Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
General Testimony	54	5,686	0.33	101,325
Declaration in Support of Establishing Parentage	54	2,132	0.15	17,269
Child Support Locate Request	54	142	0.05	383
Notice of Determination of Controlling Order	54	1	0.25	14
Letter of Transmittal Requesting Registration (English and Spanish)	54	8,529	0.08	36,845
Personal Information Form for UIFSA § 311	54	5,686	0.05	15,352
Child Support Agency Confidential Information Form	54	17,059	0.05	46,059
Request for Change of Support Payment Location Pursuant to UIFSA 319(b)	54	71	0.05	192
Estimated Total Annual Burden Hours				456,947

Authority: 45 CFR 303.7.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–20638 Filed 11–20–25; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0668]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Small Dispensers Assessment Under the Drug Supply Chain Security Act

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.

DATES: Submit written comments (including recommendations) on the collection of information by December 22, 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 title of this information collection is ''Small Dispensers Assessment Under the Drug Supply Chain Security Act.'' 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.

Small Dispensers Assessment Under the Drug Supply Chain Security Act

OMB Control Number 0910–NEW

I. Information Collection Authority

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. The DSCSA outlines steps to achieve interoperable, electronic tracing of products at the package level [1] to identify and trace certain prescription drugs as they are distributed in the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee-1).

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 or enhanced verification.''

We have developed a web page to provide more information to industry regarding the DSCSA. It is available at *https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.*

Under section 582(g)(3), FDA is required 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. FDA's proposed study entitled, ''Small Dispensers Assessment under the Drug Supply Chain Security Act'' (DSCSA Small Dispensers Assessment) is intended to fulfill this requirement.

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.

II. DSCSA Small Dispensers Assessment

A. Eligibility Requirements

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-

[1] As defined by section 581(11) of the FD&C Act, generally, the term ''package'' means the smallest individual saleable unit or smallest container of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

party entities (*e.g.,* solution providers, wholesale distributors, consultants).

B. Potential Issues To Examine and Evaluation Methods

The DSCSA Small Dispensers Assessment will look at the feasibility of dispensers with a total of 25 or fewer FTEs of conducting interoperable, electronic tracing of products at the package level. As part of the qualitative data analysis, respondents will submit information by answering specific questions for the assessment. Evaluation methods and analyses are expected to include qualitative analyses (for example, content analysis for responses), and quantitative analyses using descriptive statistics. In cases where quantitative data are collected, descriptive statistics—including percentages and tabulations—will be calculated and presented, along with demographic descriptions of respondents. For example, quantitative analysis could include percentages or tabulations of small dispensers with access to the necessary software and hardware to meet the requirements in section 582(g)(1) of the FD&C Act. 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.*

C. Instructions for Accessing the DSCSA Small Dispensers Assessment

After the DSCSA Small Dispensers Assessment is launched, individuals representing small dispensers interested in participating will use a link provided on the following web page, *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers.* After accessing the link, the respondent will confirm they are eligible to participate by attesting to being a small dispenser, or an entity representing a small dispenser, before being able to start the questionnaire.

D. Participation

Once the assessment link is made available on FDA's website, respondents will have 45 days to access the link and complete the assessment questionnaire. Respondents will be expected to provide responses to FDA via the assessment link.

E. Recordkeeping

FDA recommends that any records generated by a respondent while responding to the assessment questionnaire be maintained as an entity would in the normal course of business. FDA recommends that the responses to the assessment questionnaire be maintained by the respondent for at least 1 year after FDA publishes its final report of the assessment.

G. Initiation of FDA's DSCSA Small Dispensers Assessment

FDA intends to begin the DSCSA Small Dispensers Assessment upon OMB approval of the proposed collection of information.

III. Burden Estimates

In the **Federal Register** of 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. We have adjusted our estimated burden for the information collection to reflect the public comments, discussed below. These adjustments result in an increase of 30,945 total annual responses and a corresponding increase of 6,327 total hours from the estimates found in our 60-day notice.

(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. In this notice, 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 section III of this notice. The revised information collection burden estimates in this notice 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.

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

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]

DSCSA small dispensers assessment	Number of respondents	Number 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	.....	.....	28,567	.....	4,609

[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. 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 web page, 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. 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. 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.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

DSCSA small dispenser assessment	Number of recordkeepers	Number 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.

TABLE 3—ESTIMATED ONE-TIME THIRD-PARTY DISCLOSURE BURDEN [1]

DSCSA small dispensers assessment	Number of respondents	Number 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.

We have taken into consideration the time that respondents will spend coordinating with third-party entities (*e.g.,* solution providers, wholesale distributors, consultants). For the screener questions, we assume 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. We estimate 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, we assume 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 2 hours to coordinate with each partner, resulting in a total of 1,844 hours.

Lowell M. Zeta,

Deputy Commissioner of Strategic Initiatives, Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20643 Filed 11–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0008]

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice—Establishment of Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). This meeting was previously announced in the **Federal Register** of September 3, 2025. The amendment is being made to reflect changes in the **DATES**, **ADDRESSES** and **SUPPLEMENTARY INFORMATION** portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, Rm. 2404, Silver Spring, MD 20993–0002, *Evella.Washington@fda.hhs.gov,* 240–447–9160.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 3, 2025 (90 FR 42588), FDA announced that a meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee would be held on October 8, 2025. On page 42588, in the third column, ''The meeting will be held virtually on October 8, 2025, from 9 a.m. to 3:30