respect to establishing a mammography facilities certification program. The Committee shall advise the HHS Secretary and the Commissioner or designee on:

(A) Developing appropriate quality standards and regulations for mammography facilities;

(B) Developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;

(C) Developing regulations with respect to sanctions;

(D) Developing procedures for monitoring compliance with standards;

(E) Establishing a mechanism to investigate consumer complaints;

(F) Reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;

(G) Determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas;

(H) Determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and

(I) Determining the costs and benefits of compliance with these requirements.

The Committee shall consist of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Members will be invited to serve for overlapping terms of up to 4 years. Almost all members of this committee serve as Special Government Employees. The core of voting members shall include at least four individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least two practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include two nonvoting industry representative members who have expertise in mammography equipment. The Committee may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/NationalMammographyQualityAssuranceAdvisoryCommittee/ucm520365.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19108 Filed 9–2–21; 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; Proposed Collection; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by November 2, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 2, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 2, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2014–D–0609 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Drug Supply Chain Security Act Implementation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Drug Supply Chain Security Act Implementation

OMB Control Number 0910–0806—Revision

This information collection helps to support implementation of section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1). Enacted in 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) amended section 582 of the FD&C Act and outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA is intended to enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Respondents to the information collection are manufacturers, wholesalers, dispensers, and repackagers, as defined in section 581 of the FD&C Act (21 U.S.C. 360eee), of pharmaceutical drug products.

To assist respondents with statutory requirements set forth in section 582 pertaining to notifications of illegitimate products or products with a high risk of illegitimacy, we developed Form FDA 3911 entitled ''Drug Notification'' along with 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 facilitate notifications governed by section 582 by providing a uniform format for initial notifications, followup notifications, and requests for the termination of a notification.

Section 582 of the FD&C Act also provides for FDA issuance of guidance documents to facilitate implementation of the DSCSA. To that end, we continue to develop guidance documents to assist respondents with information collection provisions set forth in section 582. The procedural guidance document entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' (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*) is intended to assist respondents in identifying suspect products, as defined at section 581, and with terminating notifications of illegitimate product or products with a high risk of illegitimacy. As explained in the guidance document, beginning January 1, 2015, certain trading partners (*i.e.,* manufacturers, repackagers, wholesale distributors, or dispensers), upon determining that a product in their possession or control is a suspect product, must quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product, must notify FDA if they determine that the product is illegitimate product, and must notify certain trading partners of the illegitimate product as prescribed by section 582. Manufacturers must also notify FDA and certain immediate trading partners after determining that a product in their possession or control has a high risk of being illegitimate product.

Similarly, we developed the draft guidance document ''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*). The draft guidance explains Agency established processes by which: (1) A trading partner may request a waiver from certain requirements in section 582 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.

FDA has recently published the draft guidance document ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' (June 2021; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhanced-drug-distribution-security-package-level-under-drug-supply-chain-security-act*). The draft guidance clarifies the enhanced system requirements listed in section 582(g)(1) of the FD&C Act. This draft guidance also outlines and provides recommendations on the system attributes necessary for enabling the secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary. FDA has also published a draft guidance document entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information'' (November 2014; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs*). This draft guidance establishes initial standards for the interoperable exchange of product tracing information, in paper or electronic format, for compliance with sections 582(a) through (e) of the FD&C Act.

Two additional guidance documents help to further explain the statutory requirements of section 582. The ''Product Identifiers under the Drug Supply Chain Security Act—Questions and Answers'' guidance for industry (June 2021; available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifiers-under-drug-supply-chain-security-act-questions-and-answers*) is intended to address anticipated questions regarding product identifiers that are required under section 582 for packages and homogenous cases of certain drug products. The ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs'' draft guidance (October 2018; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/verification-systems-under-drug-supply-chain-security-act-certain-prescription-drugs*) provides recommendations for a robust verification system for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. The guidance also addresses FDA's recommendation that trading partners submit cleared product notifications. Finally, the guidance addresses the statutory requirements for verification, including verification of saleable returns, at the package level for product identifiers on packages and homogenous cases intended to be introduced in a transaction into commerce.

FDA guidance documents are issued consistent with requirements found in section 582, as well as our Good Guidance Practice regulations found in 21 CFR 10.115, which provide for public comment at any time. In addition, since enactment of the DSCSA, our Center for Drug Evaluation and Research has developed and continues to maintain a website communicating DSCSA implementation activity, including relevant resources at: *https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.*

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—NOTIFICATIONS TO FDA [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response	Total hours
Manufacturers and Repackagers	100	1	100	1	100
Wholesale Distributors	138	1	138	1	138
Dispenser	12	1	12	1	12
Total			250		250

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT [1]

Type of respondent	Number of respondents	Number of disclosures per respondent	Total disclosures	Average time per disclosure	Total hours
Manufacturers and Repackagers	100	30	3,000	* 0.20	600
Wholesale Distributors	138	1,175	162,150	* 0.20	32,430
Dispensers	12	2	24	* 0.20	5
Total			165,174		33,035

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (12 minutes.)

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR CONSULTATION WITH FDA AND TERMINATION OF NOTIFICATION [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response	Total hours
Manufacturers and Repackagers	100	1	100	1	100
Wholesale Distributors	138	1	138	1	138
Dispensers	12	1	12	1	12
Total			250		250

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

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT TERMINATION [1]

Type of respondent	Number of respondents	Number of disclosures per respondent	Total disclosures	Average time per disclosure	Total hours
Manufacturers and Repackagers	100	30	3,000	*0.20	600
Wholesale Distributors	138	1,175	162,150	*0.20	32,430
Dispensers	12	2	24	*0.20	5
Total			165,174		33,035

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (12 minutes.)

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR REQUESTS FOR WAIVERS, EXCEPTIONS, OR EXEMPTIONS [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response	Total hours
Requests to FDA for a Waiver, Exception, or Exemption	20	1	20	80	1,600
Notifications to FDA of a Material Change in Circumstances Warranting the Waiver, Exception, or Exemption	1	1	1	16	16
Requests to FDA to Renew a Waiver, Exception, or Exemption	1	1	1	16	16
Total			22		1,632

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

Based on illegitimate product notifications already received, we estimate a total of 250 respondents to the information collection. Our database for establishment and drug product listing suggests that many companies perform activities of both manufacturers and repackagers and therefore we have combined our estimated number of respondent manufacturers and repackagers. In addition, because statutory provisions specifically define ''dispensers'' to include retail pharmacies, hospital pharmacies, and groups of chain pharmacies, our estimate of the number of dispensers is intended to reflect the overall estimated number of respondents we believe to be subject to the requirements under section 582(d) of the FD&C Act. 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 assume that these three trading partners submit most notifications of illegitimate products. Upon evaluation of those notifications received in fiscal year (FY) 2020 and, thus far, in FY 2021, we assume those 250 respondents are comprised of 40 percent manufacturers (100), 55 percent wholesale distributors (138), and 5 percent pharmacies (12). We assume that annual notifications will vary from zero to two for manufacturers and repackagers, as well as from pharmacies, but that most of companies will make no notifications. Although our establishment and drug product listing database currently reflects approximately 1,400 manufacturers and repackagers, we estimate only 100 manufacturers and repackagers will notify us of illegitimate products an average of one time per year.

Relying on data from the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Hospital Association, we assume there are approximately 67,000 pharmacy sites in the United States. Based on a review of data, we estimate 12 pharmacies will notify FDA of illegitimate product an average of 1 time per year.

According to the Healthcare Distribution Alliance (formerly known as Healthcare Distribution Management Association), approximately 30 wholesale distributors are responsible for over 90 percent of drug distributions. Based on sales, and because FDA is estimating that over 1,570 small wholesale distributors may be responsible for the remaining 10 percent of drug sales, we estimate that wholesale distributors will be responsible for making approximately an average of 1 notification per year to account for the estimated 138 notifications that FDA will receive regarding illegitimate product. We

assume wholesale distributors will expend 1 hour for each notification.

Because the extent of distribution of any illegitimate product will vary, we assume a wide distribution for each illegitimate product for purposes of establishing our burden estimate. We estimate that, for each notification that a manufacturer or repackager makes to FDA, the manufacturer or repackager will notify approximately 30 trading partners (relying on the number of distributors). This formula results in approximately 3,000 notifications annually to trading partners of manufacturers and repackagers. This estimate includes the notifications by manufacturers and repackagers who have determined that an illegitimate product is in their possession or control, as well as notifications by manufacturers who have determined that a product poses a high risk of illegitimacy.

We assume that a large wholesale distributor may have up to 4,500 trading partners, where a small wholesale distributor may have 200 trading partners, averaging approximately 2,350. We had originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, as a result of our experience with the collection and informal feedback from industry, we have lowered our estimate to reflect that 138 respondents will make 1,175 disclosures for a total of 162,150 disclosures annually and that each disclosure will require approximately 12 minutes, for a total of 32,430 hours annually.

We estimate that a pharmacy purchases prescription drugs from an average of two wholesale distributors. Therefore, a pharmacy would notify 2 trading partners for each of the 12 illegitimate products identified. This estimate results in in approximately 24 notifications annually to pharmacy trading partners.

We estimate that the burden for notifying trading partners of an illegitimate product and the number of trading partners notified will be the same as the estimates for notification of termination. The estimated total burden hours to notify trading partners that the notification is terminated is approximately 33,035 hours annually.

We assume a comparable amount of time is required to provide the information necessary for requesting to terminate a notification. The time required to investigate and resolve an illegitimate product notification will vary, but we assume that each notification will eventually be terminated. We assume that the number of requests for termination of a notification per year will be the same as the original number of notifications for a given year. The estimated total burden hours to make requests for termination of notifications to FDA is 250 hours annually.

Based on communications we have had with trading partners and stakeholders since the 2013 enactment of the DSCSA, we estimate that 20 trading partners or stakeholders will submit approximately 20 requests for a waiver, an exception, or an exemption. Also based on feedback from industry stakeholders, we estimate that respondents will expend an average of 80 hours to prepare and submit each request and to submit any additional followup information that we may request. We estimate the total burden as approximately 1,600 hours.

We estimate that we will receive from approximately one respondent approximately one notification or other information informing us that there has or has not been a material change in the circumstances that warranted the waiver, exception, or exemption and that each notification will require approximately 16 hours to prepare and submit to us. We estimate the total burden as approximately 16 hours.

We estimate that we will receive approximately one renewal request from approximately one respondent and that each request will require approximately 16 hours to prepare and submit to us. We estimate the total burden as approximately 16 hours.

Our estimated burden for the information collection reflects an overall increase of 56,116 hours and a corresponding increase of 271,638 responses annually. We attribute this adjustment to an increase in the number of illegitimate product notification submissions we received in the last couple of years and the number of such submissions we have received so far this fiscal year.

Dated: August 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19061 Filed 9–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

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 October 4, 2021.

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 0910–0511 Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

OMB Control Number 0910–0511—Revision

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug