Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies

Guidance for Industry

This guidance is for immediate implementation.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

October 2020
Procedural

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Contains Nonbinding Recommendations

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies

Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

On September 24, 2019, FDA published the *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy* guidance (the 2019 Compliance Policy), where FDA announced a 1-year delay in enforcement of the requirement for wholesale distributors[2] to verify[3] saleable returned product[4] as required under section 582(c)(4)(D) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(c)(4)(D)). The 2019 Compliance Policy explained that the Agency intended to delay enforcement of this requirement until November 27, 2020. This guidance announces FDA's extension of such delay in enforcement. It also sets forth the Agency's enforcement policy with respect to section 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act (21 U.S.C. 360eee-1(d)(4)(A)(ii)(II) and (d)(4)(B)(iii)), which generally provide that, beginning November 27, 2020, a dispenser[5] must verify the product identifier[6] of suspect or illegitimate product[7] in the dispenser's possession or control.

This guidance addresses the readiness of wholesale distributors to comply with the requirement to verify the product identifier upon receipt of a returned product that the wholesale distributor

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.
[2] *Wholesale distributor* is defined in section 581(29) of the FD&C Act (21 U.S.C. 360eee(29)).
[3] *Verification* or *verify* is defined in section 581(28) of the FD&C Act.
[4] *Product* is defined in section 581(13) of the FD&C Act. *Return* is defined in section 581(17) of the FD&C Act.
[5] *Dispenser* is defined in section 581(3) of the FD&C Act.
[6] *Product Identifier* is defined in section 581(14) of the FD&C Act.
[7] *Suspect product* is defined in section 581(21) and *illegitimate product* is defined in section 581(8) of the FD&C Act.

intends to further distribute under section 582(c)(4)(D) of the FD&C Act. The requirement under section 582(c)(4)(D) of the FD&C Act for wholesale distributors to verify saleable returned products prior to redistribution went into effect on November 27, 2019.[8] FDA does not intend to take action against wholesale distributors who do not, prior to November 27, 2023, verify the product identifier prior to further distributing returned product as required under section 582(c)(4)(D) of the FD&C Act. This represents an additional 3-year delay from the delay set forth in the 2019 Compliance Policy in enforcement of the requirement for wholesale distributors to verify the product identifier prior to further distributing that returned product.

This guidance also addresses the dispenser requirement in section 582(d)(4)(A)(ii)(II) of the FD&C Act. This provision, which is effective as of November 27, 2020, requires a dispenser to verify whether the product identifier of a suspect product, including the standardized numerical identifier,[9] of at least 3 packages[10] or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier assigned to such product by the manufacturer or repackager.[11] Furthermore, this guidance addresses section 582(d)(4)(B)(iii) of the FD&C Act, which requires dispensers to verify product as described in section 582(d)(4)(A)(ii) of the FD&C Act in response to a notification of illegitimate product from FDA or a trading partner.[12] FDA does not intend to take action before November 27, 2023, against dispensers who do not verify the product identifiers of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act. In addition, FDA does not intend to take action before November 27, 2023, against dispensers who do not verify the product identifiers of illegitimate product that are the subject of a notification from FDA or a trading partner as required by section 582(d)(4)(B)(iii) of the FD&C Act. This represents a 3-year delay in enforcement of the requirements for dispensers to verify the product identifier when investigating suspect or illegitimate product.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act. This section established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, wholesale distributors, repackagers, and dispensers

[8] See section 582(c)(4)(D) of the FD&C Act.
[9] *Standardized numerical identifier* is defined in section 581(20) of the FD&C Act.
[10] *Package* is defined in section 581(11) of the FD&C Act.
[11] See section 582(d)(4)(A) of the FD&C Act.
[12] For this guidance, *trading partner* is defined as described in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the same product tracing requirements of section 582 of the FD&C Act.

to facilitate the tracing of a product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 of the FD&C Act is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and subject to enforcement action under the FD&C Act.

One requirement of the verification scheme outlined in the DSCSA is the verification of saleable returned product. Under section 582(c)(4)(D) of the FD&C Act, wholesale distributors must have systems in place that will enable them to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product. A saleable returned product may not be further distributed until the product identifier is verified.[13] The product should be handled as suspect product if the product identifier is not successfully verified (i.e., it should be quarantined and investigated).[14, 15] FDA published the 2019 Compliance Policy on September 24, 2019, announcing a 1-year delay in enforcement against wholesale distributors who do not verify the product identifier of saleable returned product prior to further distributing such product as required by section 582(c)(4)(D) of the FD&C Act.

