

FDA

- The **Food and Drug Administration (FDA or USFDA)** is a government agency of the United States Department of Health and Human Services. The FDA is responsible for regulating and supervising the safety of foods, tobacco products, dietary supplements, prescription and non-[prescription medication](#), vaccines, [biopharmaceuticals](#), [blood transfusions](#), medical devices, [electromagnetic radiation](#) emitting devices (ERED), veterinary products, and cosmetics. The FDA also enforces other laws, notably Section 361 of the [Public Health Service Act](#) and the associated regulations. Many of these regulations are not directly related to food or drugs. These include sanitation requirements on interstate travel and control of disease on products ranging from certain household [pets](#) to [sperm donation](#) for [assisted reproduction](#).

Funding

- The FDA regulates more than \$1 trillion worth of consumer goods, about 25% of consumer expenditures in the United States. This includes \$466 billion in food sales, \$275 billion in drugs, \$60 billion in cosmetics and \$18 billion in vitamin supplements. Much of the expenditures is for goods imported into the United States; the FDA is responsible for monitoring a third of all imports.[\[4\]](#)

Legal Authority

- Most federal laws concerning the FDA are part of the Food, Drug and Cosmetic Act, [\[6\]](#) (first passed in 1938 and extensively amended since) and are codified in [Title 21, Chapter 9 of the United States Code](#). Other significant laws enforced by the FDA include the [Public Health Service Act](#), parts of the [Controlled Substances Act](#), the , as well as many others. In many cases these responsibilities are shared with other federal agencies.

Challenges and Opportunities Facing FDA

- Must maintain the balance of protecting and promoting public health.
- US Consumers reliance on an effective FDA for protection from unsafe medical products and contaminated food.
- Also charged with Promoting Public Health by
 - Guiding and supporting development and availability of safe and effective new medical technologies
 - As well as nutritious new food products
- Determine Benefit versus Risk based on current available science information.

FDA 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, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for **advancing the public health** by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

FDA Strategic Action Plan

- I. Strengthen FDA for Today and Tomorrow
- II. Improve Patient and Consumer Safety
- III. Increase Access to New Medical and Food Products
- IV. Improve the Quality and Safety of Manufactured Products and the Supply Chain

Strategic Goal 1: Strengthen FDA for Today and Tomorrow

- Strengthen the scientific foundation of FDA's regulatory mission
- Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.
- Enhance partnerships and communications.
- Strengthen FDA's base of operations.

Strategic Goal 2: Improve Patient and Consumer Safety

- Strengthen the science that supports product safety
- Improve information systems for problem detection and public communication about product safety
- Provide patients and consumers with better access to clear and timely risk-benefit information for medical products
- Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition

Strategic Goal 3: Increase Access to New Medical and Food Products

- *Objective 3.1:* Increase the number of safe and effective new medical products available to patients. Improve information systems for problem detection and public communication about product safety
- *Objective 3.2:* Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.
- *Objective 3.3:* Increase access to safe and nutritious new food products.

Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain

- *Objective 4.1:* Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution. development of modern continuous manufacturing technologies, which present opportunities for remote automated monitoring; and
- *Objective 4.2:* Detect safety problems earlier and better target interventions to prevent harm to consumers.
- *Objective 4.3:* Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.

Implement New Import Safety Strategic Framework

- **Implement New Import Safety Strategic Framework:** FDA anticipates following a new direction in the future for regulating imports, as outlined in the Report to the President, *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*. It is a risk-based strategy that shifts the focus from interdiction at the border to prevention with verification. It will utilize data from all points in the full import life cycle – from production, manufacture, transport, distribution, and consumption – to assist in targeting the highest risk imported products for review, and facilitating the entry of low-risk products.. On November 6, 2007, the *Action Plan for Import Safety* (available at <http://www.importsafety.gov/report/index.html>) was released which provides specific short- and long-term recommendations to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. Within two years, accomplishments will be made in the areas of foreign operations, border operations, imported products in domestic commerce, information technology, and applied science and technology.
- **Last year, the United States imported more than \$2 trillion worth of products. These products were brought to the United States by roughly 825,000 importers, through over 300 ports of entry. All projections indicate that this volume will continue to rise, sharply, over the coming years as the scale and complexity of international trade multiplies.**

Implement New Import Safety Strategic Framework

- Imports allow consumers to enjoy the benefits of a greater variety, availability, and affordability of goods in the marketplace.
- **The growth of imports, combined with an increased focus on security, places a greater burden on border officials. These officials must manage larger volumes of imports from countries which often have less-developed regulatory systems. In addition, they must consider more complex risk scenarios, use more sophisticated screenings and examinations, and employ new technologies to ensure product safety.**

Conclusion

- As FDA celebrates more than 100 years of service to the American people as the world's gold standard regulatory agency, it looks to the future.
- FDA being a bridge, not a barrier
- The products of explosive progress in science and technology have made that future a possibility and not just a promise but the pathway requires FDA to look ahead to being a bridge and not a barrier to the delivery of safe and nutritious food and life-saving medical and health products to the people we serve.
- This strategic plan marks the path to achieve our vision for an organization that is dedicated to excellence as a science-based and science-led regulatory agency that provides global leadership in protecting public health.