Draft Guidance for Industry DSCSA Implementation: Identification of Suspect Product and Notification

Carolyn E. Becker, J.D.

Senior Regulatory Counsel

U.S. Food and Drug Administration

FDA Stakeholder Webinar

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Objectives

The purpose of this webinar is to:

- Provide an overview of this draft guidance
- Solicit your comments and feedback

Overview of the DSCSA (enacted 11/27/2013)

- Product tracing
- Product verification
  - Quarantine and investigation (steps for detection and response)
  - Notification
  - Recordkeeping
- Product identification
- Wholesaler standards for licensure
- Third-party logistics provider standards for licensure
- Enhanced system – 10 years
- Penalties
- National uniform policy

Approach and Guidance Requirements

DSCSA requirements for the guidance:

- Specific scenarios concerning suspect products
- Recommendations
- Termination of notifications about illegitimate products

But also, how do trading partners notify FDA?

Related DSCSA Requirements

- Trading partners must have systems to quarantine and conduct investigations of suspect products
- If trading partners determine a product is illegitimate, they must notify FDA and immediate trading partners
- Trading partners must have systems to enable them to terminate notifications about illegitimate product in consultation with FDA

Guidance Format

Four sections:

- Introduction
- Background
- Identification of Suspect Product
- Notification of Illegitimate Product

Definitions

Suspect Product - reason to believe that the product is potentially:

- counterfeit, diverted, or stolen;
- intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- subject of a fraudulent transaction; or
- appears otherwise unfit for distribution such that it would result in serious adverse health consequences or death to humans

Definitions (con't)

Illegitimate Product - credible evidence shows that the product is:

- counterfeit, diverted, or stolen;
- intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- subject of a fraudulent transaction; or
- appears otherwise unfit for distribution such that it would be reasonably likely to result in serious adverse health consequences or death to humans

Section 582(h)(2)(i):

*Identify specific **scenarios** that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain*

- Agency experience yielded examples
- Trading partner vigilance and awareness encouraged
- Scenarios grouped by:
  - Trading Partners and Product Sourcing
  - Supply, Demand, History, and Value of the Product
  - Appearance of the Product

Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner
- Receipt of an unsolicited sales offer from an unknown source
- Purchasing on the Internet from an unknown source
- Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products

Product Supply, Demand, History & Value

- Is generally in high demand in the U.S. market
- Is in higher demand because of its potential relationship to a public health or other emergency (e.g. antivirals)
- Has a high sales volume or price in the U.S.
- Has been previously or is currently being counterfeited or diverted (e.g. HIV, antipsychotic, or cancer drugs)

Supply, Demand, History & Value (con't)

- Has been previously or is currently the subject of a drug shortage
- Has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement about drug quality
- Has been or is the subject of an FDA counterfeit or cargo theft alert

Product Appearance

- Packaging or container seems suspicious
- Package uses foreign terms
- Package is missing information
- Packaging is missing anti-counterfeiting technologies it normally features
- Finished dosage form seems suspicious

Section 582(h)(2)(ii):

*Provide **recommendation** on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable*

- Trading partners should discuss observations/concerns about possible suspect product and
- Contact regulatory authorities, law enforcement or other available resources to aid in the determination as needed

Recommendations

- Be alert for price that's "too good to be true"
- Closely examine the package and transport container:
  - To look for signs that it has been compromised
  - To see if it has changed since it was last received for an unexplained reason
  - To see if product inserts are missing or do not correspond to the product
  - For shipping addresses, postmarks, or other materials indicating that the package came from an unexpected foreign entity or source

Recommendations (con't)

- Closely examine the label on the package, or the label on the individual retail unit for:
  - Any missing information
  - Any alteration of product information
  - Misspelled words
  - Bubbling in the surface of a label
  - Lack of an Rx symbol
  - Foreign language with little or no English provided

Recommendations (con't)

- 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 outer container

Section 582(h)(2)(iii):

*Process by which manufacturers, repackagers, wholesale distributors, and dispensers shall **terminate notifications** in consultation with the Secretary regarding illegitimate product*

- Guidance describes process trading partners should use for notifying FDA about illegitimate product
- Trading partners must use similar process for terminating notifications
- A form has been developed to serve both of these purposes.

Notifications to FDA

1) Trading partners should access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm to make notifications.

2) Trading partners should follow the instructions on the Web page for accessing Form FDA 3911 and to provide information.

3) Form FDA 3911 should be submitted by using the method provided in the form or on the Web page.

Termination of Notifications to FDA

1) Trading partners must access FDA's Web page.
2) Trading partners must follow the instructions on the Web page for accessing Form FDA 3911 and to provide information.
3) This form must be submitted by using the method provided in the form or on the Web page.
4) FDA will review the request and consult with the trading partner.

Termination of Notifications (con't)

- FDA interprets Section 582 of the FD&C Act to give authority to issue binding guidance on the process for terminating notifications of illegitimate product.
- Upon finalization of the guidance, the specified process for terminating notifications will be mandatory.
- Other sections of the draft guidance contain non-binding recommendations or describe statutory requirements.

Termination of Notifications (con't)

Consultation

- What does it mean?
- What is the timing?
- What happens next?

Additional Information

Draft Guidance and Notice of Availability:

http://www.fda.gov/drugs/drugsafety/ucm400520.htm

Docket open until August 11, 2014

FDA's DSCSA Website:

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

Thank you!

Comments or questions to:
drugtrackandtrace@fda.hhs.gov