



FDA & YOU

News for Health Educators and Students

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The FDA Centennial

Celebrating 100 years of Protecting and Promoting Public Health

It all began in 1906 with the passage of the Pure Federal Food and Drugs Act. Though the names and faces have changed over the past century, the mission of the U.S. Food and Drug Administration (FDA) has remained the same: to protect and promote the public health.

FDA is the oldest federal agency dedicated to consumer protection and is a scientific, regulatory, and public health agency that oversees products accounting for 25¢ of every dollar spent by Americans. Almost any food, cosmetic, drug, radiation product, medical device or biologic product you can think of is regulated by the FDA.

FDA includes five groups called "Centers," that regulate products you use everyday. From orange juice and lipstick to vaccines and toothbrushes, scientists and medical professionals within the centers work to ensure that the products you use are safe and effective.

Read about each Center and explore the timeline to learn about significant events in the history of the five regulatory Centers of FDA.* For more information, visit the FDA Centennial Web site at <http://www.fda.gov/centennial>.

*Material in this issue previously published on the FDA Web site.

Center for Biologics Evaluation and Research (CBER)

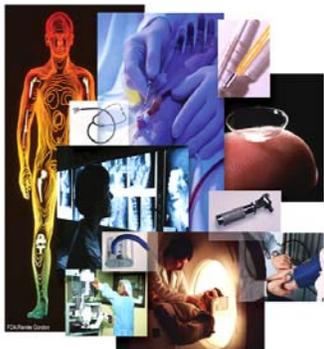
If you've ever donated blood or received a chicken pox or flu vaccine, you've been in contact with a biological product regulated by CBER. CBER regulates biological products for disease prevention and treatment. Biologics are products made from living sources, such as humans and animals; and microorganisms, like viruses and bacteria. These products can range from vaccines to allergy shots to lab tests that help doctors safely screen the nation's blood supply and diagnose diseases like HIV. CBER is responsible for ensuring the safety of our donated blood supply and the products derived from it. They also oversee the approval and production of safe and effective vaccines, the harvesting of human tissue for transplantation, and the safe and effective production of cell and gene therapy products.



<http://www.fda.gov/cber>

Center for Devices and Radiological Health (CDRH)

Do you use a toothbrush or put in a pair of contact lenses as part of your daily routine? If so, you're using a medical device regulated by CDRH. You may think of medical devices as products used by doctors and other medical professionals to diagnose and treat a disease or injury. What you may not realize is that many medical devices are also used by consumers to manage a medical condition or in everyday personal care, like brushing their teeth.



The category of medical devices is broad and includes lasers used in LASIK surgery to correct vision, pacemakers implanted to correct an irregular heart beat, glucose meters used to manage diabetes, and fetal ultrasound machines used to capture images of a baby in the womb. No matter the medical device, CDRH is responsible for ensuring that it's reasonably safe and effective.

<http://www.fda.gov/cdrh>

Center for Drug Evaluation and Research (CDER)

Aspirin, insulin, cough syrups, antibiotics, allergy medicines -- open your medicine cabinet or walk into your local pharmacy and much of what you see is regulated by CDER. CDER protects and promotes public health by assuring that safe and effective prescription and over-the-counter drugs are available to Americans. CDER also makes sure that doctors and patients have the information they need to use medicines wisely. Once drugs are on the market, CDER monitors them for problems. CDER oversees many products you might not think of as being medicines, including fluoride toothpaste, dandruff shampoos and sunscreens.



<http://www.fda.gov/cder/index.html>

Center for Food Safety and Applied Nutrition (CFSAN)



From cereal to shampoo and toothpaste, you probably use many of the products CFSAN regulates everyday. CFSAN is responsible for ensuring many cosmetics and food products sold across state lines are safe, sanitary, wholesome, and honestly labeled. Thanks to CFSAN, many of the foods in your local grocery store have nutrition labels and must provide a complete list of ingredients. The only foods CFSAN doesn't regulate are meat, poultry, and eggs. These products are under the authority of the U.S. Department of Agriculture.

<http://www.fda.gov/cfsan>

Center for Veterinary Medicine (CVM)

The average American consumes 200 pounds of meat and fish, 67 pounds of poultry, 30 pounds of eggs, and 600 pounds of dairy products each year, and CVM helps ensure that it's all safe.

CVM regulates the manufacture and distribution of food additives and drugs that will be given to animals from which human foods are derived, such as cattle, swine and chickens, as well as pets, such dogs and cats. Besides helping protect the health of consumers, CVM works to safeguard the health of animals in the U.S.



