
Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy 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)**

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Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry¹

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

This guidance is intended for wholesale distributors who must verify the product identifier upon receipt of a returned product² that the wholesale distributor intends to further distribute 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)). This guidance addresses the readiness of wholesale distributors to comply with the provisions in section 582 of the FD&C Act related to the verification of saleable returned drug products. The requirement under section 582(c)(4)(D) for wholesale distributors to verify saleable returned drug products prior to redistribution goes into effect on November 27, 2019.³

This guidance announces the Food and Drug Administration's (FDA or the Agency) compliance policy regarding enforcement of the verification of saleable returned product requirement under section 582(c)(4)(D) of the FD&C Act. FDA does not intend to take action against wholesale distributors who do not, prior to November 27, 2020, verify a product identifier prior to further distributing returned product as required under section 582(c)(4)(D) of the FD&C Act. This represents a one-year delay in enforcement of the requirement for wholesale distributors to verify a product identifier prior to further distributing that returned 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.

¹ This guidance has been prepared by the Office Regulatory Policy in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Compliance in CDER, the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² *Product* is defined in section 581(13) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee(13)). *Return* is defined in section 581(17) of the FD&C Act.

³ See section 582(c)(4)(D) of the FD&C Act.

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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 to facilitate the tracing of a product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 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.

An important 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.⁴ The product should be handled as suspect product if the product identifier is not successfully verified (i.e., it should be quarantined and investigated).⁵

III. COMPLIANCE POLICY FOR VERIFICATION OF SALEABLE RETURNED PRODUCT

In the years since passage of the DSCSA, including most recently within the past year, FDA has received comments and feedback from wholesale distributors as well as other trading partners and stakeholders expressing concern with industry-wide readiness for implementation of the verification of saleable returned product requirement for wholesale distributors. Specifically, stakeholders have described challenges with implementation of verification of the product identifier on saleable returned drug product packages or sealed homogeneous cases due to a number of factors, including: (1) the very large volume of saleable returned product 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. Through FDA's DSCSA pilot project program, FDA is aware that several pilot participants are in the early stages of developing and testing interoperable, electronic systems to enable verification and achieve interoperability between networks.

Given the concerns expressed, FDA recognizes that some wholesale distributors (in collaboration with other trading partners) may need additional time beyond November 27, 2019, before they can begin verifying returned products prior to resale or other further distribution as required by

⁴ See section 582(c)(4)(D) of the FD&C Act.

⁵ Section 582(c)(4)(A)(i) of the FD&C Act details how wholesale distributors must handle suspect product.

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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 prescription drugs in the United States, FDA does not intend to take action before November 27, 2020, 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, 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.^{6,7} Section 581(27)(E) of the FD&C Act requires that the transaction statement 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. FDA recognizes 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, prior to November 27, 2020, 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).

This compliance policy 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.⁸ This compliance policy does not affect the requirement that beginning 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).⁹ 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 a wholesale distributor. Further, beginning 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.¹⁰

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*

⁶ *Transaction, transaction history, transaction information, and transaction statement* are defined under sections 581(24), (25), (26), and (27) of the FD&C Act.

⁷ See section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.

⁸ See section 582(c)(4)(A) of the FD&C Act.

⁹ See section 582(c)(2) of the FD&C Act.

¹⁰ See section 582(c)(1)(B)(i)(II) of the FD&C Act.

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Policy for Packages and Homogenous Cases of Product Without a Product Identifier (September 2018), addresses such returns.¹¹

¹¹ We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.