Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act

Guidance for Industry

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)
Office of Regulatory Affairs (ORA)

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Table of Contents

I. INTRODUCTION 4

II. BACKGROUND 5

III. ENHANCED DRUG DISTRIBUTION SECURITY 5

A. SystemAttributes to Enable Secure Tracing 6

B. Aggregation and Inference 6

1. Aggregation 7

2. Physical Security Features 8

3. Inference 8

IV. SYSTEM STRUCTURE 9

A. Data Architecture 9

B. Adoption of Data and System Security 10

C. Confidential Commercial Information and Trade Secrets 10

D. Requesting and Providing Information 11

V. ENHANCED PRODUCT TRACING 11

A. Incorporation of the Product Identifier into Product Tracing Information 11

B. The Selling Trading Partner Should Reconcile the Transaction Information with the Product it Sells to a Purchasing Trading Partner 12

C. The Purchasing Trading Partner Should Confirm the Transaction Information and Transaction Statement is for Product it Receives from a Selling Trading Partner 12

D. Handling Aggregation Errors and Other Discrepancies 13

1. Examples of Aggregation Errors and Other Discrepancies 13

2. Steps for Resolving Aggregation Errors and Other Discrepancies 14

VI. GATHERING OF RELEVANT PRODUCT TRACING INFORMATION 14

VII. ENHANCED VERIFICATION 16

A. Verification of Distributed Product 16

B. Verification of Saleable Returned Product 17

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Guidance for Industry[1]

This guidance represents 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 office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to assist supply chain stakeholders, particularly trading partners,[2] with requirements for enhanced drug distribution security at the package[3] level under 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). Requirements for enhanced drug distribution security[4] go into effect on November 27, 2023.[5]

This guidance clarifies the enhanced drug distribution security requirements listed in section 582(g)(1) of the FD&C Act ("enhanced security requirements"). In addition, as specified in

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration (FDA).

[2] *Trading partner* is defined in section 581(23) of the Federal Food, Drug and Cosmetic (FD&C) Act, and includes a manufacturer, repackager, wholesale distributor, dispenser, or third-party logistics provider, meeting the conditions specified therein.

[3] *Package* is defined in section 581(11) of the FD&C Act to mean the smallest individual saleable unit of product that is intended for individual sale to a dispenser, as further specified therein.

[4] In the previously issued draft guidance, the interoperable, electronic, package-level product tracing systems and processes required by section 582(g) of the FD&C Act were referred to as the "enhanced system," and comments on the draft guidance expressed confusion over that term. For this final guidance, we have removed "enhanced system" when referring to the requirements in section 582(g) of the FD&C Act to avoid confusion.

[5] FDA issued compliance policy guidances that represent an enforcement policy with respect to (a) enhanced drug distribution security requirements in section 582(g)(1), and (b) verification requirements for saleable returned product for wholesale distributors in section 582(c)(4)(D) and verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii). See the compliance policy guidances, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act – Compliance Policies*, and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product--Compliance Policies, Revision 1* for more information. For this guidance, references to compliance with the November 27, 2023, date that the requirements under section 582(g)(1) take effect are subject to the enforcement policy articulated in the applicable compliance policy guidance.

section 582(h)(3) of the FD&C Act, this guidance "outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing" of product[6] at the package level, including allowing for the use of verification, inference, and aggregation, as necessary.[7] FDA considers these recommendations to be important to assist in implementing the robust supply chain security envisioned under the DSCSA. Throughout this guidance, the terms, "FDA," "the Agency," "we," and "us" refer to the Food and Drug Administration and the terms "your" and "yours" refer to regulated industry.

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

The DSCSA was signed into law on November 27, 2013. The DSCSA outlines critical steps to achieve interoperable, electronic tracing of product at the package level by November 27, 2023. These requirements will enhance the identification and tracing of certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added section 582 to the FD&C Act, which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also introduced requirements for enhanced drug distribution security that go into effect on November 27, 2023.

III. ENHANCED DRUG DISTRIBUTION SECURITY

Trading partners, along with Federal and State authorities, have an important role in ensuring the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements, which have been phased in beginning in 2013, improve supply chain security activities by trading partners involved in prescription drug manufacturing, repackaging, wholesale distribution, warehousing or related logistical activities, and dispensing. The phased implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the gradual development of enhanced drug distribution security required under section 582(g) of the FD&C Act. This guidance clarifies the enhanced security requirements and describes recommendations for the system attributes necessary[8] for secure product tracing and verification, including when the use of aggregation and inference may be appropriate.

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[6] *Product* is defined in section 581(13) of the FD&C Act, and includes, subject to the exceptions described therein, a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).

[7] See section 582(h)(3) of the FD&C Act and section III.B of this guidance.

[8] In this guidance FDA uses the term "necessary" as used in section 582(h)(3) in a technical sense, i.e., in referring to system attributes that would enable trading partners as a technical matter to meet the requirements under section 582(g)(1), including elements of required systems and processes.

A. System Attributes To Enable Secure Tracing

System attributes, as used for purposes of this guidance, are properties or capabilities that promote enhanced drug distribution security. Such system attributes, which we view as important elements of implementing the robust supply chain security envisioned under the DSCSA, should be developed based on the enhanced drug distribution security requirements in section 582(g)(1) of the FD&C Act and include (as described in this provision):

(A) The exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.

(B) Transaction information that includes the product identifier at the package level for each package included in the transaction.

(C) Systems and processes for verification of product at the package level.

(D) Systems and processes necessary to promptly respond with the relevant transaction information and transaction statement for a product upon request by FDA or other appropriate Federal or State official in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product.

(E) Systems and processes necessary to promptly facilitate the gathering of the information necessary to produce the transaction information for each transaction[9] going back to the manufacturer, as applicable—

(i) Upon request by FDA or other appropriate Federal or State official in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product, or

(ii) Upon request of an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for the purposes of investigating a suspect product or assisting FDA or other appropriate Federal or State official with a request described in clause (i).

(F) Systems and processes to associate a saleable return product with its applicable transaction information and transaction statement to allow a trading partner to accept the returned product.

B. Aggregation and Inference

Although the terms *aggregation* and *inference* are not defined in the FD&C Act, these processes and practices are referenced in the FD&C Act in the context of product verification and tracing[10]; they are used in this guidance to describe how such processes and practices can facilitate enhanced security requirements. For purposes of this guidance, we use the terms aggregation and inference as follows:

- *Aggregation* refers to the process of building a relationship between unique identifiers assigned to packaging containers. For example, a parent-child relationship would exist between the product identifiers for a package or group

[9] *Transaction* is defined in section 581(24) of the FD&C Act.

[10] See e.g., section 582(g)(1)(C) and (h)(3) of the FD&C Act, referring, respectively, to aggregation and inference in the context of describing systems and processes for verification of product at the package level and system attributes necessary to enable secure tracing of product at the package level.

of packages (the child or children) that are contained in a homogeneous case[11] or nonhomogeneous case (the parent).

- *Inference* means the practice of examining or using information for a higher level of packaging to infer information about the lower level(s) of packaging and its contents— for example, inferring information about individual packages from information about a homogeneous or nonhomogeneous case.

As such, the effective use of aggregation and inference will depend on the quality of aggregated data, documentation and shipping/packing integrity, and the ability of trading partners to effectively use aggregated data to meet FD&C Act requirements.

1. Aggregation

FDA recognizes that many trading partners currently aggregate data for logistical management of products they sell. We are also aware that some trading partners use aggregated data for other purposes, such as to comply with verification requirements or to share data with trading partners at their discretion. Because it appears to be an essential process in trading partner daily operations of supply chain and data management, whether manual or automated, FDA supports the use of data aggregation. Examples of data aggregation related to a transaction and the associated shipment of products include, but are not limited to:

- Packages of the same product that are packed into a homogeneous case: A data file that lists the standardized numerical identifier[12] of the case, as well as the standardized numerical identifiers for each package of product in that case provided by the selling trading partner to the purchasing trading partner.

