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New FDA Guidance Describing Exemptions, Exclusions, and Discretion Relating to Drug Supply Chain Security Act Requirements During the COVID-19 Public Health Emergency

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Food, Drugs, and Devices

The United States Food and Drug Administration (FDA) recently published a Guidance for Industry, Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency (Guidance), to (1) clarify the applicability of the Drug Supply Chain Security Act (DSCSA) to certain distribution activities, and (2) set forth an enforcement discretion policy with respect to certain authorized trading partner requirements. The Guidance outlines FDA's policy on these topics for the duration of the Coronavirus Disease 2019 (COVID-19) public health emergency.

Background on the DSCSA and COVID-19

In 2013, Congress enacted the DSCSA, which amended the Federal Food, Drug, and Cosmetic Act (FDCA), to establish a number of requirements to facilitate tracing of prescription drug products as they move through the pharmaceutical distribution supply chain.[1] These requirements relate to product tracing, product identifiers, authorized trading partners, and verification requirements for supply chain members.

Certain product tracing and product identification requirements do not apply to activities that are exempted from the definition of *transaction*, and certain licensure, reporting, and wholesale distributor requirements do not apply to activities excluded from the definition of *wholesale distribution*.[2] One such activity is the distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (PHSA). In 2020, the Secretary of Health and Human Services declared a public health emergency related to COVID-19 under PHSA section 319, and the President declared a

[1] *See* Title II of Pub. L. 113-54 (adding FDCA sections 581 and 582 and amending FDCA section 503).
[2] *See* FDCA section 581(24)(B)(iii) (defining *transaction*) and FDCA section 503(e)(4)(C) (defining *wholesale distribution*).

national emergency in response to COVID-19. COVID-19 therefore qualifies as a DSCSA emergency medical reason.

Supply chain members must ensure that their *trading partners* are *authorized*.[3] The term *authorized* means having a valid FDA registration for a manufacturer or repackager, having a valid state license or a DSCSA license and complying with DSCSA licensure reporting requirements for a wholesale distributor or third-party logistics provider, and having a valid state license for a dispenser.

Guidance

The Guidance addresses the types of distribution activities related to the COVID-19 public health emergency that fall under the *transaction* definition exemption and the *wholesale distribution* definition exclusion. The Guidance also announces an enforcement discretion policy with respect to the DSCSA's requirement that supply chain members are engaging with *authorized trading partners*.

In addition, the Guidance warns that some entities may seek to profit from the COVID-19 public health emergency by selling unproven and illegally marketed products with false claims, which can cause harm. Trading partners should engage in transactions with "trusted sources" and confirm with FDA and state authorities that the trading partner is working with the relevant authorities to operate during the COVID-19 public health emergency. FDA also reminds trading partners that they generally must comply with the DSCSA verification requirements to make sure suspect or illegitimate products do not reach patients.

FDA's Interpretation of the DSCSA's Public Health Emergency *Transaction* Exemption and *Wholesale Distribution* Exclusion During the COVID-19 Public Health Emergency

- Inapplicability of Product Tracing and Product Identification Requirements Triggered by a *Transaction*

The Guidance clarifies that trading partners are not required to comply with certain product tracing and product identification requirements in FDCA section 582 if they distribute product for emergency medical reasons to address the COVID-19 public health emergency. These product tracing and product identification requirements are triggered by the occurrence of a *transaction*. The Guidance identifies two specific categories of product distribution that qualify for the public health emergency *transaction* exemption: (1) the distribution of "covered COVID-19 products"; and (2) the distribution of "other affected products" that are directly impacted by the COVID-19 public health emergency.

Regarding (1), the Guidance defines "covered COVID-19 products" as prescription drug products for which FDA has issued an emergency use authorization to combat COVID-19 or that FDA has approved to diagnose, cure, mitigate, treat, or prevent COVID-19. Regarding (2), the Guidance identifies examples in which the public health emergency could affect distribution of "other affected products": (a) distribution of a product to an area with limited availability and higher demand for the product because of COVID-19; (b) distribution by an authorized trading

[3] *See* FDCA section 581(2) (defining *authorized*) and section 581(23) (defining *trading partner*).

partner that needs a new, temporary facility for distribution as a result of the COVID-19 impact on the original facility; and (c) dispenser-to-dispenser transfers of products needed as a result of COVID-19, regardless of whether there is a specific patient need.

FDA emphasizes in the Guidance that a trading partner distributing product during the COVID-19 public health emergency for purposes other than emergency medical reasons must continue to comply with all applicable DSCSA requirements with respect to the product's distribution.

- Inapplicability of Certain Licensure, Reporting, and Wholesale Distributor Requirements Triggered by *Wholesale Distribution*

The Guidance clarifies that the DSCSA's requirements related to *wholesale distribution* do not apply to distribution activities addressing the COVID-19 public health emergency while the emergency is ongoing. Entities engaging in (1) the distribution of "covered COVID-19 products," or (2) the distribution activities of "other affected products" that are directly impacted by the COVID-19 public health emergency—the two categories discussed above—are not required to comply with the DSCSA's licensure provisions and reporting requirements under FDCA section 503(e) or the wholesale distributor requirements under FDCA section 582 during the public health emergency.

FDA emphasizes in the Guidance that an entity engaged in activities that meet the definition of *wholesale distribution*, but such activities are not for emergency medical reasons, would be a wholesale distributor with respect to those activities and would need to comply with the requirements in FDCA sections 503(e) and 582(c) for the distribution of the products involved.

Compliance Policy for Authorized Trading Partner Requirements

Although the DSCSA's requirements to trade only with *authorized trading partners* generally still apply during the public health emergency, FDA does not intend to take enforcement action against trading partners for failing to comply with the authorized trading partner requirements set forth in FDCA section 582 during the COVID-19 public health emergency if the trading partner is engaging in:

- COVID-19-related distribution involving entities that would otherwise meet the definition of a *wholesale distributor* under the DSCSA, except that—as a result of the exclusion from the definition of *wholesale distribution* for emergency medical reasons—these entities would not be considered wholesale distributors because they are currently engaged in distributing product for emergency medical reasons resulting from COVID-19; or
- Distributions involving other trading partners that are not authorized solely because of circumstances directly related to the COVID-19 public health emergency, as long as these trading partners are working with or have been permitted by applicable State authorities to operate during COVID-19 and compliance with the authorized trading partner requirements would present a barrier to timely distribution of products needed during the COVID-19 public health emergency.

To best advise our clients on the rapidly evolving public health situation in the United States, our COVID-19 task force is staying abreast of daily developments and tracking the latest federal, state and local policies related to COVID-19. Please feel free to reach out to our team members listed below with any questions, and to visit Covington's website for our COVID-19: Legal and Business Toolkit.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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