I. **Policy**

As of January 1, 2015, all trading partners must notify FDA and certain immediate trading partners when it is determined that a product in its possession or control is a suspect or illegitimate product, not later than 24 hours after making the determination.

Effective July 1, 2015, dispensers; a retail pharmacy, hospital pharmacy, or group of chain pharmacies under common ownership and control, are required to provide the subsequent purchaser with product tracing information when engaging in transactions involving certain prescription drugs. Trading partners are also required to capture the product tracing information and maintain that data for not less than six years after the transaction occurs. Exceptions to the DSCSA tracing requirements:

-Intra-company distribution of any product between members of an affiliate or within a manufacturer.

-Distribution of product between hospitals or healthcare entities under common control.

-Distribution of product for emergency medical reasons, which includes a public health emergency, and excludes a drug-shortage unless caused by such a public health emergency.

-Distribution of minimal quantities by a licensed retail pharmacy or licensed practitioner for office use.

-Distribution of intravenous product intended for fluid and electrolyte replenishment (e.g. sodium, chloride, potassium) or calories (e.g., dextrose and amino acids).

-Distribution of intravenous product used to maintain equilibrium of water and minerals in the body (e.g. dialysis solution)

-Product intended for irrigation or sterile water.

-Distribution of medical gas.

-Drugs compounded in compliance with section 503A or 503B.

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Approved By:

II. **Procedure**

A. Identification of Suspect Product

1. Trading Partners and Product Sourcing

a. Purchasing from a source new to the trading partner.

b. Receiving an unsolicited sales offer from an unknown source.

c. Purchasing on the internet from an unknown source.

d. Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products.

i. A trading partner that has been involved in business transactions where they sold or delivered suspect or illegitimate product.

ii. 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.

iii. A trading partner that is reluctant to provide a transaction history or pedigree with the product being purchased, or does not do so in a timely manner.

iv. 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

a. Product that is generally in high demand in the U.S. market.

b. Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g. antiviral drugs).

c. Product that has a high sales volume or price in the United States.

d. Product that has been previously or is currently being counterfeited or diverted.

e. Product that has been previously or is currently the subject of a drug shortage.

f. 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.

g. Product that has been or is the subject of an FDA counterfeit or cargo theft alert.

3. Appearance of the Product

a. Appearance of a package or a container used for transport 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).

b. Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).

c. Package that is missing information, such as the lot number or other log identification, or the expiration date.

d. 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.

e. 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 the tablet coatings or smeared or unclear ink imprint.

B. How to Identify Suspect Product as Soon as Practical

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

   a. Look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).

   b. See if the package has changed since it was last received for an unexplained reason.

   c. See if product inserts are missing or do not correspond to the product.

   d. 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:

   a. Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.

   b. Any altered product information, such as smudged print or print that is very difficult to read.

   c. Misspelled words.

   d. Bubbling in the surface of a label.

   e. Lack of an Rx symbol.

   f. Foreign language with little or no English provided.

   g. Foreign language that is used to describe the lot number.

   h. A product name that differs from the name of the FDA-approved drug.

i. A product name that is the product name for a foreign version of the drug.

j. A product that is transported in a case or tote, when not expected under the circumstances.

k. Lot number and expiration dates on product that do not match the lot numbers and expiration dates of its out container.

C. FDA Notification

1. Access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm.

2. Follow the instructions on the Web page for accessing Form FDA 3199.

3. Submit Form FDA 3911 by using the method provided in the form or on the Web page.

D. Transaction Information

1. Main source of the transaction data, transaction history (TH)/transaction information (TI)/transaction statement (TS), will come from our wholesaler, Cardinal Health and can be downloaded on the Order Express website.

2. Cardinal Health will electronically store the information for a period of six years from the date of transaction.

3. Transaction data (TH/TI/TS) from sources other than Cardinal will be retained by the Pharmacy for six years unless storage and retrieval solution is available by the vendor.

4. Transaction data (TH/TI/TS) dispensed to non-Los Angeles County subsequent owners will be sent upon dispensing and a copy of the transaction data kept for six years from the date of dispensing. (Note: See exceptions to the DSCSA tracing requirements).