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

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Cover Sheet Form FDA 3397 submission with original NDAs and BLAs.	132	1.24	164	0.5 (30 minutes)	82
Total	.....	.....	408	.....	3,829

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

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C) of the FD&C Act) is 181, submitted by 99 different applicants.

We estimate that 35 respondents will each submit a small business waiver request annually. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that their application is their first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 22 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving six requests annually for appeal of user fee waiver determinations, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume a total of 82 hours of burden for completing and submitting the 164 forms FDA 3397 (Prescription Drug User Fee Coversheet) along with submission of NDAs or BLAs. The burdens associated with submission of NDAs and BLAs are included in OMB control numbers 0910–0001 and 0910–0338, respectively.

The information collection reflects changes and adjustments. We have clarified that the scope of the collection includes provisions found in our current commitment goals letter, negotiated with industry, pertaining to the assessment of fees, waivers, refunds, and exemptions under PDUFA VII. We have also included relevant Agency guidance documents that provide instruction in this regard and for which we attribute attendant burden. Cumulatively, these adjustments have resulted in a total decrease of 3 responses and an overall increase of 203 burden hours annually since the prior renewal of the information collection. We attribute the minor changes in the numbers to normal fluctuations in numbers of waivers, exemptions, reconsideration requests, and appeals received for assessed PDUFA fees. We do not attribute a change in the burden related to the revision request to include the Agency's commitment goals.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07574 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3675]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2025.

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–12M, 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.

Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security

OMB Control Number 0910–0806—Revision

This information collection helps support implementation of sections 581 and 582 (21 U.S.C. 360eee and U.S.C. 360eee–1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which govern the pharmaceutical distribution supply chain. Definitions set forth in section 581 of the FD&C Act prescribe specific activities that apply to the individuals identified in section 582, including recordkeeping requirements intended to effectuate the tracing of certain pharmaceutical drugs as they are distributed within the United States. The recordkeeping provisions expressly provided for in sections 582(b) through (e) of the FD&C Act cover tasks associated with product identification, product tracing, transaction data, record verification, and disclosures (exchange)

of information. Submissions to FDA, as provided for in section 582 of the FD&C Act, include making specific product notifications, requesting exemption and/or waiver from any of the statutory requirements, and requesting termination of a notification in consultation with FDA.

The requirements of section 582 of the FD&C Act included in the information collection are self-executing. We regard most of the information collection activities required by the statute to be usual and customary recordkeeping activities by respondents and have therefore excluded from our estimated burden the time, effort, and financial resources attributable to those activities consistent with 5 CFR 1320.3(b)(2). Additionally, we note that some respondents are also subject to related reporting, recordkeeping, and disclosure requirements applicable under the Controlled Substances Act (Pub. L. 91–513), for which currently active information collection approvals are maintained by the Department of Justice's Drug Enforcement Administration. At the same time, we account for notifications submitted to FDA, and estimate recordkeeping burden attributable to activities corresponding with illegitimate product notifications, including coordination of investigations of suspect products, among trading partners, as required by the statute.

To assist respondents with submitting specific product notifications to FDA regarding illegitimate product and product with a high-risk of illegitimacy, we have developed and utilize Form FDA 3911 entitled ''Drug Notification'' and the corresponding instructional document ''INSTRUCTIONS FOR COMPLETION OF FORM FDA 3911—DRUG NOTIFICATION.'' Instruction regarding the submission of Form FDA 3911 using the Center for Drug Evaluation and Research ''NextGen'' portal is available from our website at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products.* Form FDA 3911 is intended to provide a uniform format for initial notifications, followup notifications, and requests for the termination of a notification. We believe followup activities regarding suspect and/or illegitimate drug products includes information obtained during the conduct of an official Agency investigation and thus not covered by the PRA. Please see 5 CFR 1320.4(a)(2) and FDA ''General Enforcement Regulations'' in 21 CFR part 1. We have revised Form FDA 3911, and the instructions for completing the form, to add a new field requesting information about the geographic location of the incident that is the subject of the notification.

