**Food and Drug Administration (FDA)**

**What We Do**

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. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA plays a significant role in the Nation’s counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

**History**

The Food and Drug Administration is the oldest comprehensive consumer protection agency in the U. S. federal government. Its origins can be traced back to the appointment of Lewis Caleb Beck in the Patent Office around 1848 to carry out chemical analyses of agricultural products, a function that the newly created Department of Agriculture inherited in 1862. Although it was not known by its present name until 1930, FDA’s modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law a quarter-century in the making that prohibited interstate commerce in adulterated and misbranded food and drugs. Harvey Washington Wiley, Chief Chemist of the Bureau of Chemistry in the Department of Agriculture, had been the driving force behind this law and headed its enforcement in the early years, providing basic elements of protection that consumers had never known before that time.

**FDA's Origin**

The U S. Food and Drug Administration is a scientific, regulatory, and public health agency that oversees items accounting for 25 cents of every dollar spent by consumers. Its jurisdiction encompasses most food products (other than meat and poultry), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumer, medical, and occupational use, cosmetics, and animal feed. The agency grew from a single chemist in the U.S. Department of Agriculture in 1862 to a staff of approximately 9,100 employees and a budget of $1.294 billion in 2001, comprising chemists, pharmacologists, physicians, microbiologists, veterinarians, pharmacists, lawyers, and many others. About one-third of the agency's employees are stationed outside of the Washington, D. C. area, staffing over 150 field offices and laboratories, including five regional offices and 20 district offices. Agency scientists evaluate applications for new human drugs and biologics, complex medical devices, food and color additives, infant formulas, and animal drugs. Also, the FDA monitors the manufacture, import, transport, storage, and sale of about $1 trillion worth of products annually at a cost to taxpayers of about $3 per person. Investigators and inspectors visit more than 16,000 facilities a year, and arrange with state governments to help increase the number of facilities checked.

Beginning as the Division of Chemistry and then (after July 1901) the Bureau of Chemistry, the modern era of the FDA dates to 1906 with the passage of the Federal Food and Drugs Act; this added regulatory functions to the agency's scientific mission. The Bureau of Chemistry's name changed to the Food, Drug, and Insecticide Administration in July 1927, when the non-regulatory research functions of the bureau were transferred elsewhere in the department. In July 1930 the name was shortened to the present version. FDA remained under the Department of Agriculture until June 1940, when the agency was moved to the new Federal Security Agency. In April 1953 the agency again was transferred, to the Department of Health, Education, and Welfare (HEW). Fifteen years later FDA became part of the Public Health Service within HEW, and in May 1980 the education function was removed from HEW to create the Department of Health and Human Services, FDA's current home. To understand the development of this agency is to understand the laws it regulates, how the FDA has administered these laws, how the courts have interpreted the legislation, and how major events have driven all three.

States exercised the principal control over domestically produced and distributed foods and drugs in the 19th century, control that was markedly inconsistent from state to state. The illustration at right shows an act passed by Massachusetts, which led the way in state-sponsored food and drug laws. The Vaccine Act of 1813, though short-lived, was the first federal law dealing with consumer protection and therapeutic substances. Federal authority was limited mostly to imported foods and drugs. Adulteration and misbranding of foods and drugs had long been a fixture in the American cultural landscape, though the egregiousness of the problems seemed to have increased by the late 19th century (or at least they became more identifiable). By this time science had advanced significantly in its ability to detect this sort of fraud. Also, legitimate manufacturers were becoming more concerned that their trade would be undermined by purveyors of
The Division of Chemistry began investigating the adulteration of agricultural commodities as early as 1867. When Harvey Washington Wiley arrived as chief chemist in 1883, the government’s handling of the adulteration and misbranding of food and drugs took a decidedly different course, which eventually helped spur public indignation at the problem. Wiley expanded the division’s research in this area, exemplified by Foods and Food Adulterants, a ten-part study published from 1887 to 1902. He demonstrated his concern about chemical preservatives as adulterants in the newly publicized “poison squad” experiments, in which able-bodied volunteers consumed varying amounts of questionable food additives to determine their impact on health. And Wiley unified a variety of groups behind a federal law to prohibit the adulteration and misbranding of food and drugs, including state chemists and food and drug inspectors, the General Federation of Women's Clubs, and national associations of physicians and pharmacists.

