

## Ensure a Strong FDA

**Pay: +\$21,773,000**

**Rent: +\$29,626,000**

### *1. Why is this funding necessary?*

FDA must maintain a world-class workforce to fulfill its public health mandate and achieve the promise of a healthier America. FDA's mission includes a diverse portfolio of public health responsibilities. Fulfilling these responsibilities requires a large cadre of scientists and professionals with the training and experience to respond to complex and escalating public health challenges.

To maintain a strong scientific capability and achieve its public health mission, FDA must employ, train, develop, and retain highly skilled professionals. Personnel and personnel-related costs (including GSA Rent and Other Rent and Rent-Related costs) account for 80 percent of FDA's budget authority. FDA professionals perform mission critical work at headquarters, five regional offices, 20 district offices, 13 laboratories and 157 field offices across the country.

The public trusts FDA to ensure that food on the family table is safe and wholesome, that new medical products, drugs, biological products, medical devices, and radiological products are available in a timely manner with demonstrated benefits that outweigh risks, and that product information is useful and understandable. The resources in this initiative ensure that FDA fulfills these responsibilities and continue to improve the health of the American public.

The following table identifies FY 2008 spending for the Ensure a Strong FDA initiative:

### Funding to Ensure a Strong FDA

<b>Program</b>	<b>Cost of Living Pay</b>	<b>GSA Rent</b>	<b>Other Rent &amp; Rent-Related</b>
Foods	\$7,539,000	-	-
Human Drugs	\$4,914,000	-	-
Biologics	\$2,251,000	-	-
Animal Drugs and Feeds	\$1,469,000	-	-
Devices & Radiological Health	\$3,624,000	-	-
NCTR <sup>1</sup>	\$519,000	-	\$1,196,000
HQ / OC	\$1,457,000	-	-
Other Rent and Rent-Related Activities	-	-	\$23,768,000
GSA Rental Payments	-	\$4,662,000	\$0
<b>Total</b>	<b>\$21,773,000</b>	<b>\$4,662,000</b>	<b>\$24,964,000</b>

<sup>1</sup>The request funds the accumulated \$1,196,000 requirement to allow NCTR to pay mandatory increases for such items as security and utilities.

**2. *How does this initiative support important public health priorities?***

The FDA workforce allows the agency to accomplish important public health priorities. Maintaining the workforce levels funded by this initiative will permit FDA to advance these priorities, which include improving food safety, modernizing the safety and effectiveness of medical products, transforming healthcare, and securing the homeland.

**3. *What are the risks of not proceeding with the initiative?***

FDA cannot achieve its public health mandate without sufficient resources to pay its scientific and technical staff and maintain the facilities that these staff need to perform FDA's mission. Failing to fund this initiative will mean an FDA-wide loss of 406 full-time equivalent (FTE) positions. This FTE loss will impair FDA's ability to accomplish the vision articulated in the HHS 500-day plan, the HHS Strategic and Annual Plans, FDA's performance plan, and performance commitments under user fee programs. In short, the loss of 406 FTE will significantly increase the risk of mission failure.

**4. *What specific activities will these funds support?***

This initiative includes three components: Pay Costs, Other Rent and Rent-Related Requirements, and GSA Rent.

**A. *Pay Costs* +\$21,773,000**

Funding the annual pay increase enables FDA to perform its public health mission. Without these funds, FDA must reduce the number of inspectors, medical and consumer safety officers, food safety technologists, medical product reviewers, postmarket safety experts, and other public health experts to meet higher payroll obligations. These workforce reductions will limit FDA's ability to safeguard the American public.

