4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1818]

New Clinical Trials Demographic Data; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of Demographic Subgroup Data for FDA Approved Products on FDA's Internet Web site. This new posting implements Action 3.1 from Priority 3 of the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan designed to improve the availability and transparency of clinical trial demographic subgroup data. FDA is requesting comments on the format, content, and overall usability of the site to determine whether this approach is user friendly to the public.

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

ADDRESSES: Submit electronic comments on the Webpage 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: Laurie Haughey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-6511, Laurie.Haughey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of clinical trial demographic data for consumers on FDA's Internet Web site at www.fda.gov/drugtrialssnapshot.

On July 9, 2012, the President signed FDASIA (Pub. L. 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" was published in August 2014 and is available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.

Priority three of the action plan aims to make demographic data more available and transparent by, amongst other things, posting demographic composition and analysis by subgroup in pivotal clinical studies for FDA-approved medical products. The first iteration of FDA's publication of this data is available at www.fda.gov/drugtrialssnapshot.

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 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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