Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by Friday, July 17, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after July 20, 2015. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the specific topics outlined in section II. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comment on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is August 26, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comment with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic(s) you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

RAS devices, also known as computer-assisted surgical devices, are used by trained physicians in an operating room environment for laparoscopic surgical procedures in general surgery, cardiac, colorectal, gynecologic, head and neck, thoracic, and urologic surgical procedures. These medical devices enable the surgeon to use computer, software, and robotic technologies to control and move surgical instruments through the mouth or through one or more small incisions in the patient's body for a variety of surgical procedures. Some common procedures that may involve RAS devices include gallbladder, uterus, or prostate removal.

As discussed further in section II, there are several clinical and scientific challenges associated with regulation of RAS devices, such as appropriate nonclinical and clinical evaluation of RAS devices, use of third-party surgical instruments with legally marketed RAS devices, and clinical training programs. This workshop seeks to involve industry and academia in addressing these challenges in the development of RAS devices to ensure that there is a reasonable assurance of safety and effectiveness for RAS devices while promoting innovation in a rapidly-developing field. By bringing together relevant stakeholders including scientists, patient advocates, clinicians, researchers, industry representatives, and regulators, we hope to facilitate the improvement of this evolving product area.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to, the following:

1. The current landscape of RAS devices and the respective Offices, Divisions, and Branches within FDA involved in the review of pre- and postmarket data associated with these devices.

2. Challenges, needs, and benefit/risk profiles for indications in various surgical areas; *e.g.* cardio/thoracic, gynecological, otolaryngological, urological, general.

3. Unique benefits of RAS devices versus traditional surgical procedures.

4. Scientific and technical considerations for third-party manufacturers seeking to claim that their surgical instruments can be used with legally marketed RAS devices.

5. Design, administration, and certification of training programs and FDA's role in this process.

6. The future landscape of RAS and robotic surgery devices.

7. Considerations regarding appropriate selection of preclinical (bench and animal) test methods and patient-centered outcome metrics in clinical use for different stages of device development.

These topics will be presented by experts in the associated area, followed by more in-depth discussions and Q&A from all participants.

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03769 Filed 2–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0359]

National Medical Device Postmarket Surveillance System Planning Board Report; Availability, Web Site Location and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report and Web site location where the Agency has posted the report entitled ''Strengthening Patient Care: Building an Effective National Medical Device Surveillance System,'' developed by the National Medical Device Postmarket Surveillance System Planning Board. In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by April 27, 2015.

ADDRESSES: Submit electronic comments on this document 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas P. Gross, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2316, Silver Spring, MD 20993–0002, 301–796–5700, email: *Thomas.Gross@fda.hhs.gov.*

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://dcri.org/events/past-meetings/MDEpiNet-nominations*).

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]

BILLING CODE 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 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