WINSTON & STRAWN LLP

CLIENT ALERT

FDA Clarifies Scope of the Public Health Emergency Exemption and Exclusion Under the DSCSA

MAY 4, 2020

On April 30, 2020, in response to the declared COVID-19 public health emergency, the Food and Drug Administration ("FDA" or the "Agency") issued new guidance ("the Guidance") to clarify the scope of the public health emergency exemption and exclusion provisions under the Drug Supply Chain Security Act ("DSCSA"). Further, the Guidance announces the FDA's policy to exercise discretion in the enforcement of authorized trading partner requirements. The statutory exemption and exclusion provisions, as well as the FDA's enforcement discretion outlined in the Guidance, are intended to remain in effect only throughout the COVID-19 public health emergency.

See Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency Guidance for Industry (April 2020), *available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exemption-and-exclusion-certain-requirements-drug-supply-chain-security-act-during-covid-19-public.*

The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013 and Section 202 added section 582 to the Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C § 360eee-1), establishing the product tracing, product identifier, authorized trading partner, and verification requirements for trading partners (*i.e.*, manufacturers, repackagers, wholesale distributors, and dispensers) to facilitate the tracing of products through the pharmaceutical distribution supply chain. Under Section 582 of the FD&C Act, trading partners are required to capture, maintain, and provide subsequent purchasing trading partners with transaction information, transaction history, and a transaction statement (product tracing information), among other requirements.

Scope of DSCSA Exemption and Exclusion

The Guidance clarifies that under the DSCSA, specific activities are automatically excluded from certain DSCSA requirements upon the declaration of a public health emergency under the Public Health Service Act ("PHS Act"). Accordingly, the *distribution*[1] of a product for emergency medical reasons, including a public health emergency declaration, is exempted from the definition of a *transaction*[2] and excluded from the definition of *wholesale distribution.*[3] FDA interprets the exemption and exclusion to apply to products distributed to address the COVID-19

public health emergency, but may also apply to products that were already in the supply chain when the public health emergency was first declared.

As a result of the statutory exemption and exclusion provisions triggered by the public health emergency, trading partners engaged in (1) the distribution of *covered COVID-19 products* [4] or (2) distribution activities, with respect to other affected products, that are directly impacted by the COVID-19 emergency and which meet emergency medical needs, are not required to comply with the product tracing and product identification requirements of the FD&C Act. Likewise, entities engaging in (1) the distribution of covered COVID-19 products or (2) certain distribution activities directly impacted by the public health emergency, are not required to comply with the DSCSA's licensure provisions and the reporting requirements or the wholesale distributor requirements of the FD&C Act. FDA notes that this licensing exclusion is not intended to affect the ability of states to require wholesale distributor licensure under State law.

The Guidance also clarifies that the exemption provision does not extend to a trading partner who is distributing product during the public health emergency for purposes other than emergency medical reasons. That trading partner must comply with all applicable DSCSA requirements with respect to distribution of such product. Furthermore, the exemption does not extend to FDA registration requirements, licensure for authorized trading partners, or verification, including quarantine and investigation of suspect product and quarantine and disposition of illegitimate product. In addition, the exclusion provision is not applicable to an entity engaged in activities that meet the definition of wholesale distribution but where such activities are not for emergency medical reasons.

FDA Enforcement Discretion

FDA also makes clear in the Guidance that while the FD&C Act requirement to trade only with authorized trading partners will still apply in most circumstances, the Agency generally does not intend to take enforcement action against trading partners during the public health emergency for engaging in either (1) COVID-19 related distribution involving entities that would otherwise meet the DSCSA definition of a wholesale distributor but are excluded because the wholesale distribution definition does not apply to their COVID-19 related activities, or (2) distributions involving trading partners that are not "authorized" where such trading partners are working with or have been permitted by state authorities to operate during the COVID-19 public health emergency and to the extent compliance with DSCSA's authorized trading partner requirements would pose a barrier to timely distribution of needed products.

FDA guidance documents reflect the FDA's current thinking on a subject and are recommendations, not requirements. While this Guidance was issued without a prior comment period, the FDA will be accepting public comments on it going forward. The Guidance reflects FDA's intent to clarify the scope of the public health emergency exemption and exclusion under the DSCSA for the duration of the public health emergency, and further ensure adequate distribution of finished prescription drug products throughout the supply chain to combat COVID-19.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

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For further information or questions on the new Guidance on the Drug Supply Chain Security Act, please contact the Winston partners listed below, or your Winston relationship attorney.

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[1] In section 581(5) of the FD&C Act, *distribute or distribution* is defined as the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act (21 U.S.C. § 353(b)(1)) or dispensing of a product approved under section 512(b) of the FD&C Act (21 U.S.C. § 360b(b)) ·

[2] *Transaction* is defined as the transfer of product between persons in which a change of ownership occurs (section 581(24) of the FD&C Act (21 U.S.C. § 360eee(24))). For specific exemptions, *see* section 581(24)(B) of the FD&C Act.

[3] *Wholesale distribution* is defined as, "distribution of a drug . . . to a person other than a consumer or patient, or receipt of a drug . . . by a person other than [a] consumer or patient" (section 503(e)(4) of the FD&C Act). Section 503(e)(4)(C) excludes from the definition of *wholesale distribution*, "the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that . . . a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason."

[4] For purposes of the Guidance, FDA advises that *covered COVID-19 products* include prescription drug products (a) [that are] issued an emergency use authorization to combat COVID-19 or (b) approved by FDA to diagnose, cure, mitigate, treat, or prevent COVID-19.

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