

Drug Supply Chain Security Act (DSCSA)

Suspect v illegitimate product

The Drug Supply Chain Security Act (DSCSA) was established to protect the pharmaceutical supply chain by enabling the identification and tracing of prescription drugs. It is crucial for quarantining and promptly investigating drugs that have been identified as counterfeit, unapproved, or potentially dangerous. The information provided, is intended to aid dispensers determining whether a product is suspect and/or illegitimate.

Suspect Product	Illegitimate Product
a product for which there is reason to believe that such product –	a product for which credible evidence shows that the product –
(A) is potentially counterfeit, diverted, or stolen	(A) is counterfeit, diverted, or stolen
(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans	(B) is 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	(C) is the subject of a fraudulent transaction
(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans	(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

For additional information on definitions of suspect and illegitimate product [click here](#)

Trading partners (manufacturers, repackagers, wholesale distributors, dispensers) must have systems (SOPs) established to:

- to quarantine and conduct investigations of suspect products;
- to notify FDA and immediate trading partners within 24 hours, if a product is illegitimate; and
- to terminate notifications about illegitimate product in consultation with FDA

Dispensers can report suspect product to:

- Call: Customer Service / Customer Care **OR** E-mail: ProductIntegrity@amerisourcebergen.com

Provide the following information:

- NDC, lot number, manufacturer, product description, dosage strength, expiration date, serial number, quantity
- Photos of all sides of the product(s)
- Explanation as to why product is thought to be suspect
- Confirm product is in quarantine

Cencora's Product Integrity team will coordinate and work with all trading partners on suspect product investigations.

For more information on reporting and notifying the FDA of illegitimate products [click here](#)