# DOWNLOAD PDF CONSUMER PROTECTION AT THE FOOD AND DRUG ADMINISTRATION

## Chapter 1 : Food and Drug Administration | The First Amendment Encyclopedia

*The Food and Drug Administration is the oldest comprehensive consumer protection agency in the U. S. federal government. Since the federal government has used chemical analysis to monitor the.*

Early History[ edit ] Origins of federal food and drug regulation[ edit ] Up until the 20th century, there were few federal laws regulating the contents and sale of domestically produced food and pharmaceuticals, with one exception being the short-lived Vaccine Act of  A patchwork of state laws provided varying degrees of protection against unethical sales practices, such as misrepresenting the ingredients of food products or therapeutic substances. The history of the FDA can be traced to the latter part of the 19th century and the U. Under Harvey Washington Wiley , appointed chief chemist in , the Division began conducting research into the adulteration and misbranding of food and drugs on the American market. Although they had no regulatory powers, the Division published its findings from to in a ten-part series entitled Foods and Food Adulterants. Much credit is given to the deaths of many people in the s, including Eben Byers in from the ingestion of radithor and many women, some known as The Radium Girls , to making the FDA into the much more powerful organization we know today. The act applied similar penalties to the interstate marketing of "adulterated" drugs, in which the "standard of strength, quality, or purity" of the active ingredient was not either stated clearly on the label or listed in the United States Pharmacopoeia or the National Formulary. The act also banned "misbranding" of food and drugs. The resulting proposed law was unable to get through the Congress of the United States for five years, but was rapidly enacted into law following the public outcry over the Elixir Sulfanilamide tragedy, in which over people died after using a drug formulated with a toxic, untested solvent. The only way that the FDA could even seize the product was due to a misbranding problem: The new law significantly increased federal regulatory authority over drugs by mandating a pre-market review of the safety of all new drugs, as well as banning false therapeutic claims in drug labeling without requiring that the FDA prove fraudulent intent. The law also authorized factory inspections and expanded enforcement powers, set new regulatory standards for foods, and brought cosmetics and therapeutic devices under federal regulatory authority. This law, though extensively amended in subsequent years, remains the central foundation of FDA regulatory authority to the present day. These developments confirmed extensive powers for the FDA to enforce post-marketing recalls of ineffective drugs. While the science of toxicology was in its infancy at the start of this era, rapid advances in experimental assays for food additive and drug safety testing were made during this period by FDA regulators and others. This climate was rapidly changed by the thalidomide tragedy, in which thousands of European babies were born deformed after their mothers took that drug - marketed for treatment of nausea - during their pregnancies. Thalidomide had not been approved for use in the U. Individual members of Congress cited the thalidomide incident in lending their support to expansion of FDA authority. This marked the start of the FDA approval process in its modern form. Drugs approved between and were also subject to FDA review of their efficacy, and to potential withdrawal from the market. Other important provisions of the amendments included the requirement that drug companies use the "established" or "generic" name of a drug along with the trade name, the restriction of drug advertising to FDA-approved indications, and expansion of FDA powers to inspect drug manufacturing facilities. These reforms had the effect of increasing the time required to bring a drug to market. This act was intended to correct two unfortunate interactions between the new regulations mandated by the amendments, and existing patent law which is not regulated or enforced by the FDA, but rather by the United States Patent and Trademark Office. On the other hand, the new regulations could be interpreted to require complete safety and efficacy testing for generic copies of approved drugs, and "pioneer" manufacturers obtained court decisions which prevented generic manufacturers from even beginning the clinical trial process while a drug was still under patent. The Hatch-Waxman Act was intended as a compromise between the "pioneer" and generic drug manufacturers which would reduce the overall cost of bringing generics to market and thus, it was hoped,

reduce the long-term price of the drug, while preserving the overall profitability of developing new drugs. The act extended the patent exclusivity terms of new drugs, and importantly tied those extensions, in part, to the length of the FDA approval process for each individual drug. For generic manufacturers, the Act created a new approval mechanism, the Abbreviated New Drug Application ANDA , in which the generic drug manufacturer need only demonstrate that their generic formulation has the same active ingredient, route of administration, dosage form, strength, and pharmacokinetic properties "bioequivalence" as the corresponding brand-name drug. This act has been credited with essentially creating the modern generic drug industry. Louis Lasagna , then chairman of a presidential advisory panel on drug approval, estimated that thousands of lives were lost each year due to delays in approval and marketing of drugs for cancer and AIDS. A second new rule, the "parallel track policy", allowed a drug company to set up a mechanism for access to a new potentially lifesaving drug by patients who for various reasons would be unable to participate in ongoing clinical trials. The "parallel track" designation could be made at the time of IND submission. The accelerated approval rules were further expanded and codified in  Because federal law passed pursuant to Constitutional authority overrules conflicting state laws,[ citation needed ] federal authorities still claim the authority to seize, arrest, and prosecute for possession and sales of these substances, even in states where they are legal under state law. The first wave was the legalization by 27 states of laetrile in the late s. This drug was used as a treatment for cancer, but scientific studies both before and after this legislative trend found it to be ineffective. Further studies based on a Mexican formulation also showed no effectiveness in treating cancer, but did find that some patients experienced symptoms of cyanide poisoning. Though the political movement died out in the s, FDA enforcement actions against laetrile purveyors continued into the s. Though Virginia passed a law with limited effect in , a more widespread trend began in California in  In , the Obama Administration de-prioritized enforcement of federal law against patients using the drug in compliance with state law, but reversed this policy in  Medical cannabis in the United States Regulation of living organisms[ edit ] With acceptance of premarket notification k k in January , the FDA granted Dr. Ronald Sherman permission to produce and market medical maggots for use in humans or other animals as a prescription medical device. Medical maggots represent the first living organism allowed by the Food and Drug Administration for production and marketing as a prescription medical device. In June , the FDA cleared Hirudo medicinalis medicinal leeches as the second living organism to be used as a medical devices. Timeline of food and drug legislation[ edit ] Most federal laws concerning the FDA are part of the Food, Drug and Cosmetic Act, [22] first passed in and extensively amended since and are codified in Title 21, Chapter 9 of the United States Code. In many cases these responsibilities are shared with other federal agencies. Important enabling legislation for the FDA includes:

