Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 21003 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in section 506J of the FD&C Act have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
506J	Shortages Data Collection	0910–0491

IV. Other Issues for Consideration

The Agency invites comments on the ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' draft guidance, in general, and on the following questions, in particular:

- Section 506J of the FD&C Act requires notifications ''during, or in advance of'' a public health emergency. Does the draft guidance provide sufficient clarity regarding what FDA considers to be ''in advance of a public health emergency''? Is there additional information that you believe would be helpful? If so, what?
- Are there other situations or circumstances that could lead to a situation that could be considered to be ''in advance of a public health emergency''?
- FDA has proposed providing supplemental information during specific public health emergencies, which is intended to contain information specific to that public health emergency to assist manufacturers in providing notifications. Is there specific information that you believe should be conveyed in such supplements?
- Are there circumstances where it is unclear whether you should notify FDA? How could FDA provide clarity?
- Should FDA notify stakeholders when an event is considered to be ''in advance of a public health emergency'', and if so, how should FDA best do so?
- FDA recommends that manufacturers provide updates to notifications every two weeks unless otherwise indicated based on the nature of the situation, including the expected timeline for recovery, even if the status remains unchanged. Please provide feedback on this proposed frequency.
- How can FDA best disseminate supplemental information during or in advance of a public health emergency to manufacturers and other stakeholders?
- How can FDA keep all stakeholders, including healthcare providers and patients, better informed regarding shortages during or in advance of a public health emergency?
- In the draft guidance document, Appendix A displays an example of supplemental information for an epidemic or pandemic that FDA believes would be helpful to assess the overall state of the market and help inform potential mitigations. What additional information might be helpful for other public health emergencies?

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00321 Filed 1–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 10, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Drug Supply Chain Security Act Implementation

OMB Control Number 0910–0806—Revision

This information collection supports Agency implementation of provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding the pharmaceutical distribution supply chain. Section 202 of the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54), added sections 581 and 582 to the FD&C Act (21 U.S.C. 360eee and 360eee-1) and governs the tracing of certain pharmaceutical drugs, outlining critical steps for an electronic interoperable system to identify these

products as they are distributed within the United States.

To strengthen FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, section 203 of the DSCSA added enhanced security provisions to section 582 of the FD&C Act. The terms and definitions established in section 581 of the FD&C Act are applicable to provisions set forth in section 582, which require the capture, exchange, and verification of pharmaceutical drug product transaction information, transaction history, and transaction statements by respondents. Section 582 of the FD&C Act also requires that certain notifications are made by respondents to FDA and provides for respondent notification disclosures applicable to suspect and illegitimate product data elements. The recordkeeping and notification provisions included in section 582 also provide for inspection of records by FDA and establish minimum retention schedules. Finally, section 582 of the FD&C Act provides for the establishment of waivers, exceptions, and exemptions from any of the requirements.

To assist respondents with reporting requirements, we developed Form FDA 3911 entitled Drug Notification and the corresponding instructional document ''INSTRUCTIONS FOR COMPLETION OF FORM FDA 3911—DRUG NOTIFICATION.'' Form FDA 3911 and the instructions are available from, and may be completed using, our website at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-notifications-frequently-asked-questions.* Form FDA 3911 is intended to provide a uniform format for initial notifications, followup notifications, and requests for the termination of a notification. The guidance document entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' (Revision 1, June 2021; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-supply-chain-security-act-implementation-identification-suspect-product-and-notification*) was developed to assist respondents with identifying a suspect product as defined at section 581(21) of the FD&C Act and in making determinations in this regard.

We also developed the draft guidance document entitled ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act'' (May 2018; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/waivers-exceptions-and-exemptions-requirements-section-582-federal-food-drug-and-cosmetic-act*). Respondents seeking waivers, exceptions, or exemptions from any of the requirements may submit a request to FDA. The draft guidance explains Agency established processes by which: (1) A trading partner may request a waiver from certain requirements in section 582 of the FD&C Act if it would result in an undue economic hardship or for emergency medical reasons; (2) a manufacturer or repackager may request an exception to the section 582 requirements related to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the required information; and (3) FDA may determine other products or transactions that shall be exempt from requirements of section 582.

Respondents to the information collection are manufacturers, wholesale distributors (''wholesalers''), dispensers, and repackagers, as defined in section 581 of the FD&C Act, of pharmaceutical drug products.

In the **Federal Register** of September 3, 2021 (86 FR 49538), we published a 60-day notice soliciting public comment on the proposed collection of information. A few comments were received requesting that FDA clarify the scope of the information collection request. We appreciate these comments. Although our 60-day notice discussed both draft and final guidance documents pertaining to topic-specific statutory requirements found in section 582 of the FD&C Act, not all the guidance documents discussed in the notice included information collection as defined by the PRA and subject to review and approval by OMB. Rather, consistent with regulations found in 21 CFR 10.115, guidance documents are intended to communicate the Agency's thinking on a particular topic and can therefore be helpful to respondents in understanding related information collection activities.

To clarify however, this information collection request is intended to account for the burden respondents may incur from completing and submitting notifications as required by section 582 of the FD&C Act using Form FDA 3911, consistent with the corresponding instructions, as well as the burden that may be attributable to information collection associated with the required disclosures/notifications to trading partners and discussed in the guidance document entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The information collection request is also intended to account for the burden that respondents may incur associated with requesting waivers, exceptions, and exemptions provided for in section 582(a)(3) of the FD&C Act. To enable respondents to make such requests, we are currently utilizing information collection recommendations discussed in the draft guidance document entitled ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act.'' Specifically, the draft guidance instructs respondents on submitting requests and identifies responsible Agency review components.

The comments also provided feedback on the accuracy of our burden estimates. In response to these comments, we have revised our estimate of the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Sec. 582 of the FD&C Act; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Notifications of illegitimate product: Form FDA 3911	500	28.2	14,100	8	112,800
Consultation/terminations of notification of illegitimate product (Notifications Guidance, sec. IV.B)	500	1	500	1	500
582(a)(3); Waivers, exceptions, and exemptions of any requirement:					
Request submissions (Waivers Guidance, sec. III.A.)	20	1	20	80	1,600
Material changes (Waivers Guidance, sec. III.D)	1	1	1	16	16

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Sec. 582 of the FD&C Act; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Request renewals (Waivers Guidance, sec. III)	1	1	1	16	16
Total					114,932

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL DISCLOSURE BURDEN [1]

Sec. 582 of the FD&C Act; activity	Number of respondents	Number of disclosures per respondent	Total disclosures	Average time per disclosure (in hours)	Total hours
Illegitimate product notifications to trading partners (Notifications Guidance, sec. III.B)	500	310	155,000	8	1,240,000
Illegitimate product notification terminations to trading partners (Notifications Guidance, sec. III)	500	310	155,000	4	620,000
Total					1,860,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have reorganized the information collection by respondent activity and clarified where information collection elements are discussed in the respective guidance documents. Based on illegitimate product notifications FDA has already received, we previously estimated a total of 250 respondents. However, we have considered industry feedback indicating that more notifications may be submitted based on stakeholder understanding of FDA's recent clarification of stolen product in the ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' draft guidance (June 2021; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/definitions-suspect-product-and-illegitimate-product-verification-obligations-under-drug-supply*). As such, we have increased our number of estimated respondents to 500 and assume 40 percent are manufacturers (200), 50 percent are wholesale distributors (250), and 10 percent are pharmacies (50). Because manufacturers, repackagers, and wholesale distributors are collectively responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, we continue to assume that these three trading partners submit most notifications of illegitimate products.

In response to industry feedback, we have increased our estimate of the average time per response from 1 hour to 8 hours to more accurately reflect the burden respondents may incur in satisfying the information collection. We have otherwise retained the average burden per response for activities associated with consultations and waiver/exception/exemption requests. Finally, also based on public comment and industry feedback, we have increased our estimate of the average number of disclosures/notifications per respondent, as well as our assumption of the average time necessary for each disclosure notification, for an increase from 66,070 to 1,860,000 hours annually.

As a result of these adjustments, our estimated burden for the information collection reflects a cumulative increase since the last OMB review and approval. We attribute this increase to a more recent evaluation of the information collection and informal communications with industry and other interested stakeholders regarding burden estimates.

Dated: January 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00327 Filed 1–10–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 14, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting