Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry

DRAFT GUIDANCE

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

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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
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Standardization of Data and Documentation Practices for Product Tracing 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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

This guidance elaborates on the standards for the interoperable exchange of transaction information, transaction history, and transaction statements required by section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1). Section 582 was added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) and facilitates the tracing of products[2] through the pharmaceutical distribution supply chain by requiring trading partners[3] (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and transaction statements (referred to collectively in this guidance as *product tracing information*) when engaging in transactions[4] involving certain prescription drugs. This requirement took effect on January 1, 2015, for manufacturers, repackagers, and wholesale distributors, and on July 1, 2015, for dispensers.[5]

[1] This guidance has been prepared by the Office of Compliance in 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.

[2] *Product* is defined in section 581(13) of the FD&C Act as a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for the purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in section 581(24)(B)(xiv), (xv), or (xvi) of the FD&C Act, any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under the FD&C Act, or a drug compounded in compliance with sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b).

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

[4] *Transaction* is defined in section 581(24) of the FD&C Act. Generally, a transaction involves a transfer of product between persons in which a change of ownership occurs. There are several exemptions from this definition listed in section 581(24)(B) of the FD&C Act.

[5] Under section 582(d)(5) of the FD&C Act, licensed health care practitioners authorized to prescribe or administer medication under State law and other licensed individuals under the supervision or direction of such practitioners

This guidance also addresses how the product tracing requirements[6] of section 582 apply to certain prescription drugs that entered the pharmaceutical distribution supply chain before January 1, 2015.

This guidance is intended to assist trading partners in standardizing the data contained in the product tracing information that trading partners must provide, capture, and maintain under section 582. This guidance is also intended to help trading partners understand the data elements that should be included in the product tracing information, particularly in situations where trading partners are permitted by law to provide other trading partners with product tracing information that omits certain elements that would otherwise be required. In addition, this guidance recommends documentation practices that trading partners can use to satisfy the product tracing requirements of section 582. This guidance does not address all provisions of the DSCSA. As FDA works to implement other provisions of the DSCSA, the Agency expects to issue additional guidance and/or regulations and conduct public meetings to further delineate the requirements of the DSCSA.

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

On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which added new sections 581 and 582 to the FD&C Act, set forth new definitions and requirements related to product tracing. Under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act, trading partners are required to provide the subsequent purchaser[7] with product tracing information for certain prescription drugs. Trading partners are required to capture and maintain the applicable product tracing information for not less than 6 years after the date of the transaction.[8] Trading partners are also required to provide applicable product tracing information in response to a request from 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.[9]

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who dispense or administer product in the usual course of professional practice are exempt from the dispenser requirements to exchange product tracing information in section 582(d)(1).

[6] For purposes of this guidance, the term *product tracing requirements* means the requirements in section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act relating to exchange of transaction information, transaction history, and transaction statements amongst trading partners, and the requirements to provide this information to FDA or other appropriate Federal or State officials in certain circumstances upon request. For this purpose, exchanging transaction information, transaction history, and transaction statements involves providing, capturing, and maintaining such information in accordance with section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.

[7] The terms *subsequent purchaser* and *subsequent owner* are both used in section 582 of the FD&C Act. For this guidance, we use the term *subsequent purchaser* to refer to both.

[8] Sections 582(b)(1)(A)(ii), (c)(1)(A)(v), (d)(1)(A)(iii), and (e)(1)(A)(iii) of the FD&C Act.

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

Pursuant to section 582(a)(2)(A) of the FD&C Act, FDA issued a draft guidance that established initial standards for the interoperable exchange of product tracing information, in paper or electronic format, for compliance with sections 582(a), (b), (c), (d), and (e) of the FD&C Act.[10,11] In establishing such standards, FDA considered the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the product tracing information to the subsequent purchaser of a product and to facilitate the exchange of lot-level data. In addition, FDA considered the standards established under section 505D of the FD&C Act and developed standards that comply with a form and format developed by a widely recognized international standards development organization.

III. SCOPE OF THIS GUIDANCE

This guidance is intended to assist trading partners in standardizing the product tracing information that is captured, maintained, and provided to the subsequent purchaser, FDA, or other appropriate State or Federal officials pursuant to the requirements under section 582 of the FD&C Act. This guidance is also intended to help trading partners understand the data elements that should be included in the product tracing information, particularly in situations where trading partners are permitted by law to provide other trading partners with product tracing information that omits certain elements that would otherwise be required. In addition, this guidance recommends documentation practices that trading partners can use to satisfy the product tracing requirements of section 582. Use of these recommendations will facilitate the interoperable exchange of transaction information, transaction history, and transaction statements between trading partners for each transaction involving a product pursuant to section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act.

IV. TRADING PARTNER DEFINITIONS AND RECOMMENDATIONS RELATING TO CERTAIN SPECIFIC SITUATIONS

As noted above, section 582 of the FD&C Act generally requires trading partners to exchange product tracing information in connection with transactions involving products. The requirements apply to an entity that meets the definition of a manufacturer, wholesale distributor, dispenser, or repackager. The statutory definitions of these terms are set forth in section 581 of the FD&C Act. To assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the DSCSA, FDA issued a draft guidance entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act,

[10] Draft guidance for industry, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information* (November 2014). That 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 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[11] Under section 582(b)(1)(C), manufacturers are required to provide product tracing information in electronic format for certain transactions, beginning on November 27, 2017.

Guidance for Industry."[12] That draft guidance, when finalized, will explain FDA's current thinking on how certain requirements apply to entities that may be considered trading partners in the pharmaceutical distribution supply chain. Understanding which definition(s) apply to an entity will help determine its product tracing responsibilities. It is important to note that an entity may meet the definition of more than one type of trading partner, depending on the activities in which it engages.[13] An entity that meets more than one definition must comply with all applicable requirements under section 582 of the FD&C Act, but it is not required to duplicate requirements.[14] In addition, for each trading partner definition an entity meets, to be considered an authorized trading partner, the entity must have the applicable registration(s) and/or license(s) for that type of trading partner.[15] This section clarifies trading partner product tracing responsibilities for certain situations.

A. Manufacturer

FDA recognizes that there are business relationships that involve multiple entities that may meet the definition of a manufacturer under the DSCSA (e.g., a person that holds an application approved under section 505 of the FD&C Act, a co-licensed partner of such a person, or its affiliates[16]). When these situations exist, such entities should determine and specify in a written agreement which of them will be carrying out the activities required under section 582(b) of the FD&C Act.

B. Dispenser

The following section provides recommendations for dispensers.

1. Dispenser to Dispenser Sales to Fulfill a Specific Patient Need

Section 582(d)(1)(A)(ii) requires a dispenser, in each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns), to provide the subsequent purchaser with product tracing information.[17] However, dispensers are not required to provide the product tracing information in the case of a sale by the dispenser to another dispenser to fulfill a "specific patient need."[18] A sale to fulfill a specific patient need occurs when ownership of a product is transferred from one pharmacy to another pharmacy to fill a prescription for an identified patient.[19] Such sales of prescription drug products to fulfill a

[12] Draft guidance for industry, *Identifying Trading Partners Under the Drug Supply Chain Security Act* (August 2017). That 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 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[13] See section 582(a)(1) of the FD&C Act.

[14] Id.

[15] *Authorized* is defined under section 581(2) of the FD&C Act.

[16] See section 581(10) of the FD&C Act.

[17] See section 582(d)(1)(A) of the FD&C Act.

[18] See section 582(d)(1)(A)(ii) of the FD&C Act.

[19] See section 581(19) of the FD&C Act. The term "specific patient need" does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. Id.

specific patient need should be documented by each pharmacy in a manner that would facilitate appropriate actions by the pharmacy in the event of an investigation of suspect or illegitimate product, recall, or notification of illegitimate product.

2. Exception for Licensed Health Care Practitioners

Licensed health care practitioners authorized to prescribe or administer medication under State law, or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of their professional practice, are excepted from the product tracing requirements that apply to dispensers under section 582(d)(1) and (d)(5).[20] The trading partners of dispensers (including licensed health care practitioners that are dispensers), however, must be authorized trading partners.[21]

3. Third-Party Agreements

Dispensers are required to maintain the product tracing information for a transaction for not less than 6 years after the transaction.[22] Section 582(d)(1)(B) of the FD&C Act allows a dispenser to enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the product tracing information on the dispenser's behalf. FDA considers authorized trading partners and entities that are not authorized trading partners to be acceptable third parties for this purpose. When such an arrangement exists, the dispenser must maintain a copy of the written agreement.[23]

FDA recognizes that a dispenser that has entered into this type of agreement may request that the trading partner that sells product to the dispenser provide the product tracing information directly to the third-party. Pursuant to such request from the dispenser, the trading partner that is transferring ownership to the dispenser has met its obligation to *provide* product tracing information, and the dispenser has met its obligation to *capture* and *maintain* product tracing information for the transaction by providing this information directly to the third-party. Absent a request by a dispenser to provide product tracing information directly to a third party, a trading partner should not assume that providing product tracing information to a party other than the dispenser satisfies its statutory obligation to provide such information to the dispenser.

Dispensers using third-party agreements for the maintenance of product tracing information should be aware that such agreements do not relieve them of their other statutory obligations under section 582 of the FD&C Act.

[20] See section 582(d)(5) of the FD&C Act. In addition, licensed health care practitioners are also exempted from verification requirements described in section 582(d)(4) of the FD&C Act.
[21] See section 582(d)(3) of the FD&C Act.
[22] See section 582(d)(1)(A)(iii) of the FD&C Act.
[23] See section 582(d)(1)(B) of the FD&C Act.

V. STANDARDIZATION OF DATA

Wholesale distributors, dispensers, and repackagers generally must not accept ownership of a product unless the previous owner provides the transaction information, transaction history, and a transaction statement prior to, or at the time of, the transaction.[24] As required by section 582(a)(2)(A), FDA issued a draft guidance that established initial standards related to the methods for the interoperable exchange of product tracing information.[25] In this guidance, we provide recommendations for standardizing the product tracing information that trading partners are required to exchange. Certain transactions that may involve the exchange of product tracing information that is different from what is described in the statutory definitions of transaction information, transaction history, or transaction statements are also addressed in this guidance.

A. Standardizing the Transaction Information

The *transaction information* that trading partners are required to exchange generally consists of 10 distinct elements of information, which are set forth in section 581(26) of the FD&C Act. To help ensure that this information is provided in a consistent manner, trading partners should follow the recommendations set forth below when exchanging the transaction information. Examples of situations in which a trading partner may receive transaction information that omits certain elements that are otherwise required for a product are described in section VI.C. and F. of this guidance. For these situations, a trading partner should use the product information on the product label, as necessary, to complete the transaction information that it provides to a subsequent purchaser.

1. Proprietary or Established Name of the Product

A manufacturer or repackager that is creating the first transaction information for the product it is introducing into commerce should use either the proprietary name[26] or established name[27], as written on the product label, in the transaction information that it provides to subsequent purchasers.[28] Any subsequent trading partner should use the name that was provided in the transaction information it received from the product's previous owner.

Trading partners should not truncate the proprietary or established name of a product in the transaction information unless the system that is being used to provide transaction information

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

[25] Draft guidance for industry, *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information* (November 2014). That guidance, when finalized, will represent FDA's current thinking on that topic.

[26] The *proprietary name* is the exclusive name of a drug product owned by a company under trademark law regardless of registration status with the U.S. Patent and Trademark Office. See the draft guidance for industry *Best Practices in Developing Proprietary Names for Drugs* (May 2014). That 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 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[27] See Section 502(e)(3) of the FD&C Act.

[28] The *proper name* should be used for biological products. See 21 CFR 600.3(k).

has character or space limitations that make truncation necessary. If truncation cannot be avoided, a trading partner should truncate the name in such a way that makes it possible to identify the product, including, for an established name that includes multiple active pharmaceutical ingredients (APIs), each of the APIs, from the truncated name. When truncation cannot be avoided, FDA recommends truncating the product name in this manner to minimize the chance that the name will be misinterpreted by other trading partners or entities. Trading partners should avoid using abbreviations of drug names, symbols, and or dose designations that the Institute for Safe Medications Practices (ISMP) has identified as being frequently misinterpreted or involved in harmful medication errors.[29]

2. Strength and Dosage Form of the Product

Manufacturers and repackagers that are creating the first transaction information for the product they are introducing into commerce should use the strength and dosage form of the product as it is written on the product label in the transaction information that they provide to subsequent purchasers. Subsequent trading partners should use the strength and dosage form that is on the transaction information they received from the product's previous owner. The strength and dosage form of the product should remain consistent in the documents for each transaction.

a. Strength

The strength of the product that is provided in the transaction information should include the amount of each API and the corresponding unit of measure (e.g., 500 mg). Units of measure may be abbreviated (e.g., *mg* for milligram, *mL* for milliliter). For some products, the strength may be expressed in the form of a concentration (e.g., 100 mg/mL), which is composed of the amount of an API and its corresponding unit of measurement per unit of volume. Appendix C of FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) shows abbreviations used for strength at https://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071122.pdf.

b. Dosage form

The dosage form identifies the product in its physical form (e.g., tablet, capsule, solution, or powder). If abbreviations are used, they should consist of at least three letters. CDER's Dosage Form data standard shows abbreviations used for dosage forms at http://wayback.archive-it.org/7993/20171115111312/https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071666.htm.

[29] A list of abbreviations, symbols, and dose designations to avoid is available on ISMP's website. See http://www.ismp.org/tools/errorproneabbreviations.pdf.

3. National Drug Code Number of the Product

The National Drug Code (NDC) is a three-segment number comprised of the labeler code, product code, and package code. FDA publishes the listed NDC numbers for finished drugs that are submitted as part of the listing information[30] in the NDC Directory, which is updated daily.

Some prescription drugs licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), such as certain minimally manipulated human cells, tissues, and cellular and tissue-based products (HCT/Ps), may use an alternatively formatted NDC that is approved for use by the appropriate Center Director of FDA.[31]

Manufacturers and repackagers that are creating the first transaction information for the product they are introducing into commerce should use their respective NDC number. Subsequent trading partners should use the same NDC number and the same configuration that is on the transaction information they received from the product's previous owner. Repackagers, however, should provide the NDC number that they have assigned to the repackaged product.

4. Container Size

The container size should reflect the packaging configuration of the "individual saleable unit,"[32] not larger shipping units of product such as a box, case, or tote. The container size is the number of dosage forms per container. For example, for solid oral dosage forms, the container size for a 100-count bottle of tablets should be expressed as "100 tablets," and for products that are measured by volume, the container size for a 120 mL bottle of a topical solution should be expressed as "120 mL."

5. Number of Containers

The number of containers is the quantity of individual saleable units of a product of the same lot number included in a transaction. If more than one lot number is associated with the products received in a transaction, the products should be grouped by lot number, and the number of containers for each group of lot numbers should be reflected on the transaction information provided to the subsequent purchaser.

[30] See 21 CFR part 207: Registration of producers of drugs and listing of drugs in commercial distribution.

[31] See 21 CFR 207.33(b)(4).

[32] *Individual saleable unit* is defined in section 581(11)(B) of the FD&C Act.

6. Lot Number of the Product

For the purposes of this guidance, a lot number is a set of alphanumeric characters that is assigned by the manufacturer or repackager to identify a batch, or a specific identified portion of a batch, that has uniform character and quality within specified limits. A manufacturer should use the lot number it has assigned to the product in the transaction information that the manufacturer provides to subsequent purchasers. If a repackager assigns a new lot number to the product, the repackager should use the new lot number in the transaction information that it provides to subsequent purchasers. In all other situations, a trading partner should use the lot number that was on the transaction information it received from the product's previous owner in the transaction information that the trading partner provides to subsequent purchasers. If more than one lot number is associated with the products received in a transaction, each lot number should be reflected on the transaction information provided to the subsequent purchaser. Alternatively, each lot number can be represented in separate transaction information provided to the subsequent purchaser.

7. Date of the Transaction

For the purposes of this guidance, the date of the transaction is the date on which ownership of the product involved in the transaction is transferred between trading partners. If that date is specified in a contract between the trading partners, FDA recommends using the contractually specified date as the date of the transaction. Otherwise, FDA recommends that trading partners use the product's shipment date as the date of the transaction.

8. Date of the Shipment, If More Than 24 Hours After the Date of the Transaction

The shipment date should reflect the date that the product is shipped to the trading partner that is to receive the product.

9. Business Name and Address of the Person From Whom Ownership Is Being Transferred

FDA understands that a trading partner transferring ownership of a product may have multiple options regarding which address to provide in the transaction information (e.g., headquarters or corporate address, billing address, shipping address). FDA views this as business decision between trading partners, however, FDA recommends using the address of the facility from which the product is being shipped as the business address of the trading partner that is transferring ownership of the product. However, if the product is shipped from a third-party logistics provider's facility, the business address of the trading partner that is transferring ownership of the product should be used, and not the address of the third-party logistics provider.

10. Business Name and Address of the Person to Whom Ownership Is Being Transferred

FDA understands that a trading partner to whom ownership is being transferred may have multiple options regarding which address to provide in the transaction information (e.g., headquarters or corporate address, billing address, shipping address). FDA views this as a business decision between trading partners. However, FDA recommends using the address of the facility to which the product is being shipped as the business address of the trading partner that is receiving ownership of the product. However, if the product is shipped to a third-party logistics provider's facility, the business address of the trading partner that is receiving ownership of the product should be used, and not the address of the third-party logistics provider.

B. Standardizing the Transaction History

For each transaction, the transaction information should remain separate from the transaction history. The *transaction history* is defined in section 581(25) of the FD&C Act as a statement in paper or electronic form, including the transaction information for each *prior* transaction going back to the manufacturer of the product. In general, the transaction history for a product should be a compilation of the transaction information for each prior transaction involving that product. The recommendations in this section do not preclude a trading partner from providing more information than is described.

A trading partner should provide the transaction history for a product in one of the following two ways:

1. The trading partner can compile the transaction information documents that it received from the product's previous owner for each prior transaction involving the product. The transaction information documents should be arranged in reverse chronological order by transaction date.

   For certain transactions involving wholesale distributors, the lot number and transaction and shipment dates from the manufacturer are not required to be included in the transaction information (see section VI of this guidance). Consequently, some of the transaction information documents that make up the transaction history for a product might not contain this information. In these situations, the trading partner should not add the information that is omitted from the transaction information documents for prior transactions. The trading partner should instead compile the transaction information documents that it received from the product's previous owner(s) and provide this information to the subsequent purchaser as the transaction history.

2. The trading partner may create a new single document for the transaction history based on the documentation it has received from the product's previous owner. The product information for the current transaction (i.e., the proprietary or established name, strength, dosage form, NDC number, container size, lot number of the product) should be provided at the top of the document. If this information does not change from transaction to transaction, it can be stated once in the transaction history. Below the product information, the trading partner should provide the following information for each prior transaction: the number of containers, the business name and address of the person that transferred ownership, the business name and address of the person that accepted ownership and the date of the transaction, and date of the shipment (if more than 24 hours after the date of the transaction). This information should be provided in reverse chronological order by transaction date.

   The trading partner that chooses to create this new single document should ensure that the information from documentation received from the product's previous owner(s) is accurately transcribed.

C. Standardizing the Transaction Statement

Pursuant to sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act, a trading partner must provide the subsequent purchaser of a product with a transaction statement prior to, or at the time of, the transaction. Trading partners should follow the recommendations set forth below when exchanging this transaction statement.

1. Transaction Statement

Transaction statement is defined in section 581(27) of the FD&C Act as:

> a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
> (A) is authorized as required under the Drug Supply Chain Security Act;
> (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
> (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
> (D) did not knowingly ship a suspect or illegitimate product;
> (E) had systems and processes in place to comply with verification requirements under section 582;
> (F) did not knowingly provide false transaction information; and
> (G) did not knowingly alter the transaction history.[33]

The transaction statement that a trading partner provides to a subsequent purchaser should identify the trading partner as the entity transferring ownership and indicate that the trading partner is in compliance with section 581(27)(A)-(G) of the FD&C Act. A trading partner may indicate that it is in compliance by reproducing that section, word-for-word, in the transaction statements that it provides to subsequent purchasers. Alternatively, a trading partner may indicate that it is in compliance with section 581(27)(A)-(G) by including the following sentence as the transaction statement that it provides to subsequent purchasers: "For this transaction, [***Insert name of trading partner transferring ownership***] is in compliance with section 581(27)(A)-(G) of the Federal Food, Drug, and Cosmetic Act."

