4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0237]

Report to Congress; Report on the Food and Drug Administration's Policy To Be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices; Notice to Public of Web Site Location of Report to Congress

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency has posted the report entitled "Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices." In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on this document to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mike Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993-0002, 301-796-6283.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144) became law on July 9, 2012. FDASIA added section 510(n)(2) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(n)(2)). This new provision requires, no later than 18 months after enactment of FDASIA, the Secretary of Health and Human Services to submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on when a premarket notification under section 510(k) of the FD&C Act (or a "510(k)") should be submitted for a modification to a legally marketed 510(k) device. This report fulfills that requirement.

This notice announces the Web site location of "Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices." FDA invites interested persons to submit comments on this report. FDA has established a docket where comments may be submitted (see ADDRESSES). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. To access "Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices," visit FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm269873.htm.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: February 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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