
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DRAFT GUIDANCE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)
Office of Regulatory Affairs (ORA)**

**March 2018
Procedural**

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

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1 **Standardization of Data and Documentation Practices**
2 **for Product Tracing**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person
8 and is not binding on FDA or the public. You can use an alternative approach if it satisfies the
9 requirements of the applicable statutes and regulations. To discuss an alternative approach,
10 contact the FDA staff responsible for this guidance as listed on the title page.
11

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14 **I. INTRODUCTION**
15

16 This guidance elaborates on the standards for the interoperable exchange of transaction
17 information, transaction history, and transaction statements required by section 582 of the
18 Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1). Section 582 was
19 added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) and
20 facilitates the tracing of products² through the pharmaceutical distribution supply chain by
21 requiring trading partners³ (manufacturers, repackagers, wholesale distributors, and dispensers)
22 to exchange transaction information, transaction history, and transaction statements (referred to
23 collectively in this guidance as *product tracing information*) when engaging in transactions⁴
24 involving certain prescription drugs. This requirement took effect on January 1, 2015, for
25 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

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26 This guidance also addresses how the product tracing requirements⁶ of section 582 apply to
27 certain prescription drugs that entered the pharmaceutical distribution supply chain before
28 January 1, 2015.

29
30 This guidance is intended to assist trading partners in standardizing the data contained in the
31 product tracing information that trading partners must provide, capture, and maintain under
32 section 582. This guidance is also intended to help trading partners understand the data elements
33 that should be included in the product tracing information, particularly in situations where
34 trading partners are permitted by law to provide other trading partners with product tracing
35 information that omits certain elements that would otherwise be required. In addition, this
36 guidance recommends documentation practices that trading partners can use to satisfy the
37 product tracing requirements of section 582. This guidance does not address all provisions of the
38 DSCSA. As FDA works to implement other provisions of the DSCSA, the Agency expects to
39 issue additional guidance and/or regulations and conduct public meetings to further delineate the
40 requirements of the DSCSA.

41
42 In general, FDA's guidance documents do not establish legally enforceable responsibilities.
43 Instead, guidances describe the Agency's current thinking on a topic and should be viewed only
44 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
45 the word *should* in Agency guidances means that something is suggested or recommended, but
46 not required.

47

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II. BACKGROUND

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51 On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which
52 added new sections 581 and 582 to the FD&C Act, set forth new definitions and requirements
53 related to product tracing. Under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act,
54 trading partners are required to provide the subsequent purchaser⁷ with product tracing
55 information for certain prescription drugs. Trading partners are required to capture and maintain
56 the applicable product tracing information for not less than 6 years after the date of the
57 transaction.⁸ Trading partners are also required to provide applicable product tracing
58 information in response to a request from FDA or other appropriate Federal or State official in
59 the event of a recall or for the purpose of investigating a suspect or illegitimate product.⁹

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.

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60
61 Pursuant to section 582(a)(2)(A) of the FD&C Act, FDA issued a draft guidance that established
62 initial standards for the interoperable exchange of product tracing information, in paper or
63 electronic format, for compliance with sections 582(a), (b), (c), (d), and (e) of the FD&C
64 Act.^{10,11} In establishing such standards, FDA considered the feasibility of establishing
65 standardized documentation to be used by members of the pharmaceutical distribution supply
66 chain to convey the product tracing information to the subsequent purchaser of a product and to
67 facilitate the exchange of lot-level data. In addition, FDA considered the standards established
68 under section 505D of the FD&C Act and developed standards that comply with a form and
69 format developed by a widely recognized international standards development organization.

70
71

72 III. SCOPE OF THIS GUIDANCE

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

86
87

88 IV. TRADING PARTNER DEFINITIONS AND RECOMMENDATIONS RELATING 89 TO CERTAIN SPECIFIC SITUATIONS

90

91 As noted above, section 582 of the FD&C Act generally requires trading partners to exchange
92 product tracing information in connection with transactions involving products. The
93 requirements apply to an entity that meets the definition of a manufacturer, wholesale distributor,
94 dispenser, or repackager. The statutory definitions of these terms are set forth in section 581 of
95 the FD&C Act. To assist industry and State and local governments in understanding how to
96 categorize the entities in the drug supply chain in accordance with the DSCSA, FDA issued a
97 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.

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

A. Manufacturer

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111
112 FDA recognizes that there are business relationships that involve multiple entities that may meet
113 the definition of a manufacturer under the DSCSA (e.g., a person that holds an application
114 approved under section 505 of the FD&C Act, a co-licensed partner of such a person, or its
115 affiliates¹⁶). When these situations exist, such entities should determine and specify in a written
116 agreement which of them will be carrying out the activities required under section 582(b) of the
117 FD&C Act.

B. Dispenser

118
119 The following section provides recommendations for dispensers.

