FOOD AND DRUG ADMINISTRATION

Pilot Project Program
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

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 critical steps to build an electronic, interoperable system by November 27, 2023 that will identify and trace certain prescription drugs as they are distributed within 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(j) of the FD&C Act, FDA is required to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

2. Purpose and Use of the Information Collection

The DSCSA Pilot Project Program will assist the development of the interoperable electronic system established by 2023. The program goals include assessing the ability of supply chain members to: satisfy the requirements of section 582 of the FD&C Act; identify, manage, and prevent the distribution of suspect and illegitimate products as defined in sections 581(21) and 581(8) of the FD&C Act, respectively; and demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain, in addition to identifying the system attributes needed to implement the requirements of section 582 of the FD&C Act, particularly the requirement to utilize a product identifier for product tracing purposes. FDA plans to coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors.

FDA will be seeking pilot project participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA; however, FDA intends to meet with all pilot project participants to ensure the learnings from the pilot project(s) will be complementary in informing the direction of the development of the electronic, interoperable system that will go into effect in 2023. FDA encourages supply chain members to focus their proposed pilot project (s) on the DSCSA requirements related to the interoperable, electronic tracing of products at the *package level*. Specifically, the pilot project(s) should focus on the requirements for package-level tracing and verification that go into effect in 2023. If there are adequate pilot project submissions, FDA may establish more than one pilot project to accomplish the goals of the DSCSA Pilot Project Program.

3. Use of Improved Information Technology and Burden Reduction

Applicants and participants may electronically submit information to the FDA. Once the DSCSA Pilot Project Program is established, volunteers interested in participating in the DSCSA Pilot Project Program will be able to submit a request to participate by email to DSCSAPilotProjects@fda.hhs.gov.

During the applications process, volunteers will provide the following information:

- Contact information (name of point of contact, mailing address, phone number, email address)
- Names of all partnering entities that would participate in such pilot project
- Type(s) of trading partner(s) or supply chain stakeholder(s) participating in the pilot project, such as "manufacturer" or "wholesale distributor"
- Number of employees for each partnering entity of a pilot project
- Expected duration of the pilot project and commitment to start date
- Product(s) that will be used in the pilot project
- Location(s) of where pilot project will be performed
- Description of the proposed pilot project, including, but not limited to, the goals, objectives, processes that will be studied, and evaluation methods

For a group of entities that partner to participate in a pilot project, only one point-of-contact for the proposed pilot project should be provided in the request to participate.

Pilot project participants will also be expected to submit reports on the progress of their pilot projects to FDA. FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. In addition, within thirty business days of completing a pilot project, participants will provide a final report to FDA that captures the description, objectives, methods, evaluation, and key findings and lessons learned from the project. Progress reports and the final report may be submitted electronically by email.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA does not believe that duplication of submitted information is likely in the Pilot Project Program based on the goals of the program. If there are multiple pilot projects conducted, progress reports and final reports will be unique to the corresponding pilot project performed by different groups of industry stakeholders.

5. Impact on Small Businesses or Other Small Entities

As required, FDA plans to coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. The partners in any pilot project that is selected into the program will be responsible for the funding and resources necessary to conduct the pilot project.

6. Consequences of Collecting the Information Less Frequently

FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. Progress reports should be sufficient to capture details, procedures, or findings that may be key learnings for FDA and other stakeholders. Less frequent progress reports may not sufficiently capture this information.

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

There are no special circumstances relating to this information collection. (The submission of proprietary, trade secret, or other confidential information is addressed under section 10 below).

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

In the July 20, 2017 Federal Register notice (82 FR 33497), FDA requested public comment on the proposed collection of information associated with the DSCSA Pilot Project Program. A summary of the comments and FDA's responses are as follows:

The comments raised concerns with the proposed timelines related to: initiation of pilot project, duration of pilot projects, and final reports. One commenter expressed concern that 4 months (after receiving a letter of acceptance from FDA) may not be enough time for a potential participant to be ready to initiate their pilot project. Another comment suggested that the proposed duration of pilot projects (no more than 6 months) should be longer and give the participant(s) more flexibility to conduct the pilot project. In addition, another comment described concern with the proposed requirement that final reports be completed within 30 days because that may not be enough time to complete a final report.

