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

1. Why is this initiative necessary?

In FY 2008, 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. 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 the agency'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 Mandatory User Fees – Food and Animal Feed Export Certification User Fees

Description	FY 2007 Estimate ¹	FY 2008 Discretionary Budget Authority	FY 2008 Mandatory User Fee ²
CFSAN	-	(\$958,000)	\$958,000
CVM	-	(\$67,000)	\$67,000
Field	-	(\$2,716,000)	\$2,716,000
Total	0	(\$3,741,000)	\$3,741,000

¹ The Food and Animal Export Certification user fee was proposed in the FY 20007 President's Budget for a total of \$3,741,000 however, there has not yet been legislative action so the amount is not shown in the FY 2007 PB column.

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 the agency 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

²The 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.

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 aimed at ensuring the safety of domestic and imported products, and its emerging, but unmandated, 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?

The agency'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 2008, the FDA proposes \$3,741,000 in mandatory user fees to support FDA activities associated with facilitating international trade.

5. What results will FDA achieve?

The user fee proposal would allow FDA to issue an estimated 37,000 food and animal feed export certificates in FY 2008. 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 the agency's resources needed to issue food and feed export certificates benefiting U.S. food and feed manufacturers and exporters.