
DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or drugtrackandtrace@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)
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**DSCSA Standards for the Interoperable Exchange of Information for Tracing of
Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing
Information**

This draft guidance, when finalized, will represent Food and Drug Administration’s (FDA’s or Agency’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance addresses the pharmaceutical security provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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 through the pharmaceutical distribution supply chain by requiring certain trading partners² (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange transaction information, transaction history, and a transaction statement (product tracing information) when engaging in transactions involving certain prescription drugs.³ This requirement goes into effect on January 1, 2015, for manufacturers, repackagers, and wholesale distributors, and on July 1, 2015, for dispensers. FDA, in consultation with other appropriate Federal officials and pharmaceutical distribution supply chain stakeholders, is required, under section 582(a)(2)(A) of the FD&C Act, to establish initial standards for the interoperable exchange of the product tracing information related to each transaction of certain human, finished, prescription drugs covered by the statute.

This document establishes 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. These standards will help trading partners provide product tracing information to subsequent trading partners through the extension and/or use of current systems

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 “Trading partner” is defined under FD&C Act § 581(23)(A). Although third-party logistics providers are also considered trading partners under FD&C Act § 581(23)(B), the requirements of sections 582(a)-(e) are not applicable to them.

³ “Transaction information,” “transaction history,” and “transaction statement” are defined under FD&C Act §§ 581(26), (25), and (27).

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37 and processes. FDA intends to issue additional guidance to facilitate the interoperable exchange
38 of product tracing information through standardization of data and documentation practices.

39
40 This guidance is marked as a “draft” consistent with its description in section 582(a)(2)(A) of the
41 FD&C Act. Under section 582(h)(4) of the FD&C Act, FDA intends to eventually “update . . . ,
42 as necessary and appropriate, and finalize” this document to reflect standards for interoperable
43 data exchange at the package level. Because the DSCSA clearly intends for stakeholders to rely
44 upon this draft guidance document before finalization, however, FDA is immediately
45 implementing this document under 21 CFR 10.115(g)(2). As a result, it reflects FDA’s current
46 thinking on this topic and is intended to provide guidance to stakeholders as they implement the
47 DSCSA.

48
49 FDA’s guidance documents do not typically establish legally enforceable responsibilities.
50 Guidances describe the Agency’s current thinking on a topic and should be viewed only as
51 recommendations, unless specific regulatory or statutory requirements are cited. The use of the
52 word *should* in Agency guidances means that something is suggested or recommended, but not
53 required.

54 55 **II. BACKGROUND**

56
57 On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA, which
58 adds new sections 581 and 582 to the FD&C Act, sets forth new definitions and requirements
59 related to product tracing. The DSCSA outlines critical steps to build an electronic,
60 interoperable system by November 27, 2023, that will identify and trace certain prescription
61 drugs as they are distributed within the United States. The electronic, interoperable system that
62 will be established under the DSCSA will enhance FDA’s ability to help protect U.S. consumers
63 by improving detection and removal of potentially dangerous products from the pharmaceutical
64 distribution supply chain and by helping to prevent such products from entering the supply chain
65 in the first place.

66
67 Starting in 2015, trading partners are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1)
68 of the FD&C Act to provide the subsequent purchaser with product tracing information for
69 certain prescription drugs. Trading partners are also required to capture and maintain the
70 applicable product tracing information for not less than 6 years after the date of the transaction.
71 Section 582(a)(2)(A) of the FD&C Act requires FDA, in consultation with other appropriate
72 Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other
73 pharmaceutical distribution supply chain stakeholders, to issue a guidance that establishes initial
74 standards for the interoperable exchange of product tracing information, in paper or electronic
75 format, for compliance with sections 582(a), (b), (c), (d), and (e). As required by this provision,
76 in establishing such standards, FDA considered the feasibility of establishing standardized
77 documentation to be used by members of the pharmaceutical distribution supply chain to convey
78 the product tracing information to the subsequent purchaser of a product and to facilitate the
79 exchange of lot level data. As required by section 582(a)(2)(A), FDA also considered the
80 standards established under 505D and has issued standards that comply with a form and format
81 developed by a widely recognized international standards development organization.

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83 FDA obtained stakeholder input on the development of the initial standards for the interoperable
84 exchange of product tracing information, in paper and electronic formats, through a public
85 docket⁴ established in February 2014, as required under section 582(a)(2)(B), and a public
86 workshop that was held May 8-9, 2014. The public workshop provided a forum for FDA to
87 obtain input from stakeholders in the pharmaceutical distribution supply chain and to facilitate
88 the productive exchange of information and ideas.⁵ The goal of the workshop was to obtain
89 input from stakeholders on how trading partners can best comply with the requirements for the
90 interoperable exchange of product tracing information beginning in 2015, using currently
91 available standards or practices. A diverse group of stakeholders participated in the workshop,
92 including drug manufacturers, wholesale distributors, pharmacies, standards organizations, and
93 solution providers. Many supply chain stakeholders who attended the workshop, as well as some
94 who did not, submitted comments to the public docket established for the workshop.⁶ The
95 information and comments received in the public dockets and at the public workshop were
96 considered in the development of this guidance and will be considered in developing additional
97 guidance to further elaborate on the standards for the interoperable exchange of product tracing
98 information.

