WINSTON & STRAWN LLP

CLIENT ALERT

FDA Publishes Guidance on the Identification and Notification of Suspect Products as Part of the Implementation of the Drug Supply Chain Security Act

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Earlier this month, the Food and Drug Administration (FDA or the Agency) issued guidance (Guidance) to aid trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and notifying the FDA and, subsequently, terminating such notifications. The Drug Supply Chain Security Act (DSCSA) requires trading partners to notify FDA and other immediate trading partners within 24 hours of suspecting that a product in its possession or control is either illegitimate or has a high risk of illegitimacy.

To help trading partners remain vigilant and ensure the quality and integrity of the products in their control, the Guidance identifies specific scenarios that significantly increase the risk of a suspect product entering the supply chain; provides recommendations on how trading partners can identify a product as suspect as soon as possible; sets forth the process by which trading partners should notify FDA of products with a high risk of illegitimacy; and provides steps for terminating such notification upon a determination that product is not suspect.

See FDA's Guidance on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry (June 2021), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-supply-chain-security-act-implementation-identification-suspect-product-and-notification?utm_medium=email&utm_source=govdelivery.

BACKGROUND

The DSCSA added section 582(h)(2) to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which requires FDA to issue guidance to aid trading partners in identifying a suspect product and subsequently terminating notifications that a product is suspect. Section 581(21) defines suspect product as a product for which there is reason to believe it (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is 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.

Upon determining that a product in their possession or control is a suspect product, trading partners are required to promptly conduct an investigation to determine whether the product is an illegitimate product. And illegitimate

product is defined in section 581(8) of the FD&C Act as a product for which credible evidence confirms suspicions used to define a suspect product. Trading partners, who have determined that a product in their possession or control is illegitimate, must, within 24 hours, give notice of the determination to the FDA and trading partners.

Trading Partners' Identification and Notification of Suspect and Illegitimate Products

To avoid coming into possession of suspect products, FDA recommends trading partners exercise due diligence and only conduct business with authorized trading partners. Trading partners must also have systems in place to identify suspect products as soon as practicable.[1] FDA identifies scenarios that present high risk for suspect products entering the supply chain and recommends strategies that should aid trading partners in identifying those suspect products that include:

- Being alert for offers selling a product at a very low price that is "too good to be true."
- Closely examining packaging and transport containers for questionable appearance and missing security or anti-counterfeiting technologies. Features of packaging materials that may signal suspect products include:
  - Packaging that has been opened, has a broken seal, or is otherwise altered.
  - Packaging labels with misspelled words or features that differ from standard labels in color, font, or images.
  - Packages that are missing anti-counterfeiting features such as holograms and watermarks.
  - Labels that lack a "Rx only" symbol or list a product name that differs from the name that appears on the FDA-approved drug label.
- Paying special attention to the quality of products that are in higher demand because of its potential or perceived relationship to a public health or other emergency.

Trading partners must have systems in place that enable to quickly quarantine suspect product and promptly investigate to determine if a suspect product is illegitimate.[2] When investigating a suspect product, trading partners should consult with the product's manufacturer and contact regulatory authorities and law enforcement to obtain additional expertise required to make an accurate assessment of the status of a product. Suspect product generally does not require notification.

As applicable, trading partners should use the following process to notify FDA and other trading partners of suspect products they have determined to be illegitimate products:

- Trading partners should access FDA's web page at this link to begin the process of notifying FDA.
- Via the link above, trading partners should use and submit Form FDA 3911 to provide information about the person or entity initiating the notification, the product determined to be illegitimate, and a description of the circumstances surrounding the event that prompted the notification.
- FDA will acknowledge receipt of the notification and assign an incident number.
- In addition to notifying FDA, trading partners must notify all immediate trading partners that they have reason to believe may have received the illegitimate product and may use existing systems and processes for communications to do so.

