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ORGANIZATION STRUCTURE AND FUNCTIONS OF US FDA (FOOD & DRUG ADMINISTRATION)

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Abstract:

In modern mans life the drugs and medicaments, medical devices have become a part of life. One cant imagine the life without medicines today. The preparation, testing and marketing of such drugs is very crucial and essential to be regulated this is regulated by regulatory bodies of every country as per need of their citizens, environment and climatic condition of country, the main objective of this article is to enlighten and provide knowledge about regulatory body of America in brief about its organization structure and functions of US FDA.

Keywords: *United States Food & Drug Administration (USFDA), Drugs, Medical Devices*

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INTRODUCTION:

Definition of Regulatory Body:

A regulatory body is a public body or government agency responsible for the legal regulation of aspects of human activity. The role of the regulator is to establish and enforce standards and ensure their continued compliance. [1]

Public life, including transportation, education, and the sale of food and medicine. Occupational health and safety is monitored by state, national and international regulatory bodies. Regulators are also known as regulatory agencies, regulators, or regulators.[1]

FDA BEGINNING:

US FDA is an agency within the Department of Health and Human Services. Effective from March 31, 2019, US FDA began operational implementation of an agency reorganization. FDA's restructuring reflects the agency's commitment to modernize its structure to advance its mission of protecting and promoting public health and meeting the challenges of rapid innovation in FDA-regulated industries.[2]

FDA's reorganization will realign various units across the agency to advance strategic priorities and strengthen the role of centers, offices and field staff.[2]

The Food and Drug Administration is the federal government's oldest global consumer protection agency. Since 1848, the federal government has used chemical analysis to monitor the safety of agricultural products, a responsibility inherited from the Department of Agriculture in 1862 and later by the FDA.[3]

FDA regulation began with the adoption of the Pure Food and Drugs Act of 1906, a quarter-century law that prohibited interstate commerce in adulterated and mislabeled foods and drugs. that consumers had never experienced before. Since then, the FDA has changed with social, economic, political, and legal changes in the United States. [3]

Reviewing the history of these changes highlights the important role the FDA has played in promoting public health and offers lessons to consider as we assess current regulatory challenges.[3]

HISTORY MILESTONES OF FDA:

YEAR	ACHIEVMENT OR ACTS IMPLIMENTED
1862	Beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.
1902	The Biologics Control Act is passed to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans.
1906	The original Pure Food and Drugs Act is passed by Congress on June 30
1907	First Certified Color Regulations, requested by manufacturers and users, list seven colors found suitable for use in foods.
1912	Congress enacts the Sherley Amendment to prohibit the labeling of medicines with false therapeutic claims intended to defraud the purchaser, a standard difficult to prove.
1927	The Bureau of Chemistry is reorganized into two separate entities. **1.** Food, Drug, and Insecticide Administration **2.** Nonregulatory research (Bureau of Chemistry and Soils.)
1930	The name of the Food, Drug, and Insecticide Administration is shortened to the **Food and Drug Administration (FDA)** under an agricultural appropriations act.
1937	Elixir Sulfanilamide tragedy.
1938	The Federal Food, Drug, and Cosmetic Act (FD&C Act) containing the new provisions that required new drugs to be shown to be safe before marketing,
1940	Walter G. Campbell appointed as the first Commissioner of Food and Drugs.The FDA transferred from the Department of Agriculture to the Federal Security Agency
1944	The Public Health Service Act is passed including regulation of biological products and control of communicable diseases.
1949	The FDA publishes a guidance to industry for the first time
1954	The FDA carries out the first large-scale radiological examination of food
1960	The Color Additive Amendment, requiring manufacturers to establish the safety of color additives in foods, drugs, and cosmetics, is enacted.

1962	Thalidomide tragedy (A new sleeping pill, was found to have caused birth defects in thousands of babies born in Western Europe).
1968	FDA was placed in the Public Health Service (PHS).
1971	The PHS Bureau of Radiological Health is transferred to the FDA. Its mission: protection against unnecessary human exposure to radiation from electronic products in the home, industry, and the healing arts.
1972	1. Over-the-Counter (OTC) Drug Review is begun to enhance the safety, effectiveness, and appropriate labeling of drugs sold without prescription. 2. Regulation of biologics--including serums, vaccines, and blood products--is transferred from the National Institutes of Health (NIH) to the FDA.
1976	1. Medical Device Amendments are passed to ensure safety and effectiveness of medical devices, including diagnostic products. 2. Vitamins and Minerals Amendments ("Proxmire Amendments")
1980	The Infant Formula Act establishes special FDA controls to ensure necessary nutritional content and safety.
1982	Tamper-resistant packaging regulations are issued by the FDA to prevent poisonings such as deaths from cyanide placed in Tylenol capsules.
1983	The Orphan Drug Act, enabling the FDA to promote research and marketing of drugs needed for treating rare diseases, is passed.
1988	**The Food and Drug Administration Act** (establishes the **FDA** as an agency of the **Department of Health and Human Services** with a Commissioner of Food and Drugs)
1990	The Nutrition Labeling and Education Act requires all packaged foods to bear nutrition labeling
1992	The Prescription Drug User Fee Act
1994	The Dietary Supplement Health and Education Act Good Manufacturing Practice regulations for dietary supplements.
1995	Restrictions are proposed on marketing and sales of Tobacco to reduce smoking by young people.
1997	The Food and Drug Administration Modernization Act
2000	The U.S. Supreme Court, upholding an earlier decision in Food and Drug Administration that FDA does not have authority to regulate tobacco as a drug.
2002	The Best Pharmaceuticals for Children Act improves safety and efficacy of patented and off-patent medicines for children.
2003	The Animal Drug User Fee Act
2004	Project BioShield Act
2005	Formation of the Drug Safety Oversight Board, composed of FDA staff and representatives from the NIH and the Veterans Administration
2009	**Family Smoking Prevention and Tobacco Control Act** This Tobacco Control Act gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. FDA **Center for Tobacco Products** established. FDA announced a **ban on cigarettes with flavors characterizing fruit, candy, or clove**.
2O11	**FDA Food Safety and Modernization Act (FSMA).**
2012	**1. Food and Drug Administration Safety and Innovation Act (FDASIA).** 2. **Medical Device User Fee and Modernization Act (MDUFMA III).**
2013	1. **Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).** 2. **Drug Quality and Security Act.**