In addition, section 582 of the FD&C Act requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement when engaging in transactions involving certain prescription drugs.[16,17] A transaction statement must include a statement that the entity transferring ownership in a transaction had systems and processes in place to comply with verification requirements under section 582 of the FD&C Act.[18] In the 2019 Compliance Policy, FDA acknowledged that wholesale distributors may not have systems in place by November 27, 2019, to enable the wholesale distributor to timely and efficiently comply with the verification of saleable returned product requirements under section 582(c)(4)(D) of the FD&C Act without potentially causing a disruption to the pharmaceutical distribution supply chain. Therefore, the 2019 Compliance Policy indicated FDA's intent to take no enforcement action prior to November 27, 2020, against a wholesale distributor that provided a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor did not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D) of the FD&C Act.

Section 582 also includes requirements for dispensers to verify product identifiers when investigating suspect or illegitimate product. Specifically, section 582(d)(4)(A)(ii)(II) of the FD&C Act provides that, effective November 27, 2020, dispensers must verify "the product

[13] See section 582(c)(4)(D) of the FD&C Act.
[14] See *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* (October 2018). We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.
[15] Section 582(c)(4)(A)(i) of the FD&C Act details how wholesale distributors must handle suspect product.
[16] *Transaction*, *transaction history*, *transaction information*, and *transaction statement* are defined under sections 581(24), (25), (26), and (27) of the FD&C Act.
[17] See section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.
[18] See section 581(27)(E) of the FD&C Act.

identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product [in the dispenser's possession or control]".[19] Section 582(d)(4)(B)(iii) of the FD&C Act requires dispensers to verify product as described in 582(d)(4)(A)(ii) of the FD&C Act when they have received a notification of illegitimate product from FDA or a trading partner.

III. COMPLIANCE POLICY FOR WHOLESALE DISTRIBUTOR VERIFICATION OF SALEABLE RETURNED PRODUCT

After publishing the 2019 Compliance Policy, FDA has received comments and feedback from wholesale distributors, as well as other trading partners and stakeholders, expressing additional concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors. Stakeholders have explained that the primary factors FDA considered when issuing the 2019 Compliance Policy still exist: (1) the very large volume of saleable returned products requiring verification; (2) the need to refine and test verification systems during actual production using real-time volumes of saleable returned product rather than simply in pilots; and (3) the complexities of building an interoperable, electronic system with the capabilities to timely and efficiently verify the large volume of saleable returned products amid immature technologies.

Given the concerns expressed, FDA recognizes that some wholesale distributors may still need additional time beyond November 27, 2020, when the delay in enforcement set forth in the 2019 Compliance Policy expires, before they can begin verifying returned products prior to resale or other further distribution as required by section 582(c)(4)(D) of the FD&C Act in an efficient, secure, and timely manner. To minimize possible disruptions in the distribution of certain prescription drugs in the United States, FDA does not intend to take action before November 27, 2023, against wholesale distributors who do not verify a product identifier prior to resale or other further distribution of a package or sealed homogenous case of product as required by section 582(c)(4)(D) of the FD&C Act.

Additionally, FDA recognizes that wholesale distributors may still not have systems in place by November 27, 2020, to enable the wholesale distributor to timely and efficiently comply with the verification of saleable returned product requirements under section 582(c)(4)(D) of the FD&C Act without potentially causing a disruption to the pharmaceutical distribution supply chain. Therefore, prior to November 27, 2023, FDA does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D) of the FD&C Act.[20]

[19] See section 582(d)(4)(A)(ii) of the FD&C Act.

[20] See section 581(27)(E) of the FD&C Act, which defines *transaction statement* to include systems and processes to comply with the verification requirements of section 582, including the saleable returns requirements of section 582(c)(4)(D).

This compliance policy aligns with the statutory requirements that effective November 27, 2023, an enhanced system[21] be used by manufacturers, repackagers, wholesale distributors, and dispensers that allows for secure, interoperable, electronic tracing of products at the package level.[22] The enhanced system must allow for, among other things, incorporation of the product identifier into product tracing and utilization of the product identifier to verify a product at the package level.[23] FDA believes that the extension of the delay in enforcement until November 27, 2023, will allow wholesale distributors to focus resources and efforts on implementing the enhanced system. We envision that, along with other enhanced drug distribution security requirements, wholesale distributors can increase their efficiency by incorporating the saleable return verification requirements into the enhanced verification required by 2023 instead of developing separate processes or infrastructures. Extending the delay in enforcement also provides more time for wholesale distributors to test their ability to verify saleable returns using real-time volume, involving all trading partners.