FDA response: The proposed timelines were intended to enable completion of FDA's pilot project program within one year of the start date. FDA would like to complete the program in a timely manner so that the information learned can be shared and utilized by supply chain participants as they prepare and implement remaining DSCSA requirements that go into effect between 2018 to 2023. To optimize the program, FDA expects pilot project participants to be ready to initiate their pilot project within 4 months after receiving a letter of acceptance from FDA. This will help ensure that participants have worked out funding, resources, planning, and other issues in advance of initiation of the pilot project. FDA provided flexibility in the program to allow the agency to consider pilot projects that may go beyond a 6-month period; however, a pilot project duration of 6 months or less is preferred.

Another comment requested clarification of the proposed process for selecting participants. The comment described concern that FDA's pilot project program may include only those entities that are most engaged in DSCSA implementation currently. The comment also described concern that the findings and results may not accurately reflect the current environment because the program may not include supply chain members with fewer resources, less sophisticated compliance methods, or not as closely connected as other trading partners.

FDA response: Participation in the pilot project program is open to anyone in the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA plans to coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA, which may include coordination with partnering entities in a manner that may resolve some of the concerns that the findings and results may not accurately reflect the current environment of supply chain members that may have fewer resources or less sophisticated compliance methods.

Another comment did not support FDA considering products for eligibility in proposed pilot projects that may be outside the scope of "product" as defined in DSCSA, such as over-the-counter medications. The comment suggested that if FDA is expanding the scope of pilot projects to include additional products, then the timeline for pilot projects would need to be delayed beyond 2023 to allow sufficient time for supply chain participants to adjust to the needs of these expanded pilots.

FDA response: The proposed consideration for product eligibility in pilot project program for items that may be outside the scope of "product" as defined in DSCSA was included to provide flexibility to potential participant that may choose to test a process or system involving product outside the scope of "product" as defined by DSCSA. This is not a requirement; however, there may be an opportunity to learn from such pilot projects. This consideration does not justify a need to delay the timeline for the pilot projects beyond 2023. It will be up to the participants to propose the design and execution of their pilot project in their submission to FDA. FDA will consider multiple factors to ensure that the pilot project(s) selected for the program will support the program goals.

Another comment believed that having pilot participants fund their pilot projects would conflict with the need to include a diverse set of supply chain stakeholders because some supply chain stakeholders do not have the resources to participate in a pilot project.

FDA response: There is no FDA funding for the pilot project program provided in the DSCSA and participation is on a volunteer basis. FDA plans to coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. FDA expects participants to be responsible for funding and resources for the pilot project. Participants will develop and propose the design and execution of their pilot project in their submission to FDA, which may include coordination with partnering entities in a manner that may resolve resource concerns.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents associated with this announcement.

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 that is considered to be a trade secret and prohibited under section 310(j) of the FD&C Act if such information is included in the notification to FDA.

The information submitted to FDA are handled by FDA employees. The electronic files will be maintained according to FDA document retention schedules and destroyed when no longer needed for administrative, legal, or audit purposes.

11. Justification for Sensitive Questions

There are no sensitive questions associated with this announcement.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

The information collection associated with the DSCSA Pilot Project Program consists of the following:

Reporting Burden Estimates: FDA estimates that no more than 10 respondents will submit a request to participate, and that it will take approximately 80 hours to complete a request and submit the request to FDA. FDA estimates that it will select no more than eight respondents for the pilot project program. The estimated total time for respondents to submit a request to participate in the program is 800 hours. Once the request to participate is accepted, the submitter is now a participant of the DSCSA Pilot Project Program. FDA estimates that the eight respondents (i.e., participants) will submit an average of five progress reports to FDA. Because the duration of a pilot project should not exceed 6 months, the frequency of the progress reports will vary based on the length of the individual pilot project. Pilot projects of relatively shorter duration may result in shorter time intervals between progress reports so that the reports will be sufficient to capture progress while the pilot project is ongoing. FDA estimates that it will take approximately 8 hours to compile and submit each progress report. The estimated total number of hours for submitting progress reports would be 320 hours. After completion of their pilot project, each participant will provide one final report to FDA. FDA estimates that it will take the 8 participants approximately 40 hours to submit a final report. The estimated total number of hours for submitting the final report is 320 hours. The total hours for the estimated reporting burden are 1440 hours (table 1).

Recordkeeping Burden Estimates: Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the program 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 10 respondents will have

recordkeeping activities related to program participation. FDA believes that it will take 0.5 hour/year to ensure that the documents related to submitting a request to participate in the program are retained properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA). The resulting total to maintain the records related to submitting a request is 5 hours annually. For retaining records related to progress reports and the final report properly for a minimum of 1 year after the pilot project is completed (as recommended by FDA), FDA estimates that it will take approximately 0.5 hour/year. As noted previously, FDA estimates that the eight respondents will submit an average of five progress reports and one final report to FDA. The estimated total for maintaining progress reports and the final report is 20 and 4 hours, respectively. The total recordkeeping burden is estimated to be 29 hours (table 2).

In developing its burden estimate for records associated with the proposed pilot projects, FDA has taken account of existing industry practices for keeping records in the normal course of their business. In particular, FDA is aware of various supply chain stakeholders that have conducted pilot projects over the past few years, including some pilot projects that occurred before the DSCSA was enacted. These pilot projects covered topics related to serialization, movement of product data, aggregation of data, and verification of product identifiers of returned products. Members of the supply chain who conduct pilot projects of their own accord created associated records as a matter of usual and customary business practice. Therefore, FDA considers these activities associated with a pilot project to be usual and customary business practice, and the burden estimates for like records are not included in the calculation of the recordkeeping burden (see 5 CFR 1320.3(b)(2)).

Third-Party Disclosure Burden Estimates: For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. For the initial request to participate, FDA estimates that eight respondents will work with their respective partnering entities, and the average number of partnering entities will be two. FDA estimates that each respondent will spend 8 hours coordinating with each partnering entity. Thus, for eight respondents with an average of two partnering entities, the estimated total burden for coordinating with partnering entities related to the submission of the request to participate in the program is 128 hours. FDA estimates that seven respondents will need to coordinate with an average of two partnering entities to create progress reports and the final report to submit to FDA. Earlier, FDA estimated that an average of five progress reports will be submitted to FDA per respondent. If a respondent has an average of 2 partners, it will coordinate 10 times with those partners on the progress reports. FDA estimates that for each progress report, it will take 4 hours to coordinate with each partner, resulting in a total of 280 hours. FDA estimates that for each final report, it will take approximately 20 hours to coordinate with each partner, resulting in a total of 280 hours. The total estimation for third-party disclosure burden is 688 hours (table 3).

Table 1--Estimated Reporting Burden[1]

DSCSA Pilot Project Program	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests to participate	10	1	10	80	800
Progress reports	8	5	40	8	320
Final report to FDA	8	1	8	40	320
Total					1440

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

Table 2--Estimated Annual Recordkeeping Burden[1]

DSCSA Pilot Project Program	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records related to requests to participate	10	1	10	0.5 (30 minutes)	5
Records related to progress reports	8	5	40	0.5 (30 mins)	20
Records related to the final report to FDA	8	1	8	0.5 (30 minutes)	4.0
Total					29

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

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

DSCSA Pilot Project Program	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Coordination with partnering entities related to requests to participate	8	2	16	8	128
Coordination with partnering entities related to progress reports	7	10	70	4	280
Coordination with partnering entities related to final reports	7	2	14	20	280
Total					688

