
Identifying Trading Partners Under the Drug Supply Chain Security Act 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DRAFT GUIDANCE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)**

**July 2022
Procedural
Revision 1**

Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry

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1 **Identifying Trading Partners Under the Drug Supply Chain**
2 **Security Act**
3 **Guidance for Industry¹**

4
5 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
6 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
7 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
8 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
9 for this guidance as listed on the title page.
10

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12
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14 **I. INTRODUCTION**

15
16 The Food and Drug Administration (FDA or Agency) is issuing this guidance to assist industry
17 and State and local governments in understanding how to categorize the entities in the drug
18 supply chain in accordance with the Drug Supply Chain Security Act (DSCSA).² This guidance
19 revises the Agency’s draft guidance for industry *Identifying Trading Partners Under the Drug*
20 *Supply Chain Security Act* (August 2017) to address the status of some entities as trading
21 partners (e.g., private-label distributors, salvagers, and returns processors and reverse logistics
22 providers), provide clarification on certain drug distribution scenarios, and address the
23 interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act),
24 which discusses third-party logistics providers (3PL) licensure status prior to the effective date of
25 the forthcoming regulations establishing licensure standards. The DSCSA establishes product
26 tracing requirements for certain trading partners in the drug supply chain, including
27 manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA also requires
28 that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must
29 meet the applicable requirements for being “authorized trading partners.”³ Additionally, the
30 DSCSA requires FDA to issue regulations that establish Federal standards for the licensing of
31 wholesale drug distributors⁴ (WDDs) and 3PLs. The Agency is currently drafting these
32 regulations. This guidance, when finalized, will explain FDA’s current thinking on how certain
33 DSCSA requirements apply to entities that are considered trading partners in the drug supply
34 chain.
35

¹ This guidance has been prepared by the Division of Drug Supply Chain Integrity in the Center for Drug Evaluation and Research in consultation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

² Title II of Public Law 113-54. In particular, see sections 503(e), 581, and 584 of the FD&C Act (21 U.S.C. 353(e), 360eee, and 360eee-3).

³ See section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1(b)(3), (c)(3), (d)(3), and (e)(3)).

⁴ For the purposes of this guidance, the terms *wholesale distributor* or *wholesale drug distributor* are considered the same and may be used interchangeably in the guidance.

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36 This guidance is intended to: (1) assist industry and State and local governments in
37 understanding the applicability of DSCSA requirements to the various types of entities that take
38 part in the distribution of prescription drugs in the United States⁵; and (2) help clarify for
39 industry whether they are engaged in activities that require licensure and annual reporting, as
40 well as other requirements related to being an authorized trading partner in the drug supply
41 chain. The guidance does not address all requirements described in the DSCSA but is limited to
42 describing the activities that would determine what type of trading partner an entity may be and
43 the applicable requirements under the DSCSA.

44
45 The contents of this document do not have the force and effect of law and are not meant to bind
46 the public in any way, unless specifically incorporated into a contract. This document is
47 intended only to provide clarity to the public regarding existing requirements under the law.
48 FDA guidance documents, including this guidance, should be viewed only as recommendations,
49 unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA
50 guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

54
55 On November 27, 2013, the DSCSA was signed into law. The DSCSA outlines requirements to
56 develop and enhance drug distribution security by 2023. In part, these changes include defining
57 the types of entities in the drug supply chain (i.e., manufacturers, repackagers, wholesale
58 distributors, 3PLs, and dispensers), requiring that the trading partners of manufacturers,
59 repackagers, wholesale distributors, and dispensers meet the applicable requirements to be
60 *authorized* trading partners, and establishing national standards for the licensing of WDDs and
61 3PLs.

A. Definitions of Drug Supply Chain Entities Under the DSCSA

64
65 The DSCSA identifies and defines five types of entities in the prescription drug supply chain:
66 manufacturers, repackagers, dispensers, wholesale distributors, and 3PLs. The DSCSA defines
67 these entities in section 581 of the FD&C Act (21 U.S.C. 360eee).

68
69 A *manufacturer* is defined in section 581(10) of the FD&C Act to mean:

70
71 [W]ith respect to a product -- (A) a person that holds an application approved under
72 section 505 or a license issued under section 351 of the Public Health Service Act for
73 such product, or if such product is not the subject of an approved application or license,
74 the person who manufactured the product; (B) a co-licensed partner of the person
75 described in subparagraph (A) that obtains the product directly from a person described
76 in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described
77 in subparagraph (A) or (B) that receives the product directly from a person described in
78 this subparagraph or subparagraph (A) or (B).

⁵ Under section 201(a)(1) of the FD&C Act, the term *state* means any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

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80 Section 581(16) of the FD&C Act defines a *repackager* to mean “a person who owns or operates
81 an establishment that repacks and relabels a product or package for – (A) further sale; or (B)
82 distribution without a further transaction.”

83

84 The term *dispenser*, as defined in section 581(3) of the FD&C Act:

85

86 (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under
87 common ownership and control that do not act as a wholesale distributor, or any other
88 person authorized by law to dispense or administer prescription drugs, and the affiliated
89 warehouses or distribution centers of such entities under common ownership and control
90 that do not act as a wholesale distributor; and (B) does not include a person who
91 dispenses only products to be used in animals in accordance with section 512(a)(5).

92

93 The DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean:

94

95 [A] person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party
96 logistics provider, or repackager) engaged in wholesale distribution (as defined in section
97 503(e)(4), as amended by the Drug Supply Chain Security Act.

98

99 Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)) defines *wholesale distribution* as
100 “distribution of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] to a
101 person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the
102 FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or patient,” but excludes
103 several specific activities.⁶

104

105 The DSCSA adds *third-party logistics providers* (3PLs) as a new entity in the drug supply
106 chain,⁷ and requires 3PL facilities to be regulated separately from wholesale distributors.⁸ The
107 DSCSA defines a *3PL* in section 581(22) of the FD&C Act to mean:

108

109 [A]n entity that provides or coordinates warehousing, or other logistics services of a
110 product in interstate commerce on behalf of a manufacturer, wholesale distributor, or
111 dispenser of a product, but does not take ownership of the product, nor has responsibility
112 to direct the sale or disposition of the product.

113

114 The key distinction between wholesale distributors and 3PLs is that, unlike a wholesale
115 distributor, a 3PL does not take ownership of the product, and does not direct the sale or
116 disposition of the product.

117

B. Authorized Trading Partners Under the DSCSA

118

119
120 The DSCSA restricts access to the distribution system for prescription drug products by
121 requiring that trading partners of manufacturers, wholesale distributors, dispensers, and

⁶ For exclusions see section 503(e)(4)(A) through (S) of the FD&C Act.

⁷ Section 581(22) of the FD&C Act.

⁸ See section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee-4(b)(2)).

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122 repackagers meet the applicable requirements for being authorized trading partners.⁹ The
123 DSCSA includes definitions for *authorized*¹⁰ and *trading partner*¹¹ with respect to each entity in
124 the drug supply chain as follows:
125

- 126 • To be considered an authorized trading partner, a manufacturer or repackager must have a
127 valid registration in accordance with section 510 of the FD&C Act and accept or transfer
128 direct ownership of a product from or to a manufacturer, repackager, wholesale
129 distributor, or dispenser.
130
- 131 • To be considered an authorized trading partner, a wholesale distributor must have a valid
132 license under State law or section 583 of the FD&C Act, in accordance with section
133 582(a)(6) of the FD&C Act, comply with the licensure reporting requirements in section
134 503(e) of the FD&C Act, and accept or transfer direct ownership of a product from or to a
135 manufacturer, repackager, wholesale distributor, or dispenser.
136
- 137 • Similarly, to be considered an authorized trading partner, a 3PL must have a valid license
138 under State law or section 584(a)(1) of the FD&C Act, in accordance with section
139 582(a)(7) of the FD&C Act, comply with the licensure reporting requirements under
140 section 584(b) of the FD&C Act (21 U.S.C. 360eee-3(b)), and accept or transfer direct
141 possession of a product from or to a manufacturer, repackager, wholesale distributor, or
142 dispenser.
143
- 144 • To be considered an authorized trading partner, a dispenser must have a valid license
145 under State law and accept or transfer direct ownership of a product from or to a
146 manufacturer, repackager, wholesale distributor, or dispenser.
147

C. Licensure and Reporting Requirements for WDDs and 3PLs

148
149
150 The DSCSA also establishes new licensure and reporting requirements for wholesale distributors
151 and third-party logistics providers.
152

153 Section 583 of the FD&C Act requires FDA to issue regulations regarding the standards for
154 licensure of wholesale distributors under section 503(e)(1) of the FD&C Act. Section 503(e) of
155 the FD&C Act establishes licensure requirements based on these standards and adds reporting
156 requirements for WDDs. Specifically, section 503(e)(1), subject to section 583 of the FD&C
157 Act, prohibits an entity from engaging in wholesale distribution of prescription drugs in any
158 State unless such entity is licensed by the State from which the drug is distributed, or by FDA if
159 such State from which the drug is distributed has not established a licensure requirement.
160 Furthermore, under certain circumstances,¹² such wholesale distributor must also be licensed by
161 the State into which the drug is distributed. Section 503(e)(2) of the FD&C Act requires WDDs

⁹ See section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1(b)(3), (c)(3), (d)(3), and (e)(3)).

¹⁰ See section 581(2) of the FD&C Act.

¹¹ See section 581(23) of the FD&C Act.

¹² See section 503(e)(1)(A)(ii) of the FD&C Act—in relevant part, “if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.”

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162 to report certain information to FDA on an annual basis, including State licensure information
163 for each license, the name and address of each licensed facility, and any significant disciplinary
164 actions taken by a State or the Federal government.¹³
165

166 The DSCSA adds section 584 to the FD&C Act, which requires FDA to issue regulations
167 regarding the standards for licensure of 3PLs and sets forth requirements for 3PL licensure in
168 accordance with those standards and for 3PL licensure reporting. Specifically, section 584(a)
169 prohibits a 3PL in any State from conducting activities in any State unless each facility of the
170 3PL is licensed by the State from which the drug is distributed by the 3PL, or by FDA if the
171 State from which the drug is distributed by the 3PL has not established a licensure requirement
172 (subject to section 582(a)(7) of the FD&C Act, discussed below). Furthermore, under certain
173 circumstances,¹⁴ the 3PL must also be licensed by the State into which the drug is distributed.
174 Section 584(b) of the FD&C Act requires 3PL facilities to report certain information to FDA on
175 an annual basis, including State licensure information for each facility and the name and address
176 of each facility.
177

178 The DSCSA also addresses the licensure status of wholesale distributors and 3PLs during the
179 period before the regulations detailing licensure standards under sections 583 and 584 of the
180 FD&C Act, respectively, are effective. With respect to wholesale distributors, section 582(a)(6)
181 of the FD&C Act provides that:

182
183 Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor
184 licensing regulations under section 583, the term ‘licensed’ or ‘authorized’, as it relates to
185 a wholesale distributor with respect to prescription drugs, shall mean a wholesale
186 distributor with a valid license under State law.¹⁵
187

188 With respect to 3PLs, section 582(a)(7) of the FD&C Act provides that:

189
190 Until the effective date of the third-party logistics provider licensing regulations under
191 section 584, a third-party logistics provider shall be considered ‘licensed’ under section
192 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider
193 does not utilize good handling and distribution practices and publishes notice thereof.¹⁶
194

195 Accordingly, until the regulations with respect to wholesale distributor licensure under section
196 583 are effective, FDA will generally consider a wholesale distributor to be fully licensed for
197 DSCSA purposes if the wholesale distributor holds a valid license under State law. Similarly,

¹³ More information about reporting is on the Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers web page, available at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm>

¹⁴ See section 584(a)(2) of the FD&C Act—in relevant part, “if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary.” For clarity, a 3PL does not need to obtain a license from the State(s) into which such 3PL ships product if that 3PL is licensed by FDA pursuant to section 584(a)(1)(B) of the FD&C Act.

¹⁵ Under section 581(9)(A) of the FD&C Act, the term *licensed* means, in the case of a wholesale distributor, “having a valid license in accordance with section 503(e) or section 582(a)(6), as applicable.”

¹⁶ Under section 581(9)(B) of the FD&C Act, the term *licensed* means, in the case of a third-party logistics provider, “having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable.”

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198 until the regulations with respect to 3PL licensure under section 584 are effective, FDA will
199 generally consider a 3PL to be fully licensed for DSCSA purposes, unless FDA determines that
200 the 3PL is not utilizing good product handling and distribution practices and publishes notice
201 thereof. Any such determination would be posted on FDA’s DSCSA webpage.¹⁷
202

203 FDA interprets this provision to mean that a 3PL is fully licensed for DSCSA purposes during
204 the period prior to the effective date of Federal 3PL licensure regulations (provided that the 3PL
205 utilizes good product handling and distribution practices), notwithstanding a situation where a
206 State requires licensure of the 3PL during this period and the 3PL does not hold such State
207 licensure. This interpretation should not be construed to impact the ability of States to require
208 licensure of 3PLs under State law or the validity of such State licensure. Rather, the Agency's
209 view reflects FDA’s understanding that in enacting section 582(a)(7) of the FD&C Act, Congress
210 intended 3PLs to be deemed licensed for DSCSA purposes to facilitate supply chain operations
211 until the Federal licensing standards take effect.
212

213

214 III. IDENTIFYING WHO IS A TRADING PARTNER

215

216 Whether an entity meets the statutory definition of a particular trading partner that would trigger
217 the applicable DSCSA requirements depends on the activities engaged in by the entity. Please
218 see the discussion below for each type of trading partner for more information.
219

220 There has been confusion about how the definitions of *wholesale distributor* and *wholesale*
221 *distribution* changed upon enactment of the DSCSA. Regulations enacted prior to the DSCSA
222 defined the term *wholesale distributor* to include:

223 . . . manufacturers; repackers; own-label distributors; private label distributors; jobbers;
224 brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug
225 warehouses, and wholesale drug warehouses; independent wholesale drug traders; and
226 retail pharmacies that conduct wholesale distributions.¹⁸
227

