
Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy

Guidance for Industry

**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)**

**September 2018
Procedural**

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Product Identifier Requirements Under the Drug Supply Chain Security 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 describes FDA’s compliance policy with regard to a requirement related to product identifiers under the Drug Supply Chain Security Act. Specifically, this guidance addresses the requirement in section 582(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(b)(2)) that manufacturers “affix or imprint a product identifier² to each package³ and homogenous case⁴ of a product⁵ intended to be introduced in a transaction⁶ into commerce” beginning not later than November 27, 2017.⁷

The compliance policy set forth in this guidance applies only to the requirement regarding product identifiers described above. In brief, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of product before November 27, 2018. This represents a one year delay in enforcement of the requirement for manufacturers to affix or imprint product identifiers.

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

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 *Product identifier* is defined in section 581(14) of the FD&C Act (21 U.S.C. 360eee(14)) as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

³ *Package* is defined in section 581(11) of the FD&C Act.

⁴ *Homogeneous case* is defined in section 581(7) of the FD&C Act. The terms “homogeneous” and “homogenous” are used interchangeably throughout the DSCSA. FDA has chosen to use only the term “homogenous” throughout this guidance.

⁵ *Product* is defined in section 581(13) of the FD&C Act.

⁶ *Transaction* is defined in section 581(24) of the FD&C Act.

⁷ See section 582(b)(2)(A) of the FD&C Act.

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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 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 product tracing scheme outlined in the DSCSA is the product identifier. Section 582 requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier in both a human-readable form and on a machine-readable data carrier. The product identifier includes the product's standardized numerical identifier,⁸ lot number, and expiration date. Manufacturers are required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.⁹

Since product packaged by a manufacturer during the one year delay in enforcement of the product identifier requirement is also subject to the policy set forth in the final guidance *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* (grandfathering policy), trading partners should read that final guidance to understand how to treat such product for the purposes of the product identifier and verification requirements.¹⁰

III. COMPLIANCE POLICY FOR THE PRODUCT IDENTIFIER REQUIREMENT

⁸ *Standardized numerical identifier* is defined in section 581(20) of the FD&C Act as a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

⁹ See section 582(e)(2)(A)(i) of the FD&C Act.

¹⁰ Final guidance for industry *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs or Biologics guidance web pages at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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In the years since passage of the DSCSA, FDA had received comments and feedback from manufacturers and other trading partners¹¹ expressing concern with industry-wide readiness for implementation of the product identifier requirements for manufacturers. Specifically, stakeholders had described challenges with implementation of manufacturer product identifier requirements due to: (1) a limited number of vendors have the expertise to provide solutions related to information technology systems for data management or specific equipment for packaging or manufacturing lines, and (2) capabilities and readiness of contract facilities that perform manufacturing operations on behalf of the manufacturer.

Given the concerns expressed, FDA has recognized that some manufacturers may need additional time beyond November 27, 2017, to ensure that products are properly affixed or imprinted with a product identifier. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of product as required by section 582(b)(2)(A) of the FD&C Act if the package and homogeneous case of product was packaged by the manufacturer on or after November 27, 2017, but before November 27, 2018.

This compliance policy applies solely to packages and homogenous cases of product without product identifiers that are packaged by a manufacturer on or after November 27, 2017, but before November 27, 2018. The compliance policy does not apply to any other provision of section 582, including the requirement for repackagers to affix or imprint a product identifier on each package or homogenous case of product intended to be introduced in a transaction into commerce beginning November 27, 2018.¹²

IV. RELATIONSHIP TO “GRANDFATHERED” PRODUCTS UNDER SECTION 582(A)(5)(A) OF THE FD&C ACT

FDA has issued the final guidance *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*, which outlines the circumstances in which packages and homogenous cases of product not labeled with a product identifier shall be subject to the grandfathering exemption set forth in section 582(a)(5)(A) of the FD&C Act (grandfathered).¹³ Specifically, a package or homogenous case of product without a product identifier that was packaged by a manufacturer or repackaged by a repackager before November 27, 2018, is grandfathered as described in that guidance. Trading partners should read the grandfathering policy for a more detailed description of their responsibilities as they relate to products without a

¹¹ For this guidance, *trading partner* is defined as described in section 581(23)(A) of the FD&C Act (21 U.S.C. 30eee(23)(A)). Although third-party logistics providers are also considered trading partners under section 581(23)(B) (21 U.S.C. 30eee(23)(B)) of the FD&C Act, the product tracing requirements of section 582 are not applicable to them.

¹² See section 582(e)(2)(A)(i) and (iii) of the FD&C Act.

¹³ Section 582(a)(5)(A) of the FD&C Act gives FDA the authority to exempt packages and homogenous cases of product without a product identifier from certain requirements of section 582. See the final guidance for industry *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier*, for more information.

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product identifier that were packaged by a manufacturer or repackaged by a repackager before November 27, 2018.