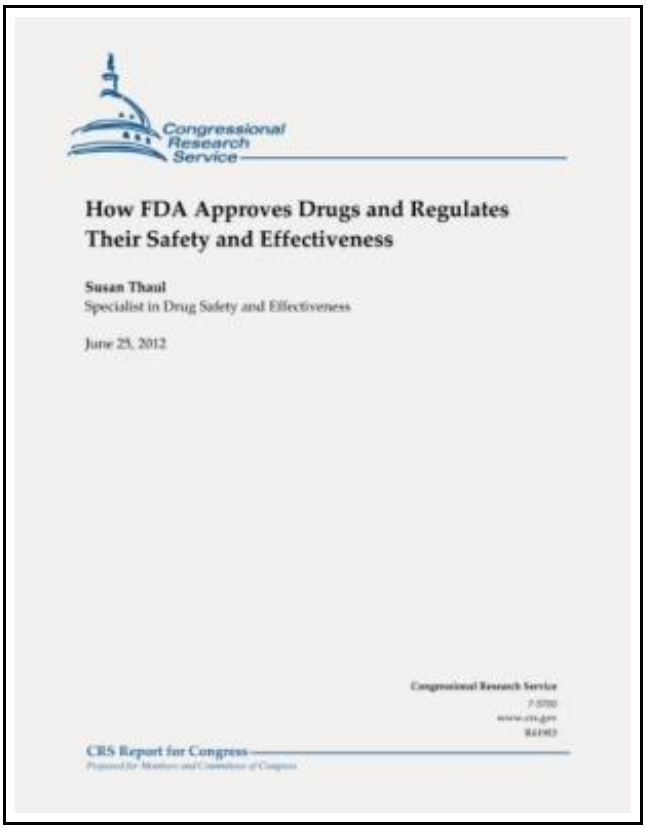
How FDA Approves Drugs and Regulates Their Safety and Effectiveness



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(Seth Fritsch)

HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS

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CreateSpace Independent Publishing Platform. Paperback. Book Condition: New. This item is printed on demand. Paperback. 26 pages. Dimensions: 11.0in. x 8.5in. x 0.1in.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 FDAs 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, FDAs 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...

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