FDA PERFORMANCE PLAN SUMMARY

FDA's FY 2002 Performance Plan is organized into two parts.

- Part One describes an overview of FDA, its mission and long term goals, strategies for achieving the goals, and how FDA will work with partners to carry out the strategies. The summary highlights thirteen strategies that are the Agency's highest priorities for protecting the health and safety of the American Public in the 21st Century. Each strategy addresses these questions:

  1. What are the desired outcomes of this strategy?

  2. What are key performance goals that will lead to the outcomes?

  3. Why is FDA's contribution important?

  4. How will FDA achieve its goals?

  5. What are the consequences of not achieving the goals?

  6. How is the Agency doing currently?

- Part Two of the Plan is organized by FDA's major programs. Each program section includes the complete inventory of FY 1999, FY 2000, FY 2001 and FY 2002 performance goals and the strategies necessary to achieve these goals. The latest status on actual performance is also provided. The figure below identifies how the strategies in Part One link to FDA's Programs discussed in Part Two.

Strategies Linkage with FDA Programs

Strategies	FDA Program					
	Foods	Human Drugs	Biologics	Animal Drugs	Medical Devices	NCTR
Rapid Access to New Medical Technologies		☆	☆		☆	☆
Safe Food Supply	☆			☆		☆
Safe Blood and Tissue Products			☆			☆
Safe Medical Products		☆	☆	☆	☆	

	Foods	Human Drugs	Biologics	Animal Drugs	Medical Devices	NCTR
Reduce Adverse Events		☆	☆		☆	
Protecting Volunteers in Clinical Research		☆	☆		☆	
Cutting Edge Risk Assessment		☆	☆		☆	☆
Improved Mammography					☆	
Managing Antibiotic Resistant Bacteria		☆		☆		☆
BSE	☆		☆	☆		
Imports and International Activities	☆	☆	☆	☆	☆	
Biotechnology	☆	☆	☆	☆	☆	☆
Dietary Supplements	☆	☆				☆

Crosswalk of FDA Strategies that Support HHS Strategic Goals

FDA Strategies	**HHS Strategic Goals**					
	1. Reduce the major threats to the health and productivity of all Americans.	**2. Improve the economic & social well- being of individuals, families, & communities in the United States.**	**3. Improve access to health services & ensure the integrity of the nation's health entitlement & safety net programs.**	**4. Improve the quality of health care & human services.**	**5. Improve the nation's public health systems.**	**6. Strengthen the nation's health sciences research enterprise & enhance its productivity.**
Quick and Safe Access to New Medical Technologies					X	X
A Safe Food Supply	X				X	
Safe Blood and Tissue Products					X	
Safe Medical Products					X	
Reduce	X					

	1. Reduce the major threats to the health and productivity of all Americans.	2. Improve the economic & social well- being of individuals, families, & communities in the United States.	3. Improve access to health services & ensure the integrity of the nation's health entitlement & safety net programs.	4. Improve the quality of health care & human services.	5. Improve the nation's public health systems.	6. Strengthen the nation's health sciences research enterprise & enhance its productivity.
Adverse Events Related to Medical Products					X	
Protecting Volunteers in Clinical Research				X	X	X
Cutting-Edge Risk Assessment to Protect Public Health				X	X	X
Early Detection of Breast Cancer Through Improved Mammography					X	
Manage the Threat of Antibiotic Resistance	X				X	
BSE	X				X	
Imports/ International Activities					X	
Biotechnology					X	X
Dietary Supplements					X	

FDA's Successes…

The overall success of FDA's efforts is reflected in a recent survey by the PEW Research Center in cooperation with Princeton Survey Research. That survey gathered constituents' opinions on government agencies. FDA received an overall favorable rating of over 80%, more than twice the approval rate of the entire government. The pollsters' report noted that "[t]he FDA is unique among the agencies we studied for how similarly - and highly - its very different customers rate its performance. Regulated industry as well as medical professionals, advocates and the chronically ill all credit the FDA for making a positive contribution to the safety of the Nation's food, drugs and other medical products."

FDA has scored several significant public health gains which reinforce our stakeholders' confidence that we are 'on the job.' Here are some illustrations that demonstrate how the public benefits when FDA achieves its goals:

When FDA Acted:	**The Public Gained:**
FDA approved NDAs, BLAs in record time.	New medicines and therapies were available to doctors and patients 18 months earlier.
FDA ensured that mammography facilities were operating at the 'gold standard.'	Mortality rates for breast cancer dropped as a result of more accurate diagnoses.
FDA approved significant new therapies for arthritis, diabetes and hepatitis C.	Over 30 million people with these diseases received new, critically needed therapies.
FDA cooperated with other federal agencies to improve a science-based food safety surveillance system.	Foodborne illness and death declined by 20%.

Selected FY 2000 Performance Highlights by Program

Foods

- On January 3, 2000, FDA set forth its overall dietary supplement strategy. This strategy establishes a clear program goal to accomplish, by the year 2010, having a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994.

- On July 6, 2000, FDA issued an import alert for bulk or finished dietary supplements and other products that may contain aristolochic acid. Aristolochic acid is a potent carcinogen and nephrotoxin.

Human Drugs

- FDA continues to exceed the rigorous performance goals agreed to for each consecutive year under the PDUFA. FocalSeal-L Surgical Sealant was approved as a surgical sealant for use in lungs to seal air leaks following removal of cancerous lung tumors.

- In 2000, FDA's Generic Drugs Program approved Taxol a drug that is used for the firstline treatment of advanced carcinoma of the ovary and non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.

Biologics

- Approved ReFacto, a biological product for the treatment and prevention of hemorrhagic episodes in patients with hemophilia A, a genetically inherited blood clotting disorder.

- Approved Prevnar, the first vaccine to prevent invasive pneumococcal diseases in infants and toddlers – diseases that can cause brain damage and, in rare cases, death.

Animal Drugs and Feeds

- FDA continues to work with its partners in industry to redesign the New Animal Drug Approval (NADA) process, thereby making it more efficient (phased review).

- FDA continues to increase the number of isolates in the National Antimicrobial Resistance Monitoring System (NARMS) database.

Medical Devices and Radiological Health

- There were no overdue submissions for the fourth consecutive year. FDA maintained high quality, timely reviews despite increasingly complex device technology.

- The quality of mammography services in the United States continues to improve. In FY 2000, the goal of ensuring that mammography facilities meet inspection standards was achieved with a 97 percent rate, the fourth consecutive year of achieving this high standard.

National Center for Toxicological Research

- Geneticists are developing and validating sensitive and predictive in vitro and in vivo systems to identify, measure and understand how chemicals damage human genes.

- Biologists are studying gene-nutrient interactions involved in carcinogenesis and birth defects.

Performance Challenges for the Future

Despite the achievements outlined above, there are many additional areas in which FDA has not yet had similar success. To illustrate:

- Rigorous and punctual review of new product applications from industry, and post-market inspections, are the backbone of FDA's system of public health protections. But FDA has been unable to completely fulfill its mandated responsibilities and public expectations in these two areas.

- A major gap exists between FDA's current clinical research monitoring capability and the level of monitoring that is necessary to assure that volunteers in these studies are being protected.

- The Agency is unable to assure the U.S. public that it can prevent unsafe imports from entering the country.