Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier

Guidance for Industry

DRAFT GUIDANCE

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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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Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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.[2] 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This draft guidance addresses product distribution security provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee). Section 582 was added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) and facilitates the tracing of products through the pharmaceutical distribution supply chain by requiring trading partners[3] (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement (product tracing information) when engaging in transactions involving certain prescription drug products. In addition, section 582 requires manufacturers and repackagers to start affixing or imprinting a product identifier to each package[4] and homogenous case[5] of product no later than November 27, 2017 (for manufacturers) and November 27, 2018 (for repackagers).[6]

[1] This guidance has been prepared by 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] This sentence does not apply to the discussion regarding the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 of the FD&C Act shall be exempted from the requirements of section 582.

[3] 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, they are not subject to the same product tracing requirements of section 582.

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

[5] *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.

[6] See section 582(b)(2)(A) and 582(e)(2)(A)(i) of the FD&C Act. See also FDA's draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* (explaining, among other things, that 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 products intended to be introduced in a transaction into commerce before November 26, 2018).

We are issuing this guidance to help trading partners understand their compliance obligations under section 582 for packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582. This guidance, which is required by section 582(a)(5)(A) of the DSCSA, specifies whether and under what circumstances such packages and homogenous cases of product shall be exempted, as grandfathered, from certain requirements of section 582. It also briefly discusses the distinctions between the grandfathering policy provisions of this guidance with the draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*.[7]

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.

An exception to that framework derives from section 582(a)(5)(A) of the FD&C Act, wherein Congress granted authorization to FDA to issue guidance specifying whether and under what circumstances packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 shall be exempted from the requirements of section 582. Accordingly, insofar as this guidance specifies such circumstances, this document is not subject to the usual restriction in FDA's good guidance practice regulations that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d). Therefore, when finalized, the portion of this guidance that specifies the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 shall be exempted from the requirements of section 582 will have binding effect, as indicated by the use of the words *must*, *shall*, or *required*.

II. BACKGROUND

A. Drug Supply Chain Security Act

The 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, which established product tracing requirements for manufacturers, repackagers, wholesale distributors, and dispensers of most prescription drugs in a finished dosage form for administration to a patient without

[7] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or FDA Biologics guidance web page at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

substantial further manufacturing (products).[8] The DSCSA phases in its new requirements over a period of 10 years.

A critical component of the product tracing scheme outlined in the DSCSA is the product identifier.[9] Section 582 requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers are required to begin affixing or imprinting (adding) a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017.[10] Repackagers are required to do the same no later than November 27, 2018.[11]

Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the DSCSA restrict trading partners' ability to engage in transactions involving packages and homogenous cases of product that are not labeled with a product identifier after specific dates. Beginning November 27, 2018, repackagers may not receive or transfer ownership of a package or homogenous case of a product that is not encoded with a product identifier.[12] Similar restrictions go into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively.[13]

Section 582(a)(5)(A) gives FDA the authority to exempt packages and homogenous cases of product without a product identifier from the product tracing requirements discussed above. We are required to issue guidance that specifies whether and under what circumstances we will exercise this authority. Only packages and homogenous cases of product that are "in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of [section 582]" are eligible for an exemption under section 582(a)(5)(A).

The draft guidance *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* (Product Identifier Compliance Policy or compliance policy) explains that FDA does not intend to take action against manufacturers who do not add a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce before November 27, 2018. This represents a 1-year delay in enforcement of section 582(b)(2)(A) of the FD&C Act. The Product Identifier Compliance Policy also explains that FDA does not intend to take action against manufacturers and other trading partners who transact such product or verify it for investigatory purposes or saleable returns without using the product identifier. The grandfathering policy in this guidance should be read in conjunction with the Product Identifier Compliance Policy, which is currently a draft guidance, but which the agency plans to finalize after considering comments received.

[8] Certain prescription drugs are excluded from the product tracing requirements of section 582. See section 581(13) of the FD&C Act for the definition of the term *product*.

[9] *Product identifier* is defined in section 581(14) of the FD&C Act.

[10] See section 582(b)(2)(A) of the FD&C Act. See also FDA's draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*.

