
Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry

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For questions regarding this document contact CDER Office of Compliance at 301-796-3130 or drugtrackandtrace@fda.hhs.gov.

**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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Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act— 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 staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses the compliance of dispensers² that engage in transactions³ with first responders⁴ and the compliance of first responders with the provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1) related to the exchange of product tracing information (i.e., transaction information, transaction history, and transaction statements) and verification. This guidance also addresses the compliance of trading partners⁵ that engage in transactions with first responders with the requirement for conducting business only with authorized trading partners. The requirements related to the exchange of product tracing information took effect on July 1, 2015 for dispensers. Requirements for verification and conducting business only with authorized trading partners went into effect for all trading partners on January 1, 2015.

This guidance describes FDA's compliance policy regarding certain requirements in section 582 of the FD&C Act for transactions with first responders. Specifically, FDA does not intend to take action against a dispenser who transfers ownership of a product⁶ directly to a first responder without providing product tracing information to the first responder, as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the FD&C Act, provided that the conditions enumerated in Section IV. A of this guidance are met. FDA also does not intend to take action against trading partners who conduct business with a first responder that is not "authorized" as a

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 "Dispenser" is defined under FD&C Act § 581(3).

³ "Transaction" is defined under FD&C Act § 581(24).

⁴ For the purpose of this guidance, the term "first responder" is defined in Section III. of this guidance.

⁵ "Trading partner" is defined under FD&C Act § 581(23)(A). Although third-party logistics providers are also considered trading partners under FD&C Act § 581(23)(B), the requirements of sections 582(a)-(e) are not applicable to them.

⁶ "Product" is defined under FD&C Act § 581(13).

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dispenser within the meaning of section 581(2)(D) of the FD&C Act. In addition, FDA does not intend to take action against a first responder who: (1) accepts ownership of product without first receiving the product tracing information as required by section 582(d)(1)(A)(i) of the FD&C Act and does not capture and maintain product tracing information as required by section 582(d)(1)(A)(iii) of the FD&C Act; or (2) does not comply with the dispenser requirements for verification of suspect or illegitimate product described in section 582(d)(4) of the FD&C Act. This compliance policy is in effect until further notice by FDA.

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. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace products as they are distributed in the United States. Section 202 of the DSCSA added sections 581 and 582 to the FD&C Act, which set forth various definitions and requirements for trading partners.

To help build the product tracing system envisioned by the DSCSA, trading partners generally are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide subsequent purchasers of product with specific product tracing information. Trading partners are also generally required under sections 582(b)(4), (c)(4), (d)(4) and (e)(4) to have systems in place to enable the verification of suspect and illegitimate product. Furthermore, sections 582(b)(3), (c)(3), (d)(3), and (e)(3) specify that the trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must be "authorized" within the meaning of section 581(2) of the FD&C Act.

III. SCOPE OF THIS GUIDANCE

This guidance applies to transactions between a trading partner and a first responder.⁷ For the purpose of this guidance, a “first responder” is any person: (1) who is authorized by law to administer a product in accordance with section 503(b)(1) of the FD&C Act, (2) is responsible for the emergency treatment of ill or injured persons, and (3) provides such emergency treatment outside of a health care facility.⁸ First responders may include employees of Federal, State, and local law enforcement, and governmental and nongovernmental fire/rescue and ambulance services.

IV. SECTION 582 REQUIREMENTS FOR TRANSACTIONS WITH FIRST RESPONDERS – COMPLIANCE POLICY

FDA understands that some dispensers, such as hospital pharmacies, provide prescription drugs to first responders for use in the emergency treatment of ill or injured persons – often in small quantities or on a periodic basis – and that such dispensers may lack the resources to provide product tracing information for these transactions. FDA also understands that some first responders may not meet the definition of “authorized” dispensers under section 581(2) of the FD&C Act because they do not have a valid license under state law. Nevertheless, they may be authorized, in accordance with applicable law, to administer certain products without a license, such as pursuant to proscribed standards of practice and medical treatment protocols. FDA also recognizes that first responders may lack the resources to comply with certain requirements under section 582(d) of the FD&C Act, including receipt, capture and maintenance of product tracing information and verification.

