



FDA News

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President's FY 2010 Budget for FDA Invests Substantially in Food and Medical Product Safety *\$3.2 billion request reflects a 19 percent increase from FY 2009*

The U.S. Food and Drug Administration is requesting a budget of \$3.2 billion to protect and promote the public health as part of the President's fiscal year (FY) 2010 budget – a 19 percent increase over the current FDA fiscal year budget.

The FY 2010 request, which covers the period of Oct. 1, 2009, through Sept. 30, 2010, includes increases of \$295.2 million in budget authority and \$215.4 million in industry user fees.

The FDA budget proposes two major initiatives for FY 2010: Protecting America's Food Supply and Safer Medical Products. It also includes increases for current law user fees and for infrastructure to support critical agency operations. The FDA is also proposing four new user fees to facilitate review of generic drugs, register and inspect food manufacturing and processing facilities, reinspect facilities that fail to meet Good Manufacturing Practices and other safety requirements, and issue export certifications for food and feed.

"This historic increase in the FDA's budget is a great investment in public health," said Joshua Sharfstein, M.D., acting commissioner of food and drugs.

The following are the FDA's key proposed budget increases:

Protecting America's Food Supply (\$259.3 million) – The goal of this effort is to protect American consumers by preventing intentional and unintentional contamination. This effort invests in priorities that strengthen the safety and security of the supply chain for foods. Supply chain safety and security relies on the principle of risk-based prevention with verification. Under this principle, the FDA holds all segments of industry accountable for ensuring that their products meet U.S. safety standards. The Protecting

America's Food Supply initiative focuses on foreign and domestic sources of ingredients, components, and finished products at all points in the supply chain, including their eventual use by the American public. Within this initiative, the FDA proposes to collect a total of \$94.4 million in new user fees to register food facilities and increase food inspections, issue food and feed export certifications, and reinspect food facilities that fail to meet the FDA's safety standards.

Safer Medical Products (\$166.4 million) – This effort provides targeted resources to improve the safety of human and animal drugs, medical devices, vaccines, blood, and other medical products. It will allow the FDA to strengthen safety and security of the supply chain for medical products. The initiative also includes \$46.6 million in new user fees for generic drug review and new fees to reinspect medical product facilities that fail to meet safety standards.

Current Law User Fees (\$74.4 million) – In addition to the new user fees proposed for FY 2010, the FDA request also includes inflationary and other authorized increases for fees that support FDA review of applications for new human drugs (+\$67.5 million), animal drugs (+\$2.3 million), and medical devices (+\$4.5 million).

Follow-on Biologics & Drug Importation (\$5 million) – Within the Safer Medical Products initiative, the budget proposes a new authority for the FDA to approve follow-on biologics through a regulatory pathway that protects patient safety and promotes innovation, and includes \$5 million for the FDA to develop policies to allow Americans to buy drugs approved in other countries.

For more information on the President's FY 2010 budget for the FDA, visit:
<http://www.fda.gov/oc/oms/ofm/budget/documentation.htm>