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## Chapter 2 : History of the Food and Drug Administration - Wikipedia

*Consumer Protection. Information from the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) on dietary supplement safety, fraud, and other consumer protection matters. Also provides information on how to file a report or complaint.*

To ensure compliance with its regulations, the FDA employs over 1, investigators and inspectors who visit over 15, food-processing, drug-manufacturing, and other facilities each year. If it finds violations of law, the FDA first encourages an offending company to voluntarily correct the problem or to recall a faulty product from the market. If the firm does not voluntarily comply with the law, the FDA may take it to court and seek criminal penalties against it. The FDA may also seize faulty products, order product recalls, seek injunctive relief, impose fines, and take other types of enforcement action. Each year, the FDA declares about 3, products and 30, import shipments to be unacceptable in various ways. The FDA employs over 2, scientistsâ€"including chemists and microbiologistsâ€"who provide the scientific evidence to back up its regulatory and inspection duties. These scientists analyze samples of products for purity and review test results of new products. The FDA itself does not do research for a new medical product. Instead, it evaluates the results of studies undertaken by the manufacturer. History Food production in the United States has been regulated since the late eighteenth century. Colonies and, later, states passed laws banning impurities from selected foods. The enforcement of food and drug laws was first assigned to the Chemical Division of the new u. The need for laws to regulate food and drug purity became increasingly urgent in the late nineteenth century, when substances such as opium, cocaine, and heroin were commonly added to medicinal elixirs and tonics. The former prohibited interstate commerce in misbranded and adulterated foods, drinks, and drugs, and the latter addressed the unsanitary conditions and use of poisonous preservatives and dyes in the meatpacking industry. In , people died after taking the elixir sulfanilamide, a supposedly healing tonic. This tragedy prompted the passage of the next major reform of food and drug law, the Federal Food, Drug, and Cosmetic Act of 21U. The FDA was then entrusted with the regulation of cosmetics and therapeutic devices and was authorized to do factory inspections. Even more importantly, the act required new drugs to be tested on animals and humans for safety before being marketed. In , the Food Additives Amendment Pub. How the FDA Approves New Drugs The process by which the Food and Drug Administration FDA approves drugs as safe and effective is generally long and complicated, though it may vary according to the type of drug and the nature of the illness for which it is being developed. The evaluation of new drugs requires the skills of many different FDA scientists and professionals performing a wide variety of tasks. Biochemists and molecular biologists evaluate the basic chemistry and biology of new chemical compounds and molecular structures. Toxicologists assess the potential harm of proposed drugs, and pharmacologists study how these drugs affect the body and are broken down and absorbed by it. Computer scientists create electronic models that aid in the understanding of new chemicals. Physicians evaluate the results of clinical trials, assessing both the beneficial and adverse effects of the drugs. And statisticians evaluate the design and results of controlled studies. It is an expensive and time consuming process, particularly for the company developing the drug, called a drug sponsor. Typically, the process takes eight and a half years and may be divided into roughly three stages: Preclinical Trials Once a sponsor has developed a drug, it must test the drug on animals in the laboratory. In doing so, the drug sponsor must follow FDA guidelines and regulations. These tests, also called preclinical trials, are usually done on more than one species of animals. After short-term lab testing has been performed and the sponsor has deemed its results adequate, the sponsor submits test data and plans for future clinical trials to the FDA. FDA scientists, together with a local institutional review board composed of scientists, ethicists, and nonscientists, then conduct a thirty-day safety review to decide whether to allow testing on humans. The vast majority of new drugs tested in the laboratory are rejected by either the sponsor or the FDA because they are unsafe or ineffective. If the FDA indicates approval, the drug sponsor may begin clinical