We have also published guidance documents, as provided for in section 582 of the FD&C Act, developed specifically to facilitate the efficient adoption of secure interoperable product tracing at the package level by respondents. The guidance documents discuss the recordkeeping activities expressly provided for in section 582 of the FD&C Act. To date we have developed and issued the following guidance documents:

- ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs'' guidance (2023 Standards for Interoperable Exchange Guidance) (September 6, 2023).
- ''Standardization of Data and Documentation Practices for Product Tracing'' draft guidance (Standardization of Data Guidance) (February 28, 2018).
- ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' guidance (Enhanced Drug Distribution Security Guidance) (August 31, 2023).
- ''Verification Systems Under the Drug Supply Chain Security Act [DSCSA] for Certain Prescription Drugs'' guidance (Verification Guidance) (December 7, 2023).
- ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' guidance (Definitions Guidance) (March 16, 2023).
- ''Product Identifiers Under the Drug Supply Chain Security Act—Questions and Answers'' guidance (Product Identifier Guidance) (June 3, 2021).
- ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' guidance (Suspect Product Guidance) (June 6, 2021).
- ''Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act'' guidance (Waivers Guidance) (August 4, 2023).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

We also maintain a web page at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/fdas-implementation-drug-supply-chain-security-act-dscsa-requirements* that communicates FDA's ongoing implementation of the DSCSA requirements. Since DSCSA enactment on November 27, 2013, FDA has established a public docket to receive information and comments on DSCSA standards for the electronic tracking system, including comments regarding paper- and electronic- formats of information. In 2018, we initiated a pilot project, consistent with section 582(j) of the FD&C Act and approved in OMB control number 0910–0859, focusing on system attributes and demonstrating interoperability. Since completion of the pilot project, we continue to focus on the interoperability of the electronic systems described in section 582 of the FD&C Act and have revised this information collection to capture standardized transaction information.

Respondents to the information collection are manufacturers, wholesale distributors, dispensers, and repackagers of pharmaceutical drug products, as defined in section 581 of the FD&C Act and identified in section 582(a)(1) of the FD&C Act. Based on Agency data, we assume 70,000 respondents: 1,230 manufacturers and 170 repackagers, (1,400 cumulatively); 1,600 distributors; and 67,000 dispensers (including online and chain pharmacies).

In the **Federal Register** of September 6, 2024 (89 FR 72848), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment from a trade association suggesting our estimate for burden attendant to requests for waiver, exception, or exemption (WEE) might not include submissions by those respondents who lack readiness to implement final DSCSA requirements and who have more recently submitted such requests to FDA. In anticipation of the end of the enhanced drug security requirements 12-month stabilization period on November 27, 2024, we received an increased number of waiver and exemption requests and have issued two exemptions from the enhanced drug distribution security requirements of section 582 of the FD&C Act for eligible trading partners. The comment thanked FDA for the recent exemptions, acknowledging they allow a phased approach to implementing trading partner data exchange as required under the DSCSA. While the comment proffered no alternative figures, we have adjusted our estimate for this activity by increasing the number of respondents submitting WEE requests from 20 to

100, as reflected in row 3 of table 1. We have made no other adjustment to our estimates but continue to monitor information collection elements applicable to the DSCSA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 U.S.C. 360eee–1(b) through (e)); information collection	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/Requests for termination of notification of illegitimate product (Suspect Product Guidance, sec. IV.B)	500	1	500	1	500
Requests for waiver, exception or exemption, including material changes and renewals (Waivers Guidance, sec. III)	100	1	100	81	8,100
Total			14,700		121,400

As reflected in table 1, reporting activities include the submission of notifications to FDA regarding illegitimate product and product with a high-risk of illegitimacy using Form FDA 3911. Form FDA 3911 is also used to submit requests for termination of a notification in consultation with FDA. FDA may request any additional information it determines necessary to complete the consultation. We believe burden that may be incurred from providing FDA with follow-up information that may be necessary with regard to suspect and/or illegitimate products is excepted from our accounting in accordance with 5 CFR 1320.3(c), and we have therefore not included this activity in our estimate of burden. Finally, an authorized trading partner or other stakeholder seeking a WEE from requirements of section 582 of the FD&C Act may submit a request to FDA, or a request for material changes to or renewal of an approved initial request. These requests are also included in the scope of reporting activities.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 U.S.C. 360eee–1(b)–(e); information collection; activity	Number of respondents	Number of records per respondent	Total annual records	Average burden per record (in hours)	Total hours
Documenting transaction (T3) information	70,000	1,000,000	70,000,000,000	0.0000017	119,000
Disclosing illegitimate product notifications and terminations to trading partners	500	620	310,000	6	1,860,000
Product identification & information exchange: encoding packages and homogeneous cases with product identifier; exchange of information only w/authorized trading partners	1,400	3,125,000	4,375,000,000	0.0000688	301,000
Verification: identify and investigate suspect product, coordinate with other trading partners, quarantine product, notify FDA of suspect product that is not determined to be illegitimate product	30,125	8	241,000	0.62	149,420
Total			74,375,551,000 ~74.4 B		2,429,420

