4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0745]

Reopening of Docket and Request for Comments on the Food and Drug Administration Safety and Innovation Act Action Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice: reopening of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the action plan issued as required by section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the reopening of a public docket for comments pertaining to the action plan.

DATES: Submit electronic or written comments by [INSERT DATE 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 INFORMATION CONTACT: Jonca Bull, Office of Minority Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4239, Silver Spring, MD, 20993-0002, 301-796-8000, jonca.bull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed FDASIA (Public Law 112-144) into law. Section 907 of FDASIA requires that FDA report on and address certain information regarding clinical trial participation by demographic subgroups and subset analysis of the resulting data. Specifically, section 907(a) of FDASIA requires the Secretary of Health and Human Services (the Secretary), acting through the FDA Commissioner, to publish on FDA's Internet Web site a report "addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA," and provide such publication to Congress. The report, entitled "Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices," was posted on FDA's Internet Web site in August 2013 and is available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on FDA's Internet Web site and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and

applicability. The action plan is due not later than 1 year after the publication of the report described previously. The action plan entitled "FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data" is being issued with this notice and is available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.

FDA is reopening the docket for 60 days to provide an opportunity for interested individuals to submit comments on the action plan. When submitting comments please reference the section of the action plan to which your comments pertain. This docket is intended to ensure that stakeholders have an opportunity to provide comments and that such information submitted to FDA is available to all interested persons in a timely fashion.

II. How to Submit 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: August 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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