4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5017]

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

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 "Health Canada and U.S. Food and Drug Administration 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 Geneva, Switzerland, scheduled for November 11 through 16, 2017. The topics to be discussed are the topics for discussion at the forthcoming ICH Assembly Meeting in Geneva.

DATES: The public meeting will be held on October 19, 2017, from 9 a.m. to 12 noon Eastern Time. Submit either electronic or written comments on this public meeting by October 26, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information. Registration to attend the meeting and requests for oral presentations must be received by October 16, 2017; see the SUPPLEMENTARY INFORMATION section for information on how to register for the meeting.

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 26, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 27, 2017. 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-2017-N-5017 for "Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting." Received comments 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, October 12, 2017, 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, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring MD, 20993, 301-796-4548, email: 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 obligations of safety and effectiveness. In 2015 the ICH was reformed to make the ICH 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. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following website: http://www.ich.org. (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. Webinar Attendance and Participation

A. Registration

If you wish to attend the meeting, please register at the following website: https://healthcanada-usfda_ich_consultation.eventbrite.ca. For those attending online, a link will be provided upon registration. In person registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the webinar.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public webinar. Public oral presentations will be scheduled between approximately 11:30 a.m. and 12 noon. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see FOR FURTHER INFORMATION CONTACT) by October 12, 2017, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public webinar will be made available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm574251.htm.

Dated: September 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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