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. FDA proposed the reinspection user fee in FY 2007.

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 to an establishment that FDA inspects, FDA conducts follow-up inspections to verify that the establishment has taken 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 2008 spending for Reinspection User Fees:

Discretionary Budget Authority and Mandatory User Fees – Reinspection User Fees

Description	FY 2007 President's Budget[1]	FY 2008 Discretionary Budget Authority	FY 2008 Mandatory User Fee[2]
Field	-	($13,014,000)	$13,014,000
Other Activities	-	($7,512,000)	$7,512,000
GSA Rent and Other Rent-Related Activities	-	($2,750,000)	2,750,000
Total	**0**	**(23,276,000)**	**$23,276,000**

[1] The FY 2007 President's Budget proposed a Reinspection User Fee, for a total of $22,000,000. However, there has not been legislative action on the proposed user fee, so this amount does not appear in the FY 2007 PB column.

[2] The FY 2008 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 2008.