testing on humans. Clinical Trials Clinical trials are scientifically controlled studies in which the drug being tested is given to one group of patients, while another treatment, often a placebo an inactive substance that looks like the drug being tested , is given to another group. Ideally, neither group of patients knows which is receiving the new drug and which is receiving the placebo. The clinical trials, like the animal tests, examine what happens to the drug in the body, including whether it is changed, or metabolized, in the body, how much of it is absorbed into the blood, and how long it remains in the body. If human tests produce unexpected results, researchers may conduct further animal tests to better understand the drug. Clinical trials proceed in three phases: Phase 1 involves testing primarily for safety and dosage level. Twenty to one hundred healthy patients are assessed over several months. If the results are within FDA safety guidelines, the trials proceed to phase 2. Phase 2 involves a greater number of patientsâ€”up to several hundredâ€”who have the condition that the drug is intended to treat. At the end of this phase, sponsors meet with FDA officials to discuss the best way to conduct the next phase of testing. In phase 3, the most crucial stage of testing, the number of patients is expanded still further, to several hundred to several thousand, and the length of the study is increased to one to four years. This phase establishes the correct dosage of the drug and how it will be labeled, and provides further evidence regarding its safety and effectiveness. Of one hundred drugs submitted for testing in humans, an average of seventy will pass phase 1. Of these seventy, on average, only thirty-three will remain after phase 2 testing, and twenty-five to thirty after phase 3. Finally, an average of only twenty will actually receive FDA approval. Once the drug sponsor has completed clinical trials, it submits a new drug application NDA to the FDA, requesting approval to market the drug. This application consists of documentation detailing the chemical composition of the drug, the design of the trials, the results of the trials, and the means by which the drug is made and packaged. Its principal goal during review is to determine whether the benefits of the new drug outweigh the risks. To reach this determination, the FDA examines the documentation provided by the sponsor and looks at samples of the drug. If inadequacies are discovered in the NDA, the FDA may require additional information, further testing, or modified labeling. In cases where it is difficult to establish clearly whether the benefits of the drug outweigh the risks, a panel of outside experts is often consulted. If the FDA approves the drug, the sponsor may begin manufacturing and marketing the drug immediately. The FDA does not stop monitoring a drug once it has been marketed. This program consists of surveys, the testing of product samples, and the analysis of reported adverse reactions. Innovative cancer treatments, for example, have been made available to patients since the s through the National Cancer Institute. However, during the s, the FDA came under increasing fire for its slow approval of new drugs. Particularly with the emergence of AIDS during the s, the public outcry for fast delivery of innovative new drugs strengthened. As science produces ever more pharmaceuticals, the FDA is called on to review drug applications as quickly as is reasonably possible. In response to the growing demand for speedy drug evaluation, the FDA has made significant changes in its review protocols. In , for example, the agency adopted "expanded access" regulations, which permit certain drugs to be designated as treatment INDs. A treatment IND may be administered to patients even while it is still undergoing clinical trials. This program allows patients with no other alternatives to undergo a treatment that may benefit their health. By August , twenty-nine agents had been designated treatment INDs, and by , more than seventy-five thousand patients had received access to new therapies through this program. New drugs used to treat patients with AIDS are made available through a similar process known as the parallel track approach. Identifying priorities is another method the FDA uses to provide more rapid access to promising new treatments. AIDS drugs, drugs that treat life-threatening or severely debilitating illnesses, and drugs that appear to offer significant improvements over existing therapies are classified as priority drugs and receive faster review than those classified as standard drugs. With priority drugs, the FDA typically becomes involved earlier in the development process, and is thereby able to more quickly review the relevant applications. Drugs are also classified as to chemical type, so that those closely similar in structure to existing drugs will receive less intensive review than those with a molecular structure that has never been marketed before. Accelerated approval is another mechanism for faster review of promising new drugs. Under this

program, created in , a product may be approved for limited use if it has been shown in trials to achieve particular resultsâ€”such as lowering blood pressure or cholesterol. Drugs approved under this program include didanosine for AIDS, interferon beta-1B for multiple sclerosis , and DNase for cystic fibrosis. Under this law, fees paid by drug manufacturers are used by the agency to hire hundreds of additional review staff and buy improved equipment, including computers that make review more efficient. The FDA is also attempting to streamline red tape and bureaucracy. In , President bill clinton and Vice President albert gore, Jr. This form would also be available in an electronic format, making it easier to distribute, prepare, and review. Results indicate that these changes have led to faster approval of important new drugs. One signal success of FDA reform was the prompt approval of taxol, a treatment for advanced ovarian cancer that was approved in December after a record 5 months. By , all new drugs were being approved by the FDA in a median time of 19 months, and priority drugs with important therapeutic uses were approved in an average of  In the late s, by comparison, the FDA took an average of 27 months to approve new drugs. These goals, to be met by , require the FDA to approve priority drugs within 6 months and standard drugs within 12 months. These laws required drug manufacturers not only to show that their drugs were safe but also to prove that their drugs achieved the effects claimed. That same year, FDA regulations were shown to be effective after the drug thalidomide, for which the FDA had delayed approval, caused thousands of birth defects in western Europe. The NOP sets the first national standards for the use of the label term organic on food items and products. The rules specifically prohibit the use of genetic engineering methods, ionizing radiation irradiation , and sewage sludge for fertilization. In addition, all agricultural products that are labeled organic must originate from farms or handling operations that have been certified by a state or private agency accredited by the USDA. Organization The FDA carries out its activities through a number of subdivisions. The Center for Drug Evaluation and Research regulates the safety, effectiveness, and labeling of all prescription and over-the-counter drugs intended for human use. It also monitors drug advertising for accuracy, ensures the safety and rights of patients in drug studies, and distributes information on drug products to the medical community and the public. The Center for Biologics Evaluation and Research regulates biological products, which include blood, vaccines, human tissues, and drugs derived from living organisms. It also conducts research on the safety of blood and blood products and inspects manufacturing plants to ensure compliance with FDA standards. The Center for Food Safety and Applied Nutrition develops regulations related to food, food additives and colorings, and cosmetics. The Center for Devices and Radiological Health seeks to ensure the safe use of potentially hazardous radiation such as that produced by X rays. It conducts research into the effects of exposure to radiation-producing medical devices and develops manufacturing standards for such devices. The Center for Veterinary Medicine evaluates the safety of drugs and devices used on animals.

