4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pilot Project Program under the Drug Supply Chain Security Act; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the start of

the Pilot Project Program Under the Drug Supply Chain Security Act (DSCSA Pilot Project

Program). The DSCSA Pilot Project Program is intended to assist FDA and members of the

pharmaceutical distribution supply chain in the development of the electronic, interoperable

system that will identify and trace certain prescription drugs as they are distributed within the

United States. Under this program, FDA will work with stakeholders to establish one or more

pilot projects to explore and evaluate methods to enhance the safety and security of the

pharmaceutical distribution supply chain. Participation in the DSCSA Pilot Project Program is

voluntary and will be open to pharmaceutical distribution supply chain members to apply to the

program. FDA will ensure that participation reflects the diversity of the supply chain, including

large and small entities from all industry sectors. This notice establishes the DSCSA Pilot

Project Program and includes instructions for submitting a request to participate and expectations

for program participants.

DATES: FDA will be accepting applications for participation in the DSCSA Pilot Project

Program beginning [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and

continuing through [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. The duration of the DSCSA Pilot Project Program will depend on the pilot project(s) accepted into the program and when the projects are completed.

FOR FURTHER INFORMATION CONTACT: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, DSCSAPilotProjects@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I.   Background

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 sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee-1, respectively). 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.

FDA is establishing the DSCSA Pilot Project Program to implement section 582(j) of the FD&C Act. This program is intended to assist FDA and members of the pharmaceutical distribution supply chain in the development of the interoperable electronic system to be established by 2023. The 2023 system has the potential to reduce diversion of drugs distributed domestically as well as help deter counterfeit drugs from entering the supply chain. The pilot program will be designed to explore issues related to utilizing the product identifier for product

tracing, improving the technical capabilities of the supply chain, identifying the system attributes that are necessary to implement the requirements established under the DSCSA, and any other issues identified by FDA (see section 582(j)(2)(B) of the FD&C Act).

Particular program goals include: (1) 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 and verification purposes and (2) 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 section 581(21) and 581(8) of the FD&C Act, respectively, and exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner. FDA plans to coordinate with stakeholders to ensure that pilot projects reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors. The DSCSA Pilot Project Program is intended to help identify and evaluate the most efficient processes and/or systems to operationalize supply chain security requirements.

II.   The DSCSA Pilot Project Program

FDA is seeking pilot project participants from the pharmaceutical distribution supply chain (e.g., authorized manufacturers, repackagers, wholesale distributors, and dispensers) and other stakeholders. FDA expects potential participants to propose the design and execution of their pilot project in their submission to FDA; however, FDA intends to meet with selected pilot project participants to ensure that the learnings from the pilot project(s) will be complementary in informing all stakeholders in the development of the electronic, interoperable system that will go into effect in 2023. FDA encourages potential participants 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 enhanced requirements for package-level tracing and verification that go into effect in 2023. Such pilot projects will likely be more useful than pilot projects dedicated to lot-level tracing. If there is an adequate number of pilot project submissions, FDA may establish more than one pilot project to accomplish the goals of the DSCSA Pilot Project Program.

A. Products Eligibility

Pilot projects should focus on applicable requirements to any prescription drug that is a "product" within the meaning of section 581(13) of the FD&C Act. FDA anticipates that packages and homogenous cases of product that are part of a pilot project will generally bear a "product identifier" as described in sections 581(14) and 582(a)(9) of the FD&C Act. FDA may also consider proposed pilot projects involving product that may be subject to a waiver, exception or exemption of certain DSCSA requirements, products that are grandfathered, in addition to products that are outside the scope of section 581(13) of the FD&C Act (e.g., over-the-counter medicines) if such project(s) could further the objectives of the DSCSA Pilot Project Program.