WHAT DOES FDA REGULATE'S [4,5]:

The scope of FDA's regulatory authority is very broad. 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 is a list of traditionally-recognized product categories that fall under FDA's regulatory jurisdiction; however, this is not an exhaustive list.
In general, FDA regulates:

Foods, including:

- dietary supplements
- bottled water
- food additives
- infant formulas
- other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)

Drugs, including:

- prescription drugs (both brand-name and generic)
- non-prescription (over-the-counter) drugs

Biologics, including:

- vaccines for humans
- blood and blood products
- cellular and gene therapy products
- tissue and tissue products
- allergenics

Medical Devices, including:

- simple items like tongue depressors and bedpans
- complex technologies such as heart pacemakers
- dental devices
- surgical implants and prosthetics

Electronic Products that give off radiation, including:

- microwave ovens
- x-ray equipment
- laser products
- ultrasonic therapy equipment
- mercury vapor lamps
- sunlamps

Cosmetics, including:

- color additives found in makeup and other personal care products
- skin moisturizers and cleansers
- nail polish and perfume

Veterinary Products, including:

- livestock feeds
- pet foods
- veterinary drugs and devices

Tobacco Products, including:

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco

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 a federal agency that regulates many types of advertising. The FTC protects consumers by stopping unfair, deceptive or fraudulent practices in the marketplace. Consumers may write to FTC at 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2222.

Alcohol:

The Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates aspects of alcohol production, importation, wholesale distribution, labeling, and advertising. Consumers may write to TTB at 1310 G St. N.W., Box 12, Washington, DC 20005; telephone (202) 453-2000 or see the TTB Contact page.

Consumer Products:

The Consumer Product Safety Commission (CPSC) works to ensure the safety of consumer products such as toys, cribs, power tools, cigarette lighters, household chemicals, and other products that pose a fire, electrical, chemical or mechanical hazard. 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:

The Department of Justice's Drug Enforcement Administration (DEA) works to enforce the controlled substances laws and regulations of the United States, including as they pertain to the manufacture,

distribution, and dispensing of legally produced controlled substances. Inquiries regarding DEA activities may be sent to the Drug Enforcement Administration, Office of Diversion Control 8701 Morrissette Drive Springfield, VA 22152; telephone (202) 307-1000.

Meat and Poultry:
The U.S. Department of Agriculture's Food Safety and Inspection Service regulates aspects of the safety and labeling of traditional (non-game) meats, poultry, and certain egg products. 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:
The Environmental Protection Agency (EPA) regulates many aspects of pesticides. EPA sets limits on how much of a pesticide may be used on food during growing and processing, and how much can remain on the food you buy. 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.

Vaccines for Animal Diseases:
The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics, regulates aspects of veterinary vaccines and other types of veterinary biologics. Public inquiries regarding APHIS's Center for Veterinary Biologics should be mailed to Center for Veterinary Biologics, 1920 Dayton Ave, P.O. Box 844, Ames, Iowa, 50010; telephone (515) 337-6100 or see the APHIS Contact page.

Water:
The Environmental Protection Agency (EPA) regulates aspects of drinking water. EPA develops national standards for drinking water from municipal water supplies (tap water) to limit the levels of impurities.

DOCUMENTS USED IN FDA [6-10]:

Reports:
This collection contains budgets, the strategic action plan, user fee reports, performance plans, economic analyses of FDA regulations, and reports on agency policies and initiatives.

Staff Manual Guides:
The FDA Staff Manual Guides (SMGs) are the Agency directives that document organizations and functions; delegations of authority; and administrative and program policies, responsibilities and procedures.

Forms:
This collection includes forms for applications and submissions, reports and accountability, certifications, and inspections. Forms are listed by topic area (e.g., Cosmetics, Foods, Human Drugs, Safety & Problem Reports, Field Operations, etc.) or can be sorted alphabetically or numerically.

CONCLUSION:

Each country has its own regulatory body for USA FDA is the regulatory body one of the oldest and inspiring regulatory authority to world so its essential to learn about its functions, organization and duties so that the present generation of pharmacists may gain knowledge and realize their duties as pharmacist toward the socity and country and in all towards the mankind.

CAUTION:

This article was ment only for education and to provide knowledge it has nothing to do with critizing or to go beyond copyrights.

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