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## Chapter 3 : NCDA&CS - Food & Drug Protection

*Search Department of Consumer Protection Search the current Agency with a Keyword Filtered Topic Search Food and Drug Administration The Food and Drug Administration (FDA) enforces laws to ensure that foods are safe, pure and wholesome, that drugs and medical devices are safe and effective; that cosmetics are safe and that all are honestly and informatively labeled and packaged.*

LaGrou stored products for customers. Manager knew of rats â€" talked to company president, Stewart, about the problem. Rats were caught daily; food the rats chewed on thrown away. Customers not told of rats â€" rather told that the food had been damaged in shipment and destroyed. Expert said structural changes in the building needed to eliminate holes for rats. Stewart said that was too expensive. Two USDA inspectors saw rodent droppings, etc. Huge number of violations found. Warehouse ordered to closed; 22 million lbs. President and manager of company were also convicted. Affirmed as consistent with federal law. Situation at the warehouse was dire. Poor ventilation system â€" pathogens and viruses could have become airborne. Also leaking roofs and dripping pipes carried food-borne pathogens all over. FDA has strict regulations concerning testing and adoption of new drugs. FDA has responsibility for oversight of medical devices, surgical equipment, power wheelchairs, artificial hearts, pacemakers, etc. FDA approval is evidence of safety, not a shield against liability of drug companies. If claims are misleading or safety is an issue, FDA can force removal of product from the market Costly for drug companies for research and development Slide 8 International Perspective: FDA standards are generally tougher than Europe or Japan. Foreign producers selling in the U. Development costs are high â€" so costs of drugs high to cover investment. People in low income countries cannot pay U. Canada buys all drugs for their market; bargaining keep prices lower. Drug market becoming more fragmented. Foreigners expect drugs that carry U. Over 50 people died in Panama from cough syrup from China that contained chemical like anti-freeze. Wasted money and injuries to health from taking worthless drugs people think are real. FDA knows of huge problems--difficult to control , drugs around world. FDA known to take bribes to grant approval for products that enter U. Slide 9 Nutraceutical Corp. Nutraceutical sued FDA claiming ban was unlawful. Lower court held for Nutraceutical. Slide 10 Nutraceutical Corp. Summary judgment for FDA should have been entered. Reversed and remanded for entry of judgment in favor of FDA. Mailings were sent to 4. On the back in fine print said if you cashed the check, you subscribed to access service and agreed to be billed monthly by a charge added to phone bill. One-quarter million people cashed the check. Most did not read the fine print. FTC sued for unfair and deceptive trade practices. Slide 16 Federal Trade Commission v. Fine print notices did not prelude liability of owners. Nearly , individuals and small business were deceived. Slide 17 Regulating Advertising Claims Advertising substantiation program Must have reasonable basis for claims FTC considers following in what is reasonable basis: Slide 18 False Advertising and the Lanham Act Private parties can bring civil actions under the Lanham Act Usually similar to FTC cases, but can also get damages States play similar roles as FTC, bringing suit against those involved in scams and dubious business practices. Advertise products cost less than others on the market. Ab Force is an electronic muscle stimulation abdominal EMS belt. Sends small electric current into abdominal muscles. FTC sued for false and misleading advertising claims re: Slide 20 Telebrands Corp. Entered an order against Telebrands. There was no substantiation that Ab Force could deliver advertised results. Standard is that an ad is illegal if it misrepresents a product â€"U. Ad is illegal if it simply misleads â€"Japan: Air worked on system as needed, but in , refused to honor warranty. Said warranty too costly. Air contended that Schuchmann must prove that Air intended to default on the warranty from the very beginning of the sale. National Action Financial Services National Action, a debt collector, mailed Chuway a letter which identified the credit card company she owed money to. Please remit the balance listed above in the return envelope provided. To obtain your most current balance information, please call  Our friendly and experienced representatives will be glad to assist you and answer any questions you have. Slide 37 Chuway v.

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Credit card company not debt collector may charge interest until the debt is finally paid. Communications must be clear. For the debt collector to collect running interest or other charges, must use specific language:

## Chapter 4 : Food and Drug Administration - Wikipedia

*Match each consumer protection agency with its objective. Tiles Food and Drug Administration Federal Communications Commission Federal Trade Commission.*