B. Potential Issues to Examine and Evaluation Methods to Use in Pilot Projects

On April 5-6, 2016, FDA held a public workshop entitled "Proposed Pilot Project(s) Under the Drug Supply Chain Security Act (DSCSA)." This public workshop provided a forum for members of the pharmaceutical distribution supply chain to discuss the design objectives of pilot projects established by FDA under section 582(j) of the FD&C Act. Based on the information gathered at that workshop and from the comments submitted to the public docket for the workshop (Docket No. FDA-2016-N-0407), FDA identified several potential issues to

examine, and evaluation methods to use, in pilot projects established under the DSCSA Pilot

Project Program. These potential issues and evaluation methods are summarized in table 1. This

table is intended only to assist in the design of potential pilot projects; it does not represent

FDA's views or policies regarding the issues described in the table. For ease of reference, the

potential issues to examine and evaluation methods have been grouped by focus areas for the

pilot projects.

Table 1.--Potential Issues to Examine and Evaluation Methods to Use in Pilot Projects

Pilot Project Focus Area	Potential Issues to Examine	Potential Evaluation Methods

Product Identifier	• Processes related to the requirement for manufacturers to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce
	• Methods used to issue and manage serial numbers (e.g., including a contract manufacturer's role if applicable or how a repackager associates its product identifier with the product identifier assigned by the original manufacturer)
	• Different representations for the product identifier (e.g., different formats of the National Drug Code or serial number)
		• Impacts of different representations of the product identifier on systems or processes
		  – Number of errors
		  – Time to process
		  – Time to reconcile differences

Barcodes	• Readability of a barcode either printed or affixed to product, including impact of environmental and human factors
	• Application of linear barcode and 2D barcode on product
	• Distinguishing which barcode to read/use
		• Barcode read error rates
		  – Number of items unnecessarily quarantined or held up
		  – Time and resource impacts

Interoperability	• Process and technical challenges due to a variety of potential solutions (e.g., type of database used and system architecture for exchanging information among trading partners)
	• Maintaining the integrity of information contained in the barcode of serialized product throughout the distribution supply chain (e.g., a trading partner goes out of business or one acquires another business)
	• Different methods for exchanging information (e.g., the use of Electronic Data Interchange, Electronic Product Code Information Services, and other solutions separately)
		• For both decentralized and centralized models, time implications
		  – To investigate suspect and illegitimate products
		  – For notifications required within the statutory timelines
		  – Related to scaling up from pilot to full production
		• Product tracing information (across multiple partners)
		  – Capability to retrieve the information
		  – Accuracy of the information (within and between systems)
		• Security and access
		  – Evaluate and document access levels for trading partners

Pilot Project Focus Area	Potential Issues to Examine	Potential Evaluation Methods

Data/Database/ System Issues	• Data quality from beginning to end of the product lifecycle and vice versa
	• System performance when full or partially loaded with data
	• Data format or processes for data transfer
	  – Use of technical standards for defining data attributes to enable interoperable transfers
	  – Methods to handle the "master data" (product-specific data) and transaction data separately to minimize "master data" redundancy
	• Integration into individual/company data systems
	• Control and access to data by trading partners, FDA, or other federal or state officials (data governance)
	• Ability of the system to record product status (e.g., to indicate expired, illegitimate, in error, quarantined) at all packaging levels
		• System Performance and Effectiveness
		  – Time to access and use product tracing information once that data is received into a system
		  – Quality of product tracing information
		  – Number of breaches to system
		  – Number of attempts to breach the system that were prevented or minimized
		• Data and product flow
		  – Number of unsuccessful attempts to access data and operational impacts
		  – Number of system interactions within one, and amongst multiple, trading partners
		  – Time and resource changes on operations when data and product not moving at same time (e.g., product arrives before data arrives)
		  – Time for location/ownership/status changes to be reflected in the system
		  – Time of product flow delays and associated costs due to system or data problems

Aggregation/ Disaggregation	• Multiple levels of adoption of inference, by different trading partners Impact of inference gaps, changes or errors in data, particularly downstream when searching or examining the data; how can errors be corrected	• Number of system and product interactions within one, and amongst multiple, trading partners • Time required to conduct aggregate/disaggregate operations and transactions • Accuracy of aggregation data (measure error counts) • Time to gather aggregation/disaggregation data for investigations and notifications • Time to resolve errors in data

