



FDA's Role in Assuring Safe and Effective Drugs

Under the authority of the Federal Food, Drug, and Cosmetic Act and other laws, the Food and Drug Administration (FDA) ensures that new drugs developed by pharmaceutical companies are safe and effective and supported by rigorous scientific research. This typically requires pharmaceutical companies to conduct extensive pre-clinical and clinical testing spanning 12 to 15 years and costing upwards of \$800 million for each new drug.

Pre-clinical Testing

Before a new drug can be tested in human volunteers (clinical testing), it must be shown to be reasonably safe in pre-clinical tests. Pre-clinical testing—which involves testing the drug product in animals—provides an early warning regarding possible safety risks of a drug product. The FDA reviews the pre-clinical testing of a new drug and examines the company's proposed research plan before allowing trials in humans to begin.

Clinical Studies

Clinical studies—which involve testing a drug product in human volunteers—are carefully controlled and must follow the pre-set research plan approved by the FDA. Also, the FDA requires an Investigational Review Board (IRB) composed of community health care practitioners and lay people to review and approve all studies involving human subjects. IRBs ensure that the risks to patients are minimized, that patients' rights are protected, and that informed consent and privacy are obtained. Once the trials have started, information gathered from the study is regularly submitted to the FDA for ongoing review. Controlled clinical studies are the only legal basis for the FDA to conclude that a new drug is safe and effective for use.



Drug Approval

After all clinical studies have been completed, the FDA reviews the data and decides whether the drug can be placed on the market. To be considered for approval, the following information must be submitted to the FDA:

- *documentation of the clinical test results;*
- *the drug's components;*
- *results of animal studies;*
- *how the drug reacts in the body;*
- *how the drug is manufactured, processed, and packaged;*
- *drug samples;*
- *the proposed drug label with complete prescribing information.*

Before approving a drug, the FDA makes on-site visits to the investigators responsible for the clinical studies. The FDA approves the drug if the results of controlled clinical studies show effectiveness of the drug and that the product is safe under the conditions of use in the proposed labeling. Once a drug is approved, the FDA continues to monitor the safety and quality of the drug by, among other things, requiring drug manufacturers to comply with the FDA's good manufacturing-practices requirements. The FDA also oversees the promotion and advertising of prescription drugs. Companies continue their responsibility by monitoring for safety and promptly reporting serious side effects of the drug to the FDA.

Importance of Drug Labeling

The drug labeling that accompanies a drug product—also known as the “package insert”—is the FDA's approved guidance on how the drug should be used. An FDA team of physicians, statisticians, chemists, and pharmacologists reviews all of the submitted data and decides what information should be included in the drug labeling regarding proper dosage, directions for use, side effects, and warnings. The FDA-approved package insert distills the mountain of data submitted to the FDA, including data from all clinical and pre-clinical studies, into a set of instructions that permits physicians to use the drug product safely and effectively.



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