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

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

[13] See sections 582(c)(2), (d)(2) of the FD&C Act.

B. Scope of This Guidance

This guidance specifies the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582, including saleable returned packages and homogenous cases of product, shall be exempted, as grandfathered, from certain requirements of section 582. This guidance does not address products or transactions for which a waiver, exception, or exemption has been granted under section 582(a)(3) of the DSCSA from the requirement to bear a product identifier on packages and homogenous cases. FDA intends to address waivers, exceptions, and exemptions under section 582(a)(3) in a separate guidance.

III. INTERPRETATION OF SECTION 582(a)(5)(A) OF THE DSCSA

Under section 582(a)(5)(A), packages and homogenous cases of product that are not labeled with a product identifier are eligible to be exempted from the requirements of section 582 if they are "in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section [(i.e., section 582)]." For the purposes of this guidance, a package or homogenous case of product is "in the pharmaceutical distribution supply chain" if it was packaged by the product's manufacturer before November 27, 2018. We interpret "the effective date of the requirements of this section" as referring to the date set forth in section 582(e)(2)(A)(i) of the DSCSA regarding when repackagers must begin adding product identifiers to packages and homogenous cases of product (i.e., no later than November 27, 2018).

Consequently, a package or homogenous case of product that is not labeled with a product identifier is eligible for an exemption under section 582(a)(5)(A) as described in this guidance only if the product's manufacturer packaged the product before November 27, 2018.

IV. GRANDFATHERING POLICY[14]

FDA has determined that there are circumstances under which it would be appropriate to exempt packages and homogenous cases of product meeting the conditions of section 582(a)(5)(A) of the FD&C Act (i.e., the packages and homogenous cases of product that are not labeled with a product identifier and are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582) from certain requirements of section 582. Those circumstances, and the statutory requirements from which packages and homogenous cases of product without a product identifier shall be exempted, as grandfathered, are set forth below. Our policy for saleable returned packages and homogenous cases of product meeting the conditions of section 582(a)(5)(A) is also described below.

[14] Insofar as section IV of this guidance specifies the circumstances under which packages and homogenous cases of product that are not labeled with a product identifier and that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 of the FD&C Act shall be exempted from the requirements of section 582, it will have binding effect, once finalized.

A. Grandfathering Exemption[15] from Certain Transaction-Related Requirements of Section 582

1. Scope of Grandfathering Exemption

A package or homogenous case of product that is not labeled with a product identifier shall be exempted from certain requirements in section 582 (i.e., grandfathered) where there is documentation that it was packaged by a manufacturer before November 27, 2018. For example, if a package or homogenous case of product not labeled with a product identifier is accompanied by transaction information or a transaction history that includes a sale before November 27, 2018, that trading partner can reasonably conclude the product was packaged by a manufacturer before that date.

If the transaction information or transaction history does not include a sale before November 27, 2018, and absent other indicia that a product may be suspect or illegitimate, the transaction statement is one indication that the product was in the pharmaceutical distribution supply chain before that date.[16] Furthermore, manufacturers retain packaging date information in the ordinary course of business and as a part of batch recordkeeping, and they should provide the packaging date to subsequent trading partners if they request it.

2. Trading Partner Requirements under the Grandfathering Exemption

The specific requirements of section 582 from which a grandfathered product is exempted are set forth below. To assist trading partners in understanding how the grandfathering exemption applies to their activities, the requirements for trading partners are addressed separately below.

- Manufacturer Requirements

  Manufacturers are exempted from two requirements of section 582 in situations where there is documentation that the product involved in the transaction was in the pharmaceutical distribution supply chain before November 27, 2018.

  - First, in those circumstances, manufacturers investigating suspect product without a product identifier to determine whether that product is illegitimate are exempted from that part of section 582(b)(4)(A)(i)(II) which requires that they verify product at the package level using the product identifier beginning November 27, 2017; specifically, manufacturers shall not be required to verify the product at the package level using the product identifier. However, a manufacturer must still validate any applicable transaction history and transaction information in its possession and otherwise investigate the product

[15] As used in this guidance, the term *grandfathering exemption* refers to an exemption from the requirements of section 582 that is established by this guidance under the authority of section 582(a)(5)(A) of the FD&C Act.

