United States Food and Drug Administration

Small Dispensers Assessment under the Drug Supply Chain Security Act

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

   This information collection supports the requirement under section 582(g)(3) of the Food Drug and Cosmetic Act (FD&C Act) for the Food and Drug Administration (FDA, us, or we) to enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees (FTEs) conducting interoperable, electronic tracing of products at the package level. Under enhanced drug distribution security requirements in section 582(g)(1), dispensers and other trading partners will be required to, among other requirements, exchange transaction information and transaction statements in a secure, interoperable, electronic manner for each package; implement systems and processes for package level verification, including the standardized numerical identifier; and implement systems and processes to facilitate gathering the information necessary to produce the transaction information and statement for each transaction going back to the manufacturer if FDA or a trading partner requests an investigation in the event of a recall or a suspect or illegitimate product. These enhanced drug distribution security requirements are also referred to as "enhanced product tracing," "enhanced verification," or "interoperable, electronic tracing of products at the package level." FDA's assessment entitled, "Small Dispensers Assessment under the Drug Supply Chain Security Act" (DSCSA Small Dispensers Assessment) is intended to fulfill the requirement for FDA to assess the feasibility of dispensers with 25 or fewer full-time employees (FTEs) conducting interoperable, electronic tracing of products at the package level.

   As described in section 582(g)(3)(C), issues to be addressed in the assessment questions are related to the accessibility of the necessary software and hardware to such dispensers; whether the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and if the necessary hardware and software can be integrated into business practices. Respondents will submit information by answering the assessment questions using a link provided on FDA's website. We have developed a web page to further assist industry regarding the DSCSA Small Dispensers Assessment, available at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers.

   We therefore request OMB approval of the proposed collection of information required by section 582(g)(3) of the FD&C Act, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The assessment is being planned to meet the requirement of section 582(g)(3) of the FD&C Act. The product tracing, product identification, and verification requirements of the DSCSA minimize the likelihood that potentially dangerous drug products will enter the distribution supply chain because they identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA requires the results of the assessment be considered to help FDA determine if alternative methods of compliance are necessary for small businesses or a process be established by which a dispenser may request a waiver from any of the requirements, in addition to other considerations.

FDA plans to use the data collected under this clearance to inform the Agency of the feasibility of dispensers with a total of 25 or fewer FTEs of conducting interoperable, electronic tracing of products at the package level. FDA will use the information gained from the assessment to determine if timelines for compliance by small businesses and a process for a dispenser to request a waiver of such requirements is needed.

3. Use of Improved Information Technology and Burden Reduction

Assessment respondents will include self-identified individuals representing dispensers with a total of 25 or fewer FTEs (small dispenser) and individuals representing small dispensers' third-party entities (e.g., solution providers, wholesale distributors, consultants). After the DSCSA Small Dispensers Assessment is launched, individuals representing small dispensers interested in participating will electronically submit their responses to the assessment questionnaire using a link provided on the following webpage, https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The main goal of this assessment is to measure the feasibility of small dispensers (described as having 25 or fewer FTEs in section 582(g) of the FD&C Act) conducting interoperable, electronic tracing of products at the package level. The assessment itself is a one-time assessment and should not have a significant impact on small businesses. The results of the assessment may have some impact on small business such that, as noted, FDA will use the information gained from the assessment to determine if timelines for compliance by small businesses and a process for a dispenser to request a waiver of such requirements is needed. We provide information on small business assistance on the FDA website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection of information as required by the DSCSA in section 582(g)(3) of the FD&C Act. Failure to conduct the assessment and collect the necessary information would result in missing the opportunity to assess the feasibility of small dispensers conducting interoperable, electronic tracing of products at the package level. The information collection schedule is consistent with statutory requirements.

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

There are no special circumstances for the collection of information.

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

In the *Federal Register* March 13, 2024 (89 FR 18415), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comment letters from pharmaceutical trade associations.

(Comment) Both comment letters expressed concern that the information collection burden estimates provided in the notice reflected a decision that our sample size would be limited to 200. One comment letter estimated that a sample size of 200 would only represent roughly 1% of the independent pharmacies in the United States. This comment argued that a 1% sample size would not allow FDA to adequately assess the cost and burdens on small dispensers or determine alternative methods of compliance that would not impose economic hardship on small businesses.

(Response) The estimate of 200 respondents provided in our 60-day notice represented our best estimate at that time regarding how many respondents would complete the assessment questionnaire. We have revised our information collection burden estimates by, among other things, increasing the estimated number of respondents who will be sent an invitation to 18,430 and increasing the estimated number of respondents who will complete the assessment questionnaire to 922, as described in section12. The revised information collection burden estimates reflect the interest we have received regarding the DSCSA Small Dispensers Assessment. We also note that the intent of the proposed information collection is to understand the experiences of small dispensers. We expect this qualitative research to develop descriptions of themes of those experiences. For the qualitative open-ended questions, past research indicates that themes reach saturation within dozens of respondents. For the proportional, multiple-choice questions, the results will not be analyzed using metrics of statistical confidence and margins of error.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

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This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted includes point of contact name, work email address, and work phone number. FDA determined that although PII is collected, the collection 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 does not use names or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under the Freedom of Information Act (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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Description of Respondents: Respondents to this information collection are pharmacists and pharmacy technicians. Pharmacists are health-care professionals licensed to engage in pharmacy with duties including dispensing prescription drugs, monitoring drug interactions, administering vaccines, and counseling patients regarding the effects and proper usage of drugs and dietary supplements. Pharmacy technicians locate, dispense, pack, and label a prescribed medication for a patient that is then reviewed for accuracy by a pharmacist before dispensed to the patient.

