transform a broad array of FDA operations: from bioinformatics, to import surveillance, to scientific computing, to detecting adverse events. Not funding these IT priorities will limit FDA's ability to protect the public health and assure the safety and security of medical products that Americans rely on to protect and improve their health.

D. Cost of Living Pay Increase for FDA Medical Product Programs

Not receiving these funds means that FDA must reduce core public health programs, particularly the professional staff that perform our FDA mission. Failing to fund this initiative will also limit FDA's ability to perform analysis on the safety and effectiveness of medical products that Americans rely on to sustain or improve their health.

Failing to fund the cost of living pay increase will result in an FDA-wide loss of 81 FTEs in medical product program areas. This total includes 24 Field FTEs who conduct inspections and perform other medical product safety work.

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 limit FDA's ability to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to effectively regulate the safety and security of the supply chain of medical products and protect the health and security of the American people.

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