For example, the FDA regulates almost every facet of prescription drugs, including testing, manufacturing, labeling, advertising, marketing, efficacy, and safetyâ€”yet FDA regulation of cosmetics focuses primarily on labeling and safety. The FDA regulates most products with a set of published standards enforced by a modest number of facility inspections. Inspection observations are documented on Form  In June , the FDA released a statement regarding new guidelines to help food and drug manufacturers "implement protections against potential attacks on the U. Regulation of food and dietary supplements by the U. Food and Drug Administration The regulation of food and dietary supplements by the U. Pursuant to the Federal Food, Drug, and Cosmetic Act "the Act" and accompanying legislation, the FDA has authority to oversee the quality of substances sold as food in the United States, and to monitor claims made in the labeling about both the composition and the health benefits of foods. The FDA subdivides substances that it regulates as food into various categoriesâ€”including foods, food additives , added substances man-made substances that are not intentionally introduced into food, but nevertheless end up in it , and dietary supplements. Specific standards the FDA exercises differ from one category to the next. Furthermore, legislation had granted the FDA a variety of means to address violations of standards for a given substance category. Through their governing of processes, however, the FDA does have a set of regulations that cover the formulation, manufacturing, and use of nonstick coatings. The Center for Drug Evaluation and Research uses different requirements for the three main drug product types: A drug is considered "new" if it is made by a different manufacturer, uses different excipients or inactive ingredients, is used for a different purpose, or undergoes any substantial change. The most rigorous requirements apply to new molecular entities: A drug that is approved is said to be "safe and effective when used as directed". The studies are progressively longer, gradually adding more individuals as they progress from stage I to stage III, normally over a period of years, and normally involve drug companies, the government and its laboratories, and often medical schools and hospitals and clinics. However, any exceptions to the aforementioned process are subject to strict review and scrutiny and conditions, and are only given if a substantial amount of research and at least some preliminary human testing has shown that they are believed to be somewhat safe and possibly effective. Advertising and promotion for over-the-counter drugs is regulated by the Federal Trade Commission. The drug advertising regulation [31] contains two broad requirements: Also, an advertisement must contain a "fair balance" between the benefits and the risks side effects of a drug. The term off-label refers to drug usage for indications other than those approved by the FDA. Postmarket safety surveillance[ edit ] After NDA approval, the sponsor must review and report to the FDA every patient adverse drug experience it learns of. They must report unexpected serious and fatal adverse drug events within 15 days, and other events on a quarterly basis. While this remains the primary tool of postmarket safety surveillance , FDA requirements for postmarketing risk management are increasing. As a condition of approval, a sponsor may be required to conduct additional clinical trials , called Phase IV trials. Food and Drug Administration FDA requires scientific evidence that the generic drug is interchangeable with or therapeutically equivalent to the originally approved drug. Generic drug scandal[ edit ] In , a major scandal erupted involving the procedures used by the FDA to approve generic drugs for sale to the public. When its application to manufacture generics were subjected to repeated delays by the FDA, Mylan, convinced that it was being discriminated against, soon began its own private investigation of the agency in  Mylan eventually filed suit against two former FDA employees and four drug-manufacturing companies, charging that corruption within the federal agency resulted in racketeering and in violations of antitrust law. Brancato, Walter Kletch pleaded guilty to criminal charges of accepting bribes from generic drugs makers, and two companies Par Pharmaceutical and its subsidiary Quad Pharmaceuticals [39] pleaded guilty to giving bribes.

Furthermore, it was discovered that several manufacturers had falsified data submitted in seeking FDA authorization to market certain generic drugs. Vitarine Pharmaceuticals of New York, which sought approval of a generic version of the drug Dyazide , a medication for high blood pressure, submitted Dyazide, rather than its generic version, for the FDA tests. In April , the FDA investigated 11 manufacturers for irregularities; and later brought that number up to  Dozens of drugs were eventually suspended or recalled by manufacturers. In the early s, the U. Securities and Exchange Commission filed securities fraud charges against the Bolar Pharmaceutical Company, a major generic manufacturer based in Long Island, New York. New biologics are required to go through a premarket approval process called a Biologics License Application BLA , similar to that for drugs. The original authority for government regulation of biological products was established by the Biologics Control Act , with additional authority established by the Public Health Service Act. Originally, the entity responsible for regulation of biological products resided under the National Institutes of Health ; this authority was transferred to the FDA in  Medical and radiation-emitting devices[ edit ] The Center for Devices and Radiological Health The Center for Devices and Radiological Health CDRH is the branch of the FDA responsible for the premarket approval of all medical devices , as well as overseeing the manufacturing, performance and safety of these devices. CDRH also oversees the safety performance of non-medical devices that emit certain types of electromagnetic radiation. Examples of CDRH-regulated devices include cellular phones , airport baggage screening equipment , television receivers , microwave ovens , tanning booths , and laser products. CDRH regulatory powers include the authority to require certain technical reports from the manufacturers or importers of regulated products, to require that radiation-emitting products meet mandatory safety performance standards, to declare regulated products defective, and to order the recall of defective or noncompliant products. CDRH also conducts limited amounts of direct product testing. Approved requests are for items that are new or substantially different and need to demonstrate "safety and efficacy", for example it may be inspected for safety in case of new toxic hazards. Both aspects need to be proved or provided by the submitter to ensure proper procedures are followed. Cosmetic products are not, in general, subject to premarket approval by the FDA unless they make "structure or function claims" that make them into drugs see Cosmeceutical. However, all color additives must be specifically FDA approved before manufacturers can include them in cosmetic products sold in the U. The FDA regulates cosmetics labeling, and cosmetics that have not been safety tested must bear a warning to that effect. Though the cosmetic industry is predominantly responsible in ensuring the safety of its products, the FDA also has the power to intervene when necessary to protect the public but in general does not require pre-market approval or testing. Companies are required to place a warning note on their products if they have not been tested. Experts in cosmetic ingredient reviews also play a role in monitoring safety through influence on the use of ingredients, but also lack legal authority. The implementation date is uncertain, due to ongoing proceedings in the case of R. Food and Drug Administration. Reynolds , Lorillard , Commonwealth Brands Inc. District Court for the District of Columbia temporarily halted the new labels, likely delaying the requirement that tobacco companies display the labels. Supreme Court ultimately could decide the matter. Ronald Sherman permission to produce and market medical maggots for use in humans or other animals as a prescription medical device. Medical maggots represent the first living organism allowed by the Food and Drug Administration for production and marketing as a prescription medical device. In June , the FDA cleared Hirudo medicinalis medicinal leeches as the second living organism to be used as a medical device. The FDA also requires milk to be pasteurized to remove bacteria. Science and research programs[ edit ] FDA lab at Building 64 in Silver Spring, Maryland In addition to its regulatory functions, the FDA carries out research and development activities to develop technology and standards that support its regulatory role, with the objective of resolving scientific and technical challenges before they become impediments. History of the Food and Drug Administration Up until the 20th century, there were few federal laws regulating the contents and sale of domestically produced food and pharmaceuticals, with one exception being the short-lived Vaccine Act of  The history of the FDA can be traced to the latter part of the 19th century and the U. Under Harvey Washington Wiley , appointed chief