**B. *Other Rent and Rent-Related Activities* +\$24,964,000**

The second component of this initiative pays for increases in rent, security, and utility costs, all of which are unavoidable increases. Providing funds to pay these increased costs ensures that FDA will not have to transfer the increased costs to FDA programs. Therefore, funding this initiative ensures that FDA programs can maintain resource levels for mission-related activities in food safety, medical product safety, and other high-priority public health areas. Other Rent and Rent-Related Activities have increased due to the new White Oak facility. Costs attributable to White Oak increased because FDA is moving out of leased locations where costs, such as utilities and some security costs, are included in the GSA Rent bills.

**C. *GSA Rent* +\$4,662,000**

The third component of this initiative provides for the FY 2008 cost increases for GSA Rent. This mandatory item has increased due to the White Oak campus consolidation and due to higher costs for services such as utilities and security.

## **5. *What results will FDA achieve?***

Funding FDA's FY 2008 pay increase and the increased costs in Rent and Rent-Related accounts allows FDA to meet FY 2008 performance targets in the program areas highlighted below.

**Foods Program:** Funding the pay increase and the increased costs in the Rent and Rent-Related accounts allows the Foods Program to demonstrate results in four areas:

- increase training and improve performance in traceback activities (traceback involves tracking food contamination to its source)
- reduce average time to conduct a traceback
- increase the number of state partners that can respond in traceback emergencies
- restore 75 juice HACCP inspections, ensure the safe processing of fruit and vegetable juices, and reduce foodborne illnesses.

**Human Drugs Program:** Funding the pay increase and the increased costs in the Rent and Rent-Related accounts allows the Human Drugs Program to demonstrate results in three areas:

- conduct research and testing activities that maintain a solid scientific foundation to support regulatory decisions
- reduce the number of Citizen Petitions (excluding suitability petitions and OTC monograph related petitions) pending at the end of the fiscal year by five percent
- restore 35 foreign drug good manufacturing program inspections to ensure that foreign firms manufacture drugs in a safe and effective manner.

**Biologics Program:** Funding the pay increase and the increased costs in the Rent and Rent-Related account allows the Biologics Program to demonstrate results in five areas:

- improve review performance for blood bank and source plasma biological license applications (BLA) by ten percent
- improve review performance for blood bank and source plasma BLA supplements by five percent
- restore 16 domestic source plasma inspections, which will better ensure the safety of plasma used in products to prevent and treat diseases
- restore 16 Good Manufacturing Practices (GMP) Device inspections necessary to evaluate the manufacturing process for device products used for blood banking

- restore 12 foreign blood bank inspections to ensure the safety, efficacy, and proper labeling of blood and blood products.

**Animal Drugs and Feeds Program:** Funding the pay increase and the increased costs in the Rent and Rent-Related accounts allows the Animal Drugs and Feeds Program to demonstrate results in four areas:

- conduct additional for-cause actions against firms suspected of violating the ruminant feed ban rule
- increase reviews of periodic drug experience reports and adverse drug events for animal drugs, which will better safeguard the human food supply from unsafe drug residues
- conduct 250 additional BSE inspections to prevent the spread of BSE through animal feed and feed components in the United States
- collect and analyze an additional 155 domestic animal feed and feed component samples for BSE-related contaminants to ensure proper labeling.

**Devices and Radiological Health Program:** Funding the pay increase and the increased costs in the Rent and Rent-Related account allows the Devices and Radiological Health Program to demonstrate results in four areas:

- expand actively participating sites in MedSun Network to 95 percent
- conduct 20 additional device pre-approval inspections to assure that manufacturers comply with manufacturing standards and verify the accuracy of pre-market applications
- conduct 55 additional GMP inspections to identify potential problem areas and assure compliance with GMPs
- analyze of 30 additional domestic laboratory samples to ensure that electronic products meet FDA performance standards.

**NCTR:** Funding the pay increase and the increased costs in the Rent and Rent-Related account allows NCTR to demonstrate results in three areas:

- perform complex toxicological studies on important public health issues
- retain current technical and scientific staff
- conduct research and testing activities that will advance the scientific foundation for new drug products.

NCTR expects to achieve these research results during a 12-24 month period.