Manufacturer Identification and Notification of Products with a High Risk of Illegitimacy

While suspect product generally does not require notification, Section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to notify (1) FDA and (2) immediate trading partners of suspect products that pose a high risk of

illegitimacy where the circumstances surrounding the suspect products include at least one of three types of risk factors:

- Within 24 hours of determining or being notified that there is a high risk that an illegitimate product is an immediate trading partner's possession.
  - *Example*: A wholesale distributor informs a manufacturer that it believes it has a counterfeit of that manufacturer's product. The wholesale distributor sends the product to the manufacturer. The manufacturer examines the product and believes it could be counterfeit, but wants to perform a laboratory analysis or other analysis for confirmation. Once the manufacturer investigates the claim, performs the laboratory analysis, and determines the product is illegitimate, **the manufacturer should notify FDA and immediate trading partners who may be in possession of the illegitimate product**.
- Within 24 hours of determining or being notified there is a specific high risk that an illegitimate product is likely to enter the U.S. pharmaceutical distribution supply chain.
  - *Example*: A manufacturer learns from a foreign law enforcement agency that its product was stolen during transport in another country and is now on a plane destined for the United States for delivery to a dispenser. **To ensure the integrity of the supply chain, the manufacturer should notify FDA of such illegitimate product. The manufacturer may even elect to notify immediate trading partners of the "specific high risk" to aid in maintaining the integrity of the supply chain**.
- Within 24 hours of determining that there exists an "other high risk" as determined by FDA guidance pursuant to subsection 582(h).
  - *Example*: A manufacturer learns that a licensed health care practitioner is administering a drug to patients that purports to have been manufactured by that manufacturer, but the manufacturer determines that there is a high risk that the drug is a counterfeit. The licensed health care practitioner purchased the drug from a wholesale distributor, so it is not an immediate trading partner of the manufacturer. However, the manufacturer believes that the product has entered the pharmaceutical distribution supply chain. **In addition to notifying FDA of the illegitimate product, FDA recommends that the manufacturer in this scenario also notify its immediate trading partners of this "other high risk," even if the manufacturer does not have reason to believe that immediate trading partners have the high risk product in their possession**.

Manufacturers may discover a product is at high risk for illegitimacy either through their own investigation of suspect products or through information they receive from within their own company, their trading partners, FDA, or other domestic and/or foreign authorities.

FDA emphasized that Congress intended to give flexibility to manufacturers to determine systems and processes needed for verification. When manufacturers identify a product that poses a high risk of illegitimacy, they should follow the notification process described for trading partners with the addition of the following steps:

- If a product with a high risk of illegitimacy is found to be an illegitimate product, manufacturers should submit a follow-up notification that explains the updated classification and references the incident number of the original notification of high risk legitimacy.
- If a product that is the subject of a high risk of illegitimacy notification is found to not be an illegitimate product, manufacturers must submit a request for termination of the notification to FDA according to the process described below.

Process for Termination of Notification in Consultation with FDA

Trading partners must use the following process when they believe that a notification to FDA regarding an illegitimate product, or for a manufacturer, a notification of a high risk of legitimacy, is no longer necessary:

- Trading partners should access FDA's web page at this link to request the termination of a notification.

- Via the link above, trading partners should use and submit Form FDA 3911 to provide FDA information about the person or entity requesting termination, the notification that was issued, and an explanation about what actions have taken place or what information has become available that makes the notification no longer necessary.

PREVIEW OF RELATED INDUSTRY UPDATES: For further discussion on what is considered counterfeit, diverted, a fraudulent transaction, or unfit for distribution in the context of suspect and illegitimate product, Winston & Strawn will also be providing briefings summarizing newly issued FDA guidance on *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act and Enhanced Drug Distribution Security at the Package Level under the DSCSA*, which is intended to assist supply chain stakeholders by providing recommendations on system attributes necessary to enable the secure tracing of products that will fulfill requirements that will go into effect in 2023.

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For further information or questions on the new Guidance on Identification of Suspect Product and Notification 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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[1] *See* DSCSA section 582(h)(2)(A) of the FD&C Act.

[2] *See* section 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.

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Amandeep S. Sidhu

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