Whether developing and disseminating information, reviewing animal drug products for marketing to ensure they are safe and effective, monitoring marketed animal drug products, or conducting research, CVM's veterinarians, chemists, and other scientists are committed to protecting animal and human health.

<http://www.fda.gov/cvm>

FDA: The First Century



President Theodore Roosevelt



Mrs. Winslow's Soothing Syrup for teething and colicky babies, unlabeled yet laced with morphine, killed many infants



Lye looks like sugar and was packaged without a poison warning

1900s

1906 Pure Food and Drugs Act is passed by Congress on June 30 in response to the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines. Signed into law by President Theodore Roosevelt, the Act prohibits the sale of misbranded and adulterated foods, drinks and medicines across state lines.

Prior to the Act, common food preservatives of the time, including borax and formaldehyde, had been tested by a group of 12 brave volunteers from the Department of Agriculture's Bureau of Chemistry. Due to the hazards of their job they were nicknamed "The Poison Squad".

1906 Meat Inspection Act passed in response to unsanitary conditions in meat-packing plants.

1910s

1912 Sherley Amendment prohibits labeling medicines with false therapeutic claims.

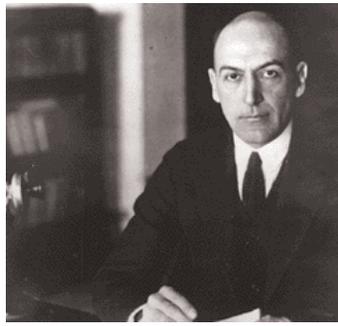
1914 Harrison Narcotic Act requires prescriptions for products that exceed the allowable limit of narcotics and requires increased record-keeping for doctors and pharmacist who dispense narcotics.

1920s

1927 Caustic Poisons Act requires a warning label on household products containing toxic acids and alkalis, including packages of lye used to make soap. The resemblance of the chemical lye to sugar and carelessness in storing lye in the home caused thousands of young children to suffer chemical burns; some were fatal.



Lash-Lure eyelash dye, blinded many women before the 1938 FDC Act



Walter G. Campbell, the first Commissioner of Food and Drugs



Atomic blasts lead to radiological examination of food

1930s

1930 The Food, Drug, and Insecticide Administration becomes the Food and Drug Administration (FDA).

1938 Federal Food, Drug, and Cosmetics (FDC) Act is passed by Congress it gives FDA regulatory authority over cosmetics and therapeutic devices, requires new drugs to be shown safe before marketing, and authorizes factory inspections.

1938 Wheeler-Lea Act charges the Federal Trade Commission (FTC) with overseeing advertising associated with products otherwise regulated by FDA, with the exception of prescription drugs.

1939 First Food Standards issued.

1940s

1940 FDA moves from the Department of Agriculture to the Federal Security Agency, with Walter G. Campbell appointed the first Commissioner of Food and Drugs.

1941 Insulin Amendment requires FDA to test and certify the safety and effectiveness of insulin used for diabetes treatment.

1950s

1950 *Alberty Food Products Co. v. U.S.*: Court of Appeals rules that drug labels must include the purpose of the drug.

1951 Durham-Humphrey Amendment formally distinguishes between prescription and over-the-counter medicines. Until that time, all drugs could be purchased over-the-counter.

1954 Miller Pesticide Amendment establishes procedures to determine safe amounts of pesticides that can remain on raw produce used as food.

1954 First large-scale radiological examination of food is carried out by FDA after receiving reports that tuna suspected of being radioactive is imported from Japan following atomic blasts in the Pacific.

1955 After a polio vaccine is linked with more than 200 cases of polio, control of biologics is moved to FDA's Division of Biologics Control.

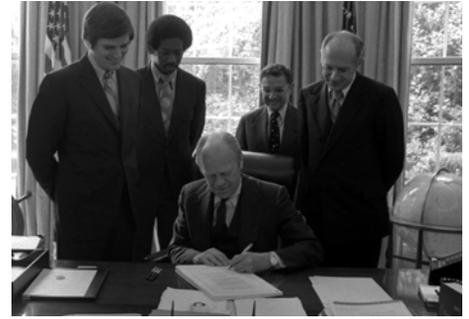
1958 Food Additives Amendment requires manufacturers to prove the safety of new food additives. The Delaney proviso bans the approval of any food additive shown to cause cancer in humans or animals.



President Kennedy confers on Dr. Frances Kelsey the highest recognition possible for federal civilian service in 1962 for her thalidomide work.



Animal Drug Amendments make cows happy!



President Gerald Ford signs the Medical Device Amendments

1960s

1960 Color Additive Amendment requires manufacturers to prove color additives used in foods, drugs and cosmetics are safe.

1960 Federal Hazardous Substances Labeling Act, requires certain hazardous household products have warning labels.

1962 Thalidomide, a new sleeping pill, is found to have caused birth defects in thousands of babies in Western Europe. Dr. Francis Kelsey, an FDA medical officer, is credited with keeping the drug off the U.S. market, and increasing public support for stronger drug regulation.

1962 Kefauver-Harris New Drug Amendments require drug manufacturers to prove their products are safe and effective before marketing.

1962 Consumer Bill of Rights is presented to Congress by President John F. Kennedy. Included are the right to safety, the right to be informed, the right to choose, and the right to be heard.

1965 Drug Abuse Control Amendments address problems caused by abuse of depressants, stimulants and hallucinogens.

1966 Fair Packaging and Labeling Act requires all consumer products sold across state lines be honestly and completely labeled.

1968 Animal Drug Amendments make approval and regulation of new animal drugs and medicated feeds more efficient.

1969 FDA establishes sanitation programs for milk, shellfish, food services, and interstate travel facilities, and for preventing poisoning and accidents.

1970s

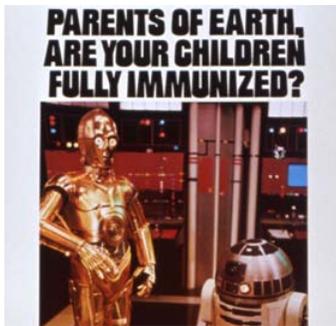
1970 FDA requires the first patient package insert; oral contraceptives must contain information for the patient about specific risks and benefits.

1971 National Center for Toxicological Research established. Its mission: to examine the biological effects of chemicals in the environment.

1972 New Over-the-Counter Drug Review enhances the safety, effectiveness and appropriate labeling of drugs sold without a prescription.

1976 Medical Device Amendments establish regulations that increase the regulatory and surveillance control of FDA and increase the safety and effectiveness of medical devices, including diagnostic products.

1976 Vitamins And Minerals Amendments ("Proxmire Amendments") stop FDA from establishing standards limiting potency of vitamins and minerals in food supplements or regulating them as drugs based solely on potency.



Dept. of Health, Education, and Welfare posters encouraged immunization



Mammography facilities must meet quality standards and pass inspections



FDA Centennial Celebration

1980s

1980 Infant Formula Act establishes special FDA controls to ensure necessary nutritional content and safety.

1982 In response to 7 deaths caused by Tylenol capsules contaminated with cyanide, Tamper-Resistant Packaging Regulations require that liquid oral hygiene products, vaginal products, contact lens solutions, and most over-the-counter medicines be packaged in tamper-resistant packages.

1983 Orphan Drug Act promotes research and marketing of drugs needed to treat rare diseases and conditions.

1985 First AIDS test to screen donated blood approved by FDA.

1986 Childhood Vaccine Act requires patient information on vaccines, gives FDA authority to recall vaccines, and establishes a system of compensating vaccine-related injuries or death.

1988 Food and Drug Administration Act officially establishes FDA as an agency of the Department of Health and Human Services with a Commissioner appointed by the President and confirmed by the Senate.

1990s

1990 Nutrition Labeling and Education Act requires all packaged foods to include standardized nutrition labeling and addresses health claims for foods.

1990 Safe Medical Devices Act requires facilities that use medical devices to report incidents that suggest a medical device caused the serious injury, illness or death of a patient.

1992 Mammography Quality Standards Act (MQSA) requires all mammography facilities in the U.S. to meet quality standards and pass annual inspections.

1994 Dietary Supplement Health and Education Act classifies "dietary supplements" and "dietary ingredients" as food, and establishes labeling requirements, regulations, and good manufacturing practices.

1996 Animal Drug Availability Act gives new flexibility to CVM to regulate animal drugs and medicated feeds.

1997 CVM implements a rule to prevent the spread of BSE, also known as "mad cow" disease.

1997 FDA Modernization Act (FDAMA) reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in FDA practices since 1938.

2000s

2002 Medical Device User Fee and Modernization Act enacted into law.

2003 CVM announces a regulatory pathway it developed that sponsors could use to seek approval of antimicrobial drugs while ensuring use of the drugs would not create resistant bacteria harmful to public health.

2003 Animal Drug User Fee Act authorizes FDA to collect fees on animal drugs to support CVM's responsibilities to ensure that new animal drug products are safe and effective, and any food from animals treated with those drugs is safe for human consumption.

2004 Minor Use/Minor Species Animal Health Act makes more medications legally available to veterinarians and animal owners to treat minor animal species, such as zoo animals, and uncommon diseases in the major animal species.

2006 100th Anniversary of the 1906 Pure Food and Drug Act.