• H.6: Manufacturer Evaluation Conclusion Codes: 12 (Design deficiency)

• H.10: To correct the condition, the beds were taken out of service. Technicians have examined the beds and have opened up a Corrective and Preventive Action (CAPA) to address the design issue.

D. Appropriate Candidates

Appropriate candidates for the pilot program are manufacturers who:

1. Are currently submitting reports to FDA using the paper Form FDA 3500A or the electronic MDR (eMDR) format.

2. Manufacture class I devices and/or those class II devices that are not permanently implantable, life supporting, or life sustaining.

3. Currently use or are willing to use eMDR to submit summary malfunction reports to the FDA during the pilot period.

4. Are in compliance with the Medical Device Reporting regulation in 21 CFR part 803.

E. Procedures

1. Nomination

A manufacturer of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining may nominate themselves for participation in the pilot program by submitting a nomination to *227pilot@fda.hhs.gov*. FDA intends to acknowledge receipt of nominations via return email. The following information will assist FDA in processing and responding to nominations:

• Name of manufacturer

• Registration number

• Contact name, address, phone number, and email address

• Model or catalog number for the device(s) that you are requesting to include in the pilot, and

• Product classification code for the device(s) that you are requesting to include in the pilot. You may access the Product Classification Code database at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*.

2. FDA Consideration

Acceptance of nominations will start 2 weeks following the publication date of this **Federal Register** notice. Because only a limited number of candidates are needed, FDA will use its discretion in choosing candidates based on the eligibility criteria in this **Federal Register** notice in section II.D. Appropriate Candidates, the needs of the pilot to include a diversity of manufacturers with regard to device type (including in vitro diagnostic devices), and expected number of malfunction events. FDA may contact the manufacturer to request supplemental information if this information is needed in order to complete our review of the request. The manufacturer must provide the supplemental information within 15 days of FDA's request; otherwise, the Agency will consider the nomination withdrawn.

F. Manufacturer Notification

FDA intends to notify manufacturers who are selected for this pilot program within 45 days from receiving their nomination or any supplemental information requested by FDA. Once FDA has selected the candidates for this pilot, FDA will notify subsequent applicants by email that the nomination period has closed.

G. FDA Review

All reports received under the pilot program will be reviewed and processed in the same manner as individual medical device reports that are submitted under part 803. A version of the report releasable under FOIA will be accessible through the public MAUDE database.

H. Duration of the Pilot

FDA intends for the pilot program to run for 2 calendar quarters for each candidate and will continue until the 2 calendar quarters have been completed for all candidates. At its discretion, FDA may terminate the pilot program before the close of this period, or FDA may extend the pilot program beyond the 2 calendar quarters. The decision to terminate or extend the pilot will be announced in the **Federal Register**.

I. Evaluation

FDA intends to evaluate all information and feedback received from the candidates and to use the information and experiences gained from the pilot program to develop criteria for summary reporting on a quarterly basis for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act.

III. Paper Reduction Act of 1995

This notice refers to previously approved collections of information that 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 part 803 have been approved under OMB control number 0910–0437; the collections of information in Form FDA 3500A have been approved under OMB control number 0910–0291.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20309 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0903]

Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines; Guidance for Industry.'' The guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed for human use with approved biologics license applications (BLAs), including individual case safety reports (ICSRs) and attachments to ICSRs (ICSR attachments), into the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine safety surveillance program that is co-sponsored by the Centers for Disease Control and Prevention (CDC) and FDA. FDA published in the **Federal Register** a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help applicants required to submit postmarketing safety reports involving vaccine products to comply with the final rule. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2014, and supersedes the document entitled ''Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS–1)'' dated September 1998.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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

FDA is announcing the availability of a document entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines; Guidance for Industry.'' The guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed for human use with approved BLAs, including ICSRs and ICSR attachments, into VAERS. VAERS is a national vaccine safety surveillance program established in response to the National Childhood Vaccine Injury Act of 1986, which requires health professionals and vaccine manufacturers to report specific adverse events that occur after the administration of routinely recommended vaccines. VAERS is co-sponsored by CDC and FDA. The guidance is applicable to vaccine products marketed for human use with approved BLAs for which CBER has regulatory responsibility. The guidance does not apply to any other biological product. Postmarketing ICSRs and ICSR attachments for biological products, which are not addressed by the guidance, are processed into the FDA Adverse Event Reporting System database.

In the **Federal Register** of June 10, 2014 (79 FR 33072), FDA published a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help those applicants required to submit postmarketing safety reports involving vaccine products to comply with the final rule.

In the **Federal Register** of July 18, 2014 (79 FR 42022), FDA announced the availability of the draft guidance of the same title dated July 2014. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance includes changes to clarify the reporting requirements and technical process for submitting reports to VAERS. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2014 and supersedes the document entitled ''Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS–1)'' dated September 1998.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines. 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.

II. Paperwork Reduction Act of 1995

This 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 part 310 and part 314 have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 310.305(e)(2), 314.80(g)(2), 329.100(c)(2), and 600.80(h)(2) (Form FDA 3500A), have been approved under OMB control number 0910–0770. The collection of information in 21 CFR part 600 is approved under OMB control number 0910–0308. The collection of information in Form FDA 3500A is approved under OMB control number 0910–0291.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20312 Filed 8–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2853]

Electronic Study Data Submission; Data Standards; Support for Study Data Tabulation Model Implementation Guide Version 3.2

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) are announcing support for the 3.2 version (see section II. Exceptions) of Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model Implementation Guide (SDTM IG 3.2), an update to the FDA Data Standards Catalog (Catalog), and availability of validation rules for the 3.2 version. SDTM IG 3.2 has been available from CDISC since December 2013. FDA is encouraging sponsors and applicants to use SDTM IG 3.2 (see section II. Exceptions) in investigational study data provided in regulatory submissions to CBER and to CDER.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring,