4164-01-P

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 for Harmonisation E2B(R3) Standards; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is re-announcing three 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 information on the plans, progress, and technical specifications to upgrade electronic submission standards for drug, biological, and drug/biologic-led combination products for 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 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) standards by holding three public meetings. FDA 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 is being rescheduled due to a previous lapse in appropriations. The rescheduled first public meeting will be held on March 25, 2019, from 9 a.m. to 4 p.m. The second public meeting will be held on July 17, 2019, from 9 a.m. to 4 p.m. The third public meeting will be held on February 19, 2020, from 9 a.m. to 4 p.m. Submit either electronic or written comments on these public meetings by April 25, 2019, for the first public meeting; by August 16, 2019, for the second public meeting, and by March 20, 2020, for the third public meeting. See the SUPPLEMENTARY INFORMATION section for registration dates and information.

ADDRESSES: The first public meeting will be held at the Silver Spring Civic Building at Veterans Plaza, The Buffalo Soldiers Great Hall, 1 Veterans Pl., Silver Spring, MD 20910. The second and third public meetings will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. 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/default.htm.

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 before or within 30 days after each public meeting (i.e., comments submitted by or before April 25, 2019, for the first public meeting; August 16, 2019, for the second public

meeting; and March 20, 2020, for the third public meeting. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 25, 2019, August 16, 2019, and March 20, 2020, after the first, second, and the third meeting, respectively. 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.

- 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: 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, email: eprompt@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, email: 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 ICH

E2B guideline[1] pertaining to the submission of adverse event reports across multiple regions: "Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification." FDA plans to incorporate ICH E2B(R3) recommended standards into the requirements for the electronic submission of adverse event reports to FAERS tentatively by April 2020. Consistent with the Prescription Drug User Fee Act (PDUFA) VI commitments, FDA is organizing several public meetings to allow industry the opportunity to provide feedback and/or participate in user acceptance testing in advance of the Agency's planned implementation of ICH E2B(R3) data standards. FDA's performance goals and procedures under the PDUFA program for the years 2018 to 2022 are outlined in the commitment letter available at: https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.

II. Topics for Discussion at the Public Meetings

FDA will present its plan to incorporate ICH E2B(R3) recommended standards into the requirements for the electronic submission of adverse event reports to FAERS. The meetings will include a general discussion of CDER's and CBER's plans to revise the FDA Regional Implementation Specifications for premarketing and postmarketing adverse event reporting. The goal of this revision is to enhance the quality of adverse event reports received by the Agency by incorporating ICH E2B(R3) recommendations into FDA Regional Implementation Specifications. 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 inform CDER's and CBER's

[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.

plans for the implementation of ICH E2B(R3) for drugs, biologics, and drug/biologic-led combination products.

During the public meetings, FDA intends to discuss: (1) E2B(R3) Regional (U.S.) Data Elements; (2) usage of data standards in E2B(R3); (3) submission paths for premarket and postmarket ICSRs; (4) data migration exceptions; and (5) FDA regional implementation specifications for ICH E2B(R3) implementation. One or more of the above 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 the following website to register: https://fdae2br3.eventbrite.com by March 22, 2019, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. Persons who registered for the first public meeting date of January 25, 2019, should visit the website to register again for the rescheduled meeting date of March 25, 2019. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone, and method of attendance (in person or web conference).

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending the public meetings must register by 11:59 p.m. Eastern Time on March 22, 2019, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit,

onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301-796-0035, email: Chenoa.Conley@fda.hhs.gov, at least 7 days before each meeting.

Request for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. All requests to make oral presentations must be received by 11:59 p.m. Eastern Time on March 19, 2019, for the first meeting, June 14, 2019, for the second meeting, and January 17, 2020, for the third meeting. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by 11:59 p.m. Eastern Time on March 20, 2019, for the first meeting, June 26, 2019, for the second meeting, and January 30, 2020, for the third meeting. FDA will notify registered presenters of their scheduled presentation time. If selected for presentation, any presentation materials must be emailed to eprompt@fda.hhs.gov no later than 11:59 p.m. Eastern Time on March 22, 2019, for the first meeting, July 10, 2019, for the second meeting, and February 12, 2020, for the third meeting. Persons registered to speak should check in before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. An agenda will be made available at least 3 days before each public meeting at https://www.fda.gov/Drugs/NewsEvents/ucm621215.htm.

Streaming Webcast of the Public Meetings and Video of the Public Meetings: The second and third public meetings will also be webcast; the URL will be posted at https://www.fda.gov/Drugs/NewsEvents/ucm621215.htm at least 1 day before each meeting. A video record of the public workshops will be available at the same website address for 1 year.

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.

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/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm.

Dated: March 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-04730 Filed: 3/13/2019 8:45 am; Publication Date: 3/14/2019]