DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

May 5, 2008

Honorable Arlen Specter
Ranking Member, Subcommittee on Labor,
Health and Human Services, Education, and Related Agencies
Washington, DC, 20510

Dear Senator Specter:

Thank you for your May 1 letter, and for your interest in ensuring that FDA has the tools it needs to meet its public health mandate.

Recent events such as worldwide contamination of heparin and the contamination of food products with melamine underscore the urgent need to accelerate the modernization of FDA and further enhance FDA's capability to protect the American public from unsafe foods and medical products. FDA has responded to these events by establishing comprehensive risk-based plans to protect the food supply and assure the safety of FDA-regulated imports, and by advancing a comprehensive response to Institute of Medicine recommendations for assuring the safety of the drug supply. These plans also require that we improve FDA's science capacity and achieve a modern, bioinformatics focused IT system so that we support the revolution that is transforming medicine today.

As you requested in your letter, I am providing to you an assessment of immediate resource needs based on my professional judgment as the FDA Commissioner and without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed. The amounts identified in the attached document support FDA's food, medical product, science, and information technology needs. These additional resources will accelerate the changes required for FDA to protect and promote the health of all Americans in a rapidly changing world that poses new, emerging threats to the safety of food and medical products.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

$275 Million in FY 2008 to Supplement FDA's Budget: Professional Judgment Budget in response to the request from Senator Specter

Strategic Investments (Dollars in Millions)	FY2008
Food Protection	$125
Safer Drugs, Devices, and Biologics	$100
Modernizing FDA Science and Workforce	$ 50
Total	**$275**

The amounts identified in this document for three strategic investment areas – protection of our food supply, assuring safer drugs, devices, and biologics, and modernizing the essential infrastructure of FDA's science and workforce. The amounts are in addition to amounts appropriated to FDA in FY 2008.

Investing in these three strategic areas permits FDA to rapidly achieve important goals that cut across strategic components of the Agency. For example, these investments will allow FDA to begin to implement the Import Safety Action Plan (relating to both foods and medical product imports), fulfill new requirements under the FDA Amendments Act of 2007, and modernize its Information Technology systems,

This document responds to the above request for the FDA Commissioner's professional judgment concerning resource needs, and was developed without regard to the competing priorities that the President and his advisors must consider as budget submissions to the Congress are developed.

Supplement to FDA's FY 2008 Budget: Food Protection Plan (+$125 million)

Core elements and strategic activities	FPP Output	$	FTE
Prevention			
1.1 Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses: FDA will ensure the safety of imports by increasing FDA's presence beyond our borders and building capacity with foreign partners.	▪ Increase FDA presence beyond our borders. Offices in two additional countries with 7/8 FDA FTE and 4/5 foreign nationals per country/region) (yields FDA presence in three of five proposed sites)	10,000,000	15
	▪ Increase technical assistance on food standards in at least 3 of the countries accounting for the major share of imports	5,000,000	2
	▪ Develop systems and tools for an international information exchange database related to inspections and quality	5,000,000	3
1.2 Identify Food Vulnerabilities and Assess Risks: FDA will conduct risk-based prevention to better protect America's food supply. FDA will better understand food safety and food defense risks and use this understanding to define the optimum preventive controls to establish.	▪ Increase capacity to collect & interpret data for risk-based prevention for products of greatest concern	5,000,000	10
	▪ Research and develop risk-based prevention strategies based on scientific data and protocols	7,000,000	20
1.3 Expand Understanding and Use of Effective Mitigation Measures: FDA will develop and validate rapid detection tools to quickly detect and mitigate a potential problem.	▪ Develop and validate rapid detection technologies and assays (see 2.3 for deploying technologies and assays); For high risk foods, commence work to develop two new priority tools and to validate two test methods for toxic chemicals or microbes developed by industry.	5,000,000	10
Sub-Total		***$37,000,000***	***60***
Intervention			
2.1 Inspections and Sampling Based on Risk: FDA will apply risk analysis to set priorities for food inspections and interventions.	▪ 20,000 more import food exams at the port of entry[1] ($300 each)	6,000,000	36
	▪ 150 more foreign food production and/or processing facility inspections and support for foreign inspections[1] (2nd year = 600 inspections @ $16.7K each)	10,000,000	33
	▪ 1,000 more domestic food safety inspections[1] (2nd year = 1,250 insp. @ $8k ea.)	10,000,000	50
2.2 Enhance Risk-Based Surveillance of Imported Foods at the Border: FDA will design and build risk-based algorithms to conduct inspections and detect food risks. Understanding the risks defines the number and types of inspections and tests needed to ensure that preventive controls are working.	▪ Integrate and assimilate risk-based information into data systems	10,000,000	15

[1]FDA will hire and train additional field inspectors throughout FY 2008. As a result, by FY 2009, the proposed investment will allow FDA to increase its inspection and surveillance capacity by the amount identified in this FPP output.

