

U.S. FDA Announces Drug Supply Chain Security Act Exemptions for Covered COVID-19 Products Until November 27, 2024

May 30, 2023

On May 11, 2023, the U.S. Food and Drug Administration (FDA) published a letter¹ listing exemptions for prescription drug products approved or authorized by FDA to diagnose, cure, mitigate, treat or prevent COVID-19 (Covered COVID-19 Products) from requirements in Section 582 of the Food, Drug & Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA). Trading partners, including manufacturers, wholesale distributors, repackagers, and dispensers, should analyze the impact of these exemptions on their processes and systems and make applicable changes to ensure compliance with the DSCSA.

For example, a repackager could choose to exit the market for Covered COVID-19 Products on or before November 27, 2024, when these exemptions from product identifier and product tracing requirements end. Notably, these exemptions effectively delay enforcement of serialization requirements, set to go into effect later this year, for Covered COVID-19 Products by one year. All trading partners, however, must still comply with suspect product and illegitimate product investigation and notification requirements, as applicable.

Background

On February 9, 2023, the U.S. Department of Health and Human Services (HHS) announced its plan to terminate the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service Act, on May 11, 2023.² To prepare for this termination and transition to a postpandemic era, FDA issued a notice³ mapping out which of its 72 COVID-19-related guidance documents expire in tandem with the PHE. Among the guidance documents that expired is “Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act”⁴; however, FDA stated that it “retains authority under section 582(a) of the FD&C Act ... to grant waivers, exemptions and exceptions to allow for continued distribution of covered COVID-19 products.”⁵ The letter referenced at the top of this alert was issued pursuant to that authority.

FDA's Letter

In its May 11 letter, “DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C

Act for Covered COVID-19 Products,” FDA issued exemptions for certain requirements in the DSCSA for Covered COVID-19 Products to “avoid potential supply chain disruptions that could harm the COVID-19 response and recovery.”⁶ These Covered COVID-19 Products are “prescription drug products approved or authorized by FDA to diagnose, cure, mitigate, treat or prevent COVID-19,” introduced by a manufacturer or repackager in a transaction into interstate commerce before November 27, 2024. The letter exempts authorized trading partners from specific requirements for Covered COVID-19 Products as follows:

Manufacturers

- product tracing requirements (Section 582(b)(1) of the FD&C Act) that require manufacturers to exchange data with each transaction
- product identifier requirements (Section 582(b)(2) of the FD&C Act) that require manufacturers to affix or imprint product identifiers on each package and homogenous case of a product
- certain product verification requirements, including requirements to
 - verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in the manufacturer’s possession (Section 582(b)(4)(A)(i)(II) of the FD&C Act) for the purposes of a suspect product investigation and responding to an illegitimate product notification under Section 582(b)(4)(B)(iii) of the FD&C Act
 - verify product using the product identifier upon request from an authorized trading partner in possession or control of a product that it believes to be made by the manufacturer⁷ (Section 582(b)(4)(C) of the FD&C Act)
 - verify the product identifier of a saleable returned product that is intended for further distribution (Section 582(b)(4)(E) of the FD&C Act)

Wholesale Distributors

- product tracing requirements (Section 582(c)(1) of the FD&C Act) that require wholesale distributors to exchange data with each transaction
- product identifier requirements (Section 582(c)(2) of the FD&C Act) that require wholesale distributors to engage in transactions with products that have a product identifier, as applicable
- certain product verification requirements, including requirements to
 - verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in the wholesale distributor’s possession (Section 582(c)(4)(A)(i)(II) of the FD&C Act) for the purposes of a suspect product investigation or responding to an illegitimate product notification under Section 582(c)(4)(B)(iii) of the FD&C Act
 - verify the product identifier of a saleable returned product that is intended for further distribution (Section 582(c)(4)(E) of the FD&C Act)