chemist in , the Division began conducting research into the adulteration and misbranding of food and drugs on the American market. The serum was originally collected from a horse named Jim , who had contracted tetanus. The act applied similar penalties to the interstate marketing of "adulterated" drugs, in which the "standard of strength, quality, or purity" of the active ingredient was not either stated clearly on the label or listed in the United States Pharmacopoeia or the National Formulary. The resulting proposed law was unable to get through the Congress of the United States for five years, but was rapidly enacted into law following the public outcry over the Elixir Sulfanilamide tragedy, in which over people died after using a drug formulated with a toxic, untested solvent. The new law significantly increased federal regulatory authority over drugs by mandating a pre-market review of the safety of all new drugs, as well as banning false therapeutic claims in drug labeling without requiring that the FDA prove fraudulent intent. Soon after passage of the Act, the FDA began to designate certain drugs as safe for use only under the supervision of a medical professional, and the category of " prescription-only " drugs was securely codified into law by the Durham-Humphrey Amendment. These developments confirmed extensive powers for the FDA to enforce post-marketing recalls of ineffective drugs. Applications grew considerably after the efficacy mandate under the Drug Amendments. This marked the start of the FDA approval process in its modern form. These reforms had the effect of increasing the time, and the difficulty, required to bring a drug to market. The act extended the patent exclusivity terms of new drugs, and tied those extensions, in part, to the length of the FDA approval process for each individual drug. For generic manufacturers, the Act created a new approval mechanism, the Abbreviated New Drug Application ANDA , in which the generic drug manufacturer need only demonstrate that their generic formulation has the same active ingredient, route of administration, dosage form, strength, and pharmacokinetic properties "bioequivalence" as the corresponding brand-name drug. This act has been credited with in essence creating the modern generic drug industry. Under the theory that federal law passed pursuant to Constitutional authority overrules conflicting state laws, federal authorities still claim the authority to seize, arrest, and prosecute for possession and sales of these substances,[ citation needed ] even in states where they are legal under state law. The first wave was the legalization by 27 states of laetrile in the late s. This drug was used as a treatment for cancer, but scientific studies both before and after this legislative trend found it to be ineffective. Though Virginia passed a law with limited effect in , a more widespread trend began in California in

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## Chapter 5 : Food and Drug Law | Wex Legal Dictionary / Encyclopedia | LII / Legal Information Institute

*(A) in a review of the foods of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in , the Food and Drug Administration found that 25 percent of.*

See Article History Alternative Titles: Such regulation may be institutional, statutory, or embodied in a voluntary code accepted by a particular industry, or it may result more indirectly from the influence of consumer organizations. Consumer representation Consumer protection organizations in one form or another are scattered throughout the world, from the industrial countries to developing countries. Governments often establish formal regulatory agencies to insure consumer protection. For example, in the United States, the Federal Trade Commission FTC , established in , is authorized to prevent deceptive practices in commerce and to regulate the package labeling of consumer products; the Food and Drug Administration FDA , established as the Food, Drug, and Insecticide Administration in the Agriculture Department in , administers consumer protection of foods, cosmetics, and other substances; and the National Highway Traffic Administration, established in , is concerned with all aspects of automobile safety. At least one government division or office dealing with consumer affairs has been set up in each of the 50 states. A leading individual consumer advocate during the midth century was Ralph Nader , who criticized the safety engineering of U. Consumers International formerly the International Organization of Consumers Unions is a worldwide association of consumer groups. One of the best protections for consumers is the availability of information. The Internet has become an important forum for information and opinions on products, businesses, and services. Consumer Reports, long considered an unbiased and up-to-date source of reviews and information on a wide range of products and services, publishes the findings of Consumers Union, an independent, nonprofit testing and information organization established in the United States in  Laws, regulations, and standards Laws have long provided certain safeguards to buyers. Other early legislation dealt mainly with adulteration of food and drugs. This was true, for example, of the Adulteration of Food and Drugs Act of England and similar, cumulative measures of , , and in the United States. The scope of such acts has been enlarged from time to time to include, for example, goods such as electrical products and automobiles, which could endanger the safety of the consumer if certain standards are not met. The provisions of such legislation are necessarily complex and vary from country to country, as well as, in the United States, from state to state. Various nonstatutory controls, such as standards laid down by national-standards institutions, also interact with statutory controls. In the following survey both the statutory and nonstatutory aspects of this subject are considered together. Controls on manufacturing and design Of all industries, food and drugs are the most controlled by legislation. Other products in general are controlled by standards institutions, which lay down basic minimum standards for many different kinds of products. Legislative controls applying to food and drug manufacturers prohibit them from adding or removing anything from the product they sell that would make it injurious to health. Although this might appear to afford absolute protection for the consumer, manufacturers sometimes unwittingly add ingredients that are subsequently found to be harmfulâ€”e. The frequency of such occurrences will clearly depend on the rigour of the standards of the official testing agencies concerned and the stringency with which such standards are applied. For nonfood products, legislation is less easily devised and far less easily enforced. Most countries, nevertheless, have developed minimum applicable standards. National-standards institutions were, in many instances, set up more for the benefit of manufacturers than for that of the ordinary, domestic consumer. In addition, government bodies were often formed to better control government purchasing. In the United States, for example, the General Services Administration laid down specifications and quality standards that had to be satisfied before the federal government would buy supplies. By the s, standards organizations had become far more aware of the needs of the ordinary consumer, but their legal status, for the most part, remained unaltered. Most recommendations are devised with the cooperation of industry, government departments, and consumers. The standards themselves are not usually legally enforceable but

