of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joann Belt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3658, Silver Spring, MD 20993–0002, *joann.belt@fda.hhs.gov,* 301–796–6836; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 17, 2018, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices.''

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until November 15, 2018. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. Significance of Guidance

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 current thinking of FDA on the process to request a review of FDA's decision not to issue certain export certificates for devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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 sections 801(e) and 802 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 381(e) and 382) have been approved under OMB control number 0910–0498; the collections of information in 21 CFR part 807, subparts A through E, have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in the guidance ''Center for Devices and Radiological Health Appeals Processes'' have been approved under OMB control number 0910–0738.

Dated: September 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21597 Filed 10–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3636]

United States Food and Drug Administration and Health Canada Joint Public Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting and Webcast; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and webcast; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting entitled ''U.S. Food and Drug Administration and Health Canada Joint Public Consultation on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).'' The purpose of this public meeting is to provide information and solicit public input on the current activities of ICH as well as the upcoming ICH Assembly Meeting and the Expert Working Group Meetings in Charlotte, NC, scheduled for November 11 through 15, 2018. The topics to be discussed are the topics for discussion at the forthcoming ICH Assembly Meeting in Charlotte, NC.

DATES: The public meeting will be held on October 17, 2018, from 9 a.m. to 12 p.m., Eastern Time. Submit either electronic or written comments on this

public meeting by October 31, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Sir Frederick G. Banting Research Centre, 251 Sir Frederick Banting Dr., Ottawa, ON K1Y 0M1, Canada. It will also be broadcast on the web, allowing participants to join in person or via the web.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 31, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3636 for ''U.S. Food and Drug Administration and Health Canada Joint Public Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting and Webcast; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William Lewallen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–796–3810, *William.Lewallen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation, was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In 2015, the ICH was reformed to establish ICH as a true global initiative that expands beyond the previous ICH members. More involvement from regulators around the world is expected, as they will join their counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH regulatory members. Expanded involvement is also anticipated from global regulated pharmaceutical industry parties, joining as ICH observers and industry members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development and regulation.

ICH guidelines are developed following a five-step process. In Step 1, experts from the different ICH regions work together to prepare a consensus draft of the Step 1 Technical Document. The Step 1 Technical Document is submitted to the ICH Assembly to request endorsement under Step 2a of the process. Step 2b is a ''Regulators only'' step in which the ICH regulatory members review the Step 2a Final Technical Document and take any actions, which might include revisions that they deem necessary, to develop the draft ''Guideline.'' Step 3 of the process begins with the public consultation process conducted by each of the ICH regulatory members in their respective regions, and this step concludes with completion and acceptance of any revisions that need to be made to the Step 2b draft guideline in response to public comments. Adoption of the new guideline occurs in Step 4. Following adoption, the harmonized guideline moves to Step 5, the final step of the process, when it is implemented by each of the regulatory members in their respective regions. The ICH process has achieved significant harmonization of

the technical requirements for the approval of pharmaceuticals for human use in the ICH regions since 1990. More information on the current ICH process and structure can be found at the following website: *http://www.ich.org.*

II. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by October 12, 2018. To register to attend the public meeting either in person or via webcast, please visit the following website: *https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by October 12, 2018, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, the number of participants from each organization may be limited. The agenda for the public meeting will be made available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm612657.htm* approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make presentations must be received by the close of registration on October 12, 2018. If selected for presentation, any presentation materials must be emailed to William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than October 12, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. To register to attend via webcast, please visit the following website: *https://www.eventbrite.ca/e/health-canada-us-fda-ich-consultation-tickets-47713713000.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: September 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21594 Filed 10–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Collaborative Innovation Awards Review Meeting (U01).

Date: October 24, 2018.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, Room 1068, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1073, Bethesda, MD 20892, 301–435–0810, *lourdes.ponce@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 28, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–21567 Filed 10–3–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting Allergy, Immunology, and Transplantation Research Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Allergy, Immunology, and Transplantation Research Committee AITC January 2019 Council.

Date: October 23–24, 2018.

Time: 9:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID, 5601 Fishers Lane MSC 9834, Bethesda, MD 20892–9834, (240) 669–5060, *james.snyder@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 28, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–21572 Filed 10–3–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.