

knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/ucm094137.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: April 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-08358 Filed 4-20-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1334]

Opioid Dependence: Developing Depot Buprenorphine Products for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Opioid Dependence: Developing Depot Buprenorphine Products for Treatment.” This draft guidance addresses drug development and trial

design issues relevant to the study of depot buprenorphine products (*i.e.*, modified-release products for injection or implantation).

DATES: Submit either electronic or written comments on the draft guidance by June 22, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-D-1334 for “Opioid Dependence: Developing Depot Buprenorphine Products for Treatment; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Silvana Borges, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3200, Silver Spring, MD 20993-0002, 301-796-0963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Opioid Dependence: Developing Depot Buprenorphine Products for Treatment." This draft guidance addresses drug development and trial design issues relevant to the study of depot buprenorphine products (*i.e.*, modified-release products for injection or implantation).

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 current thinking of FDA on "Opioid Dependence: Developing Depot Buprenorphine Products for Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: April 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-08361 Filed 4-20-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters and National Preparedness and Response Science Board Joint Public Teleconference

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) and National Preparedness and Response

Science Board (NPRSB) will hold a joint public teleconference on May 10, 2018.

DATES: The NACCD and NPRSB Teleconference is May 10, 2018, from 3:00 p.m. to 4:00 p.m. Eastern Daylight Time (EDT).

ADDRESSES: We encourage members of the public to attend the teleconference. To register, send an email to naccd@hhs.gov with "NACCD Registration" in the subject line, or to nprsb@hhs.gov with "NPRSB Registration" in the subject line. Submit your comments to naccd@hhs.gov, nprsb@hhs.gov, the NPRSB Contact Form located at <https://www.phe.gov/Preparedness/legal/boards/nprsb/Pages/RFNBSBComments.aspx>, or the NACCD Contact Form located at <https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/contact.aspx>. For additional information, visit the NACCD website located at <https://www.phe.gov/naccd> or the NPRSB website located at <https://www.phe.gov/nprsb>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), and section 2811A of the Public Health Service Act (42 U.S.C. 300hh-10a), as added by section 103 of the Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), the HHS Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the NACCD. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters.

The NPRSB is authorized under Section 319M of the Public Health Service (PHS) Act (42 U.S.C. 247d-7f), as added by section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act, and by Section 222 of the PHS Act (42 U.S.C. 217a). The Board is governed by the Federal Advisory Committee Act (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The NPRSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

Background: The May 10, 2018, NACCD and NPRSB Public Teleconference is dedicated to the presentation, deliberation, and vote on re-tasking the Assistant Secretary of

Preparedness and Response (ASPR) Future Strategies Work Group (FSWG) as a joint task between the NACCD and NPRSB. Established under the NPRSB in 2014, the FSWG identified future strategies that can best support successful achievement of the ASPR's and HHS's mission for preparedness, response, and recovery. In addition, the ASPR FSWG provides prioritized recommendations for guiding current efforts toward future strategies by examining such items as ASPR's current mission, strategic objectives, resources, and capabilities against projected futures. In 2017, the NACCD established the ASPR Future Strategies for Children Working Group with the aim of identifying future strategies to advance the ASPR's mission as it relates to infants, children, and teens. The joint tasking of the FSWG will enable members of the NPRSB and NACCD to collaborate on areas of shared responsibility with regard to future strategies for preparedness and response. We will post modifications to the agenda on the NACCD and NPRSB May 10, 2018, teleconference websites, which are located at <https://www.phe.gov/naccd> and <https://www.phe.gov/nprsb>.

Availability of Materials: We will post all teleconference materials prior to the teleconference on May 10, 2018, at the websites located at <https://www.phe.gov/naccd> and <https://www.phe.gov/nprsb>.

Procedures for Providing Public Input: Members of the public may attend the teleconference via a toll-free call-in phone number, which is available on the NACCD and the NPRSB websites at <https://www.phe.gov/naccd> and <https://www.phe.gov/nprsb>.

We encourage members of the public to provide written comments that are relevant to the NACCD and NPRSB teleconference prior to May 10, 2018. Send written comments by email to naccd@hhs.gov with "NACCD Public Comment" in the subject line or to nprsb@hhs.gov with "NPRSB Public Comment" in the subject line. The NACCD and NPRSB Chairs will respond to comments received by May 9, 2018, during the teleconference.

Dated: April 13, 2018.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2018-08421 Filed 4-20-18; 8:45 am]

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