What FDA Regulates

FDA is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public. Some of the agency's specific responsibilities include:

**Biologics**

- product and manufacturing establishment licensing
- safety of the nation's blood supply
- research to establish product standards and develop improved testing methods

**Cosmetics**

- safety
- labeling

**Drugs**

- product approvals
- OTC and prescription drug labeling
- drug manufacturing standards

**Foods**

- labeling
- safety of all food products (except meat and poultry)
- bottled water

**Medical Devices**

- premarket approval of new devices
- manufacturing and performance standards
- tracking reports of device malfunctioning and serious adverse reactions

**Radiation-Emitting Electronic Products**

- radiation safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems (such as baggage x-rays at airports), laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- accrediting and inspecting mammography facilities
Veterinary Products

- livestock feeds
- pet foods
- veterinary drugs and devices

What FDA Doesn’t Regulate

What FDA Does Not Regulate
(and how to contact the other Agencies that do)

FDA’s responsibilities are closely related to those of several other government agencies. Often frustrating and confusing for consumers is determining the appropriate regulatory agency to contact. The following contact information is for government agencies that have functions related to that of FDA. (Contact information is given for agency headquarters offices, which are located in the Washington, D.C., area. Local offices, listed in the phone book under U.S. Government, may be available to provide assistance as well.)

Advertising
The Federal Trade Commission is the federal agency which regulates all advertising, excluding prescription drugs and medical devices. FTC ensures that advertisements are truthful and not misleading for consumers. Consumers may write to FTC at 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2222.

Alcohol
The labeling and quality of alcoholic beverages are regulated by the Department of Justice’s Bureau of Alcohol, Tobacco, Firearms and Explosives, Consumers can write to: Bureau of Alcohol, Tobacco, Firearms and Explosives, 99 New York Avenue, NE, Washington, D.C. 20226; telephone 1-800-800-3855 (Toll Free) - 202-648-7777 (Local Number).

Consumer Products
While FDA regulates a large portion of the products that consumers purchase, the agency has no jurisdiction over many household goods. The Consumer Product Safety Commission (CPSC) is responsible for ensuring the safety of consumer goods such as household appliances (excluding those that emit radiation), paint, child-resistant packages, and baby toys. Consumers may send written inquiries to CPSC, Washington, DC 20207. CPSC operates a toll-free hot line at (800) 638-2772 or TTY (800) 638-8270 for consumers to report unsafe products or to obtain information regarding products and recalls.
Drugs of Abuse
Illegal drugs with no approved medical use--such as heroin and marijuana--are under the jurisdiction of the Drug Enforcement Administration. FDA assists DEA in deciding how stringent DEA controls should be on drugs that are medically accepted but that have a strong potential for abuse. DEA establishes limits on the amount of these prescription drugs that are permitted to be manufactured each year. Inquiries regarding DEA activities may be sent to the Drug Enforcement Administration, U.S. Department of Justice, Washington, DC 20537; telephone (202) 307-1000.

Health Insurance
FDA does not regulate health insurance, the cost of health care products or procedures, or reimbursement for health and medical expenses. Questions about Medicare should be directed to the Centers for Medicare and Medicaid Services.

Meat and Poultry
The U.S. Department of Agriculture's Food Safety and Inspection Service is responsible for the safety and labeling of traditional meats and poultry. (FDA regulates game meats, such as venison, ostrich and snake.) Consumers with questions regarding meat or poultry, including safe handling and storage practices, should write or call the Food Safety Inspection Service's Meat and Poultry Hotline, Room 2925S, Washington, DC 20250; telephone (800) 535-4555.

Pesticides
FDA, USDA, and the Environmental Protection Agency share the responsibility for regulating pesticides. EPA determines the safety and effectiveness of the chemicals and establishes tolerance levels for residues on feed crops, as well as for raw and processed foods. These tolerance levels (the amount of pesticide allowed to be present in a food product) are normally set 100 times below the level that might cause harm to people or the environment. FDA and USDA are responsible for monitoring the food supply to ensure that pesticide residues do not exceed the allowable levels in the products under their jurisdiction. Public inquiries regarding EPA should be mailed to U.S. Environmental Protection Agency, Office of Pesticide Programs Public Docket (7506C), 3404, 401M St., Washington, DC 20460; telephone (202) 260-2080.

Restaurants and Grocery Stores
Inspections and licensing of restaurants and grocery stores are typically handled by local county health departments.

Water
The regulation of water is divided between the Environmental Protection Agency and FDA. EPA has the responsibility for developing national standards for drinking water from municipal water supplies. FDA regulates the labeling and safety of bottled water.