⁷ As a general matter, we note that some, but not all, activities covered by the compliance policy described in this guidance might also be subject to certain statutory exemptions recognized in sections 581 and 582 of the FD&C Act. For example, section 581(24)(B) specifies eighteen exemptions from the definition of “transaction,” which, in turn, make the product tracing requirements specified in sections 582(c)(1)(A) and (d)(1)(A) inapplicable to activities covered by those exemptions. This guidance does not interpret the scope of section 581(24)(B) or other statutory exemptions described in sections 581 and 582.

⁸ Examples of health care facilities include physician offices, hospital emergency rooms, and urgent care centers. Although health care practitioners are not included within the definition of “first responder” under this guidance when providing treatment in a health care facility, we note that certain health care practitioners who meet the definition of “dispenser” under section 581(3) are nevertheless exempt from certain requirements of section 582(d) of the FD&C Act. Under section 582(d)(5) of the FD&C Act, the requirements of section 582(d)(1) and (d)(4) do not apply to “licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.”

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To minimize possible disruptions to the activities of first responders, FDA does not intend to take action against certain trading partners and first responders as described below. This compliance policy is in effect until further notice by FDA.

A. For trading partners transferring ownership of products to first responders

FDA does not intend to take action against a dispenser who transfers ownership of product directly to a first responder where the dispenser does not provide the first responder with product tracing information (i.e., a transaction information, transaction history, and transaction statement), as required by sections 582(c)(1)(A)(ii)-(iv) and (d)(1)(A)(ii) of the FD&C Act,⁹ provided that:

- the dispenser captures and maintains the product tracing information for such transaction (including the creation of the product tracing information, prior to, at the time of transaction, or, if necessary shortly thereafter) for not less than six years after the transaction, as required under sections 582(c)(1)(A)(v) and (d)(1)(A)(iii) of the FD&C Act; and
- the dispenser provides such product tracing information to the first responder or Secretary, if requested, not less than two business days after receiving the request or in such other reasonable time as determined by the Secretary, based on the circumstances of the request.

FDA also does not intend to take action against a trading partner that transfers ownership of a product to a first responder who is not “authorized” as a dispenser within the meaning of section 581(2)(D) of the FD&C Act.

This compliance policy does not extend to the other requirements of section 582, including the requirement for manufacturers, wholesale distributors, dispensers, and repackagers to verify suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) under sections 582(b)(4), (c)(4), (d)(4) and (e)(4) of the FD&C Act, respectively. In addition, this compliance policy does not extend to any other requirement of the FD&C Act that may apply, including sections 503 and 583.

⁹ A trading partner may meet the definition of more than one entity depending on the activities in which it engages. In the event that a trading partner meets the definition of more than one entity, pursuant to section 582(a)(1), it must comply with all applicable requirements, but trading partners are not required to duplicate requirements. For guidance on this provision, please refer to [“DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information.”](#)

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B. For first responders

FDA does not intend to take action against a first responder who:

- accepts ownership of product without first receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act and does not capture and maintain product tracing information as required by section 582(d)(1)(A)(iii) of the FD&C Act; or
- does not have systems in place to enable the verification of suspect and illegitimate product as required by section 582(d)(4) of the FD&C Act.

If a first responder believes it has received suspect or illegitimate product, FDA strongly recommends that the first responder take steps to protect patients from receiving illegitimate product, which includes quarantine and investigation of such product, contacting appropriate authorities, and working with the previous owner to prevent further distribution of such product.

This compliance policy does not extend to the other requirements of section 582, including the requirement that the first responder conduct business only with authorized trading partners under section 582(d)(3) of the FD&C Act. In addition, this compliance policy does not extend to any other requirement of the FD&C Act that may apply, including sections 503 and 583.