Standard Operating Procedure

Identifying, Quarantining and Notifying FDA of Suspect and Illegitimate Product	
Prepared by/Date:	Approved by/Date

Purpose: This procedure describes the process to identify, quarantine and notify the U.S. Food and Drug Administration (FDA) and trading partners of suspect or illegitimate product in the pharmacy.

Scope: This procedure applies to all pharmacy personnel responsible for taking possession of new product and dispensing finished product to patients.

The Drug Supply Chain Security Act: On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was signed into law. The law, in part, requires dispensers to develop protocols to identify suspect and illegitimate products by January 1, 2015.

1. The law defines a suspect product as one 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

2. The DSCSA requires trading partners, upon determining that a product in their possession is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. Illegitimate product is defined as a product for which credible evidence shows that it 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. Is 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

3. The law also requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners (that they have reason to believe may have received the illegitimate product) within 24 hours after making the determination.

FDA Guidance on "Suspect" or "Illegitimate" Product

1. The FDA has identified some specific scenarios that could significantly increase the risk of suspect products entering the drug supply chain. FDA recommends that trading partners should be particularly diligent when engaging in transactions that involve:

    a. Purchasing from a source new to the trading partner
    b. 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
    c. 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
    d. Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products
    e. Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs)
    f. Product that has been previously or is currently the subject of a drug shortage
    g. 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)
    h. Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC)
    i. Package that is missing information, such as the lot number or other lot identification, or the expiration date
    j. 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
    k. 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)

2. The FDA recommends that dispensers:

    a. Be alert for offers of product for sale at a very low price that is "too good to be true"

    b. Closely examine the package and the transport container (such as the case or tote)
        i. To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered)

ii. 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)
iii. To see if product inserts are missing or do not correspond to the product
iv. For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source

c. Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:
   i. Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug
   ii. Any altered product information, such as smudged print or print that is very difficult to read
   iii. Misspelled words
   iv. Lack of an Rx symbol
   v. Foreign language with little or no English provided
   vi. Foreign language that is used to describe the lot number
   vii. A product name that differs from the name of the FDA-approved drug
   viii. A product name that is the product name for a foreign version of the drug
   ix. Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container

Treatment of "Suspect" or "Illegitimate" Products

1. Periodically and before ordering prescription drugs from a new supplier, verify that the supplier is licensed and registered with the FDA. Verification may be obtained from the FDA's Wholesale Distributors and Third-Party Logistics Providers Search at http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm

2. Upon taking possession of new product, closely examine the package and the transport container to look for signs that it has been compromised, if it has changed unexpectedly in appearance, if product inserts are missing or do not correspond to the product, or if the shipping addresses, postmarks, or other materials indicate that the product came from an unexpected foreign entity or source

3. Before dispensing any product, closely examine the label on the package for any missing information, altered product information that makes it very difficult to read, misspelled words, or a foreign language. Determine if the product name differs from the name of the FDA-approved drug, and if the lot numbers and expiration dates on product match the lot numbers and expiration dates of its outer container.

4. Examine if the finished dosage form seems suspicious. Does it have 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?

5. In the event that all or part of a prescription drug order may meet the criteria for a potentially suspect or illegitimate product:

    a. Quarantine the product in a specially-designated area in the store and label it "QUARANTINE"
    b. Promptly conduct an investigation, in coordination with other trading partners, to determine whether a suspect product is an illegitimate product.
    c. Validate the applicable transaction information and history
    d. Remove the product from the supply chain (may include disposal and/or retaining a sample of the product if further physical examination or laboratory analysis is requested by FDA or the manufacturer)
    e. Notify the FDA and all trading partners within 24 hours after determining that a product is illegitimate using FDA Form 3911 or according to FDA's latest guidance on http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm
    f. Comply with instructions from FDA for the final disposition of illegitimate product reported on FDA Form 3911, and instructions from FDA for terminating notice of illegitimate product if notification is deemed no longer necessary.

References:

Drug Supply Chain Security Act:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

FDA Implementation Timeline for the DSCSA:
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm

FDA Draft Guidance on Identification of Suspect Product and Notification:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf

FDA Webinar on Identification of Suspect and Illegitimate Product
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm402366.htm

FDA Guidance on Product Tracing Requirements for Dispensers
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf

FDA Helpdesk for questions regarding DSCSA:
drugtrackandtrace@fda.hhs.gov

Attachment A: Delivery Inspection Checklist for Suspect Product

Purpose: For pharmacists and technicians to refer to when inspecting a delivery

Part 1: Examine the Transport Container (e.g., case, tote, box)

A. The transport container has been compromised (e.g., opened, broken seal, damaged, repaired, or altered)
B. The transport container 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)
C. The transport container product inserts are missing or do not correspond to the product
D. The transport container has shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source
E. The transport container contains product that is not expected

Part 2: Examine the individual retail unit and individual unit label

A. The label is missing information, such as the lot number or other lot identification, NDC, or strength of the drug
B. The label has altered product information, such as smudged print or print that is very difficult to read
C. The label has misspelled words
D. The label has bubbling in on its surface
E. The label lacks an "Rx" symbol
F. The label is in a foreign language with little or no English
G. The label contains foreign language that is used to describe the lot number
H. The label contains a product name that differs from the name of the FDA-approved drug
I. The label contains a product name that is the product name for a foreign version of the drug
J. The lot numbers and expiration dates on the individual unit label do not match the lot numbers and expiration dates of its outer container or shipping information