

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for CONCERTA (methylphenidate HCl) extended-release tablets. This draft guidance revises and replaces the draft guidance for industry entitled "Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability," issued on September 14, 2012 (77 FR 56851), which provided recommendations to establish BE to CONCERTA (methylphenidate hydrochloride) (NDA 021121).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for CONCERTA (methylphenidate HCl) extended-release tablets. 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. 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>.

III. 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: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Program on Biosecurity and Biosafety Policy; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: November 25, 2014.

Time: 11:00 a.m.–1:00 p.m. Eastern.

The teleconference line will be open at 10:30 a.m. to allow for check-in with the operator. (Times are approximate and subject to change.)

Agenda: Discussion regarding: (1) Finalization of draft NSABB statement regarding gain-of-function research; and (2) other business of the Board. Time will be allotted on the agenda for oral public comment, with presentations limited to three minutes per speaker.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland. (Telephone Conference call only; No in-person meeting.)

Call-in Information: Toll-Free Number: 1-888-469-1981. Participant Passcode: NSABB. The line will be open 30 minutes in advance of the meeting to allow time for operator-assisted check-in.

Contact Person: Carolyn Mosby, NSABB Program Assistant, NIH Program on Biosecurity and Biosafety Policy, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 435-5504, carolyn.mosby@nih.gov.

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice regarding federal oversight of dual use research, defined as biological research that generates information and technologies

that could be misused to pose a biological threat to public health and/or national security.

Please Note: The teleconference meeting agenda, draft statement, and other information about the NSABB will be available at <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb>. Please check this Web site for updates.

The meeting will be open to the public through a teleconference call phone number. Members of the public who participate in the teleconference will be able to listen to the meeting but will not be heard apart from during the public comment session. If you experience any technical problems with the conference call, please send an email to carolyn.mosby@nih.gov.

Public Comments: The teleconference will include opportunity for public comment. In addition, any interested person may file written comments with the committee via email to nsabb@od.nih.gov with "NSABB Public Comment" as the subject line or by regular mail to 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, *Attention:* Carolyn Mosby. Comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the commenter. Written comments received by 5:00 p.m. (Eastern) on Sunday November 23, 2014, will be provided to NSABB members prior to the teleconference.

Accommodations Statement: Individuals who participate by using this teleconference call service and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice as soon as possible.

Dated: November 3, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-26422 Filed 11-5-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0025]

Agency Information Collection Activities: Waiver of Rights, Privileges, Exemptions and Immunities, Forms I-508 and I-508F; Revision of a Currently Approved Collection.

ACTION: 60-day notice.