



THE DIRECTOR

Resp

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

March 18, 2008

The Honorable John Dingell
Chairman, Committee on Energy
and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of February 14, 2008, regarding funding for the Food and Drug Administration (FDA). I appreciate your input.

As you know, the President transmitted his FY 2009 Budget to Congress on February 4, 2008. The Budget reflects our Nation's highest priorities, including promoting economic growth, combating terrorism, and strengthening our homeland security. The Budget includes policies to boost short-term economic growth and to make tax relief permanent, as well as to improve the quality of education, expand access to affordable healthcare, address the rising cost of energy and help Americans keep their homes. The Budget makes these investments in the Nation's safety and prosperity while holding non-security spending growth to less than one percent and slowing the unsustainable growth of entitlement spending. These policies put us on a path to achieve a balanced budget by 2012.

The FY 2009 President's Budget requests \$2.4 billion for FDA, a net program level increase of \$130 million, or 5.7% over FY 2008. The increases target areas critical to FDA's mission, including food, drug and device safety, information technology infrastructure and areas of emerging science. The Budget includes \$662 million for the Protecting America's Food Supply Initiative Program. This represents an increase of \$42 million over FY 2008 and includes funding for development of new detection technology, food contamination surveillance, vulnerability assessments, emergency response planning, and collaboration with the governments and the private sector. In addition, the Medical Product Safety and Development Initiative provides an additional \$17 million to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, and animal drugs and medicated feed.

The FY 2009 Budget for FDA proposes several new and reauthorized user fees, which are an integral component of FDA's budget. The proposed Generic Drug User Fee and the Animal Generic Drug User Fee will allow FDA to improve the review process and reduce the backlog of applications for generic drugs. The FDA is also proposing a Food and Animal Feed Export Certification User fee to reinspect facilities that fail to meet Good Manufacturing Practices, and a Food and Animal Feed Export Certification User Fee for issuing food and animal feed export certificates. The Budget also proposes reauthorization of the Animal Drug User Fee.

Archives
cc:
Sopko
C Knaues
Jodi
Yvette
Kyle
Lisa
PHOB files

MAR 28 2008

Although OMB has not had the opportunity to meet with the Science Board, we reviewed the FDA Science and Mission at Risk report with interest. We will consider the points raised by the Science Board, which made funding recommendations without consideration of other national priorities or bound by reasonable fiscal constraint. Some of the points raised in your letter could be more appropriately addressed by HHS and FDA. It is my understanding that Secretary Leavitt provided information relevant to some of the issues you raised following his hearing before your Committee on February 28, 2008. In addition, I understand FDA is responding to your request for information.

The FDA has tremendous responsibilities in overseeing a vast array of food, medical, and other consumer products, including cosmetics and dietary supplements. The FY 2009 President's Budget requests an increase in resources for FDA to meet these responsibilities. We look forward to working with you and the Congress to enact the President's Budget.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jim Nussle", is written over the typed name and title.

Jim Nussle
Director

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigation

Identical Letter Sent to The Honorable Bart Stupak