Reinspection User Fee
+$23,276,000 (Mandatory User Fee)

1. Why is this initiative necessary?

FDA is proposing a new mandatory user fee to require establishments that FDA inspects to pay the full costs of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements. FDA currently funds this activity through discretionary appropriations. The reinspection user fee is one of the legislative proposals in FDA's Food Protection Plan.

The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of reinspection. When FDA identifies violations during an inspection or issues a warning letter following an inspection, FDA conducts follow-up inspections to verify that the corrective action. FDA procedures usually require that FDA conduct a follow-up inspection of the firm within 90 days of issuing a warning letter.

The Budget includes $23,276,000 in budget authority for reinspections. Upon enactment of legislation that authorizes FDA to assess and collect these fees, the Administration will work with Congress to re-categorize these fees as discretionary.

The following table identifies FY 2009 spending for Reinspection User Fees:

Discretionary Budget Authority and Mandatory User Fees – Reinspection User Fees

Description	FY 2009 Discretionary Budget Authority	FY 2009 Mandatory User Fee[1]
Field	($13,014,000)	$13,014,000
HQ/OC	($7,512,000)	$7,512,000
GSA Rent and Other Rent-Related Activities	($2,750,000)	2,750,000
Total	**(23,276,000)**	**$23,276,000**

[1] The FY 2009 Budget includes $23,276,000 in discretionary budget authority for reinspection activities. When Congress enacts authorizing legislation for the Reinspection User Fee, the Administration will work with Congress to reclassify the user fees as discretionary.

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

FDA protects the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. To meet these public health responsibilities, FDA conducts inspections and evaluates laboratory analyses to ensure that FDA products comply with the laws and regulations that the FDA enforces.

The Reinspection User Fee enhances public health by providing mandatory user fee resources for reinspections to determine if previously identified out-of-compliance firms have returned to compliance. Reinspections also determine whether FDA needs to take further FDA regulatory action.

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

If facilities that fail to comply with FDA regulations do not bear the cost of reinspections, FDA must shift resources from other high-priority program activities to conduct reinspections. Examples of these priority public health activities include efforts to assure drug safety and efforts to protect the nation's food supply from contamination and from potential terrorist acts.

While it is good business practice for firms to ensure the safety of products before they reach consumers, FDA enforcement inspections also help ensure the safety of products before they reach consumers. The Reinspection User Fee provides an additional incentive for facilities to comply with FDA regulations.

4. What activities will these funds support?

The costs recovered from industry to fully fund the reinspection user fee program will be significant:

- $13,014,000 for 102 field inspectors
- $7,512,000 for indirect and support costs (e.g., legal, science review, IT), and 16 FTE
- $2,750,000 for GSA Rent and Rent Related costs.

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers to assess their compliance with Good Manufacturing Practice requirements. ORA inspects domestic and foreign facilities. Revenue from the user fee will reimburse ORA for costs associated with 118 FTE and related expenses required to reinspect firms that fail to comply with FDA regulations designed to protect the public from unsafe products.

5. What results will FDA achieve?

FDA estimates that the user fee revenue will fund approximately 1,240 reinspections in FY 2009.

Food and Animal Feed Export Certification User Fee
+$3,741,000 (Mandatory User Fee)

1. Why is this initiative necessary?

In FY 2009, FDA estimates that the agency will issue 37,000 food and animal feed export certificates. FDA currently funds this activity through discretionary appropriations.

The Administration is re-proposing legislation authorizing FDA to collect user fees for issuing food and animal feed export certificates within 20 days of the receipt of a request. The food and animal feed certificate user fee is one of the recommended legislative proposals in FDA's Food Protection Plan.

Under this proposal, these activities will be reclassified as mandatory user fees in FY 2008. Imposing a fee would generate an estimated $3,741,000 in revenue, an amount sufficient to cover the cost of issuing certificates. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. The budget includes $3,741,000 in budget authority for export certifications. Upon enactment of legislation that authorizes FDA to assess and collect these fees, the Administration will work with Congress to re-categorize these fees as discretionary.

Discretionary Budget Authority Mandatory User Fees -
Food and Animal Feed Export Certification

Description	FY 2009 Discretionary Budget Authority	FY 2009 Mandatory User Fee[1]
CFSAN	($958,000)	$958,000
CVM	($67,000)	$67,000
Field	($2,716,000)	$2,716,000
Total	**($3,741,000)**	**$3,741,000**

[1] The FY 2008 Budget includes $3,741,000 in discretionary budget authority for reinspection activities. Once authorizing legislation is enacted, the Administration will work with Congress to reclassify the user fees as discretionary.

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

Section 801 (e)(4)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) authorizes FDA to collect user fees for export certificates for human drugs, animal drugs, and devices. However, this section does not extend to collecting user fees for export certificates for foods and animal feed. FDA expends significant resources annually to issue these certificates, and FDA needs to focus its resources on activities that are central to its public health mission.

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

FDA must ensure its resources are used for maximum public health impact. Currently, FDA resources to support food export-related activities must be diverted from appropriated funds

intended to support FDA's public health activities and programs. FDA is now finding it increasingly difficult to strike an appropriate balance between its paramount mission of protecting the health of American consumers through programs to ensure the safety of domestic and imported products, and its emerging role of facilitating the international trade of U.S.-produced foods and feeds by attesting to the safety of these products exported from the United States.

4. What activities will these funds support?

FDA's ability to issue certificates in a timely fashion depends on FDA securing the resources necessary to offset the costs associated with issuing export certificates for foods and feeds. Thus, for FY 2009, the FDA proposes $3,741,000 in mandatory user fees to support activities associated with facilitating international trade.

5. What results will FDA achieve?

The user fee proposal will allow FDA to issue an estimated 37,000 food and animal feed export certificates in FY 2009. In its *Affirmative Agenda for International Activities* report, FDA's Center for Food Safety and Applied Nutrition stated its intent to try to find effective and resource-efficient approaches to issuing export certificates for foods.

The purpose of this proposal is to cover FDA's resources needed to issue food and feed export certificates benefiting U.S. food and feed manufacturers and exporters.