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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0757]

Establishment of a Public Docket for Comment on the Report Prepared Under the Food and Drug Administration Safety and Innovation Act Section 1138

AGENCY: Food and Drug Administration, HHS.

ACTION: Establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments pertaining to the report mandated under the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 1138, enacted July 9, 2012, and posted on the FDA Web site on July 9, 2013. This docket is intended to solicit input on this report from all relevant stakeholders.

DATES: Submit electronic or written comments by [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATIONCONTACT: Jonca Bull, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4274, Silver Spring, MD 20993-0002, 301-796-8000, email: jonca.bull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed FDASIA (Public Law112-144) into law. Section 1138 of FDASIA requires that FDA review and modify, as necessary, the FDA communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

Section 1138 of FDASIA requires that FDA shall publicly post the communication plan on the Internet Web site of the Office of Minority Health of FDA, and provide links to any other appropriate Internet Web site, and seek public comment on the communication plan.

FDA is opening a docket for 60 days to solicit input from all relevant stakeholders regarding the communication plan and Internet links. This docket is intended to ensure that stakeholders have an opportunity to provide comments for further improvements to the plan.

II. 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 will be posted to the docket at http://www.regulations.gov and may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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