meeting all programmatic goals under the current SMP grant.

Dated: May 26, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–11779 Filed 6–3–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2024]

Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' The Drug Supply Chain Security Act (DSCSA) outlines critical enhanced drug distribution security requirements for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs at the package level as they are distributed within the United States. This draft guidance clarifies these requirements and provides recommendations on the system attributes necessary to enable the secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary.

DATES: Submit either electronic or written comments on the draft guidance by August 3, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2020–D–2024 for ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.''

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013. The DSCSA outlines critical steps for building 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 section 582 to the FD&C Act (21 U.S.C. 360eee–1), which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023.

Trading partners, along with Federal and State authorities, have a role in ensuring the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements, which have been phased in since 2013, improve the oversight of trading partners in the supply chain that are involved in the manufacturing, repackaging, wholesale distribution, warehousing or logistical activities, or dispensing of prescription drugs. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of an electronic, interoperable system to enhance the security of the pharmaceutical distribution supply chain.

Section 582(g)(1) of the FD&C Act sets forth the general requirements for enhanced drug distribution security, including:

- The exchange of transaction information and transaction statements in a secure, interoperable, electronic manner;
- transaction information that includes the product identifier at the package level for each package included in the transaction;
- systems and processes for verification of product at the package level; and
- systems and processes needed to promptly respond in the event of a recall or to investigate suspect and illegitimate products.

This draft guidance clarifies the enhanced drug distribution requirements and describes recommendations for system attributes necessary for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the current thinking of FDA on enhanced drug distribution security at the package level under the DSCSA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 211.132 for tamper-evident packaging of a drug product have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 201.57 for establishing anticounterfeiting technologies, such as physical-chemical identifiers, have been approved under 0910–0572. The collections of information for identifying suspect drug product have been approved under OMB control number 0910–0806. The collections of information for establishing: (1) An electronic, interoperable system and (2) system attributes necessary for enabling the secure tracing of drug product have been approved under OMB control number 0910–0859.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11734 Filed 6–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The guidance addresses provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). The guidance is intended to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain. The guidance also describes how trading partners should notify FDA of illegitimate product and sets forth a process for terminating notifications of illegitimate product in consultation with FDA. In addition, this guidance describes when manufacturers should notify FDA of a high risk that a product is illegitimate. This guidance responds to comments from stakeholders in order to clarify certain points and finalizes the remaining draft portion of the final guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification,'' issued in December 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on June 4, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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