RESOURCES

DSCSA 2023: What is the Process for Handling an Illegitimate Product?

Key Takeaways

- As the final checkpoint in the **pharmaceutical supply chain**, dispensers (including health systems and retail pharmacies) have a critical role to play in preventing illegitimate medicines from reaching patients.
- Dispensers must have systems and processes in place to respond to notifications from the FDA, manufacturers, and trading partners and to send notifications to the FDA, manufacturers, and trading partners.
- Dispensers must have systems and processes in place to terminate a notification in consultation with the FDA.

When the final phase of the **Drug Supply Chain Security Act (DSCSA)** takes effect in 2023, health systems and retail pharmacies (“dispensers”) will need systems and processes to:

- Identify a suspect product
- Respond to a notification of a potentially illegitimate product
- Notify trading partners of a potentially illegitimate product
- Terminate a notification if the product is determined to be legitimate

For dispensers, the ability to handle a potentially illegitimate product will be critical

in meeting the DSCSA goal of ensuring a safe, secure drug supply—including the ability to associate an alert of an illegitimate product with the affected product identifier when the product identifier is scanned upon receipt.

When a manufacturer discovers a potentially illegitimate product

Recent guidance from the United States Food and Drug Administration describes multiple scenarios where a manufacturer might learn that one of its products may be at a high risk of being considered illegitimate, and the process for alerting the FDA and its trading partners:

- Using Form FDA 3911, the manufacturer provides information about:
  - The person or entity initiating the notification.
  - The product that is determined to have a high risk of illegitimacy.
  - A description of the circumstances surrounding the event that prompted the notification.
- The FDA assigns an incident number to be used in all future correspondence about the product with the high risk of illegitimacy, including any request for termination.
- The manufacturer notifies all immediate trading partners that it believes may possess the drug.
- If the “at risk” product is found to be an illegitimate product, the manufacturer submits a follow-up notification that explains the updated classification, referencing the incident number.
- If it is determined that the product is not an illegitimate product, the manufacturer submits a request for termination to the FDA.

When a trading partner receives an illegitimate product

Trading partners—which include health systems and retail pharmacies—must notify the FDA and its trading partners if it determines it has an illegitimate product in its possession or control:

- Using Form FDA 3911, the trading partner provides information about:

    - The person or entity initiating the notification.
    - The product that is determined to have a high risk of illegitimacy.
    - A description of the circumstances surrounding the event that prompted the notification.
- The FDA assigns an incident number to be used in all future correspondence about the product with the high risk of illegitimacy, including any request for termination.
- In addition to notifying FDA, the trading partner must notify all immediate trading partners that it has reason to believe may have received the illegitimate product.

Terminating a notification of an illegitimate product

The trading partner making a notification to the FDA shall be responsible for making the request for termination.

- Trading partners must follow the instructions on the web page for accessing Form FDA 3911. Using this form, trading partners provides information about:
    - The person or entity initiating the request for termination
    - The illegitimate product or the product with a high risk of illegitimacy
    - The notification that was issued
    - An explanation about what actions have taken place or what information has become available that makes the notification no longer necessary.
- Trading partners must include the FDA-assigned incident number associated with the notification in the request for termination.

Getting up to speed on DSCSA?

DSCSA 2023 for Health Systems and Pharmacies: 50 Essential Terms.

Have you started planning for DSCSA 2023 yet?

Over the next 24 months, health systems and retail pharmacies need to implement new systems and processes for meeting DSCSA 2023 requirements to promptly

facilitate the gathering of information for the purposes of investigating a suspect product or an illegitimate product. Experience shows that early planning and budgeting can help to ensure a smooth transition to item-level traceability and minimize any disruption to pharmacy operations.

Contact us to learn how TraceLink can help you meet your DSCSA 2023 compliance requirements.

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Learn more about TraceLink's solutions for DSCSA 2023 compliance

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DSCSA 2023: 3 Key Requirements for Pharmacies and Health Systems

Learn why retail pharmacies and health systems need to implement new solutions to meet DSCSA 2023 interoperability requirements for compliance with FDA standards.

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DSCSA 2023: How Does the FDA Define “Suspect Product”?

Learn how recent FDA guidance provides more detailed definitions to help dispensers identify a suspect product.

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3 Scenarios: How Suspect Products Enter the Pharmaceutical Supply Chain

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Hear supply chain expert Tom McHugh discuss suspect product investigations and dispenser requirements under DSCSA.

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