Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Office of Compliance at 301-796-3130.

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)

October 2018
Procedural

Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
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
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

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)

October 2018
Procedural

TABLE OF CONTENTS

Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs
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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), established requirements to facilitate the tracing and verification[2] of certain prescription drug products through the U.S. pharmaceutical distribution supply chain. Certain trading partners[3] (manufacturers, wholesale distributors, dispensers, and repackagers) are required to have verification systems in place to comply with the requirements under section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act. For the purposes of this guidance, FDA interprets a *system* to mean a coordinated body of processes and procedures that forms an organizational scheme. Verification system requirements include quarantine and investigation of suspect products and quarantine, disposition,[4] and notification of illegitimate products.[5] If a suspect product is

[1] This guidance has been prepared by the Office of Compliance in 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 Food and Drug Administration.

[2] *Verification* or *verify* is defined in section 581(28) of the FD&C Act (21 U.S.C. 360eee(28)):

> The term "verification" or "verify" means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

[3] *Trading partner* is defined in section 581(23) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B), the provisions of section 582(b)-(e) do not impose requirements on them.

[4] *Disposition* is defined in section 581(4) of the FD&C Act:

> The term "disposition," with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

[5] *Suspect product* is defined in section 581(21) and *illegitimate product* is defined in section 581(8) of the FD&C Act.

determined after investigation not to be an illegitimate product, a trading partner is required to notify FDA that the product has been cleared, if applicable, and the product may then be further distributed (section 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii)). Trading partners must keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation (section 582(b)(4)(A)(iii), (c)(4)(A)(iii), (d)(4)(A)(iv), and (e)(4)(A)(iii) of the FD&C Act). Records of the disposition of an illegitimate product must also be kept by a trading partner for not less than 6 years after the conclusion of the disposition (section 582(b)(4)(B)(v), (c)(4)(B)(v), (d)(4)(B)(v), and (e)(4)(B)(v)).

Section 582(b)(4)(C) and (e)(4)(C) also requires manufacturers and repackagers to respond to requests for verification from other trading partners, and section 582(b)(4)(E), (c)(4)(D), and (e)(4)(E) requires manufacturers, wholesale distributors, and repackagers to verify certain information prior to further distributing returned product.[6]

FDA is issuing this guidance to describe FDA's interpretation of the requirements of section 582 of the FD&C Act regarding verification systems. This guidance provides recommendations for a robust verification system for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. The guidance also addresses the manner in which FDA recommends that trading partners submit cleared product notifications. Finally, this guidance addresses the statutory requirements for verification, including verification of saleable returns, at the package level for product identifiers on packages and homogenous cases intended to be introduced in a transaction into commerce.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and 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

A. DSCSA Verification Requirements

On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA added section 582 to the FD&C Act, which set forth verification requirements that took effect on January 1, 2015 for manufacturers, wholesale distributors, dispensers, and repackagers of certain drug products.

Under section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act, trading partners must:

- Have a system in place to enable them to identify and determine whether a product is a suspect product.

[6] These requirements will be phased in over a period of years as outlined in sections 582(b)(4)(C) & (E), (c)(4)(D), and (e)(4)(C) and (E) of the FD&C Act.

- Have a system in place to quarantine and investigate a product that has been determined to be a suspect product and to coordinate with trading partners, as applicable, in making the determination as to whether that product is illegitimate.

- Have a system in place to clear a product for distribution, as appropriate, if, after investigation, it is determined that the suspect product is not an illegitimate product. The trading partner is required to notify FDA of cleared products, if applicable.

- Have a system in place for products determined to be illegitimate to:

    - Further quarantine the illegitimate product.

    - Disposition the illegitimate product within the trading partner's possession and control.

    - Take reasonable and appropriate steps to assist another trading partner to disposition the illegitimate product.

    - Retain a sample of the illegitimate product in an adequate amount for further physical examination and laboratory analysis by the manufacturer and/or FDA or other appropriate Federal or State official.

    - Provide notification of the illegitimate product to FDA and other trading partners and, upon making a determination, in consultation with the FDA, that a notification is no longer necessary, terminate that notification. In addition, a manufacturer must have a system in place for notifying its immediate trading partners and FDA of a product that has a high risk of illegitimacy, as required under section 582(b)(4)(B)(ii)(II) of the FD&C Act.

- Have a system in place that includes procedures for taking appropriate action when the trading partner has received an illegitimate product notification or a manufacturer's notification of a high risk of illegitimacy.