remain voluntary. They usually do not reflect the quality of the product as a whole but deal only with a specific aspect of it. The mark of a standards institution, for example, may well indicate that a hair dryer is sufficiently insulated against electrical-shock hazards, but not that it dries hair satisfactorily. Although the standards institutions have assisted in raising the quality of many consumer products, their grip is weak. Most standards result from decisions of committees in which manufacturers usually have the final say. The standards laid down by manufacturers for a product can be so low that the consumer benefits little, if at all. Further, almost all standards refer to the safety of a product and not to its efficiency; and, with only a few exceptions, the recommendations of standards agencies are voluntary. The decision whether to adopt the standard is up to the company that markets the product, and such a decision necessarily involves an assessment of possible costs and returns. It is unfortunate that, in many countries, the selling power of the standards symbol is less substantial than that of a good promotion campaign. Consumers, it would appear, are not sufficiently aware of the presence and significance of these symbols, perhaps because they tend to be little publicized by the manufacturers. Apart from the formulation of standards, testing by various bodies occasionally results in the redesigning of certain products. Such testing has been most apparent in the automobile industry , in which cars have been recalled by their manufacturers so that alterations and improvements could be made. Controls on advertising Of all the criticisms levelled at manufacturers, those against their advertising probably have been the most vociferous. Advertising is necessarily vulnerable to these attacks: Although the major purpose of company advertising, which is to attract members of the public toward buying a particular product, is fairly straightforward, the methods employed in this process have become increasingly complex. As business has become more competitive, so has the advertising that sells its products. Coupled with this increased competition has been the development of more powerful mediaâ€”the most important of these being television. In the first instance it is accepted that the consumer, of his own volition, has a need that is filled by the description of the advertised product but not necessarily by the product itself , whereas in the second the need is artificial and is stimulated entirely by the media. From an economic viewpoint, critics of advertising point to the enormous amount of money involvedâ€”money that, they state, does not benefit the consumer although he is compelled to pay it. A second criticism is that advertising restricts competition because only large companies can afford expensive, nationwide campaigns, thus limiting freedom of entry of new firms into an established market. A definitive answer to these questions is obviously impossible. Regarding the first, it might be fair to say that economic growth and the creation of wealth might come about far more slowly without the aid of advertising. The development of national rather than regional brandsâ€”and the economies of scale implicit in this developmentâ€”might be retarded. For all its drawbacks, advertising informs the consumer and enables him to make not only a choice between products but also a choice between the stores at which he can buy those products. For the manufacturer it justifies a heavy investment in capital and manpower in that it assures to some degree at least the quick development of sales. Regarding the second major criticismâ€”that advertising encourages the concentration of industryâ€”there is no doubt that this is true. But not everyone agrees that industrial concentration necessarily acts against the interests of the consumer, particularly in the absence of outright monopolies or cartels. In some countries, such as the United States and Great Britain, anti-trust or monopoly laws act to restrain the more flagrant abuses of industrial power. Other countries, especially some in western Europe, have established monopolies boards, which monitor or oversee activities of large corporations in the field of takeovers and mergers. The advertising industry has for many years been aware of the various criticisms and has accepted the need for some control over advertising methods in addition to the provisions of statutory regulations that exist in many countries. The country with the most stringent advertising standards is usually thought to be Great Britain , where, for example, all advertising on private radio and television and on the Internet is regulated by the Advertising Standards Authority ASA , an independent body. The ASA bans the use, for instance, of subliminal advertising methods by which the listener or viewer might be influenced without his becoming aware of it and of advertising that plays on fear and on the minds of the superstitious. The general character of governmental

