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The FDA and the Pharmaceutical Drug Approval Process

Overview

The U.S. Food and Drug Administration (FDA), a federal agency within the Department of Health and Human Resources (HHS), is the main regulatory body for a variety of foods, cosmetics, drugs, and other products that affect human and animal health. Specifically, one of the FDA's main responsibilities is to regulate the sale of pharmaceuticals in the United States. If a company wants to sell a drug, the company must test it and the FDA must approve it. The FDA defines a drug as a "product that is intended for use in the diagnosis, cure, treatment, or prevention of disease; it is intended to affect the structure or any function of the body."[1] The Center for Drug Evaluation and Research (CDER) within the FDA establishes whether or not the drug's health benefits outweigh its known risks before it can be approved.[2]

The duration and cost of the research, development, and approval process are central concerns to manufacturers and government alike. The time between when a company applies for investigation through to approval could take between six and 13 years.[3] The average cost to research and develop a new drug is approximately $2.6 billion.[4] The regulatory process applies to both over-the-counter (OTC) and prescription drugs alike. The FDA process and regulations have significant impact on the availability of generics and brand name drugs for sale in the United States.

History

The U.S. Congress first established the FDA in 1906 with the authorization of the Food and Drug Administration Act.[5] Although it had little power to regulate the quality and safety of pharmaceuticals, Congress established the FDA in response to the fraudulent activity taking place in the 19th century drug market. Later, after 107 people died in 1937 from "elixir sulfanilamide" – a chemical known to be toxic – Congress passed a new law, the Food, Drug and Cosmetic Act of 1938, which strengthened the regulatory power of the FDA to control drug safety and quality. It was not until the 1960s, however, that drug manufacturers were required to not only demonstrate that drugs were safe but also that they were effective

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