FOOD & DRUG ADMINISTRATION

Drug Supply Chain Security Act Implementation

OMB Control No. 0910-0806 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of provisions in section 581 and 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 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 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 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.

We therefore request OMB approval of the information collection provisions found in 21 U.S.C. 360eee-1 regarding notifications of illegitimate product and product with a high risk of illegitimacy as discussed in the referenced agency guidance documents.

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.

We use the information to evaluate the likelihood that illegitimate products or products with a high risk of illegitimacy may be widely disseminated in the U.S. supply chain so that mitigation of public health risks can be expeditiously administered. Notifying FDA and trading partners that could possess the illegitimate product (or product with a high risk of illegitimacy) allows stakeholders to work collaboratively to remove potentially dangerous product from the supply chain and alert consumers about the product, if necessary.

3. Use of Improved Information Technology and Burden Reduction

We developed Form FDA 3911 as an efficient way to standardize and collect the information that we need from the various trading partners about an illegitimate product or product with a high risk of illegitimacy. It is a fillable form that simplifies the process and provides for more efficient notification by trading partners.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collections.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We believe that the recordkeeping discussed in the guidance documents is usual and customary for respondents and explain our assumptions more fully in *Question 12* below.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory 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 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. = Although our 60-day notice discussed both draft and final topic-specific guidance documents pertaining to statutory requirements found in section 582 of the FD&C Act, we explained in our 30-day notice of January 11, 2022 (87 FR 1419) that 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, and consistent with regulations found in 21 CFR 10.115, guidance documents are intended to communicate our thinking on a particular topic and can therefore be helpful to respondents in understanding related information collection activities.

To clarify however, we explained that 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 and upon consideration we revised our estimate upward to reflect additional burden as reflected in *Question 12*, below.

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

The submitted information will be handled according to Agency regulations, the Freedom of Information Act, and other applicable disclosure law. Confidentiality of the information submitted under these requirements is protected under 21 CFR part 20. The unauthorized use or disclosure of trade secrets is specifically prohibited under section 310(j) of the FD&C Act.

FDA will not disclose any information considered as a trade secret and prohibited under section 310(j) of the FD&C Act if such information is included in the notification to FDA.
FDA employees handle the information sent to FDA. We will maintain the electronic files according to FDA's document retention schedules and destroy files when no longer needed for administrative, legal, or audit purposes.

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

Table 1.--Estimated Annual Reporting Burden[1]

Sec. 582 FD&C Act; Information Collection Activity	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/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
Request renewals (Waivers Guidance, sec. III)	1	1	1	16	16
Total			14,622		114,932

Table 2.--Estimated Annual Disclosure Burden

Sec. 582 FD&C Act; Information Collection Activity	No. of Respondents	No. 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			310,000		1,860,000

As explained in our 30-day notice, we have reorganized the information collection by respondent activity and clarified where information collection elements are discussed in the respective referenced 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). 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.

12b. Annualized Cost Burden 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 $236,991,840 (114,932+1,860,000 = 1,974,932).

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

We estimate no capital, start-up, operating, or maintenance costs with this information collection.

14. Annualized Cost to the Federal Government

Consistent with cost analysis used with establishing this collection, FDA allocates 2 full time employees to review the collection. Using 2022 OPM salary rates for a GS-13/Step 5 employee in the Washington, DC area, we estimate an annual cost to the Federal Government of $242,130.

15. Explanation for Program Changes or Adjustments

As explained in *Question 12* above, we have reorganized the information collection and clarified its scope in response to public comment. We have also revised the guidance document Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, to finalizes remaining draft portions issued in December 2016. In particular, the June 2021 revision finalizes section III.C, issued for comment purposes in the December 2016. As a result of these changes and adjustments, our estimated burden for the information collection reflects a cumulative increase since last OMB review and approval of 265,390 responses and 1,962,846 hours annually. 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.

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

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 21 CFR 1320.8(b)(1)); however, because documents are more frequently being accessed electronically we are considering technological changes that will enable us to display the expiration date by linking to approval information found at www.reginfo.gov. We intend to include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current our website platform (Drupal).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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