

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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Persons with access to the internet may obtain the draft guidance at 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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3462]

Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; 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 “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” The guidance addresses the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, the guidance covers the statutory verification systems requirements that include the quarantine and investigation of a product determined to be suspect and the quarantine and disposition of a product determined to be illegitimate. The guidance also addresses the statutory requirement for notification to the Agency of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser (also referred to as “trading partners”) after a suspect product investigation because it is determined that the product is not an

illegitimate product. Finally, the guidance addresses the statutory requirement for responding to requests for verification and processing saleable returns. The guidance finalizes the revised draft guidance “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs,” issued on March 10, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on December 7, 2023.

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 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-2018-D-3462 for “Verification Systems Under the Drug Supply Chain Security

Act for Certain Prescription Drugs; Guidance for Industry; Availability.” 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 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, 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, drugtrackandtrace@fda.hhs.gov; or Anne Taylor, 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 guidance for industry entitled “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” The DSCSA (title II of Pub. L. 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established the requirement that trading partners have systems in place to enable them to comply with certain verification obligations. This guidance provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. This guidance also addresses the manner in which FDA recommends that trading partners submit cleared product notifications (*i.e.*, notifications that a suspect product is not an illegitimate product), the statutory requirements for responding to requests for verification, and the statutory requirements for processing saleable returns.

FDA initially published the draft guidance “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs” on October 25, 2018 (83 FR 53880). Comments were received on the initial draft guidance and the Agency made revisions to the draft. This guidance finalizes the revised draft guidance entitled “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs,” issued on March 10, 2022 (87 FR 13738). FDA considered comments received on the revised draft guidance in finalizing this guidance.

Changes from the revised draft to the final guidance include: (1) clarifying that dispensers need not provide transaction information for saleable return product; (2) clarifying that “verification” as defined in section 581 of the FD&C Act (21 U.S.C. 360eee) involves confirming that the product identifier affixed or imprinted upon a package or homogeneous case corresponds to the Standardized Numerical Identifier or lot number and expiration date assigned to the product by the manufacturer or repackager by more closely mirroring the statutory language; (3) further clarifying when the discussion is about the verification systems requirements in section 582 of the FD&C Act and when it is about the requirement to verify the product identifier; (4) clarifying FDA’s understanding about the statutory requirement that manufacturers and repackers respond to requests for verification within 24 hours or within other such reasonable time as determined by the Secretary of Health and Human Services; (5) clarifying that when a trading partner does not receive a timely response to a verification request, the product that is the subject of the request need not automatically be classified as suspect; and (6) clarifying that certain system attributes are suggested as best practices even though they are not specifically required under the DSCSA. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information pertaining to implementation of the Drug Supply Chain Security Act are approved in OMB control no. 0910-0806.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic 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 “Interim Policy on Compounding Using Bulk Drug Substances Under section 503A of the Federal Food, Drug, and Cosmetic Act” (draft guidance or 2023 503A Interim Policy Draft Guidance) to describe FDA’s interim policy regarding the use of bulk drug substances by human drug compounders that are not registered with FDA as outsourcing facilities while FDA develops the list of bulk drug substances that can be used in compounding under the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance, when finalized, will replace the guidance for industry entitled, “Interim Policy on Compounding Using Bulk Drug Substances under section 503A of the Federal Food, Drug, and Cosmetic Act” issued in January 2017 (2017 503A Interim Policy Guidance).

DATES: Submit either electronic or written comments on the draft guidance by January 8, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.