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

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
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Center for Drug Evaluation and Research (CDER)
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June 2021
Procedural

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Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Guidance for Industry[1]

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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, commonly referred to as the "enhanced system"[4] go into effect on November 27, 2023.

This guidance clarifies the enhanced system requirements listed in section 582(g)(1) of the FD&C Act. In addition, as described in section 582(h)(3) of the FD&C Act, this guidance outlines and provides recommendations on the system attributes necessary for enabling the secure tracing of product[5] at the package level, including allowing for the use of verification, inference, and aggregation, as necessary.[6] FDA views these recommendations as an important tool to assist in implementing the robust enhanced system envisioned under the DSCSA.

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.

[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 Food and Drug Administration.
[2] *Trading partner* is defined in section 581(23) of the FD&C Act.
[3] *Package* is defined in section 581(11) of the FD&C Act.
[4] For the purpose of this guidance, "enhanced system" refers to the interoperable, electronic, package-level product tracing systems and processes required by section 582(g) of the FD&C Act.
[5] *Product* is defined in section 581(13) of the FD&C Act.
[6] See section 582(h)(3) of the FD&C Act.

II. BACKGROUND

The DSCSA was signed into law on November 27, 2013. The DSCSA outlines critical steps for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drug products 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 imposed requirements for the enhanced system that go into effect on November 27, 2023.

III. ENHANCED DRUG DISTRIBUTION SECURITY

Trading partners, along with Federal and State authorities, have a 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 since 2013, improve the oversight of trading partners in the supply chain that are involved in the manufacturing, repackaging, wholesale distribution, warehousing or logistical activities, or dispensing of prescription drugs. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of the enhanced system as required under section 582(g) of the FD&C Act.

This guidance clarifies the enhanced system requirements and describes recommendations for the system attributes necessary for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.

A. System Attributes

System attributes are properties or capabilities of the enhanced system that promote drug distribution security. Such system attributes, which we view as important elements of implementing the robust enhanced system envisioned under the DSCSA, are addressed in section 582(g)(1) of the FD&C Act and include:

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

(B) transaction information that includes the data elements of 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[7] going back to the manufacturer 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 upon request of an authorized trading partner for the purposes of investigating a suspect product or an illegitimate product or assisting FDA or other appropriate Federal or State official with a request; and

(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 DSCSA, they are used in describing how enhanced system requirements could be met.[8] FDA considers these terms to mean the following:

- *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 of packages (the child or children) that are contained in a homogeneous case[9] (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 sealed homogeneous case.

As such, the effective use of aggregation and inference in the enhanced system will depend on the quality of aggregated data, documentation and shipping/packing integrity, and the ability of the system 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

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

[8] See e.g. sections 582(g)(1)(C) and 582(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.

[9] *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.

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[10] 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 homogeneous cases of product on a pallet: A data file that reflects the contents of the pallet, including the individual, unique product identifiers associated with each homogeneous case and/or with packages within the case 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 file(s) in a secure, efficient manner that allows the purchasing trading partner(s) to use the data file 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 lists all product identifiers of each package of product contained in a sold homogeneous case; or (2) provide the product identifier associated with the homogeneous case to the purchasing trading partner(s), who could use the product identifier to look up and access the data file containing individual product identifiers for each package of product in that case. The scenario described in example (2) could involve reading the product identifier in the linear or two-dimensional (2D) data matrix barcode for the homogeneous case to retrieve the individual product identifiers for each package of product that should be physically in the case.[11]

Although sections 582(b)(2) and (e)(2) of the FD&C Act require product identifiers to be affixed to or imprinted 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 homogeneous cases or pallets) of product to help indicate when product may have been tampered with, previously

[10] 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".

[11] Section 582(a)(9)(A) of the FD&C Act 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.

unsealed, or damaged, rendering it suspect.[12] 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 (PCIDs) in solid oral dosage forms of drug products.[13] If a trading partner determines that the integrity of a shipping unit has 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 only use inference when it receives pallets or homogeneous cases with aggregated data if the integrity of the unit is intact—in other words, the tamper-evident tape or wrap, or other security seal, has not been broken. Receiving a pallet or homogeneous case with broken tape or wrap that was not unsealed by the purchasing trading partner may render the product suspect. If the receiving trading partner determines that the product is suspect, it should not use inference for the aggregated data.

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

If there are other reasons to believe that the product package, homogeneous 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.[14]

IV. SYSTEM STRUCTURE

FDA recognizes that the development of the enhanced system across the supply chain will be complex, but views the elements described in this guidance as important parts of a robust system structure. Although each trading partner should have its own individual validated system and processes for managing its product and data, FDA recommends that the enhanced system enable the interoperable integration of such individual systems to the degree necessary to allow

[12] See FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (December 2016). 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.

[13] See FDA guidance for industry *Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting* (October 2011).

[14] See e.g., sections 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* (December 2016).

appropriate access, efficient information sharing, and data security. The enhanced system should allow FDA and other Federal and State officials to communicate with trading partners' individual systems and receive relevant information upon request.

A. Data Architecture

For the purpose of this guidance, the "data architecture" of the enhanced system refers to the type of data collected and the data validation policies and standards that govern how data is used, stored, managed, and integrated within and between organizations and individual systems. 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.[15] Although under section 582(k) of the FD&C Act the requirement to provide and receive transaction history sunsets November 27, 2023, the enhanced system must include the ability to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer.[16] There are several possible data architecture models for how the data can be used, stored, managed, and integrated for the enhanced system. Such models include centralized, distributed, or a mixture of centralized and distributed (semi-distributed).[17]

Based on stakeholder feedback about current industry practices and preferences, FDA supports 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 can use the model which best facilitates promptly providing Federal and State officials, upon their request, with complete product tracing data as required under the DSCSA.

B. Adoption of Data and System Security

FDA recommends the enhanced system use appropriate data security standards, security protocols, and security applications to protect data, trading partners' individual systems, and the enhanced system 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;FDA plans to address standards for secure, interoperable data exchange in a separate guidance.[18]

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

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

[17] 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.

[18] 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.

C. Protecting Confidential Commercial Information and Trade Secrets

Section 582(h)(3)(A)(iii) of the FD&C Act states that FDA's guidance on attributes of the enhanced system must ensure the protection of confidential commercial information and trade secrets. Trading partners should use individual system(s) and procedures that protect confidential commercial information and trade secrets. FDA expects trading partners to ensure that they will maintain the confidentiality of product tracing information[19] 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 under the Freedom of Information Act and regulations prohibiting public disclosure of confidential commercial information and trade secrets.[20]

D. System Access and Data Retrieval

The enhanced system should permit only an authorized trading partner to request relevant data related to 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, the system should enable trading partners to share relevant data in a secure manner upon request by an authorized trading partner, FDA, or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product. The DSCSA requires that trading partners provide applicable transaction information, including that which facilitates the gathering of transaction information going back to the manufacturer, and a transaction statement for the product upon such a request.[21]

V. ENHANCED PRODUCT TRACING

A. Incorporation of the Product Identifier into Product Tracing Information

The first component of the enhanced system relates to 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 must include the standardized numerical identifier (i.e., National Drug Code (NDC) and serial number), lot number, and expiration date. The transaction information currently required to be exchanged by trading partners,[22] which is defined in section 581(26) of the FD&C Act, 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

[19] For the purposes of this guidance, the term *product tracing information* refers to the transaction information, transaction history, and transaction statement associated with a product that is sold.

[20] See, e.g., 21 CFR 20.61; *Trade secrets and commercial or financial information which is privileged or confidential*.

[21] See 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.

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

homogeneous case of product intended to be introduced in a transaction into commerce).[23] Thus, to meet the section 582(g)(1)(B) requirement, the serial number and expiration date need to be incorporated into the transaction information starting November 27, 2023. FDA expects trading partners to use steps 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 Ensure that the Transaction Information and Transaction Statement Accurately Reflect the Product it Sells to a Purchasing Trading Partner

Under section 582 of the FD&C Act, before, or at the time of, each transaction, the selling trading partner must provide applicable product tracing information to the subsequent owner (i.e., the purchasing trading partner).[24] 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 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 homogeneous cases of product), selling trading partners should develop and use processes that automate the recording of the electronic data in the transaction information and transaction statement associated with the product physically shipped to the purchasing trading partner. This could be accomplished by the selling trading partner reading the 2D data matrix barcode on the packages of product to fulfill a customer's order and including that information in the product tracing information sent to the purchasing trading partner. If the transaction involves sealed homogeneous cases of product, a selling trading partner may provide transaction information listing the product identifiers for the cases that links to the aggregated package product identifiers in each case. The product tracing information that will be provided to the purchasing trading partner in an electronic format should be checked to ensure that it accurately reflects the product that will be physically shipped. 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.

If a selling trading partner cannot send electronic product tracing information to the purchasing trading partner at the same time that the physical shipment of product(s) is received by the purchasing trading partner, the selling trading partner should send electronic product tracing information to the purchasing trading partner in advance of the shipment of product(s) to the purchasing trading partner.

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

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

C. The Purchasing Trading Partner Should Reconcile the Transaction Information and Transaction Statement with Product it Receives from a Selling Trading Partner

Under section 582 of the FD&C Act, the trading partner purchasing the product must not accept ownership of the product unless the previous owner provides the product tracing information before, or at the time of, the transaction.[25] 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 homogeneous cases of product), the purchasing trading partners should develop and use processes that automate the reconciliation of the associated electronic data in the transaction information and transaction statement with the product received. A purchasing trading partner should undertake reconciliation upon physical receipt of the product and then before selling the product to help confirm the veracity of the inbound and outbound transactions. Reconciliation would involve checking that the product tracing information received in an electronic format accurately reflects the packages of product the purchasing trading partner physically received. Reconciliation could be accomplished by physically checking the product identifiers of each package against associated electronic transaction information or physically checking the product identifiers of sealed, homogeneous cases of product against associated electronic transaction information.

The purchasing trading partner can use the product identifier to automate the receipt of the shipment by reading the barcode(s) and entering the information into its individual system, in addition to checking this information against the electronic product tracing information that the purchasing trading partner received. This automation minimizes data entry errors that could occur during manual data entry into a trading partner's individual system, in addition to providing more efficiency and saving time in the processing of products 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 Ensure that the Transaction Information and Transaction Statement Accurately Reflect 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 3 business days. This may include immediately contacting the trading partner that provided the product tracing information to resolve the issue.

[25] Ibid.

The product(s) involved should not be sold to the next trading partner until the error or discrepancy has been resolved. If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, trading partners must follow steps for verification of product, including, if applicable, quarantine and investigation.[26] The examples below are potential clerical errors or discrepancies with product tracing information. The lists of examples are not exhaustive; FDA has chosen to highlight common scenarios.

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; this scenario should be considered as 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

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 through current business practices. The

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

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 should follow applicable verification requirements, including quarantine, investigation, and proper disposition.[27]

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 fill in such gaps in product tracing information received.

VI. GATHERING OF RELEVANT PRODUCT TRACING INFORMATION

In the event of a recall or for purposes of investigating a suspect product or illegitimate product, section 582(g)(1)(D) and (E) of the FD&C Act requires trading partners to have the systems and processes necessary to promptly respond with the transaction information and transaction statement for a product, and to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, upon request by a Federal or State official or (in the case of section 582(g)(1)(E)) authorized trading partner. The gathering of such information essentially builds the transaction history.

FDA envisions that the enhanced system will enable appropriate requestors to view product tracing information from all trading partners involved in transactions related to a specific product when requesting the information as part of an investigation of suspect or illegitimate product or a recall. Trading partners' individual systems and processes should be able to collect the relevant transaction information and transaction statement, as applicable, in a rapid, electronic manner from all trading partners that were involved in a transaction for a product being investigated. FDA would expect that Federal or State officials would be able to initiate a single, targeted request for information to trading partners via the enhanced system. FDA may consider involving a third party to securely manage such requests. Assuming a distributed or semi-distributed data architecture model, in the enhanced system, trading partners would receive a request and respond with relevant transaction information if they were involved in any transaction associated with the products that are subject to the request. Accordingly, to facilitate the gathering of information needed to produce the relevant transaction information for each transaction, the authorized trading partners should respond within 1 business day of the request

[27] Ibid.

with the relevant transaction information.[28] FDA believes that this approach will meet the needs of both industry and regulators by supporting the distributed architecture model while minimizing the delay in gathering the information.

VII. ENHANCED VERIFICATION

Beginning November 27, 2023, trading partners must exchange product tracing information electronically.[29] As part of the enhanced system, enhanced verification includes incorporation and use of the product identifier—specifically, verifying the product at the package level, including the NDC and serial number (i.e., standardized numerical identifier).[30]

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. Upon receiving a request to verify a product, trading partners should use processes that automate (1) verification of the product down to the package level, including instances involving aggregated data; (2) how the request is made (e.g., reading the 2D data matrix barcode to initiate the request); and (3) how the response to the request is managed and communicated back to the inquirer. The trading partner's individual system should enable quick 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 should be integrated into the enhanced system, so that FDA, other Federal and State officials, and other trading partners (requestors) can submit a verification request and receive the response in an electronic, interoperable, and standardized manner. Industry pilots[31] have demonstrated that automated verification systems enable a trading partner to respond in less than 1 minute when verifying the product identifier. Therefore, we expect a trading partner to provide a response to such a verification request within 1 minute of receipt of the request. Trading partners should refer to the FDA draft guidance for industry *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* (October 2018) for FDA recommendations for a robust

[28] 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. See section 582(m) of the FD&C Act.

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

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

[31] Section 582(j) of the FD&C Act requires FDA to establish one or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Additional information about the FDA DSCSA Pilot Program can be found at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program. For an example of a resulting industry pilot that addresses verification response times, see the MediLedger DSCSA Pilot Report at https://uploads-ssl.webflow.com/59f37d05831e85000160b9b4/5e39cafdeeb25984be53549b_MediLedger%20DSCSA%20Pilot%20Final%20Report.pdf.

verification system and other recommendations related to the verification requirements of section 582 of the FD&C Act.[32]

B. Verification of Saleable Returned Product

To support enhanced verification, a trading partner must have systems and processes in place to associate saleable returned product with the appropriate transaction information and transaction statement, as required by section 582(g)(1)(F) of the FD&C Act. 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. Under the enhanced system, trading partners should develop and use processes to automate verification of the associated electronic data in the transaction information and transaction statement with the returned product(s). In addition, the product identifier should be verified, as described in section VII.A of this guidance. This verification would provide a confirmatory step before further distribution of the product. The enhanced system should enable a trading partner's ability to associate the relevant transaction information and transaction statement with a saleable returned product, including instances involving aggregated data. In the enhanced system, trading partners' individual systems and processes may be similar for general verification and verification of saleable returns; FDA anticipates that some trading partners may use the same systems and processes for both requirements.

C. Alerts for Illegitimate Product

FDA believes that enhanced verification is essential to improve the ability of trading partners to identify illegitimate product before it enters the pharmaceutical distribution supply chain and prevent further distribution if it enters the supply chain. As such, FDA expects that the enhanced system will be able to provide a message or alert to the supply chain if a product has been identified as illegitimate or is the subject of a recall. FDA envisions that there will be two types of alerts, one for illegitimate product and one for recalled product.

The entity responsible for putting the alerts in the enhanced system depends on the type of alert warranted. A product's manufacturer or repackager should be responsible for updating the enhanced system with an alert to indicate when the product is recalled. The trading partner that submits a Form FDA 3911[33] should be responsible for updating trading partners and FDA with an alert identifying the illegitimate product using the enhanced system. As part of the enhanced system, trading partners' individual systems and processes should associate the alert with the affected product identifier, including when it is part of aggregated data. The alerts in the enhanced system can be retrieved when a trading partner scans the product identifier upon receipt or as the product is being processed for sale or shipment.

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[32] When final, this guidance will represent the FDA's current thinking on this topic. 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.

[33] Form FDA 3911 is used to make the notifications to FDA described in sections 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act related to illegitimate product determinations, and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II). The FDA guidance, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (December 2016) provides more information about the requirements and associated processes.

Trading partners should include these alerts of illegitimate or recalled products in their individual systems. This will allow trading partners to identify illegitimate or recalled product when engaging in enhanced product tracing or verification.