How FDA Approves Drugs and Regulates Their Safety and Effectiveness

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Update: On June 20, 2012, the House of Representatives passed, by voice vote and under suspension of the rules, S. 3187 (EAH), the Food and Drug Administration Safety and Innovation Act, as amended. This bill would reauthorize the FDA prescription drug and medical device user fee programs (which would otherwise expire on September 30, 2012), create new user fee programs for generic and biosimilar drug approvals, and make other revisions to other FDA drug and device approval processes. It reflects bicameral compromise on earlier versions of the bill (S. 3187 [ES], which passed the Senate on May 24, 2012, and H.R. 5651 [EH], which passed the House on May 30, 2012). The following CRS reports provide overview information on FDA's processes for approval and regulation of drugs: CRS Report R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, by Susan Thaul. CRS Report RL33986, FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective, by Susan Thaul. CRS Report R42130, FDA Regulation of Medical Devices, by Judith A. Johnson. CRS Report R42508, The FDA Medical Device User Fee Program, by Judith A. Johnson. (Note: The rest of this report has not been updated since September 1, 2011.) The Food and Drug Administration (FDA) is a regulatory agency within the Department of Health and Human Services. A key responsibility is to regulate the safety and effectiveness of drugs sold in the United States. FDA divides that responsibility into two phases: preapproval (premarket) and postapproval (postmarket). FDA reviews manufacturers' applications to market drugs in the United States; a drug may not be sold unless it has FDA approval. The agency continues its oversight of drug safety and effectiveness as long as the drug is on the market. Beginning with the Food and Drugs Act of 1906, Congress has incrementally refined and expanded FDA's responsibilities regarding drug approval and regulation. The progression to drug approval begins before FDA involvement. First, basic scientists work in the laboratory and with animals; second, a drug or biotechnology company develops a prototype drug. That company must seek and receive FDA approval, by way of an investigational new drug (IND) application, to test the product with human subjects. Those tests, called clinical trials, are carried out sequentially in Phase I, II, and III studies, which involve increasing numbers of subjects. The manufacturer then compiles the resulting data and analysis in a new drug application (NDA). FDA reviews the NDA with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's identify, strength, quality, and identity. The Federal Food, Drug, and Cosmetic Act (FFDCA) and associated regulations detail the requirements at each step. FDA uses a few special mechanisms to expedite drug development and the review process when a drug might address an unmet need or a serious disease or condition. Those mechanisms include accelerated approval, animal efficacy approval, fast track applications, and priority review. Once a drug is on the U.S. market (following FDA approval of the NDA), FDA continues to address drug production, distribution, and use. Its activities, based on ensuring drug safety and effectiveness, address product integrity, labeling, reporting of research and adverse events, surveillance, drug studies, risk management, information dissemination, off-label use, and directto- consumer advertising, all topics in which Congress has traditionally been interested. FDA seeks to ensure product integrity through product and facility registration; inspections; chain-of-custody documentation; and technologies to protect against counterfeit, diverted, subpotent, adulterated, misbranded, and expired drugs.~

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