Strategic Activity	Output	$	FTE
2.3 Better Detect Food System Signals that Indicate Contamination: FDA will deploy rapid detection technologies and assays and build laboratory infrastructure for faster testing. FDA will deploy state-of-the-art technology to improve the integration of incoming signals and achieve faster mitigation and response	▪ Improve signal detection of intentional and unintentional chemical and microbial contamination	5,000,000	5
	▪ Deploy 1-2 rapid detection assays to test high risk foods. Acquire advanced technology and deploy such equipment to FDA field and conduct technology transfer to industry.	5,000,000	5
	▪ Build high throughput rapid detection technology into laboratory infrastructure	17,000,000	10
Sub-Total		***$63,000,000***	***154***
Response			
3.1 Improve Immediate Response: FDA will enable real-time communication of lab results. FDA will develop protocols to facilitate tracebacks of foodborne illnesses. FDA will rapidly detect and respond foodborne outbreaks.	▪ Develop and implement a system for traceback from product consumption back to the source of production using, for example, electronic pedigrees and industry applied technologies of bar coding and radio frequency identification	10,000,000	20
	▪ Enhance interoperable information technology networking system between FDA and federal, state, and local testing labs	10,000,000	6
3.2 Improve Risk Communications to the Public, Industry, and Other Stakeholders: FDA will enhance risk communication though aggressive, targeted food safety campaigns that disseminate clear and effective messages with regular updates through a variety of media to all target audiences.	▪ Create a "health hazards alert" communication system using multiple media outlets to quickly inform a broad cross section of the public	5,000,000	10
Sub-Total		***$25,000,000***	***36***
GRAND TOTAL, Food Protection Plan		**$125,000,000**	**250**

Background on FDA's Food Protection Plan

On November 6, 2007, FDA unveiled its Food Protection Plan (FPP), an integrated strategy to protect America's food supply[2]. The FPP is a risk-based strategy to assure the safety of domestic and imported food. The cornerstone of the FPP is a rigorous science and information technology infrastructure designed to assure food safety at all points in the production-to-consumption cycle.

In FDA's professional judgment, the proposed increase for FY 2008 allows FDA to implement key initiatives across the core elements of the FPP: prevention, intervention, and response. This increase will allow FDA to achieve essential FPP priorities:

- identify and target the greatest threats from intentional and unintentional contamination
- perform essential research on mechanisms of food contamination and deploy new rapid food defense and food safety screening technologies for microbial and chemical contaminants
- conduct more risk-based inspections, enhance electronic systems of surveillance and establish additional multidisciplinary "rapid response" teams
- expand FDA's international presence beyond the planned office in China to include offices in India and Latin America, and establish the groundwork for offices in Europe and the Middle East
- establish IT systems to support interoperable databases that will enhance food research, threat assessment, and surveillance of adverse events.

With these investments, FDA can continue to reduce the risk to Americans from food-borne illnesses. These investments also allow FDA to respond to three of the six concerns raised by GAO in its February 2007 report designating food safety as a high-risk program[3].

[2] For FDA's Food Protection Plan, see http://www.fda.gov/oc/initiatives/advance/food/plan.pdf .
[3] For the GAO report, see http://www.gao.gov/new.items/d07449t.pdf .

Supplement to FDA's FY 2008 Budget: Ensuring Safe and Effective Medical Products (+$100 million)

Strategic Activity	Output	$	FTE
Safer Drugs, Devices, and Biologics			
1.1 Science to Improve Medical Product Safety and Development: Use new science and analysis to improve the safety of medical products. In some cases, new science creates opportunities to leverage advances from one product area to promote safety in a different area.	▪ Establish a unique device identification system to track devices, facilitate recalls, and support inventory management during disasters and terrorism response	7,500,000	17
	▪ Implement FDAAA safety requirements related to pediatric drugs and devices, postmarket study commitments, clinical trials, active drug surveillance, labeling and safe use of drugs.	17,000,000	15
Sub-Total		***24,500,000***	***32***
1.2 Data Analysis Tools to Identify Safety Issues: Develop and implement quantitative decision-making tools to assess the safety and effectiveness of drugs, biologics, and devices throughout their lifecycle	▪ Build Regulated Product Information Data Warehouse that will enable intelligence sharing with other regulatory agencies	15,000,000	0
	▪ Data access and analysis for active safety surveillance with development of scientific methods of data mining for signals of adverse events	15,000,000	6
Sub-Total		***30,000,000***	***6***

Strategic Activity	Output	$	FTE
1.3 Risk-Based Inspection and Compliance: Strengthen field operations to better protect public health. The sheer volume of products, manufacturing plants, distributors, and importers demands a more robust inspection force with better capacity to reach the community that FDA regulates.	▪ 120 more foreign medical product facility inspections[4] (uc=$45K)	5,400,000	24
	▪ Increase FDA's presence beyond our borders to three of five geographic regions of the world	7,800,000	13
	▪ 575 more domestic medical product inspections[4] (uc=17.7K)	10,200,000	40
	▪ Improve lab infrastructure and tools for rapid analysis of product/ingredient content	7,500,000	5
	▪ Increase import exams (10,000) and sampling/ laboratory analysis (300)	6,600,000	35
	▪ IT systems to achieve an integrated inventory database	3,000,000	0
	▪ Improve risk communications to public and industry	5,000,000	5
Sub-Total		***45,500,000***	***122***
GRAND TOTAL, Medical Product Safety and Effectiveness		**100,000,000**	**160**

[4] FDA will hire and train additional field inspectors throughout FY 2008. As a result, by FY 2009, the proposed investment will allow FDA to increase its inspection and surveillance capacity by the amount identified in this output.

Background on FDA Medical Product Programs: Drugs, Devices, and Biologics

The medical products that FDA regulates – human drugs, medical devices, vaccines, blood and blood products, other biological products, and animal drugs and feeds[5] – touch the lives of millions of Americans each day. FDA is responsible for the entire life-cycle of medical products, from pre-market testing and development through approval, post-market surveillance, and risk management.

FDA faces growing challenges due to the globalization of medical product development and manufacturing. Medical products are more often developed, evaluated clinically, and manufactured, in whole or in part, beyond our borders. This fundamental shift requires FDA to perform more complex analysis and deploy more sophisticated technology to ensure the safety and effectiveness of medical products before they arrive in our country through multiple portals to be processed, packaged, and disseminated in our health care delivery system.

FDA is reinvigorating and reengineering its foreign inspection program for medical products to build quality in and assure integrity of the supply chain. This includes more foreign inspections and equipping inspection teams with information and laboratory technologies to precisely target foreign inspections through accurate risk profiling. Moreover, FDA is establishing IT systems that support delineation of medical product risk profiles, detection of subtle and early signals of compromised product integrity and analysis of hazards points in the process requiring targeted inspection. These systems will also allow FDA to respond to deficiencies described by Government Accountability Office reports, such as a need to establish and maintain a comprehensive list of FDA-approved medical products, foreign manufacturing sites, clinical trials, and post-market study commitments.

[5] Assuring the safe use of animal drugs and medicated feeds in food-producing animals is essential to protect the health of the American public.

Modernizing FDA Science and Workforce (+$50 million)

Strategic Activity	Output	$	FTE
Modernizing FDA Science and Workforce			
1.1 Science Leadership and Coordination: FDA will enhance science programs across the agency, especially in emerging areas such as nanotechnology and tissue engineering. FDA will establish mechanisms to access the best scientific knowledge and expertise to modernize its regulatory science. FDA will strengthen its capacity to support emerging areas of science and manufacturing that are essential to regulating FDA products.	▪ Strengthen programs of emerging science in Centers and at the National Center for Toxicological Research and enhance integration	5,000,000	15
	▪ Strengthen capacity to support nanotechnology, cell and gene therapies, robotics, genomics and proteomics, Critical Path initiatives, and advanced manufacturing technologies	27,000,000	40
Sub-Total		***32,000,000***	***55***
1.2 Investments to Support Science-Based Regulation: FDA will upgrade its science capacity by providing more training and professional development support for FDA science staff. FDA will create an Agency-wide two-year Science Fellows Program intended to include up to two thousand trainees to develop a new cadre of emerging leaders in regulatory science. FDA will upgrade facilities that do not adequately support FDA's current or future mission.	▪ Expand science training and professional development for career employees	4,000,000	8
	▪ Launch Science Fellows Program and initiate recruitment of first 500 fellows	4,000,000	8
	▪ Improve facilities outside of the Washington region to support FDA's mission and enable these facilities to accept new food and medical product technologies	10,000,000	0
Sub-Total		***18,000,000***	***16***
GRAND TOTAL, Modernizing FDA Science and Workforce		***50,000,000***	***71***

Background on Modernizing FDA Science and Workforce

In FDA's professional judgment, the additional funds to support FDA regulation and emerging science will allow FDA to improve its science capacity and better support the revolution in science that is transforming the practice of medicine and advancing the promise of personalized medicine. These efforts help respond to the report of FDA's Science Board in late 2007 which outlined a series of urgent scientific priorities for the Agency. These efforts will improve health and quality of life for patients by supporting greater safety, efficiency, and predictability of medical products. The additional funds will also allow FDA to expand its capability to effectively model food supply risks and support the regulation and inspection of the food supply.