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

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123
124
125 Section 582(d)(1)(A)(ii) requires a dispenser, in each transaction in which the dispenser transfers
126 ownership of a product (but not including dispensing to a patient or returns), to provide the
127 subsequent purchaser with product tracing information.¹⁷ However, dispensers are not required
128 to provide the product tracing information in the case of a sale by the dispenser to another
129 dispenser to fulfill a “specific patient need.”¹⁸ A sale to fulfill a specific patient need occurs
130 when ownership of a product is transferred from one pharmacy to another pharmacy to fill a
131 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.*

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

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2. Exception for Licensed Health Care Practitioners

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137
138 Licensed health care practitioners authorized to prescribe or administer medication under State
139 law, or other licensed individuals under the supervision or direction of such practitioners who
140 dispense or administer product in the usual course of their professional practice, are excepted
141 from the product tracing requirements that apply to dispensers under section 582(d)(1) and
142 (d)(5).²⁰ The trading partners of dispensers (including licensed health care practitioners that are
143 dispensers), however, must be authorized trading partners.²¹

144

3. Third-Party Agreements

145

146
147 Dispensers are required to maintain the product tracing information for a transaction for not less
148 than 6 years after the transaction.²² Section 582(d)(1)(B) of the FD&C Act allows a dispenser to
149 enter into a written agreement with a third party, including an authorized wholesale distributor,
150 under which the third party confidentially maintains the product tracing information on the
151 dispenser's behalf. FDA considers authorized trading partners and entities that are not
152 authorized trading partners to be acceptable third parties for this purpose. When such an
153 arrangement exists, the dispenser must maintain a copy of the written agreement.²³

154

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

164

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

168

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.

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169 V. STANDARDIZATION OF DATA

170
171 Wholesale distributors, dispensers, and repackagers generally must not accept ownership of a
172 product unless the previous owner provides the transaction information, transaction history, and
173 a transaction statement prior to, or at the time of, the transaction.²⁴ As required by section
174 582(a)(2)(A), FDA issued a draft guidance that established initial standards related to the
175 methods for the interoperable exchange of product tracing information.²⁵ In this guidance, we
176 provide recommendations for standardizing the product tracing information that trading partners
177 are required to exchange. Certain transactions that may involve the exchange of product tracing
178 information that is different from what is described in the statutory definitions of transaction
179 information, transaction history, or transaction statements are also addressed in this guidance.

180

181 A. Standardizing the Transaction Information

182

183 The *transaction information* that trading partners are required to exchange generally consists of
184 10 distinct elements of information, which are set forth in section 581(26) of the FD&C Act. To
185 help ensure that this information is provided in a consistent manner, trading partners should
186 follow the recommendations set forth below when exchanging the transaction information.
187 Examples of situations in which a trading partner may receive transaction information that omits
188 certain elements that are otherwise required for a product are described in section VI.C. and F. of
189 this guidance. For these situations, a trading partner should use the product information on the
190 product label, as necessary, to complete the transaction information that it provides to a
191 subsequent purchaser.

192

193 1. *Proprietary or Established Name of the Product*

194

195 A manufacturer or repackager that is creating the first transaction information for the product it
196 is introducing into commerce should use either the proprietary name²⁶ or established name²⁷, as
197 written on the product label, in the transaction information that it provides to subsequent
198 purchasers.²⁸ Any subsequent trading partner should use the name that was provided in the
199 transaction information it received from the product's previous owner.

200

201 Trading partners should not truncate the proprietary or established name of a product in the
202 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).

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

2. Strength and Dosage Form of the Product

214
215 Manufacturers and repackagers that are creating the first transaction information for the product
216 they are introducing into commerce should use the strength and dosage form of the product as it
217 is written on the product label in the transaction information that they provide to subsequent
218 purchasers. Subsequent trading partners should use the strength and dosage form that is on the
219 transaction information they received from the product's previous owner. The strength and
220 dosage form of the product should remain consistent in the documents for each transaction.

a. Strength

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

b. Dosage form

232
233
234
235 The dosage form identifies the product in its physical form (e.g., tablet, capsule, solution, or
236 powder). If abbreviations are used, they should consist of at least three letters. CDER's Dosage
237 Form data standard shows abbreviations used for dosage forms at [http://wayback.archive-
238 it.org/7993/20171115111312/https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsS
239 ubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071666.h
240 tm](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>.

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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 information³⁰ 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.

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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

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

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380 C. Standardizing the Transaction Statement

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

386 387 1. *Transaction Statement*

388
389 *Transaction statement* is defined in section 581(27) of the FD&C Act as:

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

403
404 The transaction statement that a trading partner provides to a subsequent purchaser should
405 identify the trading partner as the entity transferring ownership and indicate that the trading
406 partner is in compliance with section 581(27)(A)-(G) of the FD&C Act. A trading partner may
407 indicate that it is in compliance by reproducing that section, word-for-word, in the transaction
408 statements that it provides to subsequent purchasers. Alternatively, a trading partner may
409 indicate that it is in compliance with section 581(27)(A)-(G) by including the following sentence
410 as the transaction statement that it provides to subsequent purchasers: “For this transaction,
411 ***[Insert name of trading partner transferring ownership]*** is in compliance with section
412 581(27)(A)-(G) of the Federal Food, Drug, and Cosmetic Act.”

