

The FDA Medical Device User Fee Program



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(Dayne Johns)

THE FDA MEDICAL DEVICE USER FEE PROGRAM



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 April 24, 2012.) The Food and Drug Administration (FDA) is the agency responsible for the regulation of medical devices. These are a wide range of products that are used to diagnose, treat, monitor, or prevent a disease or condition in a patient. A company must obtain FDA s prior approval or clearance before marketing many medical devices in the United States. The Center for Devices and Radiological Health (CDRH) within FDA is primarily responsible for medical device review...



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