99

100

101 **III. SCOPE OF THIS GUIDANCE**

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103 This guidance establishes standards to help trading partners comply with the requirements of
104 sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide the subsequent trading
105 partners product tracing information through the extension and/or use of current systems and
106 processes. Under these provisions, trading partners are also required to capture and maintain the
107 applicable product tracing information for not less than 6 years after the date of the transaction.
108 Except as otherwise specified by the DSCSA,⁷ the product tracing information can be provided
109 to subsequent purchasers in paper or electronic format.

110

111

112 **A. To whom does this guidance apply?**

113

114 This guidance applies to certain trading partners (manufacturers, wholesale distributors,
115 dispensers, and repackagers) engaged in transactions involving “products” as defined under
116 section 581(13) of the FD&C Act. As noted above, manufacturers, wholesale distributors,
117 dispensers, and repackagers are required under sections 582(a)(1), (b)(1), (c)(1), (d)(1), and
118 (e)(1) to exchange specific product tracing information in such transactions. Whether an entity⁸
119 must comply with this requirement depends on whether the entity meets the statutory definition
120 of a manufacturer, wholesale distributor, dispenser, or repackager. A trading partner may meet

⁴ For docket no. FDA-2014-N-0200, see 79 FR 9745 (February 20, 2014).

⁵ The public workshop agenda, discussion topics, slides, recorded webcasting of portions of the workshop, and summary may be found at the FDA’s public workshop Web page:
<http://www.fda.gov/Drugs/NewsEvents/ucm388993.htm>.

⁶ For docket no. FDA-2014-N-0337, see 79 FR 18562 (April 2, 2014).

⁷ For example, under section 582(b)(1)(C), starting November 27, 2017, manufacturers are required to provide tracing information in an electronic format for certain transactions.

⁸ For purposes of this guidance, “entity” or “person” interchangeably refers to the party engaging in the transaction related to the product or other activities as listed.

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121 the definition of more than one entity depending on the activities in which it engages. In the
122 event that a trading partner meets the definition of more than one entity, pursuant to section
123 582(a)(1), it must comply with all applicable requirements, but trading partners are not required
124 to duplicate requirements. Beginning on January 1, 2015, sections 582(b)(3), (c)(3), (d)(3), and
125 (e)(3) require that trading partners of manufacturers, wholesale distributors, dispensers, and
126 repackagers be authorized.⁹

127

128

B. What products are addressed by this guidance?

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131 This guidance applies to transactions involving all products that meet the definition under section
132 581(13) of the FD&C Act for “product.” In general, a “product” is a prescription drug in a
133 finished dosage form for administration to a patient without substantial further manufacturing
134 (such as capsules, tablets, and lyophilized products before reconstitution).

135

136 The definition of “product” does not include blood or blood components intended for
137 transfusion; radioactive drugs or radioactive biological products (as defined in 21 CFR 600.3(ee)
138 that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement
139 with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021));
140 imaging drugs; an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph
141 (24)(B) of section 581 of the FD&C Act; any medical gas (as defined in section 575 of the
142 FD&C Act); homeopathic drugs marketed in accordance with applicable guidance under the
143 FD&C Act; or a drug compounded in compliance with section 503A or 503B of the FD&C Act.

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145

C. What transactions are covered by this guidance?

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147
148 This guidance applies to any “transaction” as defined under section 581(24) of the FD&C Act.
149 This definition exempts transactions involving certain entities or products. We encourage
150 stakeholders to review and become familiar with these exemptions to determine whether a
151 specific transaction is exempted from the product tracing requirements of section 582.

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⁹ “Authorized” is defined under FD&C Act § 581(2).

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IV. HOW SHOULD THE TRANSACTION INFORMATION, TRANSACTION HISTORY, AND TRANSACTION STATEMENTS BE EXCHANGED AMONGST TRADING PARTNERS?

For the purposes of this guidance and establishing initial standards for the exchange of tracing information, FDA believes that “interoperability” encompasses the ability to exchange product tracing information accurately, efficiently, and consistently among trading partners. In order for any system, process, or practice to be interoperable, the subsequent purchaser must be able to successfully capture and maintain the product tracing information, regardless of whether the information is provided in a paper or electronic format. FDA may revisit this application of “interoperability” as processes and capabilities that promote more standardization become available and as electronic systems evolve and are more widely accessible.

Trading partners can utilize current paper-based or electronic-based methods for the interoperable exchange of data to provide product tracing information to subsequent purchasers as long as the selected method(s) allow information to be exchanged in a manner that complies with the requirements of section 582 (b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act. Such methods could include, but are not limited to, the use of:

- paper or electronic versions of invoices;
- paper versions of packing slips;
- Electronic Data Interchange (EDI) standards, such as 856 Advance Ship Notice (ASN), which is currently used to provide the receiving entity with advance data on shipments; and
- EPCIS (Electronic Product Code Information Services),¹⁰ which defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.

The information that must be included in the transaction information, transaction history, and transaction statement is defined under sections 581(26), (25), and (27) of the FD&C Act, respectively.

Email or Web-based platforms (such as Web portals) are acceptable means to transmit or access the product tracing information, as long as the information is captured, maintained, and provided in compliance with section 582.

As required by section 582(a)(2), in issuing this guidance, 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. The above standards allow for the exchange of standardized documentation. FDA intends to issue additional guidance to facilitate the interoperable exchange of product tracing information through standardization of data and documentation practices.

¹⁰ EPCIS (Electronic Product Code Information Services) is a standard developed by GS1. For more information see www.gs1.org.