FDA Drug Approval Process

PRE-CLINICAL

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.

2. 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.

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.

CLINICAL

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.

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.

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.

NDA 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.

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

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

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

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.

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.

Facility Inspection

Drug Approval

Drug Labeling

Source: U.S. Food and Drug Administration