Regulatory Requirements

Clinical studies involving a drug, biologic or dietary supplement

FDA's Center for Drug Evaluation and Research (CDER) is responsible for regulating manufacturing, testing and importation of pharmaceutical drugs in the US. This includes new drug approvals, abbreviated new drug approvals (generics), over-the-counter drugs, animal drugs and biologics.

A drug is defined as:

1. article intended for use in diagnosis, cure, mitigation, treatment, or prevention of the disease;
2. articles (other than food) intended to affect the structure or any function of the body;
3. articles intended to be used as components of any of the above.

Preclinical Regulatory Requirements

Preclinical testing begins after a potential drug has been identified in the lab. Preclinical testing involves lab and animal studies that evaluate the drug's toxic and pharmacologic effects. Preclinical studies are also subject to the FDA regulations known as *Good Laboratory Practices* (GLP), 21 CFR 58. The GLP regulations specify minimum standards in such areas as personnel, facilities, equipment and operations.

Preclinical testing includes pharmacokinetics, the study of how the drug moves through living organisms. Researchers examine absorption, distribution, metabolism and excretion (also abbreviated as ADME) to ensure that the drug reaches its intended target and passes through the body properly. In addition to the biological tests, researchers conduct chemistry tests to establish the drug's purity, stability and shelf life. Manufacturing tests are conducted to determine the feasibility of producing the drug on a large scale and to explore dosing, packaging and formulation (e.g., pill, inhaler, injection).

At the preclinical stage, the FDA will generally ask, at a minimum, that sponsors: (1) develop a pharmacological profile of the drug; (2) determine the acute toxicity of the drug in at least two species of animals, and (3) conduct short-term toxicity studies ranging from two weeks to three months, depending on the proposed duration of use of the substance in the proposed clinical studies.

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