

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.

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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.

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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