[1] The recordkeeping requirement includes the requirement to retain, notify third parties, the Federal government, or the public of the existence of such records; disclose such records to third parties, the Federal government, or the public; or report to third parties, the Federal government, or the public regarding such records. See 44 U.S.C. 3502(13); 5 CFR 1320.3(m).

[2] We regard activities established in section 582(b)–(e) of the FD&C Act to be usual and customary for respondents to the information collection.

As reflected in table 2, the provisions in sections 582(b) through (e) of the FD&C Act require ongoing recordkeeping that documents product identification, tracing information, and verification activities. Records are to be produced to FDA within 24 hours of a request, consistent with section 582 of the FD&C Act. Each category of respondent (manufacturer, distributer, wholesaler, repackager) may expend varying degrees of time, effort, or financial resources to generate, maintain, retain, notify, or disclose such records commensurate with the corresponding tasks prescribed for that category. Data elements required to be documented and disclosed are defined in section 581 and set forth in section 582 of the FD&C Act. A significant portion of recordkeeping activity pertains to product identification and product tracing. Verification activities comprise another significant portion of activity, where respondents expend time, effort, or financial resources respective to their role. Although we have quantified what we believe to be the average amount of time, effort, or financial resources expended cumulatively by respondents, we regard these recordkeeping activities as usual and customary and exclude them from our burden approval request submitted to OMB, consistent with 5 CFR 1320.3(b)(2).

Product Tracing and Product Identification

Information exchange activities with authorized trading partners as contemplated by section 582 of the FD&C Act include: (1) providing the

transaction information, the transaction history (when applicable), and transaction statement (T3) to the subsequent purchaser, providing relevant transaction information, transaction history, and transaction statement upon a request for information from FDA or other appropriate Federal or State officials if a recall or investigation of suspect or illegitimate product occurs, and, after the Statutory Date, facilitating the gathering of information necessary to produce the transaction information for each transaction [1] going back to the manufacturer at an authorized trading partner's request, or at the request of FDA or other appropriate Federal or State officials; and (2) capturing and maintaining transaction information, transaction history, and transaction statements for each transaction for not less than 6 years after the transaction. Product identification activities include the requirement that manufacturers and repackagers affix or imprint a product identifier to each package and homogeneous case of products that they intend to be introduced in a transaction into commerce and that they maintain product identifier information for each package and homogeneous case of product for not less than 6 years.

Verification Activities

Verification activities include: (1) coordinating with other trading partners during an investigation of a suspect product to determine whether the product is illegitimate; (2) for manufacturers and repackagers, responding to trading partners' requests for verification of product identifiers; (3) maintaining records of suspect product investigations and disposition of illegitimate product for not less than 6 years; (4) identifying suspect product; (5) quarantining suspect and illegitimate product; (6) investigating suspect product; (7) notifying FDA of suspect product that is determined not to be illegitimate product (when applicable); (8) processing saleable returns; and (9) establishing systems and processes to comply with all of these requirements.

We assume manufacturers, repackagers, and wholesale distributors will already have systems and processes to comply with many of these requirements. Such systems will therefore only need to be updated to ensure full compliance with the DSCSA. We also anticipate that a chain pharmacy will develop the required systems and processes centrally at its headquarters or at its distribution centers and then distribute to each pharmacy.

Our estimated burden for the information collection reflects some significant increases; most notably burden we attribute to the task of documenting individual transaction information. We have also increased the number of respondents submitting WEE requests.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07569 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

[1] Transaction is defined in section 581(24) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2865]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 2, 2025.

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 0910–0865. 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.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910–0865—Extension

This notice requests extension of OMB approval of the FDA information collection for a generic clearance that allows FDA to use quantitative social/behavioral science data collection techniques (*i.e.,* surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA's communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary [1] and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

[2] As defined in OMB and Agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''