

PERFORMANCE BUDGET OVERVIEW

Agency Mission Overview

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA) is responsible for promoting and protecting the health of the U.S. public. These responsibilities cover a wide range of regulatory activities.

FDA's Mission

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, Nations food supply, cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, to provide the public accurate, science-based information needed regarding medicines and foods to improve their health. FDA plays a significant role in addressing the Nation's counterterrorism capability and ensuring the security of the food supply.

FDA decisions affect virtually every American on a daily basis. Annually, consumers spent nearly \$1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA-regulated products. By operating as a knowledgeable and efficient agency responsive to our customers, FDA can provide better protection for consumers and more effectively promote their health with accurate health information.

FDA works to achieve its broad mission by managing efforts toward a comprehensive set of long-term strategic goals, continuing to place greater emphasis on linking program performance to budgetary

resources. To achieve these goals, FDA focuses its resources toward five broad strategic goals that are supported by the Agency's annual performance goals. These goals are:

FDA Strategic Goals
Improving FDA's Business Practices (Formally: More Effective Regulation through a Stronger Workforce)
Using Risk-Based Management Practices (Formally: Efficient Risk Management: The Most Public Health Bang for our Regulatory Buck)
Empowering Consumers for Better Health (Formally: Empowering Consumers: Improving Health Through Better Information)
Patient and Consumer Protection (Formally: Improving Patient and Consumer Safety)
Protecting the Homeland -- Counterterrorism (Formally: Protecting America from Terrorism)

Annual performance goals that are discussed in this overview continue to contribute toward achieving long-term outcome goals that have a significant impact on the health of the U.S. consumer.

FDA's strategic goals fully support the Department's strategic goals and priorities which include:

- enhancing health science research;
- improving health care services;
- responding to bioterrorism and other public health challenges; and,
- enhancing management practices.

The following table demonstrates the relationships between Departmental goals and priorities and those of the FDA.

**FDA STRATEGIC AND OUTCOME GOALS ALIGNED BY
HHS STRATEGIC GOALS & FY 2006 SECRETARIAL PRIORITIES**

HHS STRATEGIC GOALS	SECRETARY'S FY 2006 PRIORITIES	FDA STRATEGIC GOALS	FDA OUTCOME GOALS
Achieve Excellence in Management Practices	Strengthening Management	Improving FDA's Business Practices	Reduce administrative overhead at FDA by reducing the number of administrative staff.
Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	Preventing Disease / Illness	Using Risk-Based Management Practices	Reduce the average time to marketing approval for safe and effective new drugs, biologics, devices, and generic drugs.
Improve the Quality of Health Care Services	Accelerating the Adoption of Information Technology in Health Care	Patient and Consumer Protection	Reduce adverse drug events related to medication dispensing and administration errors. Increase the patient population covered by active surveillance of medical product safety.
		Empowering Consumers for Better Health	Increase consumer understanding of diet-disease relationships.
Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges.	Responding to Bioterrorism and other Public Health Emergencies	Protecting the Homeland -- Counterterrorism	Increase FDA's capacity to effectively analyze food samples for biological, chemical and radiological threat agents in the event of a terrorist attack.

Overview of FDA Performance

This section describes FDA's planning process, strategic goals and strategies used to achieve them, the results of the OMB program assessments in developing long-term outcome goals, and the relationship between the performance planning and traditional budget presentation.

FDA Strategic Goals

FDA's five strategic goals focus resources to accomplish its mission. These goals are:

Improve FDA's Business Practices -- This goal focuses on the critical infrastructure that provides scientific support and administration to FDA's programs. Managerial and operational efficiencies being pursued under this goal support the President's Management Agenda; the Secretary's FY 2006 priority of strengthening management by creating a more streamlined, cost-effective, and accountable organization; and the DHHS strategic goal of excellence in management practices.

Current strategies to align FDA activities with these initiatives include:

- Using competitive sourcing to maximize cost-effective performance of functions;
- Developing more robust program performance data to demonstrate progress in meeting long-term outcome goals;
- Creating flexible human resource policies and programs to recruit, reward, and retain state-of-the-art scientists and health professionals; and,

- Creating a modern and efficient infrastructure, and operating the Office of Shared Services, to support mission-critical activities.

To Improve FDA's Business Practices, the key performance goal in FY 2006 is:

<p style="text-align: center;">Improving FDA's Business Practices Performance Goal</p> <ul style="list-style-type: none">• Increase the percentage of contract dollars allocated to performance-based contracting.
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Using Risk-Based Management

Practices -- This strategic goal focuses on the safety and effectiveness of FDA-regulated products, while emphasizing risk management efficiencies. Developing and applying approaches that provide the most health protection at the least cost both improves agency cost-effectiveness and supports better industry efficiency and market competition. Ultimately, the improvements will help control health care costs.

In pursuing this goal, FDA uses the best available data and analytic methods to assess risk and target cost-effective risk management, for both pre- and post-market regulation, with continued evaluation of program performance.

FDA is employing four strategies to achieve this goal:

- Provide a timely, high quality, and cost-effective process for review of new technologies/premarket submissions;
- Provide high quality, cost-effective oversight of industry manufacturing, processing and distribution;
- Ensure the safety and security of the U.S. food and cosmetics supply to protect consumers; and,
- Identify the most effective and efficient risk management strategies and optimize regulatory decision-making.

For Risk-Based Management Practices, key FY 2006 goals include:

Risk-Based Management Practices
<p>Outcome Goals</p> <ul style="list-style-type: none"> • Reduce average time to marketing approval for safe and effective new drugs and biologics; • Reduce average time to marketing approval or tentative approval for safe and effective new generic drugs; • Reduce average time to marketing approval for safe and effective new medical devices. <p>Performance Goals</p> <ul style="list-style-type: none"> • Ensure that a safe and effective drug supply is available to the public; • Increase risk-based compliance and enforcement activities to ensure product quality; and, • Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements.

Empowering Consumers For Better Health

– This strategic goal focuses on providing the best available information of the risks and benefits of using FDA-regulated products to patients, consumers, and health professionals.

FDA believes that well-informed consumers and health professionals can bring about improved health if they have accurate and timely information to make informed decisions on diet, nutrition, and health care. FDA believes that significant public health benefits will result when consumers have access to, and use, information to aid them in their purchases, information that goes beyond just price, convenience and taste, but extends to include science-based health factors. More scientifically based information about the nutritional content and health benefits of foods can help consumers make tangible differences in their own long-term health by lowering their risk of numerous chronic disease, particularly those caused by obesity.

Strategies employed to achieve this strategic goal include:

- Developing an understanding of what information consumers need to make informed product choices;
- Developing the mechanisms necessary to communicate to a variety of audiences;
- Assuring that information communicated to consumers is based on sound scientific evidence; and,
- Determining the impact of FDA communications on constituents' understanding, behavior, and health outcomes.

Empowering Consumers For Better Health

Outcome Goal

- Increase consumer understanding of diet-disease relationships

Performance Goal

- Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the Nation's food supply.

Patient and Consumer Protection - This strategic goal focuses on improving the identification, resolution, and communications of health risks to health care professionals and to patients.

FDA strives to minimize adverse health events involving FDA-regulated products. While it is rare that risks associated with medical products are fully revealed during the premarket review process, adverse events may emerge after use in wider patient and consumer population. Some of these potential adverse health effects may be prevented if systems are upgraded to improve the speed in which risks are identified.

To accomplish this goal, FDA is pursuing these strategies:

- Enhancing the ability to quickly identify risks associated with FDA-regulated products;
- Developing analytical capability to identify and quantify medical product risk;

- Enhancing the capability to quickly resolve medical product risks; and,
- Increasing communication of risks to educate health care professionals and patients about problems and solutions associated with appropriate product use.

Patient and Consumer Protection

Outcome Goals

- Increase the patient population covered by active surveillance of medical product safety; and,
- Reduce adverse drug events related to medication dispensing and administrative errors.

Performance Goal

- Improve the safe use of drugs in patients and consumers

Protecting The Homeland -- Counterterrorism - This strategic goal focuses on FDA's preparation and response to potential acts of terror. Specific strategies are:

- Facilitating the development and availability of medical countermeasures to limit the effects of an attack on civilian or military populations;
- Enhancing FDA's emergency preparedness and response capabilities to be better able to respond to a terrorist attack;
- Ensuring the safety and security of FDA personnel, physical assets, and sensitive information; and,
- Implementing Homeland Security Presidential Directive-9 and the

Bioterrorism Act of 2002 to protect the security of foods and animal feeds.

<p style="text-align: center;">Protecting The Homeland -- Counterterrorism</p> <p>Outcome Goal</p> <ul style="list-style-type: none">• Increase the capacity to effectively analyze food samples for biological, chemical and radiological threat agents in the event of a terrorist attack; and, <p>Performance Goals</p> <ul style="list-style-type: none">• Enhance the Agency Emergency preparedness and response capabilities to be better able respond in the event of a terrorist attack.

Role of the OMB Program Assessments in Developing Long-Term Outcome Goals -

In the FY 2004 PART evaluation, OMB identified two key areas in which the FDA should strengthen its results orientation:

- Develop specific long-term outcome goals that tie to improved public health and safety; and,
- Develop efficiency goals to demonstrate more streamlined government operations.

In response, FDA developed eight long-term outcome goals (including an efficiency goal) that were then included in the FY 2005 PART review and FY 2005 Performance Plan.

As a result, OMB's FY 2005 PART evaluation yielded a much improved score, with a rating that improved to "moderately effective." FDA leadership developed baseline information for the eight outcome goals to help measure progress.

FDA Strategic Action Plan and Agency Follow-up - To meet the strategic goals' performance commitments specified by the annual performance and outcome goals, Agency leadership also developed a Strategic Action Plan (issued in August 2003) which provided the framework for meeting these commitments.

To monitor the strategic action plan's objectives and the Government Performance and Results Act performance commitments, FDA established a senior level Strategic Planning Council was established to ensure timely progress.

In January 2004, this Council agreed to establish a performance framework to systematically link an array of program activities, outputs, and outcomes to support and demonstrate progress in meeting long-term outcome goals, and directed that OMB and DHHS be informed of FDA's progress in achieving these goals. During the spring, the Council also used performance and budget information to make decisions on FY 2006 funding priorities.

Relationship Between the Strategic Action Plan and the Performance Budget - The five strategic goals outlined above constitute the foundation for both the Strategic Action Plan and the FY 2006 Performance Budget that is aligned by strategic goal within each program's justification of base presentation.

Action items emerging from the Strategic Action Plan will have several beneficial effects on performance planning. First, several of these items constitute improved ways of conducting the FDA's core business. Second, many of the action items enhance FDA's ability to identify, measure, and influence public health outcomes, resulting in a greater proportion of future performance goals being outcome-oriented.

In addition, budget and performance integration efforts have more consciously linked resources with results, presenting a more complete picture.

public health outcomes and strategic goals. The diagram below illustrates the relationship among strategic action planning, performance planning and budget presentation.

The presentation order in this performance budget is: base activities (Justification of Base); FY 2004 accomplishments; program activity data (PAD); and performance targets. The resource request funds base activities that in turn support the accomplishment of discrete workload outputs (PAD and performance goal targets) which contribute to achieving long term

Flow of Performance Information into Performance Budget

From Strategic Goals through Action Items, Outcome Goals, Performance Measures, Program Activity Data, and Base Activities to Performance Budget

