DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0444]

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 Amsterdam, Netherlands, scheduled for June 2 through 6, 2019. 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 Amsterdam.

DATES: The public meeting will be held on April 29, 2019, from 10 a.m. to 1 p.m. Submit either electronic or written comments on this public meeting by May 20, 2019. 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, the Great Room (Rm. 1503), 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 May 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on May 20, 2019. 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–2019–N–0444 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: William Lewallen, 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 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 it as a true global initiative and to expand 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 built on a 25-year track record and have allowed ICH to continue its successful delivery of harmonized guidelines for global pharmaceutical development and their regulation.

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. 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: *https://www.ich.org.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by April 22, 2019. To register for the public meeting, please visit the following website: *https://ich_regional_consultation_2019.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 22, 2019, 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/ucm624770.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 April 15, 2019.

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 April 15, 2019. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. If selected for presentation, any presentation materials must be emailed to William Lewallen (see **FOR FURTHER INFORMATION CONTACT**) no later than April 24, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Signup 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 through the following link: *https://collaboration.fda.gov/ich2019*. To register to attend via webcast, please visit the following website: *https://ich_regional_consultation_2019.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: March 21, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #120 entitled ''Veterinary Feed Directive Regulation Questions and Answers.'' This draft revised guidance document, when finalized, will aid industry in complying with the requirements of the veterinary feed directive (VFD) regulation.

DATES: Submit either electronic or written comments on the draft revised guidance by May 28, 2019 to ensure that the Agency considers your comment on this draft revised guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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://*