Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
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10903 New Hampshire Ave., Bldg. 71, Room 3128
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Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish requirements for product tracing, verification, and product identification for certain drug products that are distributed in the United States. Many of the terms used in these requirements are defined in section 581 of the FD&C Act (21 U.S.C. 360eee).

FDA is issuing this guidance to interpret the terms used in the definition of *suspect product* set forth in section 581(21) of the FD&C Act, and the definition of *illegitimate product* set forth in section 581(8) of the FD&C Act, to assist trading partners in meeting verification obligations (including notification) under section 582(b)(4), (c)(4), (d)(4), and (e)(4), respectively.

This guidance revises the draft guidance for industry *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act* issued in March 2018. This revision clarifies certain points of the March 2018 draft guidance, and also adds FDA's current understanding of the term *stolen*.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

[1] This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the FDA.

A. Definitions of *Suspect Product* and *Illegitimate Product*

On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which added section 581 to the FD&C Act, sets forth the definitions of "suspect product" and "illegitimate product," among other terms. *Suspect product* is defined in section 581(21) of the FD&C Act, and *illegitimate product* is defined in section 581(8) of the FD&C Act:

> SUSPECT PRODUCT—The term 'suspect product' means a product for which there is reason to believe that such product:
>
> 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.
>
> ILLEGITIMATE PRODUCT—The term 'illegitimate product' means 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
> 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.

B. Scope of This Guidance

This guidance applies to the definitions of *suspect product* and *illegitimate product* as described in section 581(21) and (8) of the FD&C Act, specifically as those terms are used to describe trading partners' verification obligations (including notification) under section 582(b)(4), (c)(4), (d)(4), and (e)(4), respectively. These sections require that trading partners have systems in place to identify and handle suspect and illegitimate product.

This guidance is intended to help industry identify suspect and illegitimate product in the U.S. pharmaceutical distribution supply chain by interpreting certain terms used in the definitions of *suspect product* and *illegitimate product*.[2] Trading partners are required to take specific actions if they identify such products.[3]

[2] FDA's interpretations of terms in this guidance document are limited to identifying suspect and illegitimate product as described in section 581(21) and (8) of the FD&C Act, because those terms are used to describe trading partners' verification obligations (including notification) under section 582(b)(4), (c)(4), (d)(4), and (e)(4). Furthermore, these interpretations apply only to drugs that meet the definition of "product" in section 581(13). The interpretations of the terms in this guidance do not apply to other parts of the FD&C Act or affect FDA's enforcement authority under other provisions of the FD&C Act.

[3] See section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.

The Agency issued an additional draft guidance for industry in October 2018: *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs*.[4] This draft guidance addresses other aspects of the verification requirements in section 582. In addition, the Agency previously issued, under section 582(h)(2)(A)(iii) of the FD&C Act, the guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (December 2016) that describes the processes for notifying FDA and trading partners of illegitimate product, as well as terminating those notifications.

III. INTERPRETATION OF TERMS

To comply with the verification provisions (including notification) of section 582 of the FD&C Act, trading partners[5] (manufacturers, repackagers, wholesale distributors, and dispensers) must be able to identify a suspect product and make a determination about whether that product is an illegitimate product.

To help satisfy these obligations, trading partners should focus on the potential supply chain security threats listed in the *suspect product* and *illegitimate product* definitions. These threats include drugs that are, or may be, counterfeit, diverted, stolen, intentionally adulterated, unfit for distribution, or the subject of a fraudulent transaction.

FDA is clarifying its interpretation of the terms *counterfeit*, *diverted*, *stolen, fraudulent transaction*, and *unfit for distribution* to aid trading partners in determining whether a product is suspect and/or illegitimate.

Although this guidance does not create an exhaustive list of the circumstances that may result in a counterfeit drug, a diverted drug, a stolen drug, a fraudulent transaction, or a drug that is unfit for distribution, it describes the most common scenarios that FDA believes trading partners will encounter.

A. Counterfeit

FDA interprets the term *counterfeit drug* as used in section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in section 582(b)(4), (c)(4), (d)(4), and (e)(4) to mean:

> [A] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be

[4] When final, this guidance will represent FDA's current thinking on this topic. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[5] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B), the requirements of section 582(a) through (e) are not applicable to them.

the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

See section 201(g)(2) of the FD&C Act (21 U.S.C. 321(g)(2)).

B. Diverted

For purposes of section 581(8) and (21) of the FD&C Act, and the verification obligations (including notification) in sections 582(b)(4), (c)(4), (d)(4), and (e)(4), FDA interprets the term *diverted* to refer to a:

- Product that left the U.S. pharmaceutical distribution supply chain and is reintroduced in the United States in a transaction with a trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced into the U.S. pharmaceutical distribution supply chain to a trading partner; or

- Product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. pharmaceutical distribution supply chain through a transaction with a trading partner.

A product would not be considered diverted as described above and, therefore, would generally not be considered a suspect or illegitimate product under DSCSA, solely if a trading partner obtains that drug product:

- Through surveillance activities outside the U.S. pharmaceutical distribution supply chain;

- From a consumer or patient who obtained the product from outside the U.S. pharmaceutical distribution supply chain;

- Obtained as a result of FDA's regulatory action to address a drug shortage; or

- Where an Emergency Use Authorization has been issued.

C. Stolen

For purposes of section 581(8) and (21) of the FD&C Act, and the verification obligations (including notification) in section 582(b)(4), (c)(4), (d)(4), and (e)(4), FDA interprets the term *stolen* as it applies to a package[6] of product to refer to:

- Any product in its entirety (i.e., the prescription drug and its packaging) that has been taken or removed without permission of the owner of the

[6] *Package* is defined in section 581(11) of the FD&C Act.

product (e.g., a bottle and all of its content of drug are taken or removed from the trading partner, or product taken as the result of cargo theft, warehouse theft, or courier theft[7]);

- Any packaging of a product that has been taken or removed without the permission of the owner (e.g., only the empty bottle or outer carton is taken or removed from the trading partner);

- Any prescription drug that has been taken or removed without permission of the owner of the product (e.g., all or some of the tablets are removed from a bottle and then taken or removed from the trading partner); or

- Any prescription drug and/or its packaging, in physical custody of a trading partner, that is missing all or any portion of the drug as a result of the drug being taken or removed without permission of the owner (e.g., half of the tablets are removed from a bottle and the bottle with the remaining tablets is left with the trading partner subject to the theft, or all the tablets are removed from the bottle and the bottle is left with the trading partner subject to the theft).

D. Fraudulent Transaction

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in section 582(b)(4), (c)(4), (d)(4), and (e)(4), FDA interprets the term *fraudulent transaction* as referring to a transaction in which the transaction information, transaction history, or transaction statement contains information knowingly falsified by a trading partner who has provided or received the information.

E. Unfit for Distribution

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4), and (e)(4), FDA interprets the term *unfit for distribution* as referring to a prescription drug whose sale would violate the FD&C Act and there is a reason to believe or credible evidence shows that the product would be reasonably likely to result in serious adverse health consequences or death to humans. This includes prescription drugs identified as suspect or illegitimate (see section 582(c)(4) of the FD&C Act); adulterated (see section 501 of the FD&C Act) (21 U.S.C. 351)), including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug's safety, identity, strength, quality, or purity (see section 501(a)(2)(B) of the FD&C Act); or misbranded (see section 502 of the FD&C Act (21 U.S.C. 352)) where there is a reason to believe or credible evidence shows that such product would be reasonably likely to result in serious adverse health consequences or death to humans.

[7] Stakeholders are also encouraged to report suspected criminal activity to FDA's Office of Criminal Investigations (OCI) at https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

This definition of *unfit for distribution*, used to determine whether a product could be considered suspect or illegitimate, does not include product that is awaiting reverse distribution and processing and will not be distributed to patients. These products awaiting reverse distribution are not considered unfit for distribution within the context of initiating an investigation of suspect product. Similarly, product granted a waiver, exception, or exemption under section 582(a)(3) of the FD&C Act and product grandfathered under section 582(a)(5) would not be considered unfit for distribution. Although such product is not considered unfit for distribution solely because it fits in one of these categories, such product could be unfit for distribution because it otherwise falls under the definition laid out in this section.