



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1112]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; 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 Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).” The purpose of the public meeting is to provide information and solicit public input on the current activities of the ICH, as well as the upcoming ICH Assembly Meeting and the Expert Working Group Meetings in Kobe, Japan, scheduled for June 4 through 7, 2018. The topics to be addressed at the public meeting are the current ICH guideline topics under development that will be discussed at the forthcoming ICH Assembly Meeting in Kobe.

DATES: The public meeting will be held on Friday, April 6, 2018, from 10 a.m. to 1 p.m.

Submit either electronic or written comments on this public meeting by April 30, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (Great Room), Silver Spring, MD

20993-0002. The meeting will also be broadcast on the web, allowing participants to join in person OR via the web. For those who will attend in person, the entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. For those who register to attend the public meeting remotely via the webcast, a link to access the webcast will be emailed 1 week in advance of the meeting.

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 April 30, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 30, 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 in the sections below (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-2016-N-1112 for “U.S. Food and Drug Administration and Health Canada Joint Regional Consultation on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting; 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 <https://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: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993-0002, 301-796-4548, Amanda.Roache@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 requirements for safety and effectiveness. One of the goals of harmonization is to identify and then reduce regional differences in technical regulatory requirements for pharmaceutical products while preserving a consistently high standard for drug efficacy, safety, and quality. 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 join counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH observers and 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 their 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/home.html>. (FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.)

II. Topics for Discussion at the Public Meeting

The topics for discussion at this public meeting include the current guidelines under development under the ICH. These guidelines include the following:

Topics Currently Under Regional Public Consultation (Step 3 of ICH Process):

- S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- E9(R1) Addendum: Statistical Principles for Clinical Trials

Selected Topics Recently Finalized (Step 4 of ICH Process):

- E17 General Principles on Planning/Designing Multi-Regional Clinical Trials

Electronic Standards and MedDRA (Medical Dictionary for Regulatory Activities):

- M2 Electronic Standards for the Transfer of Regulatory Information
- M8 Electronic Common Technical Document (eCTD)

- E2B Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- M1 MedDRA Terminology

Additional Ongoing Topics:

- E19 Optimization of Safety Data Collection
- E8(R1) Revision on General Considerations for Clinical Trials
- E11A Pediatric Extrapolation
- E14/S7B Discussion Group on Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation
- M9 Biopharmaceutics Classification System-Based Biowaivers
- M10 Bioanalytical Method Validation
- S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
- Q3C(R7) Impurities: Guideline for Residual Solvents
- Q3D(R1) Guideline on Elemental Impurities

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by April 3, 2018. To register for the public meeting, please visit the following website: https://ich_regional_consultation_2018.eventbrite.com. 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 April 3, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore,

FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9:30 a.m.

The agenda for the public meeting will be made available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm592065.htm> approximately 2 weeks in advance of the meeting.

If you need special accommodations due to a disability, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) no later than March 23, 2018.

Requests for Oral Presentations: If you wish to make a presentation during the public comment session, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) no later than March 23, 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 April 3, 2018. If selected for presentation, any presentation materials must be emailed to Amanda Roache (see FOR FURTHER INFORMATION CONTACT) no later than April 3, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Sign-up for making a public comment will also be available between 9 a.m. and 10 a.m. on the day of the 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://ich_regional_consultation_2018.eventbrite.com. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview.

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: February 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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