4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1280]

International Conference on Harmonisation; Electronic Transmission of Postmarket Individual Case Safety Reports for Drugs and Biologics, Excluding Vaccines; Availability of Food and Drug Administration Regional Implementation Specifications for ICH E2B(R3) Reporting to the Food and Drug Administration Adverse Event Reporting System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its FDA Adverse Event Reporting System (FAERS) Regional Implementation Specifications for the International Conference on Harmonisation (ICH) E2B(R3) Specification. FDA is making this technical specifications document available to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and ICSR attachments) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This document, entitled "FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports (ICSRs) for Drugs and Biologics, Excluding Vaccines" supplements the "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide--Data Elements and Message Specification" final guidance for industry and describes FDA's technical approach for receiving ICSRs, for incorporating regionally controlled terminology, and for adding region-specific data elements when reporting to FAERS.

DATES: Submit either electronic or written comments on the Regional Implementation Specifications document at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-1280 for "FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports for Drugs and Biologics, Excluding Vaccines." 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 Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suranjan De, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring, MD 20993, 240-402-0498, or FAERSESUB@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.

SUPPLEMENTARY INFORMATION:

I. Background

On February 21, 2014, FDA issued a Federal Register notice (79 FR 9908) announcing the availability of a final guidance for industry entitled "E2B (R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide--Data Elements and Message Specification" (ICH E2B(R3) guidance) and an appendix to the guidance entitled "ICSRs: Appendix to the Implementation Guide--Backwards and Forward Compatibility" (BFC appendix). The ICH E2B(R3) guidance and BFC appendix were issued as a package that included schema files and additional technical information to be used for creating compatible ICSR files. The preface to the ICH E2B(R3) implementation guidance makes clear that any future "technical specifications document associated with that guidance would be provided as a stand-alone document" but incorporated by reference into that guidance. Accordingly, in this notice, we are announcing the availability of a technical specifications document that will be incorporated into that final guidance.

This technical specifications document, which is available on the FDA Guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm, is to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and any ICSR attachments) to CDER and CBER. This document describes FDA's technical approach for submitting ICSRs, for incorporating its regionally controlled terminology, and for adding its regional data elements that are not addressed in the ICH E2B (R3) guidance for the following FDA-regulated products: Drug products marketed for human use with approved new drug applications and abbreviated new drug applications; prescription drug

products marketed for human use without an approved application; nonprescription (over-the-counter) human drug products marketed without an approved application; and biological products marketed for human use with approved biologic license applications.

II. Electronic Access

Persons with access to the Internet may obtain a copy of the FDA Regional Implementation Specifications for ICH E2B(R3) at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm115894.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or http://www.regulations.gov.

Dated: June 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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