The 1906 Food and Drugs Act and Its Enforcement

While Wiley was stumping for a law, muckraking journalists such as Samuel Hopkins Adams exposed in vivid detail the hazards of the marketplace. In fact, the nauseating condition of the meat-packing industry that Upton Sinclair captured in The Jungle was the final precipitating force behind both a meat inspection law and a comprehensive food and drug law. Since 1879, nearly 100 bills had been introduced in Congress to regulate food and drugs; on 30 June 1906 President Roosevelt signed the Food and Drugs Act, known simply as the Wiley Act, a pillar of the Progressive era.

This act, which the Bureau of Chemistry was charged to administer, prohibited the interstate transport of unlawful food and drugs under penalty of seizure of the questionable products and/or prosecution of the responsible parties. The basis of the law rested on the regulation of product labeling rather than pre-market approval. Drugs, defined in accordance with the standards of strength, quality, and purity in the United States Pharmacopoeia and the National Formulary, could not be sold in any other condition unless the specific variations from the applicable standards were plainly stated on the label. Foods were not defined according to analogous standards, but the law prohibited the addition of any ingredients that would substitute for the food, conceal damage, pose a health hazard, or constitute a filthy or decomposed substance. Interpretations of the food provisions in the law led to many, sometimes protracted, court battles. If the manufacturer opted to list the weight or measure of a food, this had to be done accurately. Also, the food or drug label could not be false or misleading in any particular, and the presence and amount of eleven dangerous ingredients, including alcohol, heroin, and cocaine, had to be listed. The bureau’s regulatory emphasis under Wiley centered on foods, which he believed posed a greater public health problem than adulterated or misbranded drugs. Wiley generally held a dim view of chemical additives to foods, championing an approach that considered most to be unnecessary adulterants. On this he clashed often with Secretary of Agriculture James Wilson, and on occasion President Roosevelt himself had to decide government policy on food regulation. Wiley’s personal administrative authority under the act was diluted early on when Wilson created a Board of Food and Drug Inspection in 1907 to establish agency policy in enforcing the law. Similarly, the creation of the Referee Board of Consulting Scientific Experts in the following year to advise the department on safety issues associated with food additives undercut Wiley’s scientific authority. The bureau had been developing informal standards for many foods in collaboration with outside experts since 1903, an activity that continued after the 1906 act. However, courts differed on the role these informal standards could play in cases. Separate laws established standards for some specific foods, such as apples and butter, as well as for canned foods.

The new law brought cosmetics and medical devices under control, and it required that drugs be labeled with adequate directions for safe use. Moreover, it mandated pre-market approval of all new drugs, such that a manufacturer would have to prove to FDA that a drug were safe before it could be sold. It irrefutably prohibited false therapeutic claims for drugs, although a separate law granted the Federal Trade Commission jurisdiction over drug advertising. The act also corrected abuses in food packaging and quality, and it mandated legally enforceable food standards. Tolerances for certain poisonous substances were addressed. The law formally authorized factory inspections, and it added injunctions to the enforcement tools at the agency's disposal.

Trends in the Last Quarter-Century

In the late 1960s and 1970s the FDA lost some of its responsibilities but acquired many more. Shortly after the FDA became a part of the Public Health Service, the Department of Health, Education, and Welfare transferred several functions administered by other PHS agencies to the FDA, including regulation of food on planes and other interstate
travel carriers, control over unnecessary radiation from consumer and professional electronic products, and pre-market licensing authority for therapeutic agents of biological origin. The latter originated under the predecessor of the National Institutes of Health in the Biologics Control Act of 1902, which followed the deaths of thirteen children from a tetanus-tainted batch of diphtheria antitoxin in St. Louis, and nine pediatric fatalities from similar circumstances in Camden, New Jersey. (At right, a scientist in FDA's Center for Biologics and Research is conducting research on the organism that causes the childhood disease pertussis.) Congress had authorized the FDA to regulate consumer products such as potential poisons, hazardous toys, and flammable fabrics in a number of laws dating back to 1927, but this function was transferred to the Consumer Product Safety Commission in 1973.

