

Food and Drug Administration

FY 2014 Operating Plan Narrative

Overview

The fiscal year (FY) 2014 Enacted Level for FDA is \$4.4 billion for the total program level, which is \$402 million above the FY 2013 Operating Level. This amount excludes the one-time Food and Drug Safety funding appropriated in FY 2013. Of the total FY 2014 funding received, \$2.6 billion is from budget authority (BA) and \$1.8 billion is from user fees (UF).

Budget Authority

The FY 2014 budget authority funding provides an additional \$221 million above the FY 2013 Operating Level. The FY 2014 Enacted provides an increase of \$119 million, for a total of \$1.2 billion, for Food Safety, an increase of \$95.2 million, for a total of \$1.3 billion, for Medical Product Safety, and an increase of \$2.8 million, for a total of \$24.6 million, for Medical Countermeasures. Within these amounts, \$9.8 million is included for increased pay costs and \$13.0 million is included for Infrastructure. The FY 2014 Enacted also provides an increase of \$3.9 million for Buildings and Facilities. Funding for the China Initiative is maintained.

User Fees

The FY 2014 user fee funding provides an additional \$180.6 million above the FY 2013 operating level. This includes all of the requested amounts for current law user fees in the FY 2014 President's Budget. This funding will support FDA's implementation of Titles I-IV of the Food and Drug Safety and Innovation Act (FDASIA) and the Family Smoking Prevention and Tobacco Control Act. The FY 2014 appropriation did not include funding for the two major food and feed safety user fee proposals, a Food Import Fee (\$166 million) and a Food Facility Registration and Inspection Fee (\$59 million). However, Congress restored FDA's access to an estimated \$79 million in user fees that were sequestered in FY 2013. Those resources will be applied to their respective programs.

Key Initiatives:

Food Safety Modernization

FDA received a \$119 million increase for Food Safety, which includes \$53.5 million to support the Food Safety Modernization Initiative. These resources will support Food Safety Modernization through rulemaking and guidance development, risk analysis, and investments in science-based tools and methods to improve the detection of pathogens, contaminants, and adulterants. In addition, FDA will be able to provide training and expert back-up for inspectors to ensure high quality and consistent inspections, deliver technical assistance to small growers and processors, support state involvement through grants and training, and improve safety oversight of imports.

Medical Product Innovation and FDASIA implementation

FDA has significant new authorities and mandates from FDASIA to modernize medical product safety and innovation. Some of the funding provided in FY 2014 will enable FDA to equip and obtain certification for two already-built labs. These labs will not only be a cornerstone for FDA's effort to modernize regulatory science and promote medical product innovation, they will be a resource for the entire federal government, for example, on development of new Medical Countermeasures to help protect the American people from attack or epidemic.

The budget for the Medical Countermeasures Initiative (MCMi) for FY 2014 is \$24.6 million. FDA's MCMi focuses on facilitating the development and availability of medical countermeasures to counter chemical, biological, radiological, and nuclear (CBRN) and emerging infectious disease threats, such as pandemic influenza. The additional resources will support science and partnerships to improve medical countermeasure development timelines and the success rates. The resources are prioritized to program areas that provide the most direct support to U.S. government medical countermeasure priorities for protecting civilian and military personnel.

NCTR

FDA received a \$7.5 million increase for NCTR compared to the FY 2013 Operating Level. This will provide additional funding to support NCTR's important research activities.

Enhanced Oversight of the Global Supply Chain

The FY 2014 FDA budget provides \$10 million in base funding for safety inspections in China. This funding will result in identification of safety problems before products reach the U.S., fewer import emergencies, and a reduction in illnesses and injuries.

Infrastructure and Rent

The funding provided an additional \$13.0 million that will cover upgrading and improving facilities for FDA to carry out cutting-edge research and ensure that FDA is providing the best possible oversight of the food supply, medical products, and tobacco.

Buildings and Facilities (B&F) Program

FDA received a \$3.9 million increase in B&F funding for a total of \$8.8 million. These funds will be used to construct, renovate, repair and improve FDA's 85 owned buildings and the associated infrastructure for six sites, including numerous laboratory facilities, where operations critical to FDA's public health mission are conducted. Approximately 1,212 staff and contractors are employed at these sites.