I. Background

In the **Federal Register** of November 18, 2022 (87 FR 69278), FDA published a notice with a 60-day comment period to request comment on the guidances for industry entitled, ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' The Agency has received a request for a 60-day extension of the comment period for the notice. FDA has considered the request and is reopening the comment period for the notice until April 18, 2023. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03385 Filed 2–16–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4002]

Electronic Submission of Adverse Event Reports to the Food and Drug Administration Adverse Event Reporting System Using International Council of Harmonisation E2B(R3) Standards; 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, the Agency, or we) is announcing a series of two public meetings entitled ''Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) Using International Council for Harmonisation (ICH) E2B(R3) Standards.'' The purpose of these public meetings is to provide the pharmaceutical industry and other interested parties with updated information on the plans, progress, and technical specifications to upgrade electronic submission standards for drug, biological product, and drug- or biologic-led combination products in the premarket and postmarket safety surveillance programs managed by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). These meetings are part of a public meeting series initiated by FDA in 2019 to communicate FDA's implementation plan and regional requirements for ICH E2B(R3). The 2023 meetings will focus on enhancements to electronic submission of Individual Case Safety Reports (ICSRs) in FAERS using ICH E2B(R3) standards. FDA is seeking input from stakeholders as it fulfills its commitment to implement ICH E2B(R3) and will use the information provided by the public to inform the enhancements to FAERS required for the implementation of ICH E2B(R3) standards and relevant regional variations.

DATES: The first public meeting will be held on April 4, 2023, from 9 a.m. to 3 p.m. The second public meeting will be held on November 7, 2023, from 9 a.m. to 12 p.m. Submit either electronic or written comments on these public meetings by May 3, 2023, for the first public meeting, and by December 6, 2023, for the second public meeting. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information.

ADDRESSES: The public meeting will be held virtually, by webcast only.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. For timely consideration, we request that electronic comments be submitted no later than 30 days after each public meeting (*i.e.,* comments submitted by or before May 3, 2023, for the first public meeting; and December 6, 2023, for the second public meeting. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2023). 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–4002 for ''Electronic Submission of Adverse Event Reports to FAERS using ICH E2B(R3) Standards.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Suranjan De, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993–0002, 240–402–0498, *eprompt@fda.hhs.gov;* or Katie Rivers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7336, Silver Spring, MD 20993–0002, 301–796–1818, *eprompt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieving the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. FDA participated in the development of an ICH E2B guideline [1] pertaining to the submission of adverse event reports to the FAERS system: ''Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification.'' In the Prescription Drug User Fee Act VI commitment letter, FDA committed to the goal of allowing industry to participate in user acceptance testing and/or organizing a meeting to provide industry an opportunity to provide feedback in advance of the Agency's implementation of ICH E2B(R3) data standards for electronic submission of adverse event reports. The commitment letter outlines FDA's performance goals and procedures under the Prescription Drug User Fee Act VI program for the years 2018–2022 (available at *https://www.fda.gov/media/99140/download*). In 2019 and 2020 FDA had conducted a series of three public meetings to communicate FDA's implementation plan and regional requirements for ICH E2B(R3). FDA incorporated the recommendations received in the comments from the 2019 and 2020 public meetings as ICH E2B(R3) regional technical specifications.

II. Topics for Discussion at the Public Meeting

The public meetings will include a general discussion of the updated specifications for premarketing and postmarketing ICSRs listed in the FDA Regional Implementation Guide for E2B(R3) Electronic Submission of Individual Case Safety Reports for Drug and Biological Products that published in April 2022 (available at *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions*). The goal of this discussion is to communicate the updated specific regional requirements that will enhance the quality of adverse event reports received by the Agency. The information exchange at the meetings will enhance the pharmaceutical industry's knowledge of the processes needed to implement ICH E2B(R3) into their systems. In addition, the comments provided by participating stakeholders will continue to inform CDER and CBER's plans for the implementation of ICH E2B(R3) for drugs, biological products, and drug- or biologic-led combination products.

During the public meetings, FDA intends to discuss: (1) E2B(R3) Regional (U.S.) data elements and business rules; (2) usage of data standards in E2B(R3); (3) submission paths for premarket and postmarket ICSRs; (4) forward compatible rules; (5) review of FDA Regional Implementation Specifications for ICH E2B(R3) Implementation; and (6) FDA ICSR XML Instances. One or more topics may be discussed in each meeting. FDA will consider all comments made at these public meetings or received through the docket (see **ADDRESSES**).

III. Participating in the Public Meeting

Registration: To register for the public meetings, please visit *https://fdae2br3.eventbrite.com* by March 31, 2023, for the first meeting and November 3, 2023, for the second meeting. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

An agenda will be made available at least 3 days before each public meeting at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using.*

Streaming Webcast of the Public Meetings and Video of the Public Meetings: These public meetings will only be webcast; the URL will be posted at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using* at least 1 day before each meeting. A recording of the public workshops will be available at the same website address for 1 year.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using.*

Dated: February 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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[1] The ICH E2B(R3) IG guideline (*http://estri.ich.org/e2br3/index.htm*) provides technical and business specifications for the harmonized, core set of ICH data elements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific