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]

BILLING CODE 4164–01–P

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,

MD 20993–002, 301–796–5333, email: *ronald.fitzmartin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data) posted on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data is December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support (see section II. Exceptions) of the 3.2 version of CDISC STDM IG is March 15, 2017. Although SDTM IG version 3.2 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2018. The Catalog will list March 15, 2018, as the ''date requirement begins.'' When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

II. Exceptions

The following SDTM IG 3.2 domains have not completed testing and acceptance and are not supported at this time: Death Details and Exposure as Collected. The therapeutic area (TA) standards (*http://www.cdisc.org/*) that are included in SDTM IG 3.2 have not completed testing and acceptance and are not supported at this time. The specific domain and the TA standard are listed in the table that follows:

SDTM IG 3.2 Domain	TA User guide
1. Healthcare Encounters	Cardiovascular Studies, 1.0; Polycystic Kidney Disease, 1.0; Asthma, 1.0.
2. Microscopic Findings	Tuberculosis, 1.0; Parkinson's, 1.0.
3. Morphology	Cardiovascular Studies, 1.0; Parkinson's, 1.0; Polycystic Kidney Disease, 1.0; Alzheimer's, 1.0; Multiple Sclerosis, 1.0.
4. Procedures	Cardiovascular Studies, 1.0; Polycystic Kidney Disease, 1.0; Alzheimer's, 1.0.
5. Reproductive System	Polycystic Kidney Disease, 1.0.
6. Disease Response	Tuberculosis, 1.0.
7. Skin Response	Asthma, 1.0.

Sponsors and applicants with questions on how to implement the FDA-supported study data standards should contact and work with FDA technical staff. For questions, contact CDER at *cder-edata@fda.hhs.gov* or CBER at *cber.cdisc@fda.hhs.gov*.

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 proposed recommendations at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov*.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20316 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before October 19, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–New–60D.

Information Collection Request Title: Evaluation of the Office on Women's Health Coalition for a Healthier Community Initiative

Abstract: This collection is to provide data for the national evaluation of the U.S. Department of Health and Human Services (HHS), Office on Women's Health (OWH) Coalition for a Healthier Community (CHC) Initiative. The initiative supports 10 communities with grants to support coalitions in implementing gender-based public health systems approaches, evidence-based health interventions, and outreach and education activities to reduce barriers to and enhance facilitators of improvements in women and girls' health. Each of the grantees has implemented an IRB-approved local evaluation; however, OWH is seeking to