Pilot Project Focus Area	Potential Issues to Examine	Potential Evaluation Methods

Verification/ Notification	• Process for investigation of suspect or illegitimate product, including any communication or coordination
	  – Making and responding to verification requests
	  – Making, responding to, and termination of notifications
	  – Responding to requests for information
	  – Testing boundaries of the system
		• Response times: current vs. future process
		• Time needed to obtain product tracing information to respond to a request for verification
		• Time needed to make, respond to, or terminate a notification
		• Time to gather product tracing information to support an investigation for a suspect or illegitimate product, or a recall
		• Percentage of items that are successfully verified vs. those that were targeted for verification
		• Number of connections/queries needed to gather product tracing information in response to a verification or notification request

Exception Handling/ Errors/ Inconsistencies	• Identify 'honest errors' (e.g., over/under shipments, clerical errors, or aggregation errors)
	• Correcting 'honest errors'
		• Percent of errors detected: compare exceptions introduced vs. exceptions detected
		  – Identify the first step in the process where an error is detected
		• Number of new or changed processes needed to accomplish DSCSA goals
		  – Time and resource impacts
		• 'Honest Errors'
		  – Number of items unnecessarily quarantined and held up
		  – Time required to detect and correct errors
		  – Impact on trading partners to correct errors
		• Barcode read error rates
		  – Number of items unnecessarily quarantined or held up
		  – Time and resource impacts

Special Scenarios	• Situations when data and product do not move together
	• Situations when serialized product are sold and distributed along with non-serialized product
		• Error rates for special processes
		  – Number of items unnecessarily quarantined or held up
		  – Time and resource impacts
		• Accuracy of linkage between original manufacturer product identifier and repackager-issued product identifier

In addition to the information in table 1, workshop participants and comments submitted

to the public docket recommended factors that FDA should take into consideration when

establishing pilot projects. The recommended factors include the extent to which the pilot projects:

- Represent the mix of products and levels of packaging in the supply chain

- Include a diverse set of supply chain stakeholders (types and sizes) and transaction types

- Use adaptive design to make the pilot projects more efficient.

- Target known weaknesses in the supply chain

- Can be completed in such a time frame to provide useful information for trading partners

- Evaluate human factors that could present implementation challenges

- Simulate illegitimate products/transactions to test a process or system

  - Document costs to implement, use, and maintain piloted solutions

Although the Agency intends to take these factors into consideration when establishing pilot projects, FDA also recognizes that a single pilot project is unlikely to satisfy every factor. Accordingly, requests to establish a pilot project need not satisfy all the factors listed in this document.

C. Instructions for Submitting a Request to Participate in the DSCSA Pilot Project Program

Stakeholders interested in participating in the DSCSA Pilot Project Program may submit a request to participate by email to DSCSAPilotProjects@fda.hhs.gov. For a group of entities that partner to participate in a pilot project, only one submission and one point-of-contact for the proposed pilot project should be provided in the request to participate. Requests to participate may also consider other ideas for a pilot project that are not included in this notice.

D. Submission Content for Requesting to Participate in the DSCSA Pilot Project Program

The following information should be included in the request:

- Contact information for the submitter or point of contact, if different from the submitter (name, mailing address, phone number, email address)

- Names of all partnering entities that would participate in the pilot project (name of company and name of company representative)

- Type(s) of each partnering entity participating in the pilot project (e.g., manufacturer, repackagers, wholesale distributor, dispenser, third-party logistics provider, solution provider, trade association, etc.); Partnering entities may include authorized trading partners or other supply chain stakeholders

- Number of employees for each partnering entity to reflect company size

- Proposed start and finish dates of the pilot project

- Commitment to start the pilot project within 4 months of receiving a letter of acceptance from FDA

