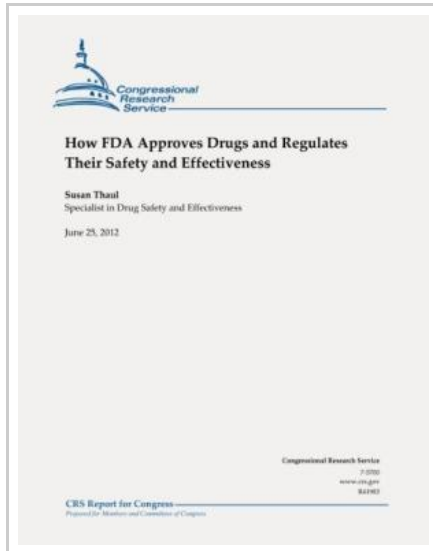




How FDA Approves Drugs and Regulates Their Safety and Effectiveness

By Susan Thaul

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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 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,...



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