

FDA FY 2014 Budget Request

Overview

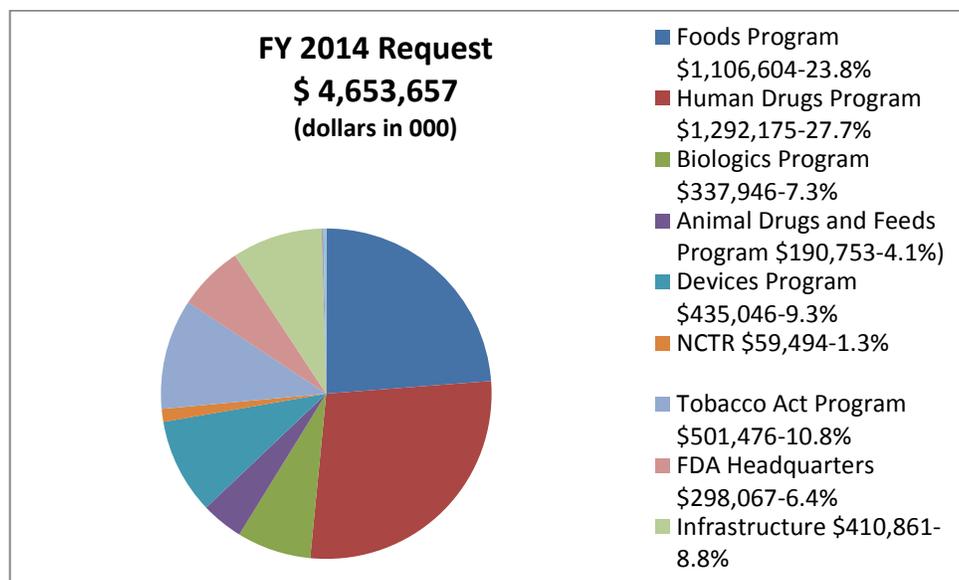
The fiscal year (FY) 2014 President’s Budget request for FDA is \$4,653,657,000 comprised of \$2,557,693,000 in budget authority and \$2,095,964,000 in total user fees.

The FY 2014 budget request provides a total program level increase of \$821,453,000 above the amount enacted into law for FY 2012 distributed between a budget authority increase of \$51,884,000 and a total user fee increase of \$769,569,000. The user fee increases are \$269,434,000 for proposed new user fees, \$175,510,000 for current law user fees, and \$324,625,000 for indefinite user fees.

The following table summarizes the FDA budgets for fiscal years 2012, 2013 and 2014.

FY 2014 Overview Food and Drug Administration (Dollars in thousands)					
	FY 2012 Enacted	FY 2012 Actuals	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Total	\$3,832,204	\$3,556,161	\$4,183,570	\$4,653,657	\$821,453
Budget Authority	\$2,505,809	\$2,506,553	\$2,521,145	\$2,557,693	\$51,884
User Fees	\$1,326,395	\$1,049,608	\$1,662,425	\$2,095,964	\$769,569
FTE	13,496	13,382	14,416	15,424	1,928

The distribution of the FY 2014 Request by programs is illustrated in the following chart.



Priority Investments

In an increasingly global economy, and facing revolutionary advances in science and technology, FDA must modernize and transform operations to address the emerging needs of the 21st century. We envision a transformed and integrated global food safety system, focused on prevention and improved nutrition. We envision patients and families benefiting from decades of investment in medical science and technology. We also envision a strong foundation of regulatory science to support FDA efforts to ensure the safety and effectiveness of new medical products throughout their life cycles.

1. Transforming Food Safety

Budget Authority: +\$43,410,000 / +59 FTE

User Fees: +\$252,269,000 / +548 FTE

FDA will use the resources in this initiative to build prevention-focused domestic and import food and feed safety systems that implement FSMA authorities and oversight tools. These investments will provide industry with consistent and transparent food and feed safety guidance to assure the safety of America's food and feed supply. This investment is modest compared to the economic value it can deliver: reduced costs to industry, government, and the health care system due to less foodborne illness. Currently 48 million foodborne illnesses occur each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths. The average cost per case of foodborne illness is estimated at \$1,626 – more than \$78 billion per year.

2. Medical Product Innovation and FDASIA implementation

2a. Current Law User Fees +\$500,135,000 / 1,248 FTE

The User Fee programs allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The fees collected are used to support the review and surveillance of human and animal drugs, medical and mammography devices, color additives, exports, and tobacco products. Approximately \$2.5m of the Current Law User Fee increases are for Transforming Food Safety activities.

Existing user fee laws authorize user fee increases for many of the FDA user fee programs. These requested increases would expand the available options for treating and curing diseases and addressing other important public health needs.

2.b. White Oak Consolidation

Budget Authority: +\$17,658,000 / 0 FTE

User Fees: +283,000 / 0 FTE

Supportive of FDA's public health mission, Congress directed FDA and GSA to construct up-to-date facilities for FDA to carry out cutting-edge research to ensure that FDA is providing the best possible oversight over its regulated products to protect the American public. The requested funds are needed to support the outfitting and required certification and operation of the two largest laboratories – Buildings 52 and 72, the Life Sciences-Biodefense Complex (LSBC) and the expansion of the vivarium (Complex) to be completed and be ready for occupancy in FY 2014.

These funds will be the last leg of a \$300 million investment that will enable FDA to properly equip and operate the LSBC and begin occupancy and utilization of the Complex. The lab is largely complete; these funds support final build-out and the certifications needed for occupancy. Failure to make this final, small investment will delay the return on investment on this facility and place FDA's substantial prior investment in this facility in jeopardy.

2.c. Medical Countermeasures (MCMi)

Budget Authority: +\$3,510,000

According to the U.S. intelligence community, chemical, biological, radiological and nuclear (CBRN) weapons and emerging infectious diseases present real, substantial and growing threats to the national security of the United States.

MCMi supports important national security and public health priorities. Through the MCMi, FDA is helping to ensure that Americans have access to the medicines and vaccines they need to counter a deliberate CBRN attack or a naturally occurring epidemic.

Funding this initiative will support a strong FDA workforce with enhanced expertise in CBRN issues, faster development and availability of MCMs, a more resilient Nation that is better able to cope with the CBRN and infectious disease threats, and stronger national security.

3. Oversight of the global supply chain- Safety Inspections in China

Budget Authority: +\$10,000,000 / 19 FTE

FDA will strengthen the supply chain for foods, drugs, and ingredients manufactured in China. The China Initiative, in which we work with Chinese industry and train our regulatory counterparts in China, is essential to improving the safety of exports from this vast country. Although we will increase the number of inspectors based in China, FDA cannot assure the safety of the huge and

growing number of Chinese exports through inspections alone. Through this initiative, Chinese regulators will enhance their understanding of FDA requirements and strengthen their own capacity to assure the safety of the food and drugs that their industries export to the United States

The result will be fewer import safety emergencies, less foodborne illness and earlier identification of safety problems associated with foods, drugs, and ingredients manufactured in China.

Details of the FDA FY 2014 Initiatives

The FDA Congressional Budget Justification contains business case papers justifying the funding increases described above. Within each business case paper, FDA identifies the need for the FY 2014 funding, the activities that FDA will conduct, and the performance that FDA will achieve.