

FDA Proposed User Fees
+\$269,434,000 / +518 FTE

FDA's proposed new user fee programs support food and medical product safety. The following table displays funding levels from FY 2012 Enacted through FY 2014 Request.

Proposed User Fee Funding
(Dollars in Thousands)

Proposed Programs	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Food Import	\$0	\$0	\$0	\$165,690	\$165,690
Food Facility Registration and Inspection	\$0	\$0	\$0	\$58,936	\$58,936
Cosmetics	\$0	\$0	\$0	\$19,074	\$19,074
Medical Product Reinspection	\$0	\$0	\$0	\$15,043	\$15,043
International Courier	\$0	\$0	\$0	\$5,692	\$5,692
Food Contact Notification	\$0	\$0	\$0	\$4,999	\$4,999
Total	\$0	\$0	\$0	\$269,434	\$269,434

Food Import User Fee

FDA is proposing a new Food Import User Fee in FY 2014 to support FDA's food and feed safety efforts. The fee will have exemptions for small importers and a maximum charge for large importers. An important component of FDA's safety efforts is modernizing the import system, which has become more critical as the number of food and feed imports has been growing 10 percent per year. These imports pose a unique challenge to FDA since there are over 100,000 food and feed manufacturers in 130 countries exporting food and feed to the United States.

The new import fees target activities associated with the improvements to the import process. More specifically, these fees would both enhance the safety protections for imported food and feed while simultaneously improving the efficiency and speed of food and feed entry decisions by FDA inspectors, thus assisting the smooth flow of international trade in safe food and feed.

Food Facility Registration and Inspection User Fee

FDA is proposing a new Food Facility Registration and Inspection Fee in FY 2014 to support food and feed safety modernization activities. Revenue from registration fees will target new and improved activities required by the Food Safety Modernization Act (FSMA), to modernize FDA's inspection system. The fees will enable FDA to increase the

effectiveness of inspections through adoption of preventive controls, training of personnel to inspect against the new prevention standards, and developing new ways to educate and inform industry.

Fees will also support improvements in food and feed safety science and risk analysis, so that knowledge of the methods of food and feed contamination can contribute to preventing food and feed safety outbreaks, and ensure that resources are better focused on areas of greatest risk.

Cosmetics User Fee

FDA is proposing new legislative authority to require domestic and foreign cosmetic manufacturers to pay an annual registration fee to support FDA cosmetic safety and other FDA cosmetic responsibilities. The user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

During the past decade, Americans have seen an explosion in the numbers and types of cosmetic products sold annually. In the face of this growth, FDA has inadequate, incomplete, and often outdated data on cosmetic products and ingredients. The cosmetic industry is also undergoing rapid and significant change. Manufacturing has become more global, cosmetic technology has become increasingly sophisticated, and cosmetic ingredients have become more complex. For example, the use of nanotechnology in cosmetics may pose safety challenges.

FDA proposes to strengthen the FDA Cosmetics Program by relying on user fees to supplement appropriations of budget authority. With these resources, FDA will conduct priority Cosmetics Program activities that meet public health and industry goals.

Food Contact Substance Notification User Fee

FDA has statutory responsibility for the safety of all food contact substances in the United States. To ensure the safety of these products, the Food and Drug Administration Modernization Act of 1997 (FDAMA) established a premarket notification process for food contact substances, known as the Food Contact Notification (FCN) Program.

Section 409(h)(5) of the FD&C Act specifies that the FCN program can operate only if adequately funded. The requirement for adequate funding protects public health by ensuring that FDA has sufficient resources to prevent the marketing of unsafe food contact substances.

FDA is proposing this new user fee to assure that the FCN program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations.

International Courier User Fee

FDA is proposing a new International Courier User Fee to support activities associated with increased surveillance of FDA-regulated commodities, predominantly medical products, at express courier hubs. The user fee will address the growing volume of imports that enter through international couriers and the cost of FDA import operations to support international courier activities. Funding generated from this user fee program will allow FDA to conduct the following essential import safety activities:

conduct entry reviews

collect samples and conduct physical exams to determine whether a product can be admitted into the United States.

initiate compliance actions to prevent release of unsafe products

establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

Of the \$5,692,000 requested in FY 2014, \$1,175,000 supports Food Safety and \$4,517,000 supports Medical Product Safety.

Medical Product Reinspection User Fees

FDA is proposing a new user fee to require establishments that FDA inspects to pay the full costs of reinspections and associated follow-up work. 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 will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements.

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.