413
414 Trading partners should be aware that, for certain transactions, they may receive transaction
415 information that does not contain certain elements listed in section 581(26) of the FD&C Act, or
416 no transaction information, and a transaction statement that differs from section 581(27) of the
417 FD&C Act (see section VI of this guidance).

418 419 2. *Direct Purchase Statement*

420
421 Section 582(c)(1)(A) of the FD&C Act requires wholesale distributors that purchased a product
422 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.

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423 that purchased directly from the manufacturer, to provide a statement relating to the direct
424 purchase (referred to in this guidance as a *direct purchase statement*) with the transaction
425 statement³⁴ provided to a subsequent purchaser. For purposes of this guidance, a wholesale
426 distributor conducts a *direct purchase* if it purchases product directly from the manufacturer, the
427 exclusive distributor of the manufacturer, or a repackager that purchased directly from the
428 manufacturer.

429
430 The direct purchase statement must state, as required by section 582(c)(1)(A)(ii)(I)(aa)(AA), that
431 the wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased
432 the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a
433 repackager that purchased directly from the manufacturer. For this purpose, FDA recommends
434 that wholesale distributors that conduct a direct purchase use the following language in the direct
435 purchase statement that they provide to subsequent purchasers: “[***insert name of wholesale***
436 ***distributor that made a direct purchase***] purchased this product directly from the manufacturer,
437 exclusive distributor of the manufacturer, or a repackager that purchased directly from the
438 manufacturer.” A direct purchase statement will help purchasing trading partners understand
439 why the transaction history they received may not include transaction information that goes back
440 to the manufacturer.

441
442 If a wholesale distributor purchases a product from another wholesale distributor that made a
443 direct purchase of the product as described above, it must inform subsequent purchasers of the
444 product that it received a direct purchase statement from the wholesale distributor that made the
445 direct purchase.³⁵ In these situations where a wholesale distributor is transferring ownership of a
446 product it purchased from another wholesale distributor that made a direct purchase of the
447 product, FDA recommends that the wholesale distributor inform subsequent purchasers that it
448 received a direct purchase statement from the previous wholesale distributor by including the
449 following language in the transaction statement: “[***insert name of wholesale distributor that***
450 ***received a direct purchase statement***] received a direct purchase statement from the previous
451 wholesale distributor.”

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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).

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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.

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

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498 The manufacturer must provide the following:³⁷

- 499
- 500 • The transaction information, which must include all of the information specified in
501 section 581(26) of the FD&C Act, including the lot number of the product,
502 transaction date, and shipment date, if more than 24 hours after the date of the
503 transaction.
 - 504
 - 505 • The transaction history, which must include all of the information specified in section
506 581(25) of the FD&C Act for each prior transaction going back to the manufacturer,
507 including the lot number of the product, transaction date, and shipment date.
 - 508
 - 509 • The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act
510 (see section V.C).

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

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515 The repackager must provide the following:³⁸

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- 517 • The transaction information, which must include all of the information specified in
518 section 581(26) of the FD&C Act, including the lot number of the product,
519 transaction date, and shipment date, if more than 24 hours after the date of the
520 transaction.
 - 521
 - 522 • The transaction history, which must include all of the information specified in section
523 581(25) of the FD&C Act for each prior transaction going back to the manufacturer,
524 including the lot number of the product, transaction date, and shipment date.
 - 525
 - 526 • The transaction statement, as defined in section 581(27)(A)-(G) of the FD&C Act
527 (see section V.C).
- 528

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.

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

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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

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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?

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

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- 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).

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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?

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The wholesale distributor must provide the following:⁴²

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- 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.

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

571
572 • The transaction statement, as defined in section 581(27)(A)-(G) and which must also
573 include a direct purchase statement (see section V.C).

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

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

- 584
- 585 • The transaction information, which must include all of the information specified in
586 section 581(26) of the FD&C Act, including the lot number of the product,
587 transaction date, and shipment date, if more than 24 hours after the date of the
588 transaction .
 - 589 • The transaction history, which must include all of the information specified in section
590 581(25) of the FD&C Act for each prior transaction going back to the initial
591 wholesale distributor that conducted the direct purchase.
 - 592 • The transaction statement, as defined in section 581(27)(A)-(G), and which must also
593 include a statement informing the subsequent purchaser that the wholesale distributor
594 received a direct purchase statement from the initial wholesale distributor that
595 conducted the direct purchase (section V.C).
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⁴³ See section 582(c)(1)(A)(iii) and (iv) of the FD&C Act.

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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, the 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.

⁴⁴For 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.

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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*

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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.

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651 3. *Transaction Statement*

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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.