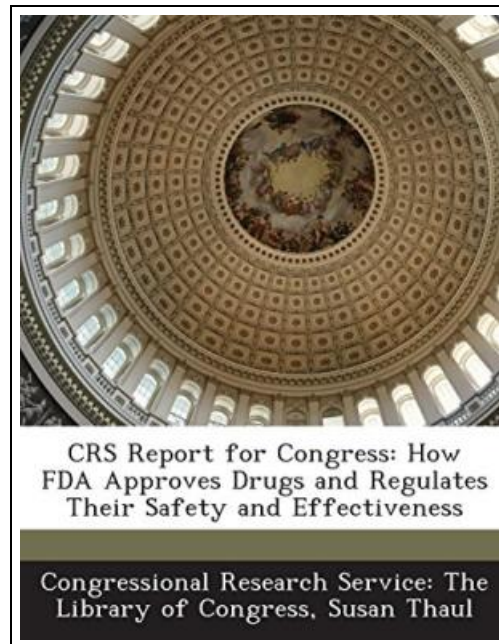


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CRS REPORT FOR CONGRESS: HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS (PAPERBACK)



Bibliogov, United States, 2013. Paperback. Condition: New. Language: English . Brand New Book ***** Print on Demand *****. UPDATE: S. 3187, the Food and Drug Administration Safety and Innovation Act, scheduled for floor consideration, is an amended version of S. 2516, reported by the Senate Committee on Health, Education, Labor, and Pensions. The House Committee on Energy and Commerce voted favorably to report H.R. 5651, the Food and Drug Administration Reform Act of 2012. Both the Senate and House bills include titles to reauthorize FDA prescription drug and medical device user fee programs, authorize new user fee programs for generic drugs and biosimilar biological products, and amend the Federal Food, Drug, and Cosmetic Act regarding the regulation of drugs and medical devices. (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.



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