- Have a system in place for creating and maintaining records related to suspect product investigations and disposition of illegitimate products for a minimum of 6 years as required by section 582 of the FD&C Act.

In addition, manufacturers, wholesale distributors, and repackagers have additional requirements outlined in section 582(b)(4)(C) and (E), (c)(4)(D), and (e)(4)(C) and (E) of the FD&C Act:

- Manufacturers must have systems in place that will allow them to respond to requests from trading partners to confirm that a particular product identifier, including the standardized numerical identifier, on the product that is the subject of the request corresponds to the product identifier that was affixed or imprinted on that product by the manufacturer of that product.

- Repackagers must have systems in place that will allow them to respond to requests from trading partners to confirm that a particular product identifier, including the standardized numerical identifier, on the product that is the subject of the request corresponds to the product identifier that was affixed or imprinted on that product by the repackager of that product.

- Manufacturers, wholesale distributors, and repackagers must have systems in place that will allow them, upon receipt of a saleable returned product, to verify the product identifier, including the standardized numerical identifier, for each sealed homogenous case or package before further distributing such product.

To satisfy the requirements under section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act, these verification systems may be based on existing standard operating procedures (SOPs) or processes, new SOPs or processes, or a combination of both that ensure that the trading partner meets its verification obligations under section 582. These systems may include the use of a secure electronic database as provided under section 582(b)(4)(D), (c)(4)(C), (d)(4)(C), and (e)(4)(D) of the FD&C Act.

B. Scope of This Guidance

This guidance applies to the verification systems that manufacturers, wholesale distributors, dispensers, and repackagers must have in place as described in section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.

This guidance is intended to provide assistance to industry in understanding the verification systems requirements under section 582 of the FD&C Act and to provide guidance on what should be included in these systems. This guidance does not address all of the provisions in section 582 of the FD&C Act related to verification. For example, the Agency previously issued a guidance on identification of suspect products and notification of illegitimate products (Suspect Product and Notification Guidance) that includes processes by which notifications to FDA and other trading partners of illegitimate product are made, as well as termination of those notifications, as described in section 582(h)(2)(A)(iii) of the FD&C Act.[7]

When designing and implementing the verification systems required under the DSCSA, trading partners are cautioned that although section 582 of the FD&C Act may not require that a product be withheld or removed from the U.S. pharmaceutical distribution supply chain because it does not fit within the definition of *suspect product* or *illegitimate product*, trading partners have other obligations under the FD&C Act and the Public Health Service Act regarding the introduction of products into interstate commerce. Violation of those requirements may result in enforcement actions regardless of a trading partner's compliance with section 582. For example, an adulterated product may not be a suspect product because it is not within the definition in section 581(21) of the FD&C Act, but it is a prohibited act to introduce or deliver for introduction into

[7] FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*; 2016 (Suspect Product and Notification Guidance). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

interstate commerce an adulterated drug under section 301(a) of the FD&C Act (21 U.S.C 331(a)).

III. VERIFICATION SYSTEMS UNDER SECTION 582

Section 582 of the FD&C Act requires manufacturers, wholesale distributors, dispensers, and repackagers to have "systems in place to enable [them] to comply" with certain requirements relating to the identification and handling of suspect and illegitimate products. Specific requirements include quarantine and investigation of a product determined to be a suspect product and quarantine, disposition, and notification of a product determined to be an illegitimate product.[8]

A. Systems to Determine That a Product Is Suspect

Trading partners must have systems in place to make a determination as to whether a product is a suspect product.[9] These systems should ensure that, when appropriate, a trading partner makes a consistent, effective, and timely determination that a product is suspect. In order to help ensure patient safety, it is essential that this system be well-designed to detect and assess suspect product, because the determination that a product is suspect triggers quarantine and investigation under section 582 of the FD&C Act. In making these determinations, trading partners should focus on drugs that potentially fall into one of the categories of drugs listed in the definition of suspect product in section 581(21) of the FD&C Act: product that may be counterfeit, diverted, stolen, intentionally adulterated, subject of a fraudulent transaction, or unfit for distribution. In the previously published draft guidance, *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act,* FDA clarified its interpretation of the following terms listed in the definition of suspect product in section 581(21) of the FD&C Act: counterfeit, fraudulent transaction, unfit for distribution, and diverted.[10]

In particular, trading partners should consider the risk of such product entering the U.S. pharmaceutical distribution supply chain and the scenarios that could significantly increase such risk. The Suspect Product and Notification Guidance provides recommendations on how trading partners can identify a suspect product and determine whether the product is a suspect product as soon as practicable. The list of scenarios and recommendations in that guidance are not all-inclusive, and trading partners should exercise due diligence at all times to ensure that a suspect product is identified.

