



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1114]

Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is soliciting information regarding issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the requirements established under the Drug Supply Chain Security Act (DSCSA). The information gathered from public comments will assist with the design and development of the pilot project(s) that FDA establishes under the DSCSA.

DATES: Submit written or electronic comments and information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-1114 for "Pharmaceutical Distribution Supply Chain Pilot Projects; Request for Information."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the 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, which will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added new sections 581 and 582 to the Food Drug and Cosmetic Act (21 U.S.C. 360eee and 360eee-1). Under section 582(j), 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. The projects established by FDA will take into consideration any pilot projects that were conducted prior to enactment of the DSCSA.

II. Purpose of the Request for Information

The request for information is intended to provide interested persons an opportunity to submit comments relating to FDA's implementation of the DSCSA. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include: Manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, standards organizations, and other interested persons. FDA is particularly interested in learning about the

practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- Technical capabilities each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product;
or
- System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may assist with FDA's development of a pilot project under the DSCSA.

Dated: April 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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