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/GuidanceCompliance RegulatoryInformation/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 This draft guidance revises and replaces the draft guidance for industry entitled ''Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability,'' issued on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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for CONCERTA (methylphenidate HCl) extended-release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.*

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]

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.

SUMMARY: Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information or new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until January 5, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0025 in the subject box, the agency name and Docket ID USCIS–2008–0015. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* You may access the **Federal Register** Notice and submit comments via the Federal eRulemaking Portal Web site by visiting *www.regulations.gov.* In the search box either copy and paste, or type in, the e-Docket ID number USCIS–2008–0015. Click on the link titled Open Docket Folder for the appropriate Notice and supporting documents, and click the Comment Now tab to submit a comment;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Waiver of Rights, Privileges, Exemptions and Immunities.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–508 and Form I–508F. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This form is used by the USCIS to determine eligibility of an applicant to retain the status of an alien lawfully admitted to the United States for permanent residence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

- Form I–508: 1,728 responses at .33 hours (20 minutes) per response, and
- Form I–508F: 200 responses at .33 hours (20 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 636.24 hours.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

Dated: November 3, 2014.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014–26423 Filed 11–5–14; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2014–N232; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before December 8, 2014. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by December 8, 2014.

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*