FDA estimates the burden of this collection of information as follows:

Reporting Burden

Table 1.--Estimated One-time Reporting Burden[1]

DSCSA Small Dispensers Assessment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[2]
Invitation email	18,430	1	18,430	0.1	1,843
Screener	9,215	1	9,215	0.1	922
Assessment questions response	922	1	922	2	1,844
Total			0		0

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

information.
[2] Totals have been rounded to the nearest whole number.

We plan to invite small dispensers to participate in the assessment by sending an email invitation (Attachment A). We estimate that we will send 18,430 emails to companies that are on our existing industry stakeholder list. We assume that all emails we send will be opened and reviewed and estimate that it will take 0.1 hour (6 minutes) to read the email invitation and decide how to respond to it, for a total of 1,843 hours. We assume that fifty percent of the companies invited to participate, or 9,215 companies, will decide to participate, navigate to our webpage, and click on the link to the assessment to access it. Once the company accesses the assessment, it will be presented with a two-part screening question (Attachment B). We estimate that all companies will answer the screening question and that it will take 0.1 hour (6 minutes) to read and answer the screening question, for a total of 921.5 hours, rounded to 922 hours. We estimate that only ten percent of those companies, or 921.5 respondents, rounded to 922 respondents, will complete the entire questionnaire (Attachment C). We estimate that it will take, based on the various levels of availability and resources by company, approximately 2 hours on average to compile the necessary information and to respond to all of the questions in the assessment questionnaire, for a total of 1,844 hours. The total estimated reporting burden is 4,609 hours (table 1).

Recordkeeping Burden

Table 2.--Estimated One-time Recordkeeping Burden[1]

DSCSA Small Dispenser Assessment	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records related to assessment questions response	922	1	922	0.5	461

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

We expect that companies will compile information needed to respond to the questions in the assessment questionnaire and that they will keep copies of that information in their records either electronically or on paper. We recommend that companies retain these records for at least a year after the assessment is completed. We estimate that these recordkeeping activities will take approximately 0.5 hour per company, for a total of 461 hours.

Third-Party Disclosure Burden

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

DSCSA Small Dispensers Assessment	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[2]
Coordination with third-party entities related to screener questions	692	2	1,384	0.1	138
Coordination with third-party entities related to assessment questions response	461	2	922	2	1,844
Total			2,306		1,982

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

FDA is taking into consideration the time that respondents will spend coordinating with third-party entities (e.g., solution providers, wholesale distributors, consultants). For the screener questions, FDA estimates that seventy-five percent of the 922 respondents, or 691.5 respondents, rounded to 692, will work with their respective partnering entities and the average number of partnering entities will be 2, for a total of 1,384 disclosures. FDA estimates that each disclosure will take approximately 0.1 hours (6 minutes) for a total of 138.4 hours, rounded to 138 hours. For the assessment questionnaire response, FDA estimates that fifty percent of the 922 respondents, or 461 respondents, will coordinate with a total of two partners for a total of 922 disclosures. We estimate it will take approximately 2 hours to coordinate with each partner, resulting in a total of 1,844 hours. The total estimated third-party disclosure burden is 1,982 hours (table 3).

The estimated burden for this information collection request changed after we published the 60-day notice. We adjusted our estimated burden for the information collection to reflect the interest we have received regarding the DSCSA Small Dispensers Assessment. These adjustments resulted in an increase of 30,945 total annual responses and a corresponding increase of 6,327 total hours.

12b. Annualized Cost Burden Estimate

For healthcare professionals, responses to the assessment would likely be completed during business hours as part of the duties assigned. The estimated annualized reporting costs to respondents (pharmacists and/or the designated representative in this information collection for 4,609 hours is $375,956.13. According to the U.S. Department of Labor, Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for the United States (located at https://www.bls.gov/oes/current/oes_nat.htm), the average industry wage rate is $62.22 per hour for pharmacists and $19.35 per hour for pharmacy technicians. We have doubled this wage rate to account for benefits and overhead, yielding an hourly wage rate of $124.44 for pharmacists and $38.70 for pharmacy technicians.

Assuming that all of the estimated 922 assessment questionnaires are completed, we estimate a total of 4,609 reporting hours. Dividing that time equally between pharmacists and pharmacy technicians, we estimate the one-time cost burden as shown in the table below.

Table 4.--Estimated One-time Cost Burden

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Pharmacists	2,304.5	$124.44	$286,771.98
Pharmacy technicians	2,304.5	$38.70	$89,184.15
	4,609		$375,956.13

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

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Assuming a cost of $336,269 per one full-time equivalent (FTE) (salary plus overhead, full-time 40-hour week) divided by the total number of hours worked (2,080 hours) per year, the fully loaded wage rate is $162 per hour. Three FTEs may devote 25% (1,560 hours) of their time preparing, reviewing, and monitoring resulting in $252,720 (1,560 hours x $162/hour) spent annually. There is also an annual cap of $360,000 in contractor costs. Therefore, we estimate the annual cost to the Federal Government to be $612,720.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Techniques will include both qualitative and quantitative analyses for the results of the assessment. In cases where quantitative data is collected, descriptive statistics - including percentages, cross tabulations, and averages - may be calculated and included in the final report.

The assessment link will be open for data collection for 45 days. Once the assessment's data collection ends, the contractor will provide the final report within 3 weeks. FDA will publish the final assessment for public comment and hold a public meeting no later than 180 calendar days after receiving the final assessment where stakeholders will have the opportunity to present their views on the assessment, as required by section 582(g)(3).

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

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

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18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.