[16] Per section 581(27)(d) of the FD&C Act, the transaction statement indicates that an owner did not knowingly ship a suspect or illegitimate product.

to determine if it is illegitimate in accordance with section 582(b)(4)(A)(i)(II); the exemption does not extend to these requirements.

- Second, in those circumstances, manufacturers are exempted from that part of section 582(b)(4)(C) of the DSCSA which, beginning November 27, 2017, requires that upon request from an authorized trading partner in possession or control of a product that believes is from the manufacturer, such manufacturer verifies[17] a product at the package level using the product identifier. However, a manufacturer must still follow all other steps as described in 582(b)(4)(C).

Manufacturers must comply with all other applicable requirements of section 582 when engaging in transactions pursuant to this exemption.

- Wholesale Distributor Requirements

Wholesale distributors are exempted from two requirements of section 582 in situations where there is documentation that the product involved in the transaction was in the pharmaceutical distribution supply chain before November 27, 2018.

- First, in those circumstances, wholesale distributors are exempted from section 582(c)(2), which requires that they engage in transactions involving only product encoded with a product identifier beginning November 27, 2019.

- Second, in those circumstances, wholesale distributors are exempted from that part of section 582(c)(4)(A)(i)(II) of the DSCSA which requires that they undertake certain activities to determine whether a product is illegitimate. Specifically, wholesale distributors shall not be required to verify the product at the package level using the product identifier beginning November 27, 2019. However, wholesale distributors must still validate any applicable transaction history and transaction information in their possession and otherwise investigate the suspect product to determine if it is illegitimate. The exemption does not extend to these requirements of section 582(c)(4)(A)(i)(II).

Wholesale distributors must comply with all other applicable requirements of section 582 when engaging in transactions pursuant to this exemption.

- Dispenser Requirements

Dispensers are exempted from two requirements of section 582 in situations where there is documentation that the product involved in the transaction was in the pharmaceutical distribution supply chain before November 27, 2018.

[17] *Verify* is defined in section 581(28) of the FD&C Act.

- First, in those circumstances, dispensers are exempted from section 582(d)(2) of the DSCSA, which requires that they engage in transactions involving only product encoded with a product identifier beginning November 27, 2020.

- Second, in those circumstances, dispensers are exempted from section 582(d)(4)(A)(ii)(II), which requires that they verify the product identifier of a portion of packages beginning November 27, 2020, as part of an investigation conducted to determine whether a product is illegitimate. However, dispensers must still verify the lot number of a suspect product as described in section 582(d)(4)(A)(ii)(I), validate any applicable transaction history and transaction information in their possession as described in section 582(d)(4)(A)(ii)(III), and otherwise investigate the product to determine if it is illegitimate as required by section 582(d)(4)(A)(ii)(IV). The exemption does not extend to these requirements of section 582(d)(4)(A)(ii) of the DSCSA.

Dispensers must comply with all other applicable requirements of section 582 when engaging in transactions pursuant to this exemption.

- Repackager Requirements

  FDA has also determined that the grandfathering exemption applies to certain repackager activities in situations where there is documentation that the product involved in the transaction was in the pharmaceutical distribution supply chain before November 27, 2018.

  - First, in those circumstances, repackagers are partially exempted from the requirement of section 582(e)(2)(A)(iii) of the DSCSA to only engage in transactions of product encoded with a product identifier beginning November 27, 2018; specifically, repackagers may ***accept*** ownership of packages or homogenous cases of product without a product identifier after November 27, 2018. However, if a repackager wishes to ***transfer*** ownership of a package or homogenous case of product without a product identifier on or after November 27, 2018, it must, in accordance with section 582(e)(2)(A)(i), first add a product identifier to the package or homogenous case of product.

  - Second, in those circumstances, repackagers investigating suspect product without a product identifier to determine whether that product is illegitimate are also exempted from that part of section 582(e)(4)(A)(i)(II) which requires that they verify product at the package level using the product identifier beginning November 27, 2018; specifically, repackagers shall not be required to verify the product at the package level using the product identifier. However, a repackager must still validate any applicable transaction history and transaction information in its possession and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(e)(4)(A)(i)(II); the exemption does not extend to these requirements.

