WINSTON & STRAWN LLP

CLIENT ALERT

FDA Interprets Terms Used in Definitions of Suspect and Illegitimate Product Under the DSCSA

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Earlier this month, in an effort to assist trading partners in meeting verification obligations (including notification) under sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA or the Agency) issued draft guidance (the Guidance) interpreting terms used in the definitions of suspect and illegitimate product.

The Guidance addresses verification obligations (including notification) under sections 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act and interprets terms used in the definitions for suspect product in section 581(21) and illegitimate product in section 581(8) of the FD&C Act.

The Guidance revises draft guidance for industry, *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act*, which was issued in March 2018. Additionally, the Guidance clarifies certain points of the March 2018 draft guidance and adds FDA's current understanding of the term "stolen."

***See FDA's Draft Guidance on Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry (June 2021)*,** available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/definitions-suspect-product-and-illegitimate-product-verification-obligations-under-drug-supply?utm_medium=email&utm_source=govdelivery

BACKGROUND

Section 202 of the Drug Supply Chain Security Act (DSCSA) added section 581 to the FD&C Act and set forth the definitions of suspect and illegitimate product. Section 581(21) defines **suspect product** as a product for which there is reason to believe the product is (A) potentially counterfeit, diverted, or stolen; (B) potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. Section 581(8) defines **illegitimate product** as a product for which credible evidence shows that the product is (A) counterfeit, diverted, or stolen; (B) intentionally adulterated such that the product would result in serious adverse health consequences or

death to humans; (C) the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

FDA's Interpretation of Terms

To comply with the verification provisions (including notification) of section 582 of the FD&C Act, trading partners must be able to identify a suspect product and make a determination about whether that product is an illegitimate product. To aid trading partners in determining whether a product is suspect and/or illegitimate, the Guidance clarifies FDA's interpretation of the terms "counterfeit drug," "diverted," "stolen," "fraudulent transaction," and "unfit for distribution" as used in sections 581(8) and (21) of the FD&C Act.

A. Counterfeit Drug

FDA interprets the term ***counterfeit drug*** to mean:

[A] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

B. Diverted

FDA interprets the term ***diverted*** to refer to a:

- Product that left the U.S. pharmaceutical distribution supply chain and is reintroduced in the United States in a transaction with a trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced into the U.S. pharmaceutical distribution supply chain to a trading partner; or
- Product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. pharmaceutical distribution supply chain through a transaction with a trading partner.

A product would not be considered diverted as described above and, therefore, would generally not be considered a suspect or illegitimate product under DSCSA, solely if a trading partner obtains that drug product:

- Through surveillance activities outside the U.S. pharmaceutical distribution supply chain;
- From a consumer or patient who obtained the product from outside the U.S. pharmaceutical distribution supply chain;
- As a result of FDA's regulatory action to address a drug shortage; or
- Where an Emergency Use Authorization has been issued.

C. Stolen

FDA interprets the term ***stolen*** as it applies to a package of a product to refer to:

- Any product in its entirety (i.e., the prescription drug and its packaging) that has been taken or removed without permission of the owner of the product (e.g., a bottle and all of its content of drug are taken or removed from the trading partner, or product taken as the result of cargo theft, warehouse theft, or courier theft);
- Any packaging of a product that has been taken or removed without the permission of the owner (e.g., only the empty bottle or outer carton is taken or removed from the trading partner);
- Any prescription drug that has been taken or removed without permission of the owner of the product (e.g., all or some of the tablets are removed from a bottle and then taken or removed from the trading partner); or
- Any prescription drug and/or its packaging, in physical custody of a trading partner, that is missing all or any portion of the drug as a result of the drug being taken or removed without permission of the owner (e.g., half of

the tablets are removed from a bottle and the bottle with the remaining tablets is left with the trading partner subject to the theft, or all the tablets are removed from the bottle and the bottle is left with the trading partner subject to the theft).

D. Fraudulent Transaction

FDA interprets the term ***fraudulent transaction*** as referring to a transaction in which the transaction information, transaction history, or transaction statement contains information knowingly falsified by a trading partner that has provided or received the information.

E. Unfit for Distribution

FDA interprets the term ***unfit for distribution*** as referring to a prescription drug whose sale would violate the FD&C Act and where there is reason to believe or credible evidence shows that the product would be reasonably likely to result in serious adverse health consequences or death to humans. This includes prescription drugs identified as suspect or illegitimate; adulterated (see section 501 of the FD&C Act) (21 U.S.C. 351)), including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (see section 501(a)(2)(B) of the FD&C Act); or misbranded (see section 502 of the FD&C Act (21 U.S.C. 352)), where there is a reason to believe or credible evidence shows that such product would be reasonably likely to result in serious adverse health consequences or death to humans.

This definition of unfit for distribution, used to determine whether a product could be considered suspect or illegitimate, does not include product that is awaiting reverse distribution and processing and will not be distributed to patients. Similarly, product granted a waiver, exception, or exemption under section 582(a)(3) of the FD&C Act and product grandfathered under section 582(a)(5) would not be considered unfit for distribution. Although such product is not considered unfit for distribution solely because it fits in one of these categories, such product could be unfit for distribution because it otherwise falls under the definition laid out in this section.

RELATED INDUSTRY UPDATES: For more on how to use the definitions described above to help identify suspect and/or illegitimate products and meet FDA notification requirements, see Winston & Strawn's briefing, *FDA Publishes Guidance on the Identification and Notification of Suspect Products as Part of the Implementation of the Drug Supply Chain Security Act* (available here). Our next briefing will be on FDA's draft *Guidance on Enhanced Drug Distribution Security at the Package Level Under the DSCSA.*

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For further information or questions on the draft Guidance and the obligations it may create, please contact T. Reed Stephens, Amandeep S. Sidhu, Stephanie Turner, or your Winston relationship attorney.

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