- Multiple cases of product on a pallet: A data file that reflects the contents of the pallet, including the individual, unique product identifiers associated with the packages within all nonhomogeneous cases provided by the selling trading partner to the purchasing trading partner.

A selling trading partner and its purchasing trading partner(s) should decide how they will share data in a secure, efficient manner that allows the purchasing trading partner(s) to use the aggregated data file(s) for determining the information that is associated with each package of product. For example, a selling trading partner may choose to: (1) send the data file in its entirety to the purchasing trading partner(s), which includes all product identifiers of each package of product contained in a sold homogeneous or nonhomogeneous case; or (2) provide the product identifier associated with the homogeneous case to the purchasing trading partner(s), who could

[11] *Homogeneous case* is defined in section 581(7) of the FD&C Act. The terms "homogeneous" and "homogenous" are used interchangeably throughout the DSCSA. FDA has chosen to use only the term "homogeneous" throughout this guidance.

[12] The term "standardized numerical identifier" is defined in section 581(20) of the FD&C Act as "a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters."

use the case product identifier to look up and access the data file containing individual product identifiers for each package of product in that case.[13] The scenario described in example (2) could involve automated data retrieval from the seller's system or database if proper interoperable configurations exist.

Although sections 582(b)(2) and (e)(2) of the FD&C Act require manufacturers and repackagers, respectively, to affix to or imprint product identifiers upon packages and homogeneous cases of product, a trading partner may voluntarily encode a product identifier on packages of drugs that do not meet the definition of product in section 581(13) of the FD&C Act or on nonhomogeneous cases, as long as the addition does not interfere with other Federal requirements.

2. Physical Security Features

FDA recommends the use of security features on shipping units (such as cases or pallets) of product to help indicate when product may have been tampered with, previously unsealed, damaged, or otherwise rendered suspect.[14] Examples of package security features that help improve the security of the product include, but are not limited to, tamper-evident tape or wrap, color-shifting inks, and holograms. FDA also supports the use of anticounterfeiting technologies like physical-chemical identifiers (also referred to as PCIDs) in solid oral dosage forms of drug products.[15] If a trading partner determines that the physical security features of a shipping unit have been compromised, the trading partner should treat the product contained within as suspect.

3. Inference

FDA recognizes that inference is currently a common business practice and enables members of the supply chain to handle data, processes, and products during shipping and receiving steps (although we note that members of the supply chain have indicated that future automated solutions may enable expedient package scanning for large volumes of product, thus making the practice of inference unnecessary). A trading partner should limit use of inference to circumstances when it receives pallets or cases (either homogeneous or nonhomogeneous) with aggregated data if the integrity of the unit is intact—in other words, the tamper-evident tape or wrap, or other security seal that originated with the manufacturer or repackager, has not been broken or altered. Receiving a pallet or case with broken or altered tape or wrap that was not unsealed by the purchasing trading partner would render the product suspect, and the trading partner should not infer the contents of the case based on the aggregated data.

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[13] Section 582(a)(9)(A) of the FD&C Act generally requires packages to have product identifiers encoded in a 2D data matrix barcode, and homogeneous cases to have product identifiers encoded in either a linear or 2D data matrix barcode.

[14] *Suspect product* is defined in section 581(21) of the FD&C Act. See also FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.* We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[15] See FDA guidance for industry *Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting*. We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

If a federal or state authority breaks a security feature to allow for examination or testing and provides documentation that it has done so, the product should not be treated as suspect absent other indications that the product may be suspect. For example, when FDA screens shipments of product for admissibility for import, if FDA has unsealed and resealed a case or pallet, trading partners should not treat this product as suspect solely for that reason.

If there are other reasons to believe that the product package, case, or shipping unit is suspect product, trading partners should not infer that aggregated data reflects the physical shipment of product and must comply with the applicable requirements regarding suspect product.[16]

IV. SYSTEM STRUCTURE

FDA views the elements described in this guidance as important to achieve secure, electronic interoperability[17] across the supply chain. Each trading partner should have its own individual systems and processes for accessing and managing its products and associated data. Such individual systems and processes should permit secure, appropriate, and efficient sharing of electronic information (i.e., data) between trading partners; more specifically, individual systems and processes should allow for trading partners to exchange data with each other for product tracing and verification in an accurate, interoperable manner that also protects confidential commercial information and trade secrets. Additionally, trading partners should be able to easily retrieve their own stored information and (as further described in section VI) provide appropriate elements of such information when requested by FDA or Federal and State officials, or by other authorized trading partners when required to do so.[18]

A. Data Architecture

For the purpose of this guidance, "data architecture" refers to the type of data collected and the data validation policies, standards, and safeguards that govern how data is stored, managed, and used within and between organizations and respective organizations' individual systems. The FD&C Act, as amended by the DSCSA, defines the type of product tracing data that must be provided, received, and stored as the transaction information, transaction history, and transaction statement.[19] Although under section 582(k)(1) of the FD&C Act the requirement to provide and

[16] See e.g., section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act; see also FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*. We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[17] As described in the Agency guidance, "*DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs,*" for the purpose of the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act, FDA interprets interoperability for enhanced drug distribution security to encompass the ability to securely exchange, capture, and maintain electronic transaction information and transaction statements accurately, efficiently, and consistently among trading partners, in a manner that enables compliance with all enhanced drug distribution security requirements. We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[18] See sections 582(g)(1)(D) and (E) of the FD&C Act.

[19] *Transaction information, transaction history,* and *transaction statement* are defined in section 581(26), (25), and (27) of the FD&C Act, respectively.

receive transaction history sunsets on November 27, 2023, the enhanced security requirements include the ability to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable.[20] There are several possible data architecture models for data storage, management, and use that can be used to meet enhanced security requirements. Such models include centralized, distributed, or semi-distributed (a mixture of centralized and distributed) data architectures.[21]

Based on stakeholder feedback about current industry practices and preferences, FDA recommends a distributed or semi-distributed data architecture model because either model can allow each trading partner to maintain control over its own data. In addition, trading partners should use the model which best facilitates promptly providing Federal and State officials, upon request, with product tracing data as required under the DSCSA.[22]

In addition, to help standardize how the data is captured and exchanged, FDA recommends that trading partners use the Electronic Product Code Information Services (EPCIS) standard.[23] More information about FDA's recommendation of EPCIS can be found in the guidance, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.*[24]

B. Adoption of Data and System Security

FDA recommends the use of appropriate data security standards, security protocols, and security applications to protect data, trading partners' individual systems and processes, and information exchanges between individual systems from falsification, malicious attacks, and breaches. Trading partners should ensure data security by adopting standards and/or protocols developed by a widely recognized international standards development organization.

C. Confidential Commercial Information and Trade Secrets

Section 582(h)(3)(A)(iii) of the FD&C Act states that FDA's guidance on attributes for enhanced security requirements must "ensure the protection of confidential commercial information and trade secrets." Trading partners should use individual systems and procedures that protect confidential commercial information and trade secrets. FDA expects trading partners to ensure

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[20] See section 582(g)(1)(E) of the FD&C Act.

[21] For the purpose of this guidance, a "centralized" data architecture model refers to a configuration in which required trading partner data is stored in one database; a "distributed" data architecture model refers to a configuration in which required trading partner data is stored across multiple databases; and a "semi-distributed" data architecture model refers to a configuration in which required trading partner data is stored in a few select databases.

[22] See sections 582(g)(1)(D) and (E) of the FD&C Act; see also provisions related to requests for information in sections 582(b)(1)(B), (c)(1)(C), (d)(1)(D), and (e)(1)(C) of the FD&C Act.

[23] Section 582(h)(4)(A) of the FD&C Act specifies that FDA issue a guidance to identify and make recommendations with respect to the standards necessary for adoption to support the secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

[24] We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

that they will maintain the confidentiality of product tracing information[25] through usual business practices. FDA will treat any information provided to the Agency like other information submitted to us by industry or stakeholders, including complying with requirements prohibiting public disclosure of confidential commercial information and trade secrets.[26]

D. Requesting and Providing Information

Trading partners' individual systems and processes should permit responding to an authorized trading partner who requests relevant information related to verification activities[27] for a product the authorized trading partner sold or purchased (e.g., product tracing information associated with a product the authorized trading partner sold or purchased). In addition, as discussed in section VI, the individual systems and processes should enable trading partners to provide relevant information upon request by FDA or other appropriate Federal or State official (or an authorized trading partner) in the event of a recall or for the purpose of investigating a suspect or illegitimate product, as applicable.[28]

V. ENHANCED PRODUCT TRACING

A. Incorporation of the Product Identifier Into Product Tracing Information

The first component of the enhanced security requirements addresses the secure, interoperable exchange of product tracing information. Specifically, section 582(g)(1)(A) of the FD&C Act requires the transaction information and transaction statements to be exchanged in a "secure, interoperable, electronic manner." Additionally, section 582(g)(1)(B) of the FD&C Act requires that the transaction information include "the product identifier at the package level for each package included in the transaction." Under section 581(14) of the FD&C Act, the product identifier includes the standardized numerical identifier (i.e., National Drug Code (NDC) and serial number), lot number, and expiration date. For transactions occurring before the November 27, 2023 effective date of the enhanced security requirements, the transaction information required to be exchanged by trading partners,[29] which is defined in section 581(26) of the FD&C Act, generally includes the NDC and lot number, but not the additional product identifier elements (although manufacturers and repackagers must affix the complete product identifier to each package and homogeneous case of product intended to be introduced in a transaction into commerce).[30] Thus, to meet the section 582(g)(1)(B) requirement, the serial number and expiration date will also need to be incorporated into the transaction information starting November 27, 2023, to represent the complete product identifier. FDA expects trading partners

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[25] For the purposes of this guidance, the term product tracing information refers to the transaction information and transaction statement associated with a product.

[26] See, e.g., 21 CFR 20.61.

[27] See sections 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act. See also section 582(g)(1)(C) of the FD&C Act.

[28] See sections 582(g)(1)(D) and (E) of the FD&C Act; see also provisions related to requests for information in section 582(b)(1)(B), (c)(1)(C), (d)(1)(D), and (e)(1)(C) of the FD&C Act.

[29] See sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.

[30] See sections 582(b)(2) and (e)(2) of the FD&C Act.

to use processes and technical functions to enhance security that accommodate the inclusion of the standardized numerical identifier, expiration date, and lot number in the transaction information to meet this requirement.

B. The Selling Trading Partner Should Reconcile the Transaction Information With the Product It Sells to a Purchasing Trading Partner

Beginning November 27, 2023, the selling trading partner must provide applicable electronic product tracing information to the subsequent owner (i.e., the purchasing trading partner) before, or at the time of, each transaction.[31] The selling trading partner that is shipping product and providing product tracing information is expected to incorporate and store information related to the transaction into its individual systems in such a manner that the data can be used for product tracing purposes.

With electronic product tracing information and product identifier information (in the 2D data matrix barcode for packages of product and in the linear or 2D data matrix barcode for homogeneous cases of product),[32] selling trading partners should develop and use systems and/or processes to reconcile the electronic data in the transaction information and transaction statement associated with the product physically shipped to the purchasing trading partner. Reconciliation would involve confirming that the product tracing information sent in an electronic format accurately reflects the packages of product the selling trading partner physically ships. Reconciliation could be accomplished by physically or electronically checking the product identifiers of each package against associated electronic transaction information or physically checking the product identifiers of cases of product with unbroken security seals that originated with the manufacturer or repackager, against associated electronic transaction information. This step helps to ensure that the product that is physically packed into a shipping unit is properly associated with the data that is provided to the purchasing trading partner.

C. The Purchasing Trading Partner Should Confirm the Transaction Information and Transaction Statement Is for Product It Receives From a Selling Trading Partner

Beginning November 27, 2023, the trading partner purchasing the product must not accept ownership of the product unless the previous owner provides the applicable electronic product tracing information before, or at the time of, the transaction.[33] The purchasing trading partner receiving product and product tracing information is expected to incorporate this information into its individual system in such a manner that the data can be used for product tracing purposes.

With electronic product tracing information and product identifier information (in the 2D data matrix barcode for packages of product and in the linear or 2D data matrix barcode for

[31] See section 582(g)(1)(A) of the FD&C Act; see also sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.
[32] See section 582(a)(9)(A) of the FD&C Act.
[33] See section 582(g)(1)(A) of the FD&C Act; see also sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.

homogeneous cases of product), the purchasing trading partners should develop and use systems and/or processes to confirm electronic data in the transaction information and transaction statement is for the product received.

When the purchasing trading partner sells the product, the trading partner should follow the recommendations in section V.B, *The Selling Trading Partner Should Reconcile the Transaction Information with the Product it Sells to a Purchasing Trading Partner*.

D. Handling Aggregation Errors and Other Discrepancies

FDA expects the product tracing information to be true, accurate, and complete. FDA recognizes that there may be situations where there is a clerical error or discrepancy in the product tracing information that may not be indicative of a suspect product. If a wholesale distributor, dispenser, or repackager purchases product and identifies a potential clerical error or other discrepancy in the product tracing information it received, that trading partner should resolve the error or discrepancy within 10 business days.

1. Examples of Aggregation Errors and Other Discrepancies

Aggregation errors between product tracing information and associated shipments of product may occur during the aggregation or packing process. For example, trading partners may encounter the following:

- Missing product: The product tracing information reflects 10 bottles of product; however, the purchasing trading partner only received 9 bottles.

- Extra product: The product tracing information reflects 10 bottles of product; however, the purchasing trading partner received 12 bottles of product.

- Duplicate data: The product tracing information contains the same information twice, such as the product being listed twice. (This should not be confused with the scenario in which duplicate serial numbers are listed for two packages of product; product in this scenario should be considered suspect.)

- Missing data: The product identifier for the homogeneous case is missing; therefore, there is no other identifier to associate with the product identifiers of the packages of product physically received within the case.

Other discrepancies may occur during the ordering, shipment, or receipt of product. For example:

- The transaction information is missing the address of the purchasing trading partner.

- The transaction information misstates the address of the purchasing trading partner.

- The transaction information is missing the quantity of product, but the purchasing

trading partner received the quantity of product that it ordered.

2. Steps for Resolving Aggregation Errors and Other Discrepancies

The product(s) involved should not be sold to the next trading partner until the error or discrepancy has been documented and resolved. A resolution may include confirming with the selling trading partner that an error or discrepancy is clerical (as applicable), coordinating and reaching an agreement with the selling trading partner on how to correct the clerical error or discrepancy, and ensuring that accurate product tracing information is available to provide for subsequent transactions. If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product,[34] trading partners must refrain from further distributing or dispensing the product and follow steps for verification of product, including, if applicable, quarantine and investigation.[35]

If aggregation errors or other types of discrepancies occur, a trading partner should first notify the trading partner that it purchased the product from and determine the reason for the error. The trading partners should then work together to promptly resolve the error. Finally, the trading partners should document that they resolved the error. The documentation should include the nature of the error, a description of how the error was resolved, the names of the persons involved, and the date of resolution. If either trading partner determines the product is suspect or illegitimate, the trading partners must follow applicable verification requirements, including quarantine, investigation, and proper disposition.[36]

Examples of how trading partners may resolve such errors include:

- The selling trading partner may provide new and revised product tracing information that reflects the products received by the purchasing trading partner.
- The selling trading partner may provide new product tracing information only for the extra product received by the purchasing trading partner.
- Either trading partner may use internal resources for identifying trading partners and their contact information to address such gaps in product tracing information received.

