Date Issued: **May 11, 2023**

Subject: **DSCSA Exemptions From Certain Requirements Under Section 582 of the FD&C Act for Covered COVID-19 Products**

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug and Cosmetic Act (FD&C Act) to grant exemptions for covered COVID-19 products, as outlined in these exemptions, from certain requirements in section 582 of the FD&C Act.[1]

The U.S. Department of Health and Human Services (HHS) has announced[2] that, based on current COVID-19 trends, they are planning for the COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service Act to expire on May 11, 2023. In the Federal Register of March 13, 2023, FDA published a notice[3] addressing the Agency's COVID-19-related guidance documents, including which of those guidance documents will no longer be in effect after the expiration of the PHE, and which of those guidance documents FDA is revising to temporarily continue in effect.

In that notice, FDA explained that while the guidance document titled "Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency" (hereafter "COVID-19 DSCSA guidance") would expire at the end of the PHE, "the Agency retains authority under section 582(a) of the FD&C Act (21 U.S.C. 360eee-1(a)) to grant waivers, exemptions, and exceptions to allow for continued distribution of covered COVID-19 … products, as appropriate, which may be used to avoid disruption beyond the expiration of such declaration."[4]

Thus, in an effort to transition after the end of the COVID-19 PHE and to avoid potential supply chain disruptions that could harm the COVID-19 response and recovery, FDA grants the following exemptions from certain requirements under section 582 of the FD&C Act, as added by the Drug Supply Chain Security Act (DSCSA). The FDA has determined that these exemptions are appropriate to maintain public health and has determined that these exemptions address prescription drug products approved or authorized by FDA to diagnose, cure, mitigate, treat, or prevent COVID-19. For the purposes of these exemptions, we are referring to these products collectively as *covered COVID-19 products.*

[1] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued draft guidance on waivers, exceptions and exemptions from section 582 requirements, that includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or - if an exception or exemption applied to a broad segment of industry - a posting on its website). An exception or exemption that is established by FDA may be limited in duration or valid until further notice from FDA." Consistent with that guidance, we are posting these exemptions on our website.

[2] See COVID-19 Public Health Emergency (PHE) | HHS.gov.

[3] See 88 FR 15417.

[4] See 88 FR 15417, n. 4.

These exemptions apply to covered COVID-19 products introduced by a manufacturer or repackager in a transaction into interstate commerce before November 27, 2024, and are effective until expiry of such product.[5] Trading partners must comply with all other applicable requirements of section 582 that are not identified in the exemptions for transactions of covered COVID-19 products introduced by a manufacturer or repackager in a transaction into commerce before November 27, 2024. The exemptions described here do not extend to trading partners' transactions of any other product; in such cases, all applicable requirements of section 582 must be met unless otherwise exempted.

To the extent that compliance with DSCSA requirements covered by the exemptions is not a barrier to timely distribution of covered COVID-19 products, trading partners should continue to comply with those requirements.

If a trading partner relies on the exemptions outlined here, we recommend communicating such reliance to its trading partners to further facilitate distribution without difficulty or delay.

Please contact the FDA at DSCSA-WEER@fda.hhs.gov if you have any questions.

FDA has determined that the following exemptions, which generally align with those described in the expired COVID-19 DSCSA guidance, are appropriate:

- Manufacturers are exempted from the following section 582 requirements for covered COVID-19 products they introduce in a transaction into commerce before November 27, 2024:
  - The section 582(b)(1) product tracing requirements.
  - The section 582(b)(2) product identifier requirements.
  - The section 582(b)(4)(A)(i)(II) 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 for the purposes of a suspect product investigation, responding to an illegitimate product notification under section 582(b)(4)(B)(iii). However, manufacturers must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(b)(4)(A)(i)(II), and, upon determining such product is illegitimate, follow the requirements in section 582(b)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.
  - The section 582(b)(4)(C) requirement that upon request from an authorized trading partner in possession or control of a product that it believes to be made by the manufacturer, such manufacturer verify the product using the product identifier. However, if the manufacturer has reason to believe the product is an illegitimate product, the manufacturer must still advise the person making the request of such belief at the time such manufacturer responds to the request for verification; the exemptions do not extend to this requirement.

