4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3103]

Development of Small Dispensers Assessment Under the Drug Supply Chain Security Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is seeking stakeholder comments on the development of a technology and software assessment that examines the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. FDA would like to obtain information regarding issues to be addressed in the assessment 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.

DATES: Either electronic or written comments on the notice must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2023-N-3103 for "Development of Small Dispensers Assessment under the Drug Supply Chain Security Act; Request for Comments." 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: 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, daniel.bellingham@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law. The DSCSA outlines steps to achieve interoperable, electronic tracing of products at the package level 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 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 conducting interoperable, electronic tracing of products at the package level. Under section 582(g)(1), dispensers and other trading partners will be required to, amongst 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 the gathering of 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 for purposes of investigating a suspect or illegitimate product. These enhanced drug distribution security requirements are also referred to as "enhanced product tracing" or "enhanced verification."

II. Purpose of the Request for Comments

FDA is issuing this request for public comments prior to beginning the assessment, in accordance with section 582(g)(3)(D). The statement of work requires the selected firm to conduct an assessment that will address the proposed questions articulated below. In addition to

commenting on the proposed questions below, stakeholders may provide comments on any aspect of the small dispenser assessment under the DSCSA.

Stakeholders that may be interested in responding to this request for information include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, and standards organizations, among others. FDA is particularly interested in receiving comments from the various sectors of the dispenser community, particularly pharmacies. FDA is seeking comments on the following proposed questions for small dispensers (i.e., dispensers with 25 or fewer full-time employees). We are interested in receiving feedback on the questions themselves and whether or not they should be edited to be more useful for the assessment. FDA is also interested in any new questions that stakeholders may recommend.

- Have you begun preparations for DSCSA requirements regarding the interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (i.e., enhanced product tracing or enhanced verification)?
- How are you currently exchanging data with your trading partners (e.g., by paper-based methods, electronic methods, or both)?
- If not currently exchanging data with trading partners in a fully electronic manner, will you be able to in the near future? If not, what are the barriers? Elaborate on why or how, as appropriate. Please specify issues related to:
    - accessibility of necessary software and hardware;
    - cost to obtain, install, and maintain necessary software and hardware, particularly if it is prohibitively expensive;
    - integration of necessary software and hardware into business practices, such as with wholesale distributors;
    - other relevant information related to feasibility of dispensers with 25 or fewer full-time employees to conduct interoperable, electronic tracing of product at the package level.

- What type of software systems and hardware do you currently utilize to facilitate the electronic exchange of DSCSA-related data for transactions of products?
- What new or modified software systems and hardware do you anticipate putting in place to comply with the interoperable, electronic tracing requirements?
- How likely are you to change and upgrade your existing software systems that are already in use so that you can comply with the interoperable, electronic tracing requirements?
- Have you or do you plan to connect your system(s) with your trading partner(s) (e.g., manufacturer(s), repackager(s), or wholesale distributor(s)) in order to facilitate electronic DSCSA-related data exchange? If so, have you experienced technical issues when attempting to establish connectivity? If not, how do you or how do you plan to manage electronic DSCSA-related data received from an upstream trading partner (e.g., maintain the data in your dispenser system or use a third-party agreement for another entity to confidentially maintain the DSCSA-related data on your behalf (e.g., use of a secure web portal provided by your wholesale distributor))?
- Have you considered data integrity and security concerns when establishing agreements with third-party entities (e.g., solution providers or wholesale distributors) for electronic data exchange and maintenance?
- Have you ever received transaction information from a trading partner, such as your wholesale distributor, that does not match the product that you received? If so, how long did it take to resolve the discrepancy on average? What if any unique challenges arose from these situations? How often does this happen?
- If you currently routinely scan a 2D data matrix barcode, how often do you receive a 2D data matrix barcode of the product identifier that cannot be scanned or read? Why are you unable to scan or read the 2D data matrix barcode (e.g., barcode quality, scanner performance, software issue) and what is your process for handling these situations,

including when manual steps are taken by your staff when an automated process was inadequate or failed?

- If you currently routinely scan the 2D data matrix barcode, how often you encounter a 2D data matrix barcode with missing or inaccurate data? What are the reasons for this and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?
- What new demands do you expect the DSCSA requirements in section 582(g)(1) of the FD&C Act to have on your current staff resources?
- How long do you expect it will take to train staff on the new requirements, how to use any new software or hardware, and any process changes? What additional resources do you anticipate needing to comply with the interoperable, electronic tracing requirements?
- Are there additional challenges not already identified when operationalizing new systems and processes for interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (i.e., enhanced product tracing or enhanced verification)?

Stakeholders may provide other relevant information that may inform the development of the small dispenser assessment under the DSCSA.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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