
Drug Supply Chain Security Act (DSCSA) FAQ 1: Strategies to Mitigate and Identify the Risk of Suspect Product Entering the Pharmaceutical Distribution Chain

Q: Does the FDA provide guidance on instituting processes to demonstrate an organization is taking steps to mitigate the risk of suspect drug product entering the pharmaceutical distribution chain?

A: Yes. The FDA industry guidance document, [Drug Supply Chain Security Act \(DSCSA\) Implementation: Identification of Suspect Product and Notification](#), provides information that organizations should take into consideration when developing policies and procedures. The guidance lists three types of specific scenarios (see boxed text below) that could significantly increase the risk of a suspect product entering the pharmaceutical distribution chain that might increase risk which should be mitigated and/or reviewed.¹

1. *Trading Partners and Product Sourcing*

- *Purchasing from a source new to the trading partner.*
- *Receiving an unsolicited sales offer from an unknown source.*
- *Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.*
- *Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.*
- *Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products, such as:*
 - *A trading partner that has been involved in business transactions where they sold or delivered suspect or illegitimate product.*
 - *A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.*
 - *A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased, or does not do so in a timely manner.*
 - *Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.*

2. *Supply, Demand, History, and Value of the Product*

- *Product that is generally in high demand in the U.S. market.*
- *Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).*
- *Product that has a high sales volume or price in the United States.*
- *Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).*
- *Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at: <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm> and <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> for more information).*
- *Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.*
- *Product that has been or is the subject of an FDA counterfeit or cargo theft alert (See <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/co186/underfeitmedicine/default.htm> and <http://www.fda.gov/iceci/criminalinvestigations/ucm182888.htm> for more information).*

3. *Appearance of the Product*

- *Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).*
- *Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).*
- *Package that is missing information, such as the lot number or other lot 201 identification, or the expiration date.*
- *Package that is missing anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, or watermarks.*
- *Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).*

Boxed text is verbatim language from the [FDA guidance for industry](#).

Q: Does the FDA provide guidance on strategies to identify suspect product to demonstrate an organization is taking steps to mitigate the risk of suspect drug product entering the pharmaceutical distribution chain and patient care settings?

A: Yes. The [FDA guidance for industry](#) provides information organizations should consider when developing policies and procedures and lists strategies to identify suspect product. Organizations should create staff awareness and education on these strategies.¹ Strategies to identify suspect product include, but are not limited to, the three recommendations below.

1. **Be alert for offers of product for sale at a very low price or one that is “too good to be true.”**
2. **Closely examine the package and the transport container (such as the case or tote)**
 - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
 - To see if it has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
 - To see if product inserts are missing or do not correspond to the product.
 - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.
3. **Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:**
 - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
 - Any altered product information, such as smudged print or print that is very difficult to read.
 - Misspelled words
 - Bubbling in the surface of a label.
 - Lack of an Rx symbol.
 - Foreign language with little or no English provided.
 - Foreign language that is used to describe the lot number.
 - A product name that differs from the name of the FDA-approved drug.
 - A product name that is the product name for a foreign version of the drug.
 - A product that is transported in a case or tote, when not expected under the circumstances.
 - Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

Boxed text is verbatim language from the [FDA guidance for industry](#).

Reference

1. **U. S. Department of Health and Human Services, Food and Drug Administration. [Guidance for Industry – Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification](#). June 2014.**

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