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Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ ATSDR)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR). This meeting is open to the public, limited only by available seating. The meeting room accommodates approximately 60 people. The public is also welcome to listen to the meeting by calling 888-989-4501, passcode 9885805, limited by 100 lines. The deadline for notification of attendance is May 14, 2018. The public comment period is scheduled on June 5, 2018 from 2:30 p.m. until 2:45 p.m., EDT and June 6, 2018 from 10:10 a.m. until 10:25 a.m., EDT. Individuals wishing to make a comment during Public Comment period, please email your name, organization, and phone number by May 7, 2018 to Amanda Malasky at amalasky@cdc.gov.

DATES: The meeting will be held on June 5, 2018, 8:30 a.m. to 4:00 p.m., EDT and June 6, 2018, 8:30 a.m. to 11:30 a.m., EDT.

ADDRESSES: CDC, 4770 Buford Highway, CDC Building 106, Room 1B, Atlanta, GA 30341.

FOR FURTHER INFORMATION CONTACT: Shirley Little, Program Analyst, NCEH/ATSDR, CDC, 4770 Buford Hwy., Mail Stop F-45, Atlanta, GA 30341, telephone (770) 488-0577; email snl7@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC

and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and wellbeing; and (3) train state and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters to be Considered: The agenda will include discussions on Recovery Efforts to Address Environmental Health Impacts after the 2017 Hurricanes, NCEH/ATSDR Program Responses to BSC Guidance and Action Items, PFAS multi-site study, PEASE, Biomonitoring for PFAS in children, Use of Citizen Science for Assessment of Health Risks, Statistical Inferences in Environmental Epidemiology, and NCEH/ATSDR work with tribes/Tribal Programs. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elizabeth Millington,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018-08367 Filed 4-20-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1242]

Advisory Committee; Arthritis Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Arthritis Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Arthritis Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 5, 2020.

DATES: Authority for the Arthritis Advisory Committee will expire on April 5, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Yinghua Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: AAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Arthritis Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities

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.

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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