- Third, if a repackager initially repackaged and sold product without a product identifier before November 27, 2018, it is exempted from that part of section 582(e)(4)(C) of the DSCSA which, beginning November 27, 2018, requires that upon request from an authorized trading partner in possession or control of a product it believes is from the repackager, such repackager verifies the product using the product identifier. However, a repackager must still follow all other steps as described in 582(e)(4)(C).

Repackagers must comply with all other applicable requirements of section 582 when engaging in transactions pursuant to this exemption.

Trading partners may engage in transactions involving products exempted as grandfathered per the conditions of the grandfathering policy until product expiry, regardless of when the transaction occurs. Although there is no sunset date for the grandfathering exemption, FDA expects there to be relatively few, if any, of these packages and homogenous cases of product without a product identifier in the pharmaceutical distribution supply chain by November 27, 2023.[18]

The FDA guidance *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* notes that a package missing product tracing information is a scenario that could significantly increase the risk of a suspect product entering the drug supply chain.[19] As product identifier requirements are implemented over time, trading partners should be diligent when engaging in a transaction of a package or homogenous case of product without a product identifier to ensure it is subject to the grandfathering policy, other type of exemption, or a compliance policy.

FDA emphasizes that trading partners must comply with all other applicable requirements of section 582 when engaging in transactions covered by the exemption established by this guidance. For example, a wholesale distributor that transfers ownership of a package or homogenous case of product without a product identifier after November 27, 2019 that is subject to the grandfathering exemption must provide the subsequent owner with the product's transaction information, transaction history, and transaction statement prior to, or at the time of, the transaction.

B. Saleable Returned Packages and Homogenous Cases of Product

Section 582 addresses trading partners' ability to accept and redistribute product that is returned to them in saleable condition. Manufacturers, wholesale distributors, and repackagers are required under sections 582(b)(4)(E), (c)(4)(D), and (e)(4)(E), respectively, to verify the product identifier of a saleable returned package or sealed homogenous case of product that is intended for further distribution. This requirement goes into effect on November 27, 2017 (per the

[18] We note that the enhanced drug distribution security provisions of section 582(g) go into effect on November 27, 2023.

[19] See guidance for industry at https://www.fda.gov/downloads/drugs/guidances/ucm400470.pdf.

statute) for manufacturers, November 27, 2018, for repackagers, and November 27, 2019, for wholesale distributors. [20]

For returns[21] of saleable packages and homogeneous cases of product without product identifiers that were in the pharmaceutical distribution supply chain before November 27, 2018, manufacturers, wholesale distributors, and repackagers are exempted from the requirements of sections 582(b)(4)(E), (c)(4)(D), and (e)(4)(E), respectively, to verify the product identifier of a saleable returned package or sealed homogenous case of product that is intended for further distribution. Manufacturers are exempted from the requirements of 582(b)(2)(A) to add product identifiers before redistributing such product. Repackagers are exempted from the requirements of 582(e)(2)(A)(i) and (e)(2)(A)(iii) to add product identifiers before redistributing such product if they initially repackaged and sold the product without a product identifier before November 27, 2018. Trading partners must comply with all other applicable requirements of section 582 when engaging in returns. For example, wholesale distributors must still meet the requirements of section 582(c)(1)(B)(i)(II) and only accept returned product from a dispenser or repackager beginning November 27, 2019, if they can associate the returned product with the transaction information and transaction statement for that product.

V. DISTINCTIONS BETWEEN THE GRANDFATHERING POLICY AND THE COMPLIANCE POLICY FOR PRODUCT IDENTIFIER REQUIREMENTS UNDER THE DSCSA

The grandfathering and compliance policies have different legal statuses and apply in different scenarios. Under the grandfathering policy, eligible packages and homogenous cases of product are exempted, as grandfathered, from certain DSCSA requirements. The Product Identifier Compliance Policy, by contrast, describes FDA's intention not to take action against certain trading partners in certain circumstances; the DSCSA requirements remain in effect, but the Agency intends to exercise discretion in how it enforces the law.

[20] See also FDA's draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*.

[21] *Return* is defined in section 581(17) of the FD&C Act.