

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FDA is announcing the availability of a draft guidance for industry entitled "Opioid Dependence: Developing Depot Buprenorphine Products for Treatment." This draft guidance addresses drug development and trial design issues relevant to the study of depot buprenorphine products (*i.e.*, modified-release products for injection or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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Opioid Dependence: Developing Depot Buprenorphine Products for Treatment."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Persons with access to the internet may obtain the draft guidance at either 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.

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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.

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