

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

FDA's Center for Devices and Radiological Health is responsible for protecting the public health by assuring the safety and effectiveness of medical devices. A key part of this mission is to monitor medical devices for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

In September 2012, the FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," that proposed a strategy for improving the current system for monitoring medical device safety and effectiveness. In April 2013, the FDA issued an update to the September 2012 report that incorporated public input received and described the next steps towards fulfilling the vision for building a national postmarket surveillance system. These reports can be found at FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>.

One of these next steps consisted of establishing a multistakeholder planning board to identify the governance structure, practices, policies, procedures, methodological approaches, and business model(s) necessary to facilitate the creation of a sustainable, integrated medical device postmarket surveillance system that leverages and complements existing and ongoing efforts. Under a cooperative agreement with the FDA, the Engelberg Center for Health Care Reform at the Brookings Institution convened the National Medical Device Postmarket Surveillance Planning Board (the Planning Board) in 2014. The Planning Board membership included representatives from a broad array of stakeholder groups and areas of expertise including patients, provider organizations, hospitals, health plans, industry, and government agencies, as well as methodologists and academic researchers.

The Planning Board was tasked with developing a set of long-term principles and priorities for a National Postmarket Surveillance System. The task included identifying potential governance and business models that address legal and privacy considerations, system

financing and stability, mechanisms to support the appropriate use of data, and policies to ensure system transparency. The Planning Board was also asked to provide recommendations about how to leverage the system to meet the needs of other medical device stakeholders and groups seeking to develop better evidence (<http://www.brookings.edu/about/centers/health/call-for-nominations> and <https://dcricri.org/events/past-meetings/MDEpiNominations>).

This notice announces the availability and Web site location of the Planning Board's report entitled "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System." FDA invites interested persons to submit comments on this report. We have established a docket where comments may be submitted (see **ADDRESSES**). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. The report "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System" can be found at FDA's Web site <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.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 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-03886 Filed 2-24-15; 8:45 am]

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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 April 27, 2015.

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/FederalFoodDrugandCosmeticAct/FDCAct/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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Division of Cancer Epidemiology and Genetics (DCEG) Fellowship Program and Summer Student Applications (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 9, 2014 (Vol. 79, P. 19632) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if