The compliance policy described in this section is limited to the requirements that wholesale distributors verify saleable returned products prior to further distribution and have verification systems in place to comply with the requirements of section 582(c)(4)(D) of the FD&C Act; it does not extend to the other requirements in section 582 of the FD&C Act. For example, it does not affect the requirement that a wholesale distributor must have verification systems in place to determine whether a returned product is a suspect product.[24] This compliance policy does not affect the requirement that as of November 27, 2019, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to section 582(a)(5) of the FD&C Act).[25] This compliance policy does not relieve a manufacturer of its verification obligations pursuant to section 582(b)(4)(C) of the FD&C Act upon receiving a request for verification from an authorized wholesale distributor. Further, as of November 27, 2019, wholesale distributors must only accept returned product from a dispenser or repackager if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product.[26] FDA previously issued the draft guidance, *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* (October 2018) (Verification Systems Draft Guidance) to describe FDA's interpretation of the requirements of section 582 of the FD&C Act regarding verification systems.[27] Wholesale distributors should refer to the Verification Systems Draft Guidance for a detailed description of responsibilities that are applicable to them.

This compliance policy is not applicable with respect to returns of saleable packages and sealed homogeneous cases of product without product identifiers that were in the pharmaceutical distribution supply chain before November 27, 2018. The guidance for industry *Grandfathering*

[21] For the purpose of this guidance, *enhanced system* refers to the interoperable, electronic, package-level product tracing systems and processes required by section 582(g) of the FD&C Act.
[22] See section 582(g)(1)(A) of the FD&C Act.
[23] See section 582(g)(1)(B) and (C) of the FD&C Act.
[24] See section 582(c)(4)(A) of the FD&C Act.
[25] See section 582(c)(2) of the FD&C Act.
[26] See section 582(c)(1)(B)(i)(II) of the FD&C Act.
[27] When final, this guidance will represent the FDA's current thinking on this topic.

Policy for Packages and Homogenous Cases of Product Without a Product Identifier (September 2018), addresses such returns.[28]

IV. COMPLIANCE POLICY FOR THE DISPENSER VERIFICATION REQUIREMENTS

In the years since the passage of the DSCSA, FDA has received comments and feedback from dispensers expressing concern with readiness for implementation of certain requirements under section 582(d) of the FD&C Act, including the verification requirements addressed in this compliance policy. Specifically, dispensers have described challenges with implementation of these provisions in the DSCSA due to the time necessary to develop technologies and processes that would support a robust verification system.

Given the concerns expressed, FDA recognizes that some dispensers may need additional time beyond November 27, 2020, before they can begin to verify the statutorily-designated portion of product identifiers of suspect and illegitimate products as described in sections 582(d)(4)(A)(ii)(II) and (B)(iii) of the FD&C Act. To minimize possible disruptions in the distribution of certain prescription drugs in the United States, FDA does not intend to take action before November 27, 2023, against dispensers who do not verify the statutorily-designated portion of product identifiers of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FD&C Act. In addition, FDA does not intend to take enforcement action before November 27, 2023, against dispensers who do not verify, as required by section 582(d)(4)(B)(iii) of the FD&C Act, the statutorily-designated portion of product identifiers of product that is the subject of an illegitimate product notification by FDA or a trading partner.

Dispensers should refer to the Verification Systems Draft Guidance for a detailed description of responsibilities that are applicable to them, as the compliance policy described in this section applies only to the dispenser requirements regarding verification of product identifiers described in sections 582(d)(4)(A)(ii)(II) and (B)(iii) of the FD&C Act and does not apply to any other provision in section 582 of the FD&C Act. This compliance policy does not address any of the other verification requirements set forth in section 582(d)(4) of the FD&C Act. For example, this compliance policy does not affect the requirement that as of November 27, 2020, a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to section 582(a)(5) of the FD&C Act),[29] and this compliance policy does not affect the other activities required by section 582(d)(4)(A) and section 582(d)(4)(B) by incorporation (e.g., dispensers must still quarantine product, conduct investigations, and disposition illegitimate product). This compliance policy does not relieve a manufacturer of its verification obligations pursuant to section 582(b)(4)(C) of the FD&C Act upon receiving a request for verification from an authorized dispenser.

This compliance policy aligns with the statutory requirements for an enhanced drug distribution system discussed above in section III of this guidance. When effective on November 27, 2023,

[28] For the most recent version of the guidance, check the FDA guidance web page.
[29] See section 582(d)(2) of the FD&C Act.

the enhanced system must include as part of the transaction information the product identifier for each package in the transaction.[30] The enhanced system must also allow for the verification of product at the package level.[31] In addition, the enhanced system must allow for the ability to promptly generate and provide specific product and transaction documentation upon request by FDA, another Federal or State official, or an authorized trading partner for purposes of investigating suspect or illegitimate product.[32] FDA believes that dispensers can use this 3-year period to ensure the systems and processes that are put into place to meet the enhanced system requirements by November 27, 2023, will also fulfill all dispenser verification requirements under section 582(d)(4) of the FD&C Act.

[30] See section 582(g)(1)(B) of the FD&C Act.
[31] See section 582(g)(1)(C) of the FD&C Act.
[32] See section 582(g)(1)(D) of the FD&C Act.