Trading partners should be aware that, for certain transactions, they may receive transaction information that does not contain certain elements listed in section 581(26) of the FD&C Act, or no transaction information, and a transaction statement that differs from section 581(27) of the FD&C Act (see section VI of this guidance).

2. Direct Purchase Statement

Section 582(c)(1)(A) of the FD&C Act requires wholesale distributors that purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager

[33] For additional information on trading partner requirements related to transaction statements, please refer to section 582(b), (c), (d), (e), and (f) of the FD&C Act.

that purchased directly from the manufacturer, to provide a statement relating to the direct purchase (referred to in this guidance as a *direct purchase statement*) with the transaction statement[34] provided to a subsequent purchaser. For purposes of this guidance, a wholesale distributor conducts a *direct purchase* if it purchases product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer.

The direct purchase statement must state, as required by section 582(c)(1)(A)(ii)(I)(aa)(AA), that the wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer. For this purpose, FDA recommends that wholesale distributors that conduct a direct purchase use the following language in the direct purchase statement that they provide to subsequent purchasers: "[***insert name of wholesale distributor that made a direct purchase***] purchased this product directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer." A direct purchase statement will help purchasing trading partners understand why the transaction history they received may not include transaction information that goes back to the manufacturer.

If a wholesale distributor purchases a product from another wholesale distributor that made a direct purchase of the product as described above, it must inform subsequent purchasers of the product that it received a direct purchase statement from the wholesale distributor that made the direct purchase.[35] In these situations where a wholesale distributor is transferring ownership of a product it purchased from another wholesale distributor that made a direct purchase of the product, FDA recommends that the wholesale distributor inform subsequent purchasers that it received a direct purchase statement from the previous wholesale distributor by including the following language in the transaction statement: "[***insert name of wholesale distributor that received a direct purchase statement***] received a direct purchase statement from the previous wholesale distributor."

[34] Apart from the addition of the direct purchase statement, the transaction statement should adhere to the content and format recommendations described in this guidance.

[35] See FD&C Act § 582(c)(1)(A)(iv).

D. Clerical Errors and Other Discrepancies

FDA recognizes that clerical errors and other discrepancies in product tracing information may occur. If a wholesale distributor, dispenser, or repackager purchases product and identifies a potential clerical error or other discrepancy in the product tracing information it has received, that trading partner should resolve the error or discrepancy as quickly as possible. This may include immediately contacting the trading partner that provided the product tracing information to resolve the issue. 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.[36]

VI. DOCUMENTATION PRACTICES

This section focuses on documentation practices and provides recommendations for how trading partners can meet their relevant product tracing obligations under section 582 of the FD&C Act. This section clarifies the product tracing information that should be provided to subsequent purchasers in situations where a trading partner is permitted by law to provide product tracing information that omits certain elements that are set forth in section 581(26), (25), and (27) of the FD&C Act for transaction information, transaction history, or transaction statements, respectively. These situations involve:

- *Direct purchases* by a wholesale distributor, in addition to transactions by a trading partner that further sells product that was purchased from a wholesale distributor that conducted a direct purchase.

- Drop shipments to a dispenser.

- Transactions involving grandfathered products under section 582(a)(5)(B) of the FD&C Act.

The descriptions below of transaction information, transaction history, and transaction statement that omit certain elements that would otherwise be required do not apply to transactions by dispensers or repackagers that purchase product directly from a manufacturer or from a repackager who purchased directly from the manufacturer. For example, if you are a repackager that purchased product directly from the manufacturer, you must provide all of the elements for the product tracing information as required by section 582(e)(1)(A)(ii). In addition, the recommendations in this section do not preclude a trading partner from providing additional information in the transaction information, transaction history, or transaction statement beyond what is required by law.

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

A. Product Tracing Information That a Manufacturer Must Provide to a Subsequent Purchaser

The manufacturer must provide the following:[37]

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer, including the lot number of the product, transaction date, and shipment date.

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

B. Product Tracing Information That a Repackager Must Provide to a Subsequent Purchaser

The repackager must provide the following:[38]

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer, including the lot number of the product, transaction date, and shipment date.

- The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act (see section V.C).

[37] See section 582(b)(1)(A)(i) of the FD&C Act.
[38] See section 582(e)(1)(A)(ii) of the FD&C Act.

C. Transactions Involving a *Direct Purchase* by Wholesale Distributors

As noted above, for purposes of this guidance, a wholesale distributor conducts a *direct purchase* if it purchases product directly from the manufacturer, the manufacturer's exclusive distributor, or a repackager that purchased directly from the manufacturer. Wholesale distributors are subject to the product tracing requirements set forth in section 582(c) of the FD&C Act.[39]

1. What Product Tracing Information Must a Wholesale Distributor or an Exclusive Distributor Provide to a Subsequent Purchaser for Product That Was Purchased Directly From the Manufacturer?

The wholesale distributor or exclusive distributor must provide the following:[40]

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product and the initial transaction and shipment dates from the manufacturer.[41]

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer except the lot number of the product and the initial transaction and shipment dates from the manufacturer.

- The transaction statement, as defined in section 581(27)(A)-(G) and which must also include a direct purchase statement (see section V.C).

2. What Product Tracing Information Must a Wholesale Distributor Provide to a Subsequent Purchaser for Product That Was Purchased Directly From the Manufacturer's Exclusive Distributor or From a Repackager That Purchased Directly From the Manufacturer?

The wholesale distributor must provide the following:[42]

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act except the lot number of the product.

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the manufacturer except the lot number of the product and the initial transaction and shipment dates

[39] See section 582(c)(1)(A) of the FD&C Act.
[40] See section 582(c)(1)(A)(ii) of the FD&C Act.
[41] For the purposes of this guidance, FDA has interpreted "the initial transaction date" in section 582(c)(1)(A)(ii)(II) of the FD&C Act as the transaction date from the manufacturer.
[42] See section 582(c)(1)(A)(ii) of the FD&C Act.

from the manufacturer. The transaction history should include the transaction date, shipment date, and the business name and address of the trading partner from whom the wholesale distributor received ownership (either the manufacturer's exclusive distributor or the repackager who purchased directly from the manufacturer).

- The transaction statement, as defined in section 581(27)(A)-(G) and which must also include a direct purchase statement (see section V.C).

D. Subsequent Transactions of Product After a *Direct Purchase*

This section describes the product tracing information that a wholesale distributor must provide to the subsequent purchaser of a product, when that wholesale distributor obtained the product from a wholesale distributor that conducted a *direct purchase*. Although this transaction is not considered a direct purchase, the product that is being transferred to the subsequent purchaser was obtained from a wholesale distributor that conducted a *direct purchase* (initial wholesale distributor). For these transactions, the wholesale distributor that is transferring ownership of the product must provide the following to the subsequent purchaser:[43]

- The transaction information, which must include all of the information specified in section 581(26) of the FD&C Act, including the lot number of the product, transaction date, and shipment date, if more than 24 hours after the date of the transaction .

- The transaction history, which must include all of the information specified in section 581(25) of the FD&C Act for each prior transaction going back to the initial wholesale distributor that conducted the direct purchase.

- The transaction statement, as defined in section 581(27)(A)-(G), and which must also include a statement informing the subsequent purchaser that the wholesale distributor received a direct purchase statement from the initial wholesale distributor that conducted the direct purchase (section V.C).

[43] See section 582(c)(1)(A)(iii) and (iv) of the FD&C Act.

E. Drop Shipments to Dispensers

For the purposes of this guidance, a drop shipment means distribution of product to the dispenser by a wholesale distributor that does not physically handle or store the product, but arranges for a manufacturer, a repackager, or another wholesale distributor to directly ship the product to a dispenser on its behalf. In drop shipment situations, section 582(f) of the FD&C Act allows wholesale distributors that do not physically handle or store product to be exempt from certain provisions of section 582 of the FD&C Act, provided that the manufacturer, repackager, or other wholesale distributor that distributes the product provides the contact information of the wholesale distributor on whose behalf the product was distributed.[44] In these situations, he contact information of the wholesale distributor on whose behalf the product was distributed must be included on the transaction information and transaction history provided to the dispenser,[45] and should consist of the wholesale distributor's business name, address, and email address and/or phone number.

