

the extent to which progress has been made toward eliminating tuberculosis.

Matters for Discussion: Agenda items include the following topics: (1) Update on Global TB Coordination Activities; (2) Profile of Foreign-Born TB cases; (3) Impact of funding cuts on TB programs in the field; and (4) other tuberculosis-related issues.

Agenda items are subject to change as priorities dictate. *Contact Person for More Information:* Margie Scott-Cseh, Centers for Disease Control and Prevention, 1600 Clifton Road NE., M/S E-07, Atlanta, Georgia 30333, telephone (404) 639-8317; Email: zkr7@cdc.gov

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.

Catherine Ramadei,

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

[FR Doc. 2015-02887 Filed 2-11-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Advisory Committee Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the charters of the committees listed in the following table for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed in the following table. This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.).

DATES: Authority for these committees will expire on the dates indicated in the following table unless the Commissioner formally determines that renewal is in the public interest.

Name of committee	Date of expiration
Cardio and Renal Drugs Advisory Committee.	August 27, 2016.
Endocrinologic and Metabolic Drugs Advisory Committee.	August 27, 2016.

Name of committee	Date of expiration
Oncologic Drugs Advisory Committee.	September 1, 2016.
Anti-Infective Drugs Advisory Committee.	October 7, 2016.
Dermatologic and Ophthalmic Drugs Advisory Committee.	October 7, 2016.
Cellular, Tissue, and Gene Therapies Advisory Committee.	October 28, 2016.
Technical Electronic Product Radiation Safety Standards Committee.	December 24, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael Ortwerth, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-443-0572 or 1-800-741-8138. For further information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: February 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-02909 Filed 2-11-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0152]

Alcoholism: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Alcoholism: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of alcoholism.

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 April 13, 2015.

ADDRESSES: 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 Bldg., 4th Floor, Silver Spring, MD 20993. 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.

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.

FOR FURTHER INFORMATION CONTACT:

Rachel Skeete, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3191, Silver Spring, MD 20993-0002, 301-796-2280.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Alcoholism: Developing Drugs for Treatment." There is a need for additional pharmacologic treatments for alcoholism. Traditionally, alcoholism treatments have been assessed based on the number of patients who refrain from drinking altogether. Patients who attain and sustain complete abstinence from alcohol may be assumed to accrue clinical benefit. However, other patterns of drinking also may be valid surrogates for clinical benefit. This guidance provides supporting information for endpoints based on patterns of drinking that may be considered appropriate measures of clinical benefit.

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 the development of drugs for the treatment of alcoholism and appropriate endpoints for clinical trials of drugs to treat alcoholism. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 312 and 314 have been approved under OMB

control numbers 0910–0014 and 0910–0001, respectively.

III. 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>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02908 Filed 2–11–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Meeting of the Cellular, Tissue and Gene Therapies Advisory Committee and the Oncologic Drug Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee and the Oncologic Drug Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 29, 2015, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Janie Kim or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 301–796–9016 or 240–402–8072, email: Janie.Kim@fda.hhs.gov or Rosanna.Harvey@fda.hhs.gov, or FDA Advisory Committee Information Line, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/WhatsNew/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committees will discuss talimogene laherparepvec, Amgen, Inc., biologics license application (BLA) 125518, an oncolytic immunotherapy for the treatment of patients with injectable regionally or distantly metastatic melanoma.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 15, 2015. Oral presentations from the public will be scheduled between approximately 11:40 a.m. to 12:40 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of

the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 7, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 8, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Janie Kim at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02910 Filed 2–11–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant