Recent 483 DSCSA Observations- FOIA Request- Example A

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA.

Specifically,

(A) Your written procedure, SOP-[redacted] "Notification to the FDA of an illegitimate or suspect illegitimate product," effective [redacted], is inadequate in that it fails to describe systems and processes for (1) identifying suspect product; (2) conducting investigations of suspect product in coordination with trading partners, which must include validating any applicable transaction history and transaction information in your possession; (3) notifying the Food and Drug Administration (FDA) that suspect product is not illegitimate, when applicable; and (4) otherwise investigating to determine whether a product is an illegitimate product.

(B) Your written procedure, [redacted] titled "Receipt of Finished Drug Product," effective [redacted], states in part "Report to the Inbound Import Manager if any questionable, suspicious, misbranded, counterfeited, suspected of being counterfeit, adulterated, or otherwise unfit for human use. QA shall immediately report to the appropriate State Board of Pharmacy and FDA within [redacted]." The Drug Supply Chain Security Act requires that trading partners notify FDA and immediate trading partners within 24 hours after determining a product in a trading partner's possession or control is an illegitimate product. Additionally, the statute requires manufacturers to notify FDA and immediate trading partners within 24 hours after determining a product is at high risk for illegitimacy.

(C) Your written procedure, SOP-[redacted], titled "Notification to the FDA of an illegitimate or suspect illegitimate product," effective [redacted], is inadequate in that it fails to describe systems and processes to notify FDA and immediate trading partners within 24 hours after determining a product is at high risk for illegitimacy, and terminate notifications that are no longer necessary.

(D) Your firm, upon receiving a notification of illegitimate product from FDA or a trading partner, does not have systems and processes in place to identify and investigate illegitimate product subject to the notification that is in your firm's possession or control.

(E) Your firm does not have written systems and processes for responding to requests for verification of the product identifier from FDA or an authorized trading partner in possession or control of a product they believe to be manufactured by your firm.

OBSERVATION 2

Your firm failed to notify FDA within 24 hours after determining that product in your possession or control is an illegitimate product.

Specifically,

On [redacted], your firm was alerted to an instance of cargo theft involving prescription drug products in your firm's control. Where there is credible evidence that a product is stolen, that product is illegitimate product under the Drug Supply Chain Security Act. Upon becoming aware of the theft, your firm did not submit a notification of illegitimate product to FDA within 24 hours. A notification of illegitimate product must be submitted to FDA within 24 hours after a product is determined to be illegitimate product. [redacted]

Recent 483 DSCSA Observations- FOIA Request- Example B

OBSERVATION 4
Your firm lacks sufficient systems and processes to enable compliance with the verification

requirements of Section 582(b)(4) of the Food, Drug and Cosmetic Act, as amended by the Drug Supply Chain Security Act (DSCSA).

Specifically,

Your written procedure [redacted] *Special Procedures for Drug Supply Chain Security Compliance*, effective date: [redacted], is inadequate because it lacks systems and processes for:

(a) responding to requests for verification of product identifiers from FDA or authorized trading partners;

(b) responding to notifications of illegitimate product from FDA and immediate trading partners; and

(c) identifying suspect product. While the SOP recognizes that returned product may be suspect product, it does not sufficiently detail specific systems and processes for identifying suspect product and it does not acknowledge that suspect product in the firm's possession or control is not limited to returned products.