[5] Separate from the exemptions described below, certain DSCSA requirements may be the subject of compliance policies under which FDA intends to not take action to enforce such requirements until a specific date. A list of DSCSA compliance policies, along with all DSCSA guidance, can be found at: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies.

  - The section 582(b)(4)(E) requirement to verify the product identifier of a saleable returned product that is intended for further distribution.

- Wholesale distributors are exempted from the following section 582 requirements for covered COVID-19 products introduced by a manufacturer or repackager in a transaction into commerce before November 27, 2024:

  - The 582(c)(1) product tracing requirements.

  - The section 582(c)(2) product identifier requirements.

  - The section 582(c)(4)(A)(i)(II) requirements to verify product at the package level using the product identifier and validate any applicable transaction history and transaction information in its possession for the purposes of a suspect product investigation or when responding to an illegitimate product notification under section 582(c)(4)(B)(iii). However, such wholesale distributors must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(c)(4)(A)(i)(II) and, upon determining such product is illegitimate, follow the requirements in section 582(c)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

  - The section 582(c)(4)(D) requirement to verify the product identifier of saleable returned product packaged without product identifiers that is intended for further distribution.

- Dispensers are exempted from the following section 582 requirements for covered COVID-19 products introduced by a manufacturer or repackager in a transaction into commerce before November 27, 2024:

  - The section 582(d)(1) product tracing requirements.

  - The section 582(d)(2) product identifier requirements.

  - The section 582(d)(4)(A)(ii)(II) requirement to verify a portion of suspect products at the package level using the product identifier], and section 582(d)(4)(A)(ii)(III) requirement to validate any applicable transaction history and transaction information in a dispenser's possession for the purpose of an investigation of suspect product under 582(d)(4)(A) or when responding to an illegitimate product notification under section 582(d)(4)(B)(iii). However, dispensers must still verify lot number in accordance with section 582(d)(4)(A)(ii)(I) and otherwise conduct an investigation the product to determine if it is illegitimate as required by section 582(d)(4)(A)(ii)(IV), and, upon determining such product is illegitimate, follow the requirements in section 582(d)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

- Repackagers are exempted from the following section 582 requirements for covered COVID-19 products introduced by a manufacturer or repackager in a transaction into commerce before November 27, 2024:

  - The section 582(e)(1) product tracing requirements.

  - The section 582(e)(2) product identifier requirements.

- The section 582(e)(4)(A)(i)(II) requirements to verify product at the package level using the product identifier] and validate any applicable transaction history and transaction information in its possession for the purposes of a suspect product investigation, responding to an illegitimate product notification under section 582(e)(4)(B)(iii) or when prompted by a request for verification under 582(e)(4)(C). However, repackagers must still promptly conduct an investigation in coordination with trading partners as applicable and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(e)(4)(A)(i)(II) and, upon determining such product is illegitimate, follow the requirements in section 582(e)(4)(B)(i) and (ii); these exemptions do not extend to these requirements.

- The section 582(e)(4)(C) requirement that upon request from an authorized trading partner in possession or control of a product that it believes to be repackaged by the repackager, such repackager verify the product using the product identifier. However, if the repackager has reason to believe the product is an illegitimate product, the repackager must still advise the person making the request of such belief at the time such repackager responds to the request for verification; these exemptions do not extend to this requirement.

- The section 582(e)(4)(E) requirement to verify the product identifier of a saleable returned product that is intended for further distribution.

Sincerely,

[E-SIGNATURE PLACEHOLDER]

Michael M. Levy -S Digitally signed by Michael M. Levy -S
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