meeting will be based on space availability.

If you wish to present at the meeting, please include your presentation materials along with your registration information to *GenericDrugPolicy@fda.hhs.gov* by June 1, 2015. Early requests for oral presentations are recommended due to possible space and time limitations. FDA will accommodate as many requests for oral presentations as possible and will do so on a first-come, first-served basis. The time allotted for presentations may depend on the number of persons who wish to speak. Those requesting to present will receive confirmation once they have been accepted. If presentations exceed time and space limitations prior to the meeting, FDA will place a notice on *http://www.fda.gov/gdufa.* Onsite requests for oral presentations on the day of the meeting will be based on time and space availability. If the entire meeting time is not needed, FDA may end the public meeting early.

If you need special accommodations because of a disability, please contact Connie Wisner or Kimberly Giordano (see **FOR FURTHER INFORMATION CONTACT**) by June 8, 2015.

For those unable to attend in person, FDA will provide a live Adobe Connect Webcast of the meeting. In order to connect to the Webcast, you must have Adobe Connect. To join the meeting via the Adobe Connect Webcast, please go to: *https://collaboration.fda.gov/gdufaii.*

IV. Comments

Regardless of participation at the public meeting, interested persons may submit either electronic or written comments regarding this document. To ensure consideration, all comments should be received by July 15, 2015. Submission of comments prior to the meeting is strongly encouraged.

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. Identify all comments with the docket number found in the 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.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov/gdufa.* It may be viewed at the Division of Dockets Management (see section IV). A transcript also will be available in either hard copy or on CD–ROM upon submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09091 Filed 4–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0975]

Acceptance of Medical Device Clinical Data From Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance articulates FDA's current policy of accepting scientifically valid clinical data obtained from foreign clinical studies in support of premarket submissions for devices. The guidance describes special considerations that apply when using such data, including applicability to populations within the United States and study design issues and provides recommendations to assist sponsors in ensuring their data are adequate under applicable FDA standards to support approval or clearance of the device in the United States. This guidance is not intended to announce new policy, but to describe FDA's existing approach to this topic. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 20, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance 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: Aaliyah Eaves-Leaños, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5420, Silver Spring, MD 20993–0002, 301–796–2948. For questions regarding this document concerning devices regulated by CBER, contact Stephen Ripley, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112–144 (2012), adding a new provision, section 569B, to the Federal Food, Drug, and Cosmetic Act (FD&C Act) codifying FDA's longstanding policy of accepting adequate, ethically-derived, scientifically valid data without regard to where a clinical study is conducted. Sponsors may choose to conduct multinational clinical studies under a variety of scenarios. FDA acknowledges, however, that certain challenges exist in using data derived from studies of devices from sites from outside the United States (OUS) to support an FDA

marketing decision. These challenges may include differences between the OUS and U.S. clinical conditions, regulatory requirements (including human subject protections), and/or study populations that may be sufficient to affect the adequacy of the data for use in establishing the safety and/or effectiveness of the studied device. This guidance focuses on considerations sponsors of device submissions should take into account when initiating, or relying on previously collected data from, an OUS clinical study to support an Investigational Device Exemption, Premarket Notification (510(k)), De Novo Petition, Humanitarian Device Exemption, or Premarket Approval Application. This guidance also notes other important considerations to take into account when initiating or relying on OUS data. FDA believes that promoting greater clarity concerning FDA's use of foreign study data will minimize the possibility for additional or duplicative U.S. studies, further efforts to harmonize global clinical trial standards, and promote public health and innovation.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on acceptance of clinical data from foreign studies conducted OUS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Centers for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 has been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09176 Filed 4–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2015.

The National Advisory Committee on Rural Health and Human Services will convene its seventy seventh meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: May 27, 2015, 8:45 a.m.—5:00 p.m.; May 28, 2015, 8:30 a.m.—5:15 p.m.; May 29, 2015, 8:30 a.m.—11:00 a.m.

Place: Natural Bridge State Park, 2135 Natural Bridge Rd, Slade, KY 40376, (606) 663–2214.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Wednesday morning, at 8:45 a.m., the meeting will be called to order by the Chairperson of the Committee: The Honorable Ronnie Musgrove. The Committee will examine the issue of an increasing difference between life expectancy among the urban and rural populations of the United States. The day will conclude with a period of public comment at approximately 4:45 p.m.

Thursday morning at approximately 8:30 a.m., the Committee will break into Subcommittees and depart for site visits. Subcommittees will visit the Center of Excellence in Rural Health in Hazard, Kentucky, and the Marcum & Wallace Memorial Hospital in Irvine, Kentucky. The day will conclude at the Natural Bridge State Park with a period of public comment at approximately 5:00 p.m.

Friday morning at 8:30 a.m., the Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, 17W29–C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Catherine Fontenot at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945–0897 or by email at *cfontenot@hrsa.gov*. The Committee