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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for a single hard copy of the draft guidance to the Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Drive, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Burford, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857, *Lola.Burford@fda.hhs.gov,* 240–402–5865.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) added section 501(j) to the FD&C Act (21 U.S.C. 351(j)) to deem adulterated a drug that ''has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.'' Section 707(b) of FDASIA required the Food and Drug Administration to issue guidance that defined the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the FD&C Act. In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced the availability of a guidance for industry entitled, ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection'' (hereinafter, 2014 guidance).

Subsequently, on August 18, 2017, FDARA (Pub. L. 115–52) was signed into law. Section 702 of FDARA amended the scope of section 501(j) of the FD&C Act to provide that, as the case with drugs, devices are deemed to be adulterated if an FDA inspection is delayed, denied, limited, or refused by the owner, operator, or agent of the establishment at which the device is manufactured, processed, packed, or held. This draft guidance is intended to update the 2014 final guidance to incorporate devices and to explain the circumstances that FDA would consider to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, resulting in a drug or device manufactured in the facility being deemed adulterated. The 2014 guidance will remain in effect and will continue to reflect FDA's current thinking regarding circumstances that would constitute delaying, deny, or limiting inspection, or refusing to permit entry or inspection, for purposes of 501(j) of the FD&C Act with respect to drug inspections, until this draft guidance is finalized.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' and will supersede the 2014 guidance. 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Persons unable to download an electronic copy of ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' may send an email request to *ORAPolicyStaffs@fda.hhs.gov* to receive an electronic copy of the document.

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27344 Filed 12–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1206]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice correction that appeared in the **Federal Register** of August 20, 2020. The document announced the correction dates that the support and requirement were to begin for version 1.7 of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM), and version 3.3 of the SDTM Implementation Guide (SDTMIG), and for version 2.1 of the Define-Extensible Markup Language (Define-XML). The document erroneously provided the

incorrect dates for these electronic study data standards. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *cderdatastandards@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 20, 2020 (85 FR 51450), in FR Doc. 2020–18236, the following correction is made:

On page 51450, in the second and third columns, the last paragraph of the document is corrected to read as follows: ''On page 40659, in the first column, the last three sentences of the document are corrected to read as follows: Support for version 1.7 of the CDISC SDTM, version 3.3 of the SDTMIG, and version 2.1 of the Define-XML will begin on March 15, 2021, and the date that the requirement begins will be on March 15, 2022, for new drug applications, abbreviated new drug applications, and certain biologics license applications. For certain investigational new drug applications, the date that requirement begins will be March 15, 2023. Support and requirement for version 1.3 of the CDISC SDTM and version 3.1.3 of the SDTMIG will end on March 15, 2021.''

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27346 Filed 12–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990-new]

Agency Information Collection Request: 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 17, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV.* When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Strategy for a Resilient Public Health Supply Chain Paperwork Reduction Act Clearance.

Type of Collection: New Father Generic ICR.

OMB No. 0990-new—Administration for Strategic Preparedness and Response—Office of Strategy, Policy, Planning, and Requirements.

Abstract: The Office of Strategy, Policy, Planning, and Requirements, within the Department of Health and Human Services (HHS), Administration for Strategic Preparedness and Response (ASPR), is seeking OMB approval of a new Generic clearance. In July 2021, the White House published the *National Strategy for a Resilient Public Health Supply Chain* (National Strategy), which provides a strategic approach to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. HHS is working with the White House and across the federal interagency to launch a multiyear implementation of the National Strategy involving the identification and coordination of measurable activities across the U.S. government, State, Local, Tribal, and Territorial (SLTT) jurisdictions, and the private sector.

HHS is requesting a 3-year PRA generic clearance for purposes of implementation to engage with SLTTs, trade groups, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, local communities, and other partners to: gain a better understanding of the public health supply chain; develop future strategic goals and recommendations for building immediate and long-term resilience through increased visibility, agility, and robustness in the public health supply chain to prepare for and mitigate future public health emergencies; and to ensure ASPR, HHS, and the broader U.S. government have current data and information to inform program and policy decision-making.

Cross-sectoral engagement underpins many of the interdependent implementation activities. For example, one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency. Other potential engagements include, but are not limited to questionnaires, stakeholder meetings, requests for information, town hall meetings, and workshops. Stakeholder engagement frequency will vary depending on the type of stakeholder and the information collection needs. Therefore, some engagements may only occur once, while others may require a series of recurring meetings.