

FOOD & DRUG ADMINISTRATION

Drug Supply Chain Security Act Requirements

OMB Control No. 0910-0806 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

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, 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, 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-dcsa/notify-fda-illegitimate-products>. Form FDA 3911 is intended to provide a uniform format for initial notifications, follow-up notifications, and requests for the termination of a notification. We believe follow-up 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 [DSCSA] Act 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 FDA 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 therefore request OMB approval of the information collection provisions found in section 582 of the FD&C Act (21 U.S.C. 360eee-1), information collection discussed in the associated

topic-specific guidance issued in accordance with section 582(h) as referenced in this supporting statement, and FDA Form 3911.

2. Purpose and Use of the Information Collection

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. 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). This information collection is intended to ensure the security and integrity of the pharmaceutical distribution supply chain.

3. Use of Improved Information Technology and Burden Reduction

Enhanced drug distribution security requires interoperable, electronic tracing of product at the package level. This includes elements such as electronic exchange of transaction information, systems and processes for verification, responding to requests from FDA, facilitating the gathering of information necessary to produce the transaction information, and systems to process saleable returns. Our Center for Drug Evaluation and Research has developed the DSCSA Portal, available on our CDER NextGen website at https://cdernextgenportal.fda.gov/Login_CDER?ec=302&startURL=%2Fs%2F, to communicate with respondents and facilitate the exchange information in compliance with section 582 requirements. As our limited resources allow, we intend to deploy system enhancements to increase the utility of the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. In 2018, we initiated a pilot project, consistent with section 582(j) of the FD&C Act (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 established this information collection to capture standardized transaction information and to account for associated recordkeeping.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with applicable statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

No special circumstances are associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

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.

Additionally, we maintain a webpage 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. we communicate through and make available on our website information regarding DSCSA implementation, including announcements of public meetings, agency guidance documents, and relevant regulatory resource information.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts to respondents are associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii) and agency regulations in 21 CFR § 20.20, data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally

identifiable information (PII), it is collected in the context of the subject individuals’ professional capacity and the FDA-related performed for their employer (e.g., point of contact at a regulated entity). The PII is submitted via **Form FDA 3911** (“Drug Notification”). The PII submitted via Form FDA 3911 is the individual’s name, e-mail address, and telephone number. Through appropriate form and design, FDA limited submission fields and minimized the PII collected to protect the privacy of individuals. We have determined that the PII collected is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA do not use name or any other personal identifier to routinely retrieve records from the information collected.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no sensitive questions associated with this information collection.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

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).

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Section 582(b) through (e) FFDC (21 USC360eee-1(b) through (e)); Information Collection	No. of Respondents	No. 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			0		0

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 waiver, exception, or exemption 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	No. of Respondents	No. of Records per Respondent	Total Annual Records	Average Burden per Record (in hours)	Total Hours
Documenting transaction (T3) information	70,000	1M	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			0 ~74.4 B		0

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 (21 U.S.C. 360eee-1(b)-(e)) to be usual and customary for respondents to the information collection.

As reflected in table 2, the provisions in sections 582(b) through (e) 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. Each category of respondent (manufacturer, distributor, 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 transaction¹ 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

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

will develop the required systems and processes centrally at its headquarters or at its distribution centers and then distribute to each pharmacy.

12b. Annualized Cost Estimate

Assuming an average wage rate of \$120 per hour (using the Bureau of Labor Statistics data for positions ranging from pharmacists to distributors) and multiplying that figure by the annual burden hours we calculate an estimated cost to respondents of \$292,376,400 (7,050+2,429,420 =2,436,470).

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

Estimated Annual Operating and Maintenance (O&M) Costs Associated with the Enhanced Security and Product Identifier Requirements

Category of Respondent	Number of Respondents	Total O&M per Respondent (\$)	Total O&M Cost
Manufacturers and Repackagers	1,400	70k	98M
Wholesale Distributors	1,600	86k	137M
Dispensers:			
Chain Pharmacies	40,000	2,000	80M
Other Pharmacies	27,000	500	13.5M
Dispenser Subtotal			93.5M
TOTAL O&M Cost			328.5M

14. Annualized Cost to the Federal Government

Based on current information received by FDA under these DSCSA provisions and considering efficiencies FDA observes with other electronic systems, FDA estimates that FDA will spend a total of approximately 22 hours annually reviewing the information submitted to the agency under this collection. Assuming 2025 wage rates for a CDER employee in the Washington, DC area, we estimate an annual cost to the Federal Government of approximately \$3,800.

15. Explanation for Program Changes or Adjustments

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 in response to public comment and as discussed at Q-12, above. We also note significant ongoing recordkeeping attributable to documenting activities along the supply chain that we regard as usual and customary in complying with the self-executing requirements of Drug Supply Chain Security Act set forth in sections 581 and 581 (*Subchapter H – Pharmaceutical Distribution Supply Chain*) of the FD&C Act.

16. Plans for Tabulation and Publication and Project Time Schedule

No plans for tabulation and publication and project time scheduling are associated with this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number and its expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification in 5 CFR 1320.9.