FDA Drug Approval Process

Prescription Drug User Fee Act (PDUFA) has enabled the Food and Drug Administration to bring access to new drugs faster if the drug companies agree to pay fees that boost FDA resources and for the faster time frames for its review of new drug applications.

PRE-CLINICAL

Drug Developed

Drug sponsor develops a new drug compound and seeks to have it approved by FDA for sale in the United States.

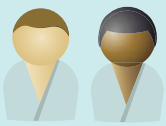
Animals Tested

1 Sponsor must test new drug on animals for toxicity. Multiple species are used to gather basic information on the safety and efficacy of the compound being investigated/researched.

IND Application

2 The sponsor submits an **Investigational New Drug (IND) application** to FDA based on the results from intial testing that include the drug's composition and manufacturing, and develops a plan for testing the drug on humans.

CLINICAL



IND Review Phase I

3 **20–80** is the typical number of healthy volunteers used in this phase which emphasizes safety. The goal here is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted.

IND Review Phase II

4 The typical number of patients used in this phase is in the **100s**, which emphasizes effectiveness. The goal is to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment—usually a placebo, or a different drug. Safety continues to be evaluated, and short-term side effects are studied.

IND Review Phase III

5 **1000s** of patients are used in this phase. These studies gather more information about safety and effectiveness, different populations and different dosages, and uses of the drug in combination with other drugs.

NDA REVIEW

NDA Application

6 After a pre-meeting, the drug sponsor formally asks FDA to approve a drug for marketing in the United States by submitting a **New Drug Application (NDA)**. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.

Application Review

7 After an NDA is received, FDA has 60 days to decide whether to file it so it can be reviewed. If FDA files the NDA, the FDA review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.

Drug Labeling

8 FDA reviews the drug's professional labeling and assures appropriate information is communicated to health care professionals and consumers.

Facility Inspection

9 FDA inspects the facilities where the drug will be made.

Drug Approval

10 FDA reviewers will approve the application or issue a response.

The **Accelerated Approval program** allows earlier approval of drugs that treat serious diseases and that fill an unmet medical need. The FDA's **Fast Track program** reduces the time for FDA's review of products that treat serious or life-threatening diseases and unmet medical needs. For more information on these programs visit magazine.wsu.edu/extra/fdatracks.

POST-MARKET

11 Once FDA approves a drug, the post-marketing monitoring stage begins. The sponsor (typically the manufacturer) is required to submit periodic safety updates to FDA.

FDA's **MedWatch** voluntary system makes it easier for physicians and consumers to report adverse events. When new risks are uncovered, the risks are added to the drug's labeling and the public is informed through letters, public health advisories, and other education. The use of the drug may be substantially limited. In rare cases, the drug will be withdrawn.

SOURCE: U.S. FOOD AND DRUG ADMINISTRATION