



Drug Supply Chain Security Act – Summary of Law and Guidance

Alan G. Minsk and Kelley Coleman Nduom

FDA recently released its first draft guidance document as part of the implementation of the Drug Supply Chain Security Act (DSCSA).¹ Signed into law in November 2013 as Title II of the Drug Quality and Security Act, the DSCSA outlines a 10-year plan to establish a standard electronic, interoperable track and trace system for prescription drugs.² The law is significant in that it creates a national, uniform system for tracking prescription drugs, as opposed to the varying requirements that have been implemented over the years by some states. Companies can expect greater regulatory oversight and additional documentation requirements as FDA issues implementing regulations and guidance.

Key provisions to be implemented include requirements for product identification, tracing and verification; suspect drug detection and response; notification of illegitimate drugs; wholesaler licensing, and third-party logistics provider licensing. In addition to other requirements, the statute requires the Food and Drug Administration (FDA) to develop standards, issue guidance documents, implement pilot programs, and conduct public meetings as part of implementation efforts. FDA's website provides a detailed implementation plan, including estimated target dates for each deliverable.³

The draft guidance aims to assist trading partners (defined, for purposes of the guidance, as manufacturers, repackagers, wholesale distributors, or dispensers) in identifying a "suspect product" and outlines the process for terminating notifications to the agency regarding "illegitimate product." Each topic is discussed in further detail below.

"Suspect product" is defined in the statute as a product 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.⁴

"Illegitimate product" is defined as a product for which credible evidence shows that the product:

- A. is counterfeit, diverted, or stolen;
- B. is 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

¹ Draft Guidance for Industry – Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (June 2014), available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf>.

² The full text of Title II of the Drug Quality and Security Act, the Drug Supply Chain Security Act, is available on FDA's website at the following link: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>.

³ See Drug Supply Chain Security Act (DSCSA) Implementation Plan, available at: <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm>.

⁴ FDCA § 581(21), 21 U.S.C. § 360eee(21).

- 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.⁵

Identification of Suspect Product

As of January 1, 2015, the law requires that trading partners have implemented systems to quarantine suspect product in their possession or control and conduct an investigation to determine whether the product is illegitimate. The draft guidance provides the following examples of scenarios that could lead to suspect product entering the pharmaceutical distribution supply chain (not an exhaustive list).

- Purchasing from source new to the trading partner
- Receiving an unsolicited sales offer from an unknown source
- Purchasing on the Internet from an unknown source
- Purchasing from a source the trading partner knows or has reason to believe has transacted business involving suspect products
- Product that is generally in high demand in the U.S. market
- Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency
- Product that has a high sales volume or price in the U.S.
- Product that has been previously or is currently being counterfeited or diverted
- Product that has been previously or is currently the subject of a drug shortage
- 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
- Appearance of a package or container used for transport that seems suspicious
- Package that uses foreign terms, such as a different drug identification number rather than the NDC Code
- Package that is missing information, such as the lot number or other lot identification, or the expiration date
- Package that is missing typical anti-counterfeiting technologies, such as holograms or watermarks
- Finished dosage form that seems suspicious (e.g., a different shape, color, or odor)

The draft guidance recommends that trading partners be alert for offers that seem “too good to be true” and closely examine the package, transport container, and all labeling for signs the product has been compromised. Among other recommendations, trading partners are advised to look for missing or mismatched product inserts, smudged print, or misspelled words. Trading partners are encouraged to consult regulatory authorities, law enforcement, or other resources for assistance in determining whether a product is suspect.

Notification of Illegitimate Product and Process for Terminating Notices

Notification requirements regarding illegitimate product also take effect January 1, 2015. Within 24 hours of determining that any product is illegitimate, trading partners will be required to notify FDA and any immediate trading partners that they have reason to believe received the product. Manufacturers specifically have an additional notification requirement; they must notify FDA and immediate trading partners within 24 hours of determining or becoming aware that there is a high risk that the product is illegitimate. The draft guidance instructs trading partners to access a Form FDA 3911 on FDA’s website and provide the requested information.⁶ The form should be submitted using either the method provided in the form itself or on the website.

To request terminations of such notifications, trading partners are instructed to submit another Form FDA 3911, explaining what actions have taken place or what information has become available that make notification no longer necessary. The agency will consider the submission a request for a consultation with the agency. This is relevant because the draft guidance explains that the agency interprets the language in the statute requiring trading partners to “mak[e] a determination, in consultation with the Secretary, that a notification is no longer necessary” to require that trading partners

⁵ FDCA § 581(8), 21 U.S.C. § 360eee(8).

⁶ Trading partners should access the following web page for notifications: www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm. It is not clear from the law or guidance whether FDA will publish notifications and terminations of notifications on its website.

allow the agency an opportunity to provide input before terminating such notification. Therefore, trading partners must wait for an agency response before notifying other trading partners that a notification is being terminated. The agency aims to provide a response within ten business days. Trading partners can explain any exigent circumstances requiring an expedited review (such as a drug shortage) in the termination request. Once a response is received from the agency that the notification has been terminated, trading partners may inform other trading partners via their website, email, or other existing methods of communication.

Notably, the statute granted FDA authority to issue binding guidance on the process for terminating notifications of illegitimate product. Therefore, once finalized, the portions of the guidance that describe the termination process will have legal effect.

Authors and Contributors

Alan G. Minsk

Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Kelley Coleman Nduom

Associate, Atlanta Office
404.870.5797
kelley.nduom@agg.com

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Atlanta Office

171 17th Street NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office

1775 Pennsylvania Ave., NW,
Suite 1000
Washington, DC 20006

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