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.

[FR Doc. 2019–05955 Filed 3–27–19; 8:45 am]

BILLING CODE 4164–01–P

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://*

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–2010–N–0155 for ''Veterinary Feed Directive Regulation Questions and Answers.'' Received comments 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.

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

Submit written requests for single copies of the draft revised guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised guidance document.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5944, *dragan.momcilovic@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 30, 2015 (80 FR 58602), FDA announced the availability of GFI #120 to assist industry in complying with the VFD regulation in 21 CFR part 558. This guidance also serves as a Small Entities Compliance Guide (SECG), to aid industry in complying with the requirements of the VFD final rule that published in the **Federal Register** on June 3, 2015 (80 FR 31708). FDA prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121). This document provides guidance to small businesses on the requirements of the final rule. We are announcing the availability of draft revised GFI #120 to provide additional information in response to questions that have been submitted by interested parties since 2015.

II. Significance of Guidance

This level 1 draft revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the current thinking of FDA on ''Veterinary Feed Directive Regulation Questions and Answers.'' 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. Paperwork Reduction Act of 1995

This draft revised 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 21 CFR 558.6 have been approved under OMB control number 0910–0363.

IV. Electronic Access

Persons with access to the internet may obtain the draft revised guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 22, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–05976 Filed 3–27–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0169]

Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.