If a wholesale distributor and the trading partner that conducts the drop shipment directly to the dispenser do not exercise the exemption under 582(f), the wholesale distributor should provide the product tracing information to the dispenser as required under section 582(c).

F. Transactions Involving Grandfathered Products Under Section 582(a)(5)(B)

Section 582(a)(5)(B) of the FD&C Act addresses the tracing requirements for products that entered the pharmaceutical distribution supply chain before January 1, 2015 (pre-2015 products). The section exempts authorized trading partners from the requirement to provide transaction information for pre-2015 products under sections 582(b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii) of the FD&C Act.[46] It also requires that the transaction history for a pre-2015 product begin with the product's owner on January 1, 2015 (initial owner).[47] In addition, section 582(a)(5)(B)(iii) exempts the initial owner of pre-2015 product from asserting in a transaction statement that it received transaction information and a transaction statement from the prior owner of the product.[48] FDA recommends that trading partners follow the practices set forth below when providing product tracing information for pre-2015 products.

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[44] For additional information on drop shipments, please refer to section 582(f) of the FD&C Act.

[45] See section 582(f)(1) of the FD&C Act.

[46] See section 582(a)(5)(B)(i) of the FD&C Act.

[47] See section 582(a)(5)(B)(ii) of the FD&C Act.

[48] As noted above, section 582(a)(5)(B)(i) exempts authorized trading partners from the requirement to provide transaction information for pre-2015 products under section 502(c)(1)(A)(ii) (addressing requirements applicable to a wholesale distributor that made a direct purchase). In addition, FDA does not intend to take action against an authorized trading partner based on a failure to provide transaction information for pre-2015 products as described in section 582(c)(1)(A)(iii) (addressing requirements applicable to a wholesale distributor that *did not* make a direct purchase), or based on a failure by such authorized trading partner to assert receipt of transaction information and a transaction statement from the prior owner with respect to such products.

633 *1. Transaction Information*
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635 A trading partner should inform subsequent purchasers that the transaction involves pre-2015
636 product and that the trading partner is exempt from providing transaction information for such
637 product pursuant to section 582(a)(5)(B)(i) of the FD&C Act. FDA recognizes that some trading
638 partners will provide transaction information to subsequent purchasers of pre-2015 product even
639 though they are exempt from doing so under section 582(a)(5)(B)(i), in the interest of supply
640 chain security. In these situations, FDA recommends that the trading partner inform subsequent
641 purchasers that the transaction information is for a pre-2015 product.
642
643 *2. Transaction History Omitting Certain Elements*
644
645 Pursuant to section 582(a)(5)(B)(ii), the transaction history that an initial owner provides to a
646 subsequent purchaser of pre-2015 product (second owner) starts with the initial owner. For all
647 transactions after the initial owner-second owner transaction, the transaction history that is
648 provided to a subsequent purchaser of pre-2015 product should go back to the product's initial
649 owner.
650
651 *3. Transaction Statement*
652
653 An initial owner is required to provide a transaction statement to a subsequent purchaser but,
654 pursuant to section 582(a)(5)(B)(iii) of the FD&C Act, is not required to assert in that transaction
655 statement that the initial owner "received transaction information and a transaction statement
656 from the prior owner of the product, as required under section 582." Although this statement
657 described in section 581(27)(C) of the FD&C Act may, as a result, be absent from a transaction
658 statement received from the initial owner, the absence of this statement will not prevent a trading
659 partner that purchases pre-2015 product from the initial owner from having received the
660 transaction information and transaction statement that is required under section 582. When this
661 trading partner transfers ownership of the product to a subsequent purchaser, it must provide a
662 transaction statement that includes the statement set forth in section 581(27)(C).[49]

[49] See section 582(b)(1)(A)(i), (c)(1)(A)(ii) and (iii), (d)(1)(A)(ii), and (e)(1)(A)(ii) of the FD&C Act related to transaction statements.