

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993-0002, [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." In July 2012, FDASIA was signed into law (Pub. L. 112-144). Sections 701 and 702 of FDASIA direct the Secretary of Health and Human Services (and by delegation, FDA) to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act (21 U.S.C. 360), as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This guidance is intended solely to address sections 701 and 702 of FDASIA. Although section 703 of FDASIA mandates the use of the same UFI system (specified for drug establishment registration) to identify excipient manufacturers in product listings, this guidance does not address implementation of section 703 of FDASIA.

This guidance specifies the UFI system for registration of domestic and foreign drug establishments. At this time, FDA's preferred UFI for a drug establishment is the Data Universal Numbering System (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting Dun and Bradstreet's Web site at <http://www.dnb.com/>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) This guidance reflects the Agency's current thinking in light of data standards, information technology, and information management resources. As these variables change over time, FDA may revisit the guidance.

In the **Federal Register** of September 6, 2013 (78 FR 54899), FDA announced the availability of the draft guidance entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." The notice

gave the public an opportunity to comment by November 5, 2013. FDA carefully considered all comments received in preparing the guidance. No substantive changes were made in finalizing the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on specification of the UFI system for drug establishment registration. 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. Paperwork Reduction Act of 1995**

This guidance contains 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 have been approved under OMB control number 0910-0045.

**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 <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <http://www.regulations.gov>.

Dated: November 3, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-26397 Filed 11-5-14; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2007-D-0369, formerly 2007D-0168]

**Bioequivalence Recommendations for CONCERTA (Methylphenidate Hydrochloride) Extended-Release Tablets; 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 "Bioequivalence Recommendations for CONCERTA (methylphenidate hydrochloride) Extended-Release Tablets." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) that reference the listed drug CONCERTA (methylphenidate hydrochloride (HCl)) extended-release tablets (new drug application (NDA) 021121). The draft guidance is a revised version of a previously issued draft guidance on the same subject.

**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 comments 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 January 5, 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 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.

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:** Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4726, Silver Spring, MD 20993-0002, 240-402-7959.

## 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.*

[FR Doc. 2014-26306 Filed 11-5-14; 8:45 am]

**BILLING CODE 4164-01-P**

## 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](mailto: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](mailto: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](mailto: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]

**BILLING CODE 4140-01-P**

## 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.