



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0407]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pilot Project Program Under the Drug Supply Chain Security Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to

oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Pilot Project Program 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, PRASStaff@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:

The DSCSA Pilot Project Program

OMB Control Number 0910-NEW

FDA will be establishing the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) Pilot Project Program to implement section 582(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1). This program will assist FDA in developing an interoperable, electronic system to identify and trace certain prescription drugs as the drugs are distributed in the United States by the year 2023. The Pilot Project Program goals include assessing the ability of supply chain members to: (1) satisfy the requirements of section 582 of the FD&C Act; (2) identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and (8) of the FD&C Act (21 U.S.C. 360eee(21) and (8)), respectively; and (3) 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.

Title: The DSCSA Pilot Project Program

Description of Respondents: Respondents of this collection of information are participants from the pharmaceutical distribution supply chain (authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders.

Background Information: 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 also intends to meet with all pilot project participants to ensure that lessons learned from the pilot project(s) will inform FDA's development of the electronic, interoperable system that will take 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 take effect in 2023. Such pilot projects will be more useful than pilot projects dedicated to lot-level tracing. 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.

Because there is an information collection under the PRA associated with the DSCSA Pilot Project Program, this *Federal Register* notice is being issued as part of the process for OMB approval to collect this information. After OMB approval of this information collection, FDA will accept applications to participate in the program and will select qualified applications. FDA will announce OMB's approval in the *Federal Register*, the date that applications may be submitted, and application submission procedures.

In the *Federal Register* of July 20, 2017 (82 FR 33497), FDA published a 60-day notice requesting public comment on the proposed collection of information. A summary of the comments and FDA's responses are as follows.

(Comment 1) Several comments raised concerns with the proposed timelines related to initiation of pilot projects, duration of pilot projects, and final reports. One comment 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 FDA should give the participant(s) more flexibility to conduct the pilot project. In addition, another comment expressed 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.

(Response 1) The proposed timelines were intended to enable completion of FDA's Pilot Project Program within 1 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 take effect between 2018 and 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 by allowing 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.

(Comment 2) Another comment requested clarification of the proposed process for selecting participants. The comment expressed 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 that are not as closely connected as other trading partners.

(Response 2) 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. Such coordination may help resolve some of the concern 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.

(Comment 3) Another comment did not support FDA considering products for eligibility in proposed pilot projects that may be outside the scope of the DSCSA definition of “product,” 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.

(Response 3) Allowing FDA to consider products eligible for the Pilot Project Program that may be outside the DSCSA definition of “product” was intended to provide flexibility to potential participants that may choose to test a process or system involving broader categories of products. Including products that are outside the DSCSA definition in pilot projects is not a requirement; however, we believe 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 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.

(Comment 4) 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.

(Response 4) 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 providing resources to support the pilot projects. 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.

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 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 eight 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 1,440 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 maintaining 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 during 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 8 respondents with an average of 2 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).

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

Table 1--Estimated Reporting Burden¹

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					1,440

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

Table 2--Estimated Annual Recordkeeping Burden¹

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 minutes)	20
Records related to the final report to FDA	8	1	8	0.5 (30 minutes)	4
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 Burden¹

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.

Dated: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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