VI. GATHERING OF RELEVANT PRODUCT TRACING INFORMATION

Sections 582(g)(1)(D) and (E) of the FD&C Act address system and process requirements for the provision of certain information by trading partners in circumstances involving a recall or investigation of suspect or illegitimate product. These provisions, excerpted below, take effect November 27, 2023 and require the following as part of the enhanced drug distribution security requirements under section 582(g)(1):

[34] *Illegitimate product* is defined in section 581(8) of the FD&C Act.
[35] See section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.
[36] Ibid.

> "(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.
>
> "(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—
>
> > "(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or
> >
> > "(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i)."

While the requirements of sections 582(g)(1)(D) and (E) are related, they differ in certain respects. Under section 582(g)(1)(D), a trading partner must have systems and processes needed to readily, i.e., "promptly", provide both the transaction information and transaction statement for the product(s) at issue, upon a request by the Secretary or another appropriate Federal or State official in the event of a recall or for purposes of investigating either a suspect or illegitimate product. Under section 582(g)(1)(E), trading partners must have systems and processes needed to promptly facilitate *gathering the information necessary* to produce the transaction information, for each transaction going back to the manufacturer, as applicable, in either of two situations:

- Per section 582(g)(1)(E)(i)—and similar to the situation addressed in section 582(g)(1)(D)—in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for purposes of investigating either a suspect product or an illegitimate product; or
- Per section 582(g)(1)(E)(ii), in the event of a request by an authorized trading partner, for purposes of investigating suspect product, or assisting the Secretary (or other appropriate Federal or State official) with a request described in section 582(g)(1)(E)(i).

Thus, requests by *other trading partners* are addressed in section 582(g)(1)(E), but not section 582(g)(1)(D), which relates solely to provision of information to Federal or State government officials. Section 582(g)(1)(E) also explicitly accounts for protecting confidential commercial information and trade secrets when responding to requests from another trading partner. The gathering of information described in section 582(g)(1)(E) essentially helps build the chain of transactions for use in the circumstances detailed in these provisions.

FDA recommends that trading partners' individual systems and processes enable appropriate requestors to receive product tracing information from trading partners involved in transactions related to a specific product as part of an investigation of suspect or illegitimate product or a

recall, as applicable. Assuming a distributed or semi-distributed data architecture model, in response to an appropriate request, each trading partner would respond with its own relevant transaction information if it directly transacted the product(s) that are subject to the request. To facilitate the gathering of information needed to produce the relevant transaction information for each transaction, as described in section 582(g)(1)(E), the authorized trading partners being queried should have the capability to readily retrieve the needed information from their own systems, in order to promptly respond to an appropriate request. FDA believes that this approach will meet the needs of both industry and regulators by supporting the semi-distributed or distributed architecture model while minimizing the delay in gathering the relevant information.

Further, as otherwise required by section 582 of the FD&C Act, authorized trading partners must respond to a request from the Secretary or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect product or illegitimate product within 1 business day (or 2 business days in the case of dispensers), or in such other reasonable time as determined by FDA based on the circumstances of the request.[37]

VII. ENHANCED VERIFICATION

Beginning November 27, 2023, trading partners must exchange product tracing information electronically.[38] Enhanced verification includes incorporation and use of the product identifier—specifically, verifying the product at the package level, including the standardized numerical identifier.[39] Trading partners should refer to the FDA guidance for industry *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* for additional FDA recommendations for a robust verification system and other recommendations related to the verification requirements of section 582 of the FD&C Act.[40]