FDA may make a request for verification to a trading partner when FDA has determined that the trading partner may have a suspect product within its possession or control.[11] Upon receipt of a request for verification, trading partners must proceed as directed by section 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) (e.g., quarantining, investigating).

---

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

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

[10] That draft guidance, when finalized, will represent FDA's current thinking on that topic. To make sure you have the most recent version of a guidance, always consult the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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

Upon receipt of an illegitimate product notification from a trading partner or a notification from FDA that a product has been determined to be an illegitimate product, a trading partner must identify all illegitimate products subject to such notification in its possession or control, including any product that is subsequently received, and conduct the activities required for suspect product, as applicable, described in sections 582(b)(4)(A), (c)(4)(A), (d)(4)(A), and (e)(4)(A).[12] Trading partners should follow these same procedures upon receipt of a notification from a manufacturer that a product has a high risk of illegitimacy.

B. System for Suspect Product Quarantine and Investigation

Upon determining that a product is suspect, or upon receiving a request for verification from FDA, a trading partner is required to quarantine and investigate the product to determine whether it is an illegitimate product.[13] Trading partners must have systems in place to enable such quarantines and investigations of suspect product.[14]

1. Quarantine

Under FDA's interpretation, quarantine of a suspect product may be accomplished using physical separation and/or other procedures such as electronic means, when applicable. The system for quarantine should be robust enough to ensure that the suspect product is not inadvertently distributed. The authority to terminate a quarantine of suspect product and release the product for further distribution should be assigned to an appropriate person(s) in the trading partner's organization. For example, a member of the Quality Control Unit for a manufacturer or repackager, a facility manager or responsible person identified by a wholesale distributor, or a pharmacist-in-charge for a dispenser may be an appropriate person to exercise such authority.

2. Components of a Robust Investigation

Trading partners are required to commence and promptly conduct an investigation, in coordination with other trading partners, as applicable, into whether a suspect product is an illegitimate product.[15] At a minimum, such investigations must include validation of any applicable transaction history and transaction information[16] and should include:

- Active communication and coordination of the investigation with the manufacturer and/or repackager and other trading partners, as appropriate, to ensure that the investigation is thorough and the conclusions are accurate.

- Use of appropriate laboratory standards, controls, and techniques in situations where laboratory testing of suspect product is necessary to determine whether the product is an illegitimate product. Note that FDA would generally consider it appropriate for trading

[12] Section 582(b)(4)(B)(iii), (c)(4)(B)(iii), (d)(4)(B)(iii), and (e)(4)(B)(iii) of the FD&C Act.
[13] See section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.
[14] See section 582(b)(4)(A), (c)(4)(A), (d)(4)(A), and (e)(4)(A) of the FD&C Act.
[15] See section 582(b)(4)(A)(i)(II), (c)(4)(A)(i)(II), (d)(4)(A)(i)(II), and (e)(4)(A)(i)(II) of the FD&C Act.
[16] See section 582(b)(4)(A)(i)(II), (c)(4)(A)(i)(II), (d)(4)(A)(ii)(III), and (e)(4)(A)(i)(II) of the FD&C Act.

partners participating in a coordinated investigation with the product's manufacturer to rely on the results of laboratory testing conducted by that manufacturer if the testing is performed in a timely manner and the trading partner receives adequate assurance from the manufacturer that the results are reliable.

After each investigation of a suspect product, a trading partner should capture the lessons learned regarding the components of the verification system that worked well and those that did not and make the appropriate adjustments to the verification system. If a trading partner determines through its investigation that a suspect product is an illegitimate product, it should conduct a root-cause analysis of how the product came to be in the possession and control of the trading partner and assess ways to strengthen its procurement process to avoid future acquisition of illegitimate products.

C. System for Cleared Product Notification Regarding Suspect Products

Under section 582 of the FD&C Act, trading partners must promptly notify the Secretary, if applicable, if they determine after investigation that the suspect product is not an illegitimate product.[17] This notification is considered a "cleared product notification." FDA expects cleared product notifications to be submitted to FDA only if the suspect product is the subject of an FDA request for verification. Other cleared product notifications should not be submitted to FDA, as described in section III.C.3 below. Trading partners should be advised that once a product has been cleared, they must ensure compliance with the other applicable provisions of the FD&C Act before the product may be further distributed. Trading partners must have systems in place for cleared product notifications.[18]

1. Components of Cleared Product Notifications

The cleared product notifications should include:

- A subject line that states: "Cleared Product Notification."
- The identity of the product that was determined to be a suspect product but has now been determined, after investigation, not to be an illegitimate product. The product should be identified by the:
    1. Proprietary or established name of the product[19]
    2. Strength and dosage form of the product
    3. National Drug Code (NDC) of the product[20]
    4. Lot number
    5. Expiration date

[17] See section 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii) of the FD&C Act.
[18] See section 582(b)(4)(A)(iii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii) of the FD&C Act.
[19] The *proper name* should be used for biological products. See 21 CFR 600.3(k).
[20] If an alternatively formatted NDC is approved for use in accordance with 21 CFR 207.33(b)(4), the alternatively formatted NDC should be used to identify the product.

6. Serial number(s) of the product(s)[21]
7. Container size
8. Number of containers

- The reason why the product was determined to be suspect and a summary of the investigation that led to the trading partner's determination that the product was not an illegitimate product.
- The date the product was cleared.
- The name and official position of the employee or officer of the trading partner who cleared the suspect product and the signature of that officer or employee.
- The distribution or disposition of the product (i.e., details about the distribution or disposition including the date that the product was distributed or appropriately dispositioned).

2. Cleared Product Notifications to be Submitted to FDA

If after investigating a product that is the subject of an FDA request for verification, a trading partner determines that the product is not an illegitimate product, the trading partner must promptly submit a cleared product notification to FDA documenting its determination.[22] The cleared product notification should be submitted to ***drugnotifications@fda.hhs.gov***. In addition to the components identified above, the cleared product notification should include the date of the FDA request for verification to which the cleared product notification applies, and the name of the FDA office and/or employee who made the request for verification.

3. Cleared Product Notifications That Do Not Need to be Submitted to FDA and Should Be Maintained by the Trading Partner

If, after investigation, a trading partner determines that a suspect product is not an illegitimate product and the product is not the subject of an FDA request for verification, the trading partner should not submit a cleared product notification to FDA. However, the trading partner should maintain the cleared product notification in the records of the investigation of the suspect product.

4. Recordkeeping of Cleared Product Notifications

Records of suspect product investigations, including all cleared product notifications, must be maintained for a period of at least 6 years after the conclusion of the investigation.[23]

[21] When a product identifier must be affixed or imprinted to a product per sections 582(b)(2) and 582(e)(2), trading partners should include the serial number along with the NDC, lot number, and expiration date as the product identifier of the product package(s) or sealed homogenous case of product (see sections 581(14) and (20)).
[22] See section 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii) of the FD&C Act.
[23] Section 582(b)(4)(A)(iii), (c)(4)(A)(iii), (d)(4)(A)(iv), and (e)(4)(A)(iii) of the FD&C Act.

D. System for Illegitimate Product Quarantine and Disposition

Trading partners must meet certain requirements for quarantine and disposition of illegitimate product, including coordination with other trading partners, as applicable. [24] In making the determination that a product is illegitimate, trading partners are required to coordinate with the manufacturer.[25]

1. Quarantine

Products determined to be illegitimate should be kept ***physically*** separated from products intended for distribution because of the higher level of public health risk associated with illegitimate products.[26] The system for quarantine should be robust enough to ensure that an illegitimate product is not inadvertently distributed. Authority to release the illegitimate product from quarantine should only be exercised by an appropriate person in the organization expressly authorized to terminate quarantine for the illegitimate product. For example, a member of the Quality Control Unit for a manufacturer or repackager, a facility manager or responsible person for a wholesale distributor, or a pharmacist-in-charge for a dispenser may be an appropriate person to exercise such authority.

2. Disposition

The method of disposition of an illegitimate product should ensure that the public health hazards associated with that product are appropriately controlled. Trading partners should have written procedures/SOPs for disposition of the illegitimate product.[27] Trading partners should also audit any contractors they hire to disposition the product to ensure that the product was appropriately and effectively disposed of. Records of the disposition of an illegitimate product must be maintained by trading partners for not less than 6 years after the conclusion of the disposition.[28]

3. Retention of Samples

Trading partners must retain a sample of the illegitimate product for further physical examination or laboratory analysis by the manufacturer or FDA (or other appropriate Federal or State official).[29] Samples should be:

- Representative of the illegitimate product.
- Of a sufficient amount, if available, to permit proper laboratory examination by both the manufacturer and FDA or another government agency.

[24] Section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act.
[25] Id.
[26] Section 582(d)(4)(B)(iii) requires dispensers to quarantine product for which they receive a notice of illegitimacy. Dispensers should also quarantine product they determine to be illegitimate.
[27] Section 582(b)(4)(B)(i)(II), (c)(4)(B)(i)(II), (d)(4)(B), and (e)(4)(B)(i)(II) of the FD&C Act.
[28] Section 582(b)(4)(B)(v), (c)(4)(B)(v), (d)(4)(B)(v), and (e)(4)(B)(v) of the FD&C Act.
[29] Section 582(b)(4)(B)(i)(IV), (c)(4)(B)(i)(IV), (d)(4)(B)(i)(III), and (e)(4)(B)(i)(IV) of the FD&C Act.

- Appropriately labeled and stored to preserve the identity and integrity of the sample.

- Handled, identified, and sealed in a manner ensuring that proper custody procedures are maintained so that the sample and/or laboratory test results can be used as evidence, if necessary. For example, a record/log identifying each person who handled the product, identifying the date they handled it, and describing the manner in which they handled it should be maintained and should accompany the sample when submitted for testing.

E. System for Illegitimate/High Risk of Illegitimacy Product Notifications

Trading partners must have systems in place for notifying FDA and immediate trading partners of an illegitimate product and, for manufacturers, products with a high risk of illegitimacy.[30] The Suspect Product and Notification Guidance sets forth the process by which trading partners should notify FDA of the illegitimate product or products with a high risk of illegitimacy, and the process they must use to terminate notifications, in consultation with FDA.[31] Refer to that guidance for specific information related to these notifications.

F. System for Responding to Requests for Verification

Manufacturers and repackagers must have systems in place to respond to requests for verification from trading partners within 24 hours of receipt of a request.[32] These systems must be in place by November 27, 2017, for manufacturers, and by November 27, 2018, for repackagers. The systems must allow the manufacturer or repackager to notify the trading partner making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by that manufacturer or repackager.[33] These systems should:

- Allow the manufacturer or repackager to respond to the request within the required timeframe with a clear statement as to whether the product identifier has been verified or not.

- Be integrated with the system used to identify suspect product and illegitimate product. If a product identifier does not correspond to the product identifier affixed or imprinted by the manufacturer or repackager, the product must be treated by the manufacturer or repackager, as applicable, as a suspect product (i.e., it must be quarantined and investigated).[34] If the manufacturer or repackager has reason to believe that the product is illegitimate, it must indicate as much in its response to the request for verification from a trading partner, and should inform them why they believe the product may be illegitimate.[35] In addition, section III.E above describes the recommendation for a system

[30] Section 582(b)(4)(B)(ii)(I) and (II), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act.
[31] For terminating notification requirements see section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act.
[32] See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.
[33] Section 582(b)(4)(C) and 582(e)(4)(C) of the FD&C Act.
[34] See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.
[35] See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.

to notify FDA and other trading partners when an illegitimate product is found (and, for manufacturers, when products with a high risk of illegitimacy are found).

G. System for Processing Saleable Returns

Manufacturers, wholesale distributors, and repackagers must have systems in place that will allow them to process saleable return products that they intend to further distribute.[36, 37, 38] These systems must allow the trading partners to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product or, if such product is not in a sealed homogeneous case, on each package of saleable returned product.[39] A saleable returned product may not be further distributed until the product identifier is verified. If the product identifier is not successfully verified, the product should be handled as a suspect product (i.e., it must be quarantined and investigated).[40]

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

[37] These systems must be in place by November 27, 2017, for manufacturers, by November 27, 2018, for repackagers, and by November 27, 2019, for wholesale distributors.

[38] *Return* is defined in section 581(17) of the FD&C Act.

[39] Section 582(b)(4)(E), (c)(4)(D), and (e)(4)(E) of the FD&C Act.

[40] For how trading partners must handle suspect product, see section 582(b)(4)(A)(i), (c)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.