Template Standard Operating Procedure (SOP)

Identifying, quarantining and investigating suspect product and notifying FDA of illegitimate product

1 Purpose

This procedure describes the minimum requirements and processes to identify, quarantine and investigate suspect product and notify the
U.S. Food and Drug Administration (FDA) and trading partners of illegitimate product by dispensers.
This template is a sample only and we recommend using your company's letterhead to create a Standard Operating Procedure (SOP) template.

2 Scope

This document shall cover the procedure for ensuring compliance for all FDA classified human prescription drugs, that are not defined as exempt per section [582(a)(24)(B)] of the Drug Supply Chain Security Act. This process applies to all pharmacy and dispensing personnel responsible for taking possession of new product and dispensing finished product to patients.

Cencora does not make any exemption status determination for anything classified as a Human Prescription Drug and defers to the position of the manufacturer on their products DSCSA exemption status.

Contents of Document

3 Acronyms and terms

The following are acronyms associated with this document:

Acronym	Definition
DSCSA	Drug Supply Chain Security Act
RX	Human Prescription Drug

The following are terms associated with this document:

Terms	Definition
DSCSA Exempt Products	Those products and transactions that are exempt from the obligations of DSCSA compliance (DSCSA Section [582(a)(24)(B)])
Illegitimate Product	The term "illegitimate product" means a product for which credible evidence shows that the product: • Is counterfeit, diverted or stolen. • Is intentionally adulterated such that the product would result in • serious adverse health consequences or death to humans. • Is the subject of a fraudulent transaction. • Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.
Product Identifier	The term 'product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.
Standardized Numerical Identifier	The combination of a products NDC Code, as represented as a global trade item number, and serial number of lengths up to 20 characters.
Supplier	Trading partners that sell pharmaceutical products to one or many of the Cencora businesses or other wholesale distributors for the purposes of DSCSA include prescription drug manufacturers, a manufacturer's exclusive distributor, or co-licensed partner.
Suspect Product	The term "suspect product" means a product for which there is reason to believe that such product: • Is potentially counterfeit, diverted, or stolen. • Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans. • Is potentially the subject of a fraudulent transaction. • Appears otherwise unfit for distribution such that the product

	would result in serious adverse health consequences or death to humans.
Verification	The term ‘verification’ or ‘verify’ means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

4 Roles and Responsibilities

The following are the roles and responsibilities outlined in this document:

Role	Responsibility

5 Procedure – Identify Suspect or Illegitimate Product and Request for verification

5.1 General Requirements

5.1.1 Dispensers shall ensure processes exist for all non-DSCSA exempt products to facilitate a way to identify suspect or illegitimate product through a Request for Verification from the distributor from whom the product was purchased.

5.1.2 Dispensers must identify and investigate suspect product to determine if it is illegitimate. Likewise, if a dispenser is notified that they received suspect or illegitimate product, they must respond to the notification and conduct any additional investigation, response or notification needed.

5.1.2 Applicable businesses shall ensure processes exist to facilitate a Request for Verification from state or federal regulators.

5.2 Suspect Product Investigations and Illegitimate Notifications

5.2.1 Suspect Product Investigations

1. Identification of Suspect Product

a) Associates handling product should examine the label on the package, or the label on the individual retail unit for anything unusual to include, but not limited to, the following FDA examples:

- *Altered product info*
- *Missing info on label*
- *Looks different than product on shelf*
- *No "Rx only" symbol*
- *Bubbling on the label*
- *Foreign language*
- *Lot numbers or expiration dates do not match the outer/inner container*
- *Missing or wrong package inserts*
- *Damaged or broken seal*
- *Open package*
- *Different product names than FDA approved version*

b) *If suspect product is identified, the product should be immediately quarantined along with all other products matching the characteristics of the identified suspect product*

2. *Suspect Product Investigation*

a) Upon identification of suspect product, dispenser must initiate a suspect product investigation and coordinate with all trading partners to include the wholesaler and manufacturer to determine legitimacy.

b) Product Determination:

- *If the product is deemed legitimate, the product may be released from quarantine and dispensed.*

3. *Illegitimate Product Notification*

a) If the product is deemed illegitimate, dispenser must file an illegitimate product notification with the FDA via form FDA 3911.

b) Upon acknowledgment and incident number assignment by the FDA, dispenser must notify all trading partners of all illegitimate products.

4. *Termination of Notification*

Upon determination that a notification is no longer necessary, a request for termination should be sent to the FDA. FDA will review the request and notify the dispenser if approved. Once FDA approval is granted, dispenser will notify all trading partners of the approved illegitimate product termination.

5. *Record Retention*

All records of suspect product investigations and illegitimate product notifications will be maintained for not less than 6 years after the conclusion of the investigation or disposition.

5.3 Request for Verification Process

5.3.1 When conducting a verification request, all four elements of the Product Identifier shall be validated: NDC (GTIN), Serial Number, Lot, and Expiration Date.

Note it is acceptable to only compare the month and year when validating the expiration date.

5.3.2 It will be within 24 hours if the product identifier is valid or not valid. Valid, for the purposes of verification, is defined as having all four product identifier elements match the records in the database and that the product identifier is in a status that would correspond to its expected state.

5.3.3 In the event that the product identifier cannot be validated, the physical product shall be considered suspect product and a suspect product investigation shall be conducted.

5.3.4 If a suspect product investigation needs to occur for product purchased from Cencora, contact your sales representative immediately and email the Cencora Product Integrity team directly at productintegrity@amerisourcebergen.com. For non-Cencora product, immediately contact the distributor or entity the product was purchased from per its suspect product procedure/guidelines.

5.4 Product Identifier System of Record

5.4.1 Verification requests shall be conducted against Cencora's enterprise DSCSA product identifier database.

5.4.2 As a dispenser, record the response and identify the next step in quarantine. This may be addressed using a PDG conformant credential.

5.4.3 The outcome and/or revision of product verification will be recorded in section 7 of the document below.

6 References

6.1 Law and Guidance

6.1.1 Title II of the Drug Quality and Security Act referred to as the Drug Supply Chain Security Act (DSCSA) (November 2013)

6.1.2 Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs - https://www.fda.gov/media/117950/download

7 Submission and Revision History

Version Number	Effective Date	Revision Details

8 Approval

Name	Title

Please note that this statement of procedure should be customized based on your specific organization's needs while adhering to regulatory guidelines outlined in DSCSA dispenser regulations.