
DSCSA Implementation: Product Tracing Requirements — Compliance Policy Guidance for Industry

This guidance is for immediate implementation.

This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with Docket Number FDA-2014-D-2254.

For questions regarding this document contact CDER Office of Compliance at 301-796-3100 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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DSCSA Implementation: Product Tracing Requirements — Compliance Policy Guidance for Industry¹

This guidance represents the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for trading partners (manufacturers, wholesale distributors, and repackagers) who must provide and capture certain product tracing information, as required under section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1). This guidance addresses the readiness of the pharmaceutical distribution supply chain to comply with the provisions in section 582 of the FD&C Act related to the exchange of product tracing information. Requirements for the tracing of products through the pharmaceutical distribution supply chain go into effect on January 1, 2015, for manufacturers, wholesale distributors, and repackagers, and on July 1, 2015, for dispensers.

This guidance announces the Food and Drug Administration's (FDA's) intention with regard to enforcement of the product tracing information requirements under section 582 of the FD&C Act. FDA does not intend to take action against trading partners (manufacturers, wholesale distributors, and repackagers) who do not, prior to May 1, 2015, provide or capture the transaction information, transaction history, and transaction statement required by section 582 of the FD&C Act (product tracing information) associated with each transaction of certain human, finished prescription drugs, as defined in section 581 of the FD&C Act (21 U.S.C. 360eee).

FDA's guidance documents do not typically establish legally enforceable responsibilities. 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 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.

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II. BACKGROUND

On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which adds new sections 581 and 582 to the FD&C Act, sets forth new definitions and requirements related to product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

Starting in 2015, trading partners are required under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide the subsequent purchaser with product tracing information when engaging in transactions involving certain prescription drugs. Trading partners are also required to capture the product tracing information and maintain the applicable information for not less than 6 years after the date of the transaction.

FDA, in consultation with other appropriate Federal officials and pharmaceutical distribution supply chain stakeholders, published a draft guidance as required under section 582(a)(2)(A) of the FD&C Act, entitled *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information* (November 2014).² This draft guidance established initial standards for the interoperable exchange of the product tracing information related to each transaction of certain human, finished, prescription drugs covered by the statute, in paper or electronic format, through the extension and/or use of current systems and processes.

III. SCOPE OF THIS GUIDANCE

This guidance applies to certain trading partners (manufacturers, wholesale distributors, and repackagers) engaged in transactions³ involving *products*, as defined in section 581(13) of the FD&C Act.

IV. PRODUCT TRACING REQUIREMENTS – COMPLIANCE POLICY

The product tracing requirements in sections 582(b), (c), and (e) of the FD&C Act take effect for manufacturers, wholesale distributors, and repackagers on January 1, 2015. However, some trading partners have expressed concern that unforeseen complications with the exchange of the required information may result in disruptions in the supply chain, and ultimately could impact

² This draft guidance, when finalized, will represent FDA's current thinking on this topic. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

³ *Transaction* is defined in section 581(24) of the FD&C Act.

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patients' access to needed prescription drugs. FDA recognizes that some manufacturers, wholesale distributors, and repackagers may need additional time beyond January 1, 2015, to work with trading partners to ensure that all of the product tracing information required under section 582 of the FD&C Act is provided to and captured by the recipient trading partner. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against trading partners who do not, prior to May 1, 2015, provide or capture the product tracing information required by section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This compliance policy is limited to the requirements that trading partners provide and capture product tracing information; it does not extend to other requirements in section 582 of the FD&C Act, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners.