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

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

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

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

IND REVIEW

FDA reviews the IND to assure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate informed consent and human subject protection.

Animals Tested

The typical number of healthy volunteers used in Phase 1; this phase emphasizes safety. The goal here in this phase is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted.

IND Application

The typical number of patients used in Phase 2; this phase emphasizes effectiveness. This 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

At the end of Phase 2, FDA and sponsors discuss how large-scale studies in Phase 3 will be done.

Animals Tested

The typical number of patients used in Phase 3. These studies gather more information about safety and effectiveness, study different populations and different dosages, and uses the drug in combination with other drugs.
**NDA REVIEW**

**Drug Labeling**

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

**Application Reviewed**

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.

**NDA Application**

The drug sponsor formally asks FDA to approve a drug for marketing in the United States by submitting an 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.

**Review Meeting**

FDA meets with a drug sponsor prior to submission of a New Drug Application.

**FASTER APPROVALS**

The Accelerated Approval program allows earlier approval of drugs that treat serious diseases and that fill an unmet medical need. The approval is faster because FDA can base the drug's effectiveness on a "surrogate endpoint," such as a blood test or X-ray result, rather than waiting for results from a clinical trial.

The Fast Track program helps reduce the time for FDA's review of products that treat serious or life-threatening diseases and those that have the potential to address an unmet medical need. Drug sponsors can submit portions of an application as the information becomes available ("rolling submission") instead of having to wait until all information is available.

**Drug Approval**

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

**Facility Inspection**

FDA inspects the facilities where the drug will be manufactured.

**POST-MARKETING**

**Drug Labeling**

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

**Application Reviewed**

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.

**NDA Application**

The drug sponsor formally asks FDA to approve a drug for marketing in the United States by submitting an 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.

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FDA inspects the facilities where the drug will be manufactured.

**Who reviews new drug submissions?**

A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists review the drug sponsor’s data and proposed labeling of drugs.

**What other drug products are regulated by FDA?**

Drugs include more than just medicines. For example, fluoride toothpastes, antiperspirants (not deodorant), dandruff shampoos, and sunscreens are all considered drugs.

**PDUFA**

**Precaution Drug User Fee Act**

Since the PDUFA was passed in 1992, more than 1,000 drugs and biologics have come to the market, including new medicines to treat cancer, AIDS, cardiovascular disease, and life-threatening infections.

PDUFA has enabled the Food and Drug Administration to bring access to new drugs as fast or faster than anywhere in the world, while maintaining the same thorough review process. Under PDUFA, drug companies agree to pay fees that boost FDA resources, and FDA agrees to time frames for its review of new drug applications.