A. Verification of Distributed Product

Section 582(g)(1)(C) of the FD&C Act requires systems and processes for verification of product at the package level. Individual systems and/or processes should enable the creation, receipt, and response to verification requests. Upon receiving a request to verify a product, trading partners should use individual systems and/or processes to verify product down to the package level,

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[37] Under section 582(m) of the FD&C Act, beginning November 27, 2023, manufacturers, wholesale distributors and repackagers must submit responses to requests for information from FDA or other appropriate Federal or State officials under section 582(b)(1)(B), (c)(1)(C), and (e)(1)(C) of the FD&C Act, respectively, no later than 24 hours after receiving the request, or in such other reasonable time as determined by FDA based on the circumstances of the request. FDA has determined that a response time of 1 business day is generally appropriate to meet the 24-hour response time requirements. Also see section 582(d)(1)(D) of the FD&C Act with respect to responses by dispensers.

[38] See section 582(g)(1) of the FD&C Act.

[39] See sections 582(g)(1)(B) and 582(g)(1)(C) of the FD&C Act.

[40] We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

including instances involving aggregated data. The trading partner's individual systems and processes should enable verification of suspect and illegitimate product, including the direct response to the requestor. In addition, as described in section IV, the trading partner's individual system and processes should permit FDA, other Federal and State officials, and other trading partners (requestors), as applicable and appropriate, to submit a verification request and receive the response in an electronic, interoperable, and standardized manner. A trading partner should provide a rapid response to such a verification request, a best practice being no later than 1 business day from receipt of the request.

B. Verification of Saleable Returned Product

To support enhanced verification, trading partners must have systems and processes in place to associate saleable returned product with the correct transaction information and transaction statement, as required by section 582(g)(1)(F) of the FD&C Act.[41, 42] FDA understands "associate" to mean that the trading partner accepting the return confirms that it has a record of the transaction information and transaction statement it generated for its initial transaction of the product to the trading partner making the return of that product. A trading partner accepting a saleable return could accomplish such association by confirming that the product identifier of the returned product matches its record of the product identifier in the transaction information for the product it initially transacted to the trading partner making the return, or through other means that assure that the returned product is the same product initially transacted to the trading partner making the return. This capability will help enable a trading partner to accept saleable returns that are appropriate for sale and distribution in the pharmaceutical distribution supply chain. Trading partners should develop and use individual systems and processes to associate the correct transaction information and transaction statement with the saleable returned product(s), including in instances involving aggregated data.

In addition, section 582(c)(4)(D) of the FD&C Act provides that wholesale distributors verify the product identifier of saleable return product before it is further distributed.[43] This verification would provide a confirmatory step before further distribution of the product. Wholesale distributors' individual systems and processes may be similar for general verification of the product identifier and verification of the product identifier for saleable returns; FDA anticipates

[41] Under section 582(g)(1)(F), "Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product".

[42] Section 582(d)(1)(C)(i) provides that dispensers need not provide transaction information and a transaction statement, as generally required under section 582(d)(1)(A), when returning saleable product to the trading partner from whom it was purchased, and sunsets on November 27, 2023 under section 582(k)(2). However, when enhanced drug distribution security requirements become effective on November 27, 2023, dispensers need not provide transaction information and a transaction statement when returning saleable product, because section 582(d)(1)(A)(ii) also exempts dispenser returns from the general section 582(d)(1)(A) requirement.

[43] Sections 582(b)(4)(E) and 582(e)(4)(E) provide that manufacturers and repackagers, respectively, verify the product identifier of saleable return product before it is further distributed. Section 582(k)(2) provides for the sunset of these provisions on November 27, 2023 (10 years after the enactment of the DSCSA). Accordingly, after the implementation of enhanced drug distribution security, manufacturers and repackagers need not verify the product identifier of saleable returned product they intend to further distribute. However, manufacturers and repackagers accepting a saleable return do need to associate the transaction information and transaction statement of saleable returned product under section 582(g)(1)(F).

that some wholesale distributors may use the same systems and processes for both requirements.