- Product(s) that will be used in the pilot project

- Location(s) where pilot project will be performed (facility address)

- Description of the proposed pilot project, including, but not limited to, the goals, objectives, processes that will be studied, and evaluation methods

E. Initiation and Duration of Pilot Projects

The selected participants should be ready to start their pilot project within 4 months of receiving a letter of acceptance from FDA into the program. The duration of a pilot project should not exceed 6 months. FDA may consider a pilot project with a later start date or longer duration depending on the proposed goal(s) and objective(s). Each pilot project is expected to be completed within the proposed duration time period. This time period does not include an additional 30 days for completion of a final report (see Section II.G. Reports).

F. Participation in Pilot Projects

Each participant that is selected into the program will be responsible for conducting its

pilot project. A group of entities (e.g., members of the pharmaceutical distribution supply chain

or other stakeholders, including trade associations) that partners to conduct a pilot project will be

considered a single participant for purposes of the DSCSA Pilot Project Program. The

participant will be responsible for the funding and resources necessary to conduct the pilot

project, and for determining each partner's role and responsibility in its pilot project.

Prior to launch of a pilot project, FDA intends to hold a design strategy meeting with the

selected pilot participant(s) to review the goal(s) and objective(s)s for the pilot project and

discuss the project plans and other pertinent details. FDA also expects pilot project participants

to submit reports on the progress of their pilot projects to FDA (see Section II.G. Reports).

Participants should evaluate their pilot projects using the evaluation methods they identified

during the pilot project design process.

G. Reports

Each pilot project is expected to be completed within the proposed duration time period,

and FDA asks that all participants submit periodic progress reports to FDA while the pilot

project is being conducted, in addition to submitting a final report after completing the pilot

project. These reports will provide insight into the systems and process needed to comply with

certain DSCSA requirements for enhanced drug distribution security.

1. Progress Report(s)

Each pilot project program participant is expected to provide reports on the progress of its

pilot project to FDA. The progress reports are intended to capture the ongoing work during the

pilot project, including but not limited to, status or results, changes, challenges, and/or lessons

learned. 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. Because the duration of

a pilot project should not exceed 6 months, the frequency of 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. For example, FDA may ask for monthly

progress reports for a 6-month pilot project, however for a 1-month pilot project, FDA may ask

for weekly progress reports.

2. Final Report

Within 30 to 45 business days of completing a pilot project, each participant is expected

to provide a final report to FDA that captures the description, objectives, methods, evaluation,

costs and key findings, and lessons learned from the project. Timely completion of pilot projects

and the final report will support FDA's DSCSA implementation, including the statutory

requirements under section 582(j) of the FD&C Act to consider information from pilot projects

in the development of guidances for unit-level tracing and standards for the interoperable data

exchange in section 582(h)(3) and (4) of the FD&C Act. FDA may also request that the

participants meet with the Agency upon the completion of their pilot project or the final report.

H. Final DSCSA Pilot Project Program Report

To ensure that all supply chain members benefit from the information generated by the

DSCSA Pilot Project Program, FDA intends to make the following information about each pilot

project of the program available to the public in a final program report: (1) the names and

industry sector(s) of the pilot project participant(s); (2) the pilot project's objectives and

evaluation methods; (3) the duration of the pilot project; and (4) the key findings and lessons

learned from the pilot project. FDA intends to post the information related to the DSCSA Pilot

Project Program and the final program report on FDA's website.

I. Recordkeeping

Any records generated by a participant while conducting a pilot project should be

maintained in accordance with the participant's normal recordkeeping practices. For pilot

projects that involve partnering entities, the partnering entities should decide who is responsible

for the records generated in the course of conducting the pilot project. FDA recommends that

participants maintain the progress reports and final report for its pilot project for at least 1 year

after completion of the pilot project.

III. Paperwork Reduction Act of 1995

This notice contains information collection provisions that are subject to review by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44

U.S.C. 3501-3520). The collection of information in this notice was approved under OMB

control number 0910-0859.

Dated: February 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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