European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; U.S. Department of Agriculture; the Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry in Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Electronic Exchange of Documents: File Format Recommendations

In November 2013, the VICH Steering Committee agreed that a draft guidance document entitled ''Draft Guidance for Industry, Electronic Exchange of Documents: File Format Recommendations'' (VICH GL53) should be made available for public comment. This draft VICH guidance document is intended to provide recommendations to industry regarding electronic file format specifications (e.g., file format, file size, file security, and cross referencing) for individual documents and collections of multiple related documents for the transfer of electronic regulatory information in support of applications for the approval of veterinary medicinal products. This draft guidance applies to communication or data exchanged as documents in the context of all regulatory procedures where regulators accept electronic transfer of such documents. This may include, but is not limited to, applications for initial marketing authorizations, related presubmission or post-authorization procedures, applications for maximum residue limits, clinical trial applications, drug/active substance master files, or requests for regulatory or scientific advice.

This draft guidance is a product of the Electronic File Format Expert Working Group of the VICH. Comments about this draft guidance document will be considered by FDA and the VICH Electronic File Format Expert Working Group.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''must,'' ''shall,'' ''require,'' or ''requirement'' unless FDA is using these words to describe a statutory or regulatory requirement.

This draft VICH guidance, when finalized, will represent the Agency's current thinking on this topic. 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.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 this guidance have been approved under OMB control number 0910–0032.

V. 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.*

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: August 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20482 Filed 8–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Risk Communications 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: Risk Communications 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 November 3 and 4, 2014, from 9 a.m. to 5 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. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, Silver Spring, MD 20993–0002, 240–402–5274, FAX: 301–847–8609, email: *RCAC@fda.hhs.gov*, 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/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.

If you are unable to join us in person, we encourage you to watch the free Webcast. Visit the Risk Communication Advisory Committee Web site at *http://*

www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/default.htm. The link will become active shortly before the open session begins at 9 a.m.

Interested persons can also log on to *https://collaboration.fda.gov/rcac/* to see and hear the proceedings.

Agenda: On November 3 and 4, 2014, the Risk Communication Advisory Committee will discuss methods for effective risk communication with a focus on messages about the importance of eating adequate amounts of fish, while avoiding certain fish with higher amounts of methyl-mercury. These messages are especially important for women who are pregnant or nursing, or for anyone who prepares food for young children.

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/Calendar/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 October 20, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 3 and 4, 2014. 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 October 10, 2014. 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 October 14, 2014.

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 Luis G. Bravo 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: August 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–20481 Filed 8–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting

SUMMARY: In accordance with the National Environmental Policy Act, 42 U.S.C. 4321–4347, the National Institutes of Health (NIH) is issuing this notice to advise the public that an environmental impact statement will be prepared for the Assure/Expand Chilled Water Capacity project located on the National Institutes of Health, Bethesda Campus, Bethesda, Maryland.

DATES: The Scoping Meeting is planned for 6:00 p.m., formal presentation to begin at 7:00 p.m., on Wednesday September 24, 2014. Scoping comments must be postmarked no later than October 18, 2014 to ensure they are considered.

ADDRESSES: The Scoping Meeting will be held on The National Institutes of Health Bethesda Campus, Building 50, Room 1227/1233, Bethesda, Maryland. All comments and questions on the Scoping Meeting and Environmental Impact Statement should be directed to Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email <*nihnepa@mail.nih.gov*>.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email <*nihnepa@mail.nih.gov*>.

SUPPLEMENTARY INFORMATION: The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In order to fulfill and uphold this mission the infrastructure of the NIH Bethesda Campus must be able to support the NIH's biomedical research programs.

Chilled water is a critical utility for the Bethesda Campus. The campus chilled water demand has exceeded the design capacity several times during the previous years. Expansion of the chilled water capacity is necessary.

The NIH has also become increasingly concerned about the vulnerability of the local water utility system, and the risk of reliably delivering water to the NIH Bethesda Campus infrastructure. A reliable water supply is vital to the NIH mission. The NIH proposes to address these concerns by construction of water storage structures to expand the Bethesda Campus chilled water capacity and to assure the availability of chilled water and potable water during a water emergency. In addition, NIH desires to improve sustainability, energy conservation, and to reduce the operating cost on the campus.

In accordance with 40 CFR 1500–1508 and DHHS environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed project. The EIS will evaluate the impacts of the alternatives should development occur as proposed. Among the items the EIS will examine are the implications of the project on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services. To ensure that the public is afforded the greatest opportunity to participate in the planning and environmental review process, NIH is inviting oral and written comments on the proposed project and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas, including recommended alternatives and environmental issues the EIS should consider. All interested parties