Dispensers

- product tracing requirements (Section 582(d)(1) of the FD&C Act) that require dispensers to exchange data with each transaction
- product identifier requirements (Section 582(d)(2) of the FD&C Act) that require dispensers to engage in transactions with products that have a product identifier, as applicable
- the product verification requirement for dispensers to verify a portion of suspect products at the package level using the product identifier (Section 582(d)(4)(A)(ii)(II) of the FD&C Act) and validate any applicable transaction history and transaction information in the dispenser's possession (Section 582(d)(4)(A)(ii)(III) of the FD&C Act) for the purpose of an investigation of suspect product under Section 582(d)(4)(A) of the FD&C Act or when responding to an illegitimate product notification under Section 582(d)(4)(B)(iii)⁸

Repackagers

- product tracing requirements (Section 582(e)(1) of the FD&C Act) that require repackagers to exchange data with each transaction
- product identifier requirements (Section 582(e)(2) of the FD&C Act) that require repackagers to affix or imprint product identifiers on each package and homogenous case of a drug product
- certain product verification requirements that require repackagers to
 - verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in the repackager's possession (Section 582(e)(4)(A)(i)(II) of the FD&C Act) for the purposes of a suspect product investigation or responding to an illegitimate product notification under Section 582(e)(4)(B)(iii) of the FD&C Act
 - verify product using the product identifier upon request from an authorized trading partner in possession or control of a product that it believes to be repackaged by the repackager⁹ (Section 582(e)(4)(C) of the FD&C Act)
 - verify the product identifier of a saleable returned product that is intended for further distribution (Section 582(e)(4)(E) of the FD&C Act)

All trading partners must still promptly conduct an investigation in coordination with other trading partners, as applicable, into a Covered COVID-19 Product identified as suspect to determine whether it is illegitimate and follow applicable requirements regarding illegitimate products.¹⁰

Beyond the narrow scope of the exemptions listed in the May 11 letter, FDA requires trading partners to comply with all other applicable requirements of Section 582 for transactions of Covered COVID-19 Products introduced by a manufacturer or repackager in a transaction into commerce before November 27, 2024. In addition, FDA encourages compliance with DSCSA requirements covered by the exemptions “to the extent that compliance ... is not a barrier to timely distribution of covered COVID-19 products.”¹¹ To the extent trading partners choose to rely on the exemptions identified in the letter, FDA recommends communicating such reliance to other trading partners in advance “to further facilitate distribution without difficulty or delay.”¹²

¹ See FDA, DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C Act for

Covered COVID-19 Products (May 11, 2023) (hereinafter Covered COVID-19 Products DSCSA Exemptions Letter).

² See HHS, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap (Feb. 9, 2023).

³ See Guidance Documents Related to Coronavirus Disease 2019, 88 Fed. Reg. 15,417 (Mar. 13, 2023).

⁴ *Id.* at 15,419 n. 4.

⁵ *Id.*

⁶ See Covered COVID-19 Products DSCSA Exemptions Letter at 1.

⁷ However, if the manufacturer has reason to believe the product is an illegitimate product, it must still advise the authorized trading partner making the request to such belief. Covered COVID-19 Products DSCSA Exemptions Letter at 2.

⁸ Dispensers are still required to verify lot numbers in accordance with Section 582(d)(4)(A)(ii)(I) of the FD&C Act. Covered COVID-19 Products DSCSA Exemptions Letter at 3.

⁹ However, if the repackager has reason to believe the product is an illegitimate product, it must still advise the authorized trading partner making the request of such belief. Covered COVID-19 Products DSCSA Exemptions Letter at 4.

¹⁰ In particular, FDA noted that the letter does not exempt the following sections of the FD&C Act applicable to illegitimate products: 582(b)(4)(B)(i) and (ii) (manufacturers); 582(c)(4)(B)(i) and (ii) (wholesale distributors); 582(d)(4)(B)(i) and (ii) (dispensers); and 582(e)(4)(B)(i) and (ii) (repackagers).

¹¹ Covered COVID-19 Products DSCSA Exemptions Letter at 2.

¹² *Id.*

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