4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2295]

Request for Information on Specific Areas of Public Health Concern Related to Racial/Ethnic Demographic Subgroups for Additional Research by the Office of Minority Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is opening a docket to obtain information and comments on specific areas of public health concern for racial/ethnic demographic subgroup populations, focusing on certain disease areas where significant outcome differences may be anticipated. The Agency is seeking public input on identifying areas that can be addressed through regulatory science research.

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

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2014-N-2295 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Merenda, Food and Drug Administration, Office of Minority Health, 10903 New Hampshire Ave., Bldg. 32, rm. 2382, Silver Spring, MD 20993, 301-796-8453, FAX: 301-847-8601, email: Christine.merenda@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Office of Minority Health (OMH) was established in 2010, as mandated by the Patient Protection and Affordable Care Act (Pub. L. 111-148). OMH serves as the principal advisor to the Commissioner on minority health and health disparities. OMH provides leadership and direction in identifying Agency actions that can help reduce health disparities, including the coordination of efforts across the Agency.

OMH advances FDA's regulatory mission in addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all. To achieve this mission, OMH has committed to identifying gaps in existing knowledge to shape further research projects intended to lead to better understanding of medical product clinical outcomes in racial/ethnic demographic subgroups. A guiding principle for FDA in meeting the health needs of patients across the demographic spectrum is the importance of encouraging diversity in clinical trials. Thus, FDA is also interested in gaining input for improving clinical trials in therapeutic areas impacted by low rates of inclusion of racial/ethnic demographic subgroup populations, ranging from issues surrounding recruitment and participation in clinical trials to clinical outcome analysis of demographic subgroup populations. Of particular note in this regard is FDA's "Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data" at http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf.

Research in regulatory science is distinctive for developing new tools, standards, and approaches for assessing the safety, efficacy, quality, and performance of all FDA-regulated products. The results can help to transform the way medical products are developed, evaluated, and manufactured. Health disparities research with a regulatory focus seeks to expand and strengthen knowledge of, and the availability of data on, medical product clinical outcomes in racial/ethnic demographic subgroups, to inform healthcare decisions by providers and patients.

II. Request for Comments and Information

OMH seeks comments and information to identify specific areas of public health concern involving racial/ethnic demographic subgroups that can be addressed through regulatory science research, including new or emerging areas of concern. We encourage comments to include

supporting information regarding the topic addressed, such as previously published peer-reviewed literature or new research findings. These comments and information will support OMH in its development of a research agenda that will inform funding decisions for the next fiscal year. (This notice is not a request for specific research or grant proposals from outside entities.) In addition to input on improving clinical trial inclusion and outcome analysis, requested comments and information identifying disease areas with outcome differences for further study may include, but are not limited to, the following:

- An area of study that could lead to a diagnostic or screening test based on the development and evaluation of biomarkers for a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- An area of study that could lead to changes in labeled indications, or dosages, for a single or class of drug(s) or biologic(s) used to treat a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- An area of study that could lead to changes in the design or use of a device to treat a disease or condition that disproportionately impacts racial/ethnic demographic subgroups.
- Research to identify effective ways to communicate with patients and consumers from racial/ethnic subgroups, including those with low health literacy and limited English proficiency, so they are informed about FDA actions (new approvals, warnings, recalls, etc.) that impact their health.
- Research evaluating methods to accommodate cultural and language differences that can improve health communications to racial/ethnic subgroups, and assess the cost of these methods to the Government.

- Research evaluating the impact of different formats and amounts of numerical information in FDA communications for patients, health care providers, health educators, and informal caregivers.

III. 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 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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