Changes in the work of the FDA have come rapidly in the past 20 years, shaped at least in part by political pressure, consumer activism, and industry involvement. Patient advocacy groups influenced a law to stimulate industry interest in developing so-called orphan drugs for rare diseases, and they played a role in the agency's development of accelerated techniques for drug approval, beginning with drugs for AIDS. Congress passed a law that simultaneously extended patent terms to account for time consumed by the drug approval process and facilitated the approval of generic human and animal drugs to offer a lower-cost alternative to brand name pharmaceuticals. Also, Congress instituted procedures for industry to reimburse the FDA for review of drugs and biologics to speed the agency's evaluations. Other laws have mandated reporting of adverse reactions to medical devices, post-market monitoring of implants and other devices that pose a serious health risk, recall authority for the FDA over medical devices, and certification and annual inspection of mammography facilities. Among food regulatory issues in the past two decades, Congress issued a singular prohibition against the FDA's banning saccharin under the Delaney Clause on the grounds that the sweetener had been shown to cause cancer in laboratory animals; instead, saccharin would have to carry a label warning. In 1990 Congress passed the Nutrition Labeling and Education Act, which completely reformulated the way food products convey basic nutritional information. Four years later, after intense lobbying by the dietary supplement industry, Congress permitted supplements to carry substantiated statements about the role of such products in health, provided they issued a disclaimer that FDA had not evaluated the statements. Moreover, the FDA rather than industry had the burden of proving that a dietary supplement was misbranded or adulterated.

The burgeoning interest in reinventing government and regulatory reform in the 1990s very much included the FDA, with the greatest interest focusing on the agency's time spent in evaluating therapeutic and other products. These were by no means original developments, at least as far as FDA was concerned. Numerous Congressional investigations, external and internal committee reports, independent fact-finding missions, and other venues of inquiry have studied the agency's mission and needs through much of the past century: precisely what one would expect for one of the oldest consumer regulatory agencies in the government, with such a broad responsibility for the public health, sometimes covering issues that have polarized large segments of American society. Such issues included sodium benzoate, sulfur dioxide, and other food preservatives during the Wiley era; Banbar in the 1930s; aminotriazole-tainted cranberries in the 1950s; vitamins in the 1970s; and breast implants in the 1990s. But these and other high visibility cases were just a small fraction of the agency's work, arcane to most of the public, but nevertheless a key ingredient in 20th century U.S. history.

**FDA regulates**

**Foods**
- safety of all food products (except for most meat and poultry products, which are regulated by the U.S. Department of Agriculture)
- labeling
- bottled water
- food additives
- infant formulas

**Dietary Supplements & Human Drugs**
- product approvals
- OTC and prescription drug labeling
- drug manufacturing standards

**Vaccines, Blood Products, and Other Biologics**
- product and manufacturing establishment licensing
- safety of the nation's blood supply
- research to establish product standards and develop improved testing methods

**Medical Devices**
- from simple items like tongue depressors, to complex technologies such as heart pacemakers
- pre-market approval of new devices
- manufacturing and performance standards
- tracking reports of device malfunctioning and serious adverse reactions
Electronic Products
- products that give off radiation, such as microwave ovens and X-ray equipment
- 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

Cosmetics
- safety - labeling

Veterinary Products
- livestock feeds - pet foods - veterinary drugs and devices
- veterinary biologics not regulated by USDA are considered new animal drugs

**FDA does not regulate**
- advertising (except for prescription drugs, medical devices, and tobacco products)
- alcoholic beverages
- some consumer products, such as paint, child-resistant packages, baby toys, and household appliances (except for those that give off radiation)
- illegal drugs of abuse, such as heroin and marijuana
- health insurance
- meat and poultry (except for game meats, such as venison, ostrich, and snake)
- restaurants and grocery stores
- vaccines for infectious animal diseases

FDA shares the responsibility for regulating these products with other government agencies:
- pesticides (FDA, the U.S. Department of Agriculture, and the Environmental Protection Agency regulate these)
- water (FDA regulates the labeling and safety of bottled water, while the Environmental Protection Agency develops national standards for drinking water from municipal water supplies)