Estimated Program Burden: ACL estimates the annual burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Area Agency on Aging: Respondent selection process	300	1	4.0	1,200
Service recipients (*i.e.,* Congregate and Home-Delivered Meal nutrition programs, Case Management, Homemaker, Transportation services) + Rotating Module	4,000	1	0.75	3,000
National Family Caregiver Support Program clients + Rotating Module	2,000	1	0.75	1,500
Total	6,300	1	*0.90	5,700

*Weighted mean.

Dated: March 7, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–05310 Filed 3–12–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0668]

Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Proposed Small Dispensers Assessment under the Drug Supply Chain Security Act (DSCSA).

DATES: Either electronic or written comments on the collection of information must be submitted by May 13, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0668 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Small Dispensers Assessment under the Drug Supply Chain Security Act (DSCSA).'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Proposed Small Dispensers Assessment Under the Drug Supply Chain Security Act

OMB Control Number 0910–NEW

I. Background

On November 27, 2013, the 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 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.

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. 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.''

[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.

II. Proposed DSCSA Small Dispensers Assessment

A. Eligibility Requirements

Assessment participants 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).

B. Potential Issues To Examine and Evaluation Methods

The proposed 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 proposed 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. Proposed Instructions for Enrollment for the Proposed DSCSA Small Dispensers Assessment

After the proposed DSCSA Small Dispensers Assessment is established, volunteers interested in participating will enroll by submitting participant information using a link to be provided on the same web page mentioned above, *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers.* Only one point-of-contact per company should be provided for the enrollment.

D. Proposed Content of the Enrollment for the Proposed DSCSA Small Dispensers Assessment

The following information should be included:

- Contact information (name, email address, phone number, mailing address)
- Confirm you are a dispenser that has 25 or fewer FTEs or you are an individual representing a small dispensers' third-party entity (*e.g.,* solution providers, wholesale distributors, consultants)
- Commitment to answer the questions contained in the assessment within 45 days of receiving
- Applicable state license number

E. Participation

Assessment participants will include those who have met eligibility requirements and completed enrollment. The assessment is expected to be completed within the proposed duration of 45 days of receiving, and participants will be expected to provide responses to FDA via the designated FDA online tool/platform.

F. Proposed Recordkeeping

Any records generated by a participant in the assessment should be maintained as an entity would in a normal course of business. FDA recommends that the responses that participants create and submit to FDA for the assessment be maintained for at least 1 year after FDA publishes its final report of the assessment.

G. Initiation of FDA's Proposed DSCSA Small Dispensers Assessment

FDA does not intend to begin the proposed DSCSA Small Dispensers Assessment or accept enrollment to participate in the assessment until OMB has approved the proposed collection of information described in this notice.

FDA estimates the burden of this one-time collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

DSCSA small dispensers assessment	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Enrollment	200	1	200	0.5	100
Assessment Questions Response	100	1	100	2	200
Total	300				300

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

Submitting an enrollment and reporting activities. FDA estimates that no more than 200 respondents (*i.e.,* the submitter or point of contact) will submit an enrollment, and that it will take, based on the various levels of resources by company, an average of 0.5 hours to complete an enrollment to FDA. FDA estimates that it will receive no more than 100 participants for the assessment. The estimated total time for respondents to submit an enrollment to participate in the assessment is 100 hours. FDA estimates that it will take, based on the various levels of resources by company, an average of 2 hours to compile and submit a response to the assessment. The estimated total number of hours for submitting a response to the assessment would be 200 hours. The total hours for the estimated reporting burden are 300 hours (table 1).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

DSCSA small dispensers assessment	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records related to enrollment	200	1	200	0.5	100
Records related to Assessment Questions Response	100	1	100	0.5	50
Total	300				150

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

Recordkeeping activities. Recordkeeping activities include storing and maintaining records related to submitting to enroll to participate in the assessment and compiling reports. Respondents can use current record retention capabilities for electronic or paper storage to achieve these activities. FDA estimates that no more than 200 respondents will have recordkeeping activities related to assessment participation. FDA believes that it will take 0.5 hour to ensure that the documents related to enrollment to participate in the assessment are retained properly for a minimum of 1 year after the assessment is completed (as recommended by FDA). The resulting total to maintain the records related to submitting a request is 100 hours annually.

For retaining records related to the response to the assessment properly for a minimum of 1 year after the assessment is completed (as recommended by FDA), FDA estimates that it will take approximately 0.5 hour. As noted above, FDA estimates that the 100 respondents will submit one response for the assessment. The estimated total for maintaining records related to the assessment is 50 hours respectively. The total recordkeeping burden is estimated to be 150 hours (table 2).

TABLE 3—ESTIMATED ANNUAL 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
Coordination with third-party entities related to enrollment	75	2	150	0.5	75
Coordination with third-party entities related to assessment questions response	50	2	100	2	200
Total	125				275

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

Third-party disclosure activities. For those assessment participants that involve third-party activities, FDA is taking into consideration the time that participants will spend coordinating with third-party entities (*e.g.,* solution providers, wholesale distributors, consultants). For the enrollment, FDA estimates that 75 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. FDA estimates that each respondent will spend 2 hours coordinating with each third-party entity. Thus, for 150 respondents with an average of 2 partnering entities, the estimated total burden for coordinating with partnering entities related to the enrollment is 75 hours. FDA estimates that for each of the 100 lists of assessment responses, it will take approximately 2 hours to coordinate with each partner, resulting in a total of 200 hours. The total estimation for third-party disclosure burden is 275 hours (table 3).

Dated: March 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05294 Filed 3–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5616]

Annual Reportable Labeling Changes for New Drug Applications and Abbreviated New Drug Applications for Nonprescription Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' This draft guidance provides recommendations to applicants of approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for nonprescription drug products on documenting minor labeling changes in the next annual report and provides examples of minor labeling changes that may be submitted in an annual report. The recommendations in this draft guidance address the types of minor labeling changes that may be appropriate to submit in an annual report to ensure that consumers have timely access to the most current labeling for a nonprescription drug product to ensure the product's safe and effective use. We anticipate that these recommendations may assist industry in understanding the circumstances in which it would be appropriate to document minor changes in the applicant's next annual report rather than submitting a prior approval supplement or ''changes being effected'' supplement, thereby reducing burden on industry and FDA.

DATES: Submit either electronic or written comments on the draft guidance by May 13, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–5616 for ''Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including