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

12b. Annualized Cost Burden Estimate

The industry burden estimate calculated above would result in labor costs. FDA Economics Staff estimates that these types of notifications would likely be by a general operations manager for manufacturers, repackagers, and wholesale distributors, and a pharmacist for a dispenser. The adjusted mean hourly wage including benefits and overhead is $152.90 for manufacturers and repackagers, as reported by the U.S. Department of Labor, Bureau of Labor Statistics, 2016 Employment Occupational Statistics for Management Occupations in Pharmaceutical and Medicine Manufacturing (North American Industry Notification, NAICS, code 325400). The mean hourly wage including benefits and overhead for wholesale distributors is $142.12 according to the U.S. Department of Labor, Bureau of Labor Statistics, 2016 Employment Occupational Statistics for Management Occupations in Drug and Druggists Sundries Merchant Wholesalers (North American Industry Notification, NAICS, 424200). The mean hourly wage including benefits and overhead for a pharmacist is $115.44 as reported by the U.S. Department of Labor, Bureau of Labor Statistics, 2016 Employment Occupational Statistics for Management Occupations for Pharmacies and Drug Stores (North American Industry Notification, NAICS, code 446110). Using these wage rates, the total labor costs for the activities listed above for each group are in table 4 below. The total labor cost for this information collection equals approximately $306,408.39.

Table 4--Annualized Cost Burden Estimate

Trading Partner	**Activity**	**Estimated Hours**	**Hourly Rate**	**Cost**
Manufacturer/Repackager	Reporting	506.7	$152.90	$77,474.43
Manufacturer/Repackager	Recordkeeping	10.5	$152.90	$1,605.45
Manufacturer/Repackager	Third-Party Disclosure	229.3	$152.90	$35,059.97
Total Manufacturer/Repackager				**$114,139.85**
Wholesale Distributor	Reporting	506.7	$142.12	$72,012.20
Wholesale Distributor	Recordkeeping	10.5	$142.12	$1,492.26
Wholesale Distributor	Third-Party Disclosure	229.3	$142.12	$32,588.12
Total Wholesale Distributor				**$106,092.58**
Pharmacist	Reporting	506.7	$115.44	$58,493.45
Pharmacist	Recordkeeping	10.5	$115.44	$1,212.12
Pharmacist	Third-Party Disclosure	229.3	$115.44	$26,470.39
Total Pharmacist				**$86,175.96**
Total Stakeholder costs				**$306,408.39**

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

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

There are no capital, start-up, operating, or maintenance costs associated with this information collection. Under the DSCSA Pilot Project Program, manufacturers/repackagers, wholesale distributors, and pharmacies may utilize existing equipment and systems for pilot projects and may use similar types of systems or processes for communications (which may include but is not limited to sending an email, telephoning, mailing or faxing a letter).

14. Annualized Cost to the Federal Government

FDA expects that participants will propose the design and execution of their pilot project in their submission to FDA; however, FDA intends to meet with all pilot project participants to ensure the learnings from the pilot project(s) will be complementary in informing the direction of the development of the electronic, interoperable system that will go into effect in 2023. FDA will work with participants to develop an appropriate schedule for the submission of progress reports based on the design and duration of the pilot project. Participants will also provide a final report to FDA that captures the description, objectives, methods, evaluation, and key findings and lessons learned from the project. FDA will review all progress and final reports submitted by participants and publish the DSCSA Pilot Project Program final report.

The annualized government cost estimates are $360,250 as indicated in Table 5.

Table 5--Government Costs

Type of Activity	Est. No. Hours	Hourly Rate	Total Cost
FDA Program Management	600	$82.00	$49,200
FDA review of project proposals	100	$82.00	$8,200
FDA review of reports	200	$82.00	$16,400
FDA publish final report	200	$82.00	$16,400
Contract Cost for Project Management			$270,050
Total Costs			$360,250

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

Note: The hourly rate is determined by dividing the Agency's fully-loaded cost of $171,154 per FTE (for FY 2018) by the number of hours per FTE per year (2,080) to arrive at $82 per hour.

15. Explanation for Program Changes or Adjustments

This is a new data collection. Comments received on the proposed program were addressed and no changes were made to the proposed program and FDA's original burden estimates.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication and project time scheduling.

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

The OMB expiration date will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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