

FDA Regulation of Medical Devices



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Createspace, United States, 2012. Paperback. Book Condition: New. 279 x 216 mm. Language: English . Brand New Book ***** Print on Demand *****.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 December 28, 2011.) Prior to and since the passage of the Medical Device Amendments of 1976, Congress has debated how best to ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices; examples...

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