and private controls over the claims and methods of advertisers may be said to be one of considerable laxity. It seems likely that this situation will be changed not so much by the introduction of more stringent codes as by challenges to particular advertisers by consumer interest groups within the framework of existing legislation regarding truth in advertising. Labeling standards Labeling can be used either to inform or to deceive the consumer, and manufacturers, in their sales efforts, are often tempted by the latter expedient. Minimum standards of labeling exist for some products, but, as with controls on manufacturing quality, legislation tends to concentrate on food and drugs. Usually, every container carries a statement of contents, but, apart from food and drugs, content identification is not usually required. If it is provided, however, it must not misrepresent. In general, this means that labeling, when it is present at all, tends to be accurate. Consumer movements and official bodies have, in many countries, seen the need for better systems of product labeling. Price labels are of further importance to the consumer; the need for goods to be priced correctly is essential. Vendors, however, are under no legal obligation to indicate prices, and a major criticism by consumer groups has been that, even when prices are indicated, it is often difficult to make price comparisons because of the lack of standardization of the weights or volumes of packages in which a product is sold. Controls on sales methods Generalizations cannot be made concerning statutory controls on sales methods because they vary from place to place. Sales practices have been controlled for over a century; early regulations were largely concerned with peddlers and hawkers. Legal progress has, in general, imposed a stricter control of selling methods to reduce the incidence of deception. Particularly difficult to control is door-to-door selling, a method that for many years has drawn criticism from the general public, even though the majority of door-to-door salespeople are fair and reputable. To persuade people to enter into a heavy financial commitment, these salespeople have been known to misstate the terms of payment or the trade-in allowance, to conceal figures on the order form or agreement, and to resort to other deceptive practices. Inquirers are personally visited by a salesperson, who, from the outset, makes no attempt to sell them the product advertised. Having convinced the inquirer that the model is not worth buying, the salesperson goes on to offer the customer another model the switch that he happens to have with him at, of course, a higher price. Although this and similar methods often are in violation of statutes governing the sale of goods, enforcement is difficult. Extra protection is provided by legislation in some countries, and, in others, nonstatutory regulations protect the consumer. Learn More in these related Britannica articles:

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## Chapter 6 : Food and Drug Administration

*Consumer protection at the Food and Drug Administration: hearing before the Ad Hoc Subcommittee on Consumer and Environmental Affairs of the Committee on Governmental Affairs, United States Senate, One Hundred Second Congress, first session, September 27,*

Index of articles from U. The Food and Drug Administration touches the lives of virtually every American every day. Feed and drugs for pets and farm animals also come under FDA scrutiny. FDA also ensures that all of these products are labeled truthfully with the information that people need to use them properly. First and foremost, FDA is a public health agency, charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws. These employees are located in district and local offices in cities across the country. Inspections and Legal Sanctions These investigators and inspectors visit more than 15, facilities a year, seeing that products are made right and labeled truthfully. As part of their inspections, they collect about 80, domestic and imported product samples for examination by FDA scientists or for label checks. If a company is found violating any of the laws that FDA enforces, FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product from the market. A recall is generally the fastest and most effective way to protect the public from an unsafe product. The agency can go to court to force a company to stop selling a product and to have items already produced seized and destroyed. When warranted, criminal penalties -- including prison sentences -- are sought against manufacturers and distributors. About 3, products a year are found to be unfit for consumers and are withdrawn from the marketplace, either by voluntary recall or by court-ordered seizure. In addition, about 30, import shipments a year are detained at the port of entry because the goods appear to be unacceptable. Some of these scientists analyze samples to see, for example, if products are contaminated with illegal substances. Other scientists review test results submitted by companies seeking agency approval for drugs, vaccines, food additives, coloring agents and medical devices. FDA also operates the National Center for Toxicological Research at Jefferson, Arkansas, which investigates the biological effects of widely used chemicals. The agency also runs the Engineering and Analytical Center at Winchester, Massachusetts, which tests medical devices, radiation-emitting products, and radioactive drugs. For example, the agency requires that drugs -- both prescription and over-the-counter -- be proven safe and effective. In deciding whether to approve new drugs, FDA does not itself do research, but rather examines the results of studies done by the manufacturer. If contaminants are identified, FDA takes corrective action. FDA also sets labeling standards to help consumers know what is in the foods they buy. FDA also ensures the purity and effectiveness of biologicals medical preparations made from living organisms and their products , such as insulin and vaccines. Medical devices are classified and regulated according to their degree of risk to the public. Devices that are life-supporting, life-sustaining or implanted, such as pacemakers, must receive agency approval before they can be marketed. The agency can have unsafe cosmetics removed from the market. The dyes and other additives used in drugs, foods and cosmetics also are subject to FDA scrutiny. The agency must review and approve these chemicals before they can be used.

## Chapter 7 : Consumer advocacy | racedaydvl.com

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## Chapter 8 : What are company organizations or agencies and their correct label

*Food and Drug Administration. One of the oldest U.S. Consumer Protection agencies, the Food and Drug Administration*

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*(FDA) protects the public from unsafe foods, drugs, medical devices, cosmetics, and other potential hazards.*

## Chapter 9 : Consumer Protection Agencies: Food and Drug Administration ( by Kevin White on Prezi

*FOOD AND DRUG ADMINISTRATION. One of the oldest U.S. consumer protection agencies, the Food and Drug Administration (FDA) protects the public from unsafe foods, drugs, medical devices, cosmetics, and other potential hazards.*