228
229 Some of these listed entities are not considered wholesale distributors under the DSCSA. In
230 addition, section 581 of the FD&C Act defines different trading partners in the drug supply
231 chain, including manufacturers, repackagers, WDDs, 3PLs, and dispensers. Neither section
232 503(e) nor section 581 of the FD&C Act lists the other types of entities included in the
233 regulations discussed above, at 21 CFR 203.3(dd). Consequently, several types of activities that
234 may fall within the definition of wholesale distribution under 21 CFR part 203 are not directly
235 addressed by the statutory definition of wholesale distribution in section 503(e) of the FD&C
236 Act. This may leave questions regarding the status of certain entities under the DSCSA. For
237 example, there has been confusion as to whether DSCSA licensure and reporting requirements
238 apply to certain types of entities, such as but not limited to jobbers, brokers, and certain
239 contractors and solution providers. To address some of the confusion expressed by industry and
240 the States, FDA discusses each type of trading partner.
241

¹⁷ See <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>.

¹⁸ 21 CFR 203.3(dd) (1999).

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A. Manufacturers as Trading Partners Under the DSCSA

The DSCSA defines a *manufacturer* in section 581(10) of the FD&C Act as:

[W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

An entity that falls within the definition of manufacturer in section 581(10) of the FD&C Act must comply with the requirements under section 582(b) of the FD&C Act.

FDA believes that most of the confusion¹⁹ is related to the inclusion of entities that hold drug approvals (i.e., holders of approved new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs)), co-licensed partners, and affiliates of such entities in the definition of manufacturer in section 581(10) of the FD&C Act, and the interaction of this definition with the requirement to register under section 510 of the FD&C Act to be “authorized” according to section 581(2) of the FD&C Act.

1. Manufacturing Establishments

Under section 510 of the FD&C Act, and part 207 (21 CFR part 207), with some limited exceptions, any person who owns or operates any establishment that manufactures, prepares, propagates, compounds, or processes drugs in the United States, or that are offered for import into the United States, must be registered with the FDA.²⁰ Thus, under section 581(2)(A) of the FD&C Act, such manufacturer establishments must be registered in accordance with section 510 of the FD&C Act to be considered an authorized trading partner.

2. NDA-, BLA-, or ANDA-Holder, or Co-Licensed Partner of a Manufacturer

While an NDA-, BLA-, or ANDA-holder or co-licensed partner of a manufacturer might not engage in the manufacturing, preparation, propagation, compounding, or processing of a drug, they could still meet the definition of manufacturer in section 581(10) of the FD&C Act. There has been confusion as to whether such manufacturers should register under section 510 of the FD&C Act to be considered an authorized trading partner. FDA believes such an entity would be an authorized trading partner without being registered under section 510 so long as the NDA-, BLA-, or ANDA-holder, or co-licensed partner is compliant with its obligations under section 510 of the FD&C Act, if applicable. While these entities need not register under section 510 of

¹⁹ Part 207 (21 CFR part 207) defines manufacturers for purposes of registration requirements under section 510 of the FD&C Act, while section 581(10) defines manufacturers differently for purposes of the DSCSA.

²⁰ 21 U.S.C. 360(b), (c), (d), and (i).

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285 the FD&C Act in order to be considered authorized trading partners, they still must comply with
286 all other relevant obligations under the DSCSA. For example, the NDA-, BLA-, or ANDA-
287 holder, or co-licensed partner should ensure that the product it transfers to another trading
288 partner was manufactured by an authorized²¹ entity that is registered under section 510 of the
289 FD&C Act.²² We note, however, that any person who owns or operates any establishment
290 manufacturing, preparing, propagating, compounding, or processing drugs in the United States,
291 or that are offered for import into the United States, must have a valid registration in accordance
292 with section 510 to comply with the FD&C Act.

293
294 For purposes of the DSCSA, FDA interprets the term *co-licensed partner* of a manufacturer,
295 referenced in section 581(10)(B) of the FD&C Act, to mean one of two or more entities that have
296 entered into a written agreement for the right to engage in the marketing of a prescription drug.
297 While the term *co-licensed partner* is not defined in the FD&C Act, the Agency believes this
298 interpretation is in alignment with industry practice and existing state laws.²³

3. *Affiliate of a Manufacturer (Section 581(10)(C) of the FD&C Act)*

301
302
303 *Affiliate* is defined in section 581(1) of the FD&C Act as:

304 [A] business entity that has a relationship with a second business entity if, directly or
305 indirectly—

306 (A) one business entity controls, or has the power to control, the other business
307 entity; or

308 (B) a third party controls, or has the power to control, both of the business entities.

309
310
311 FDA generally considers the situation described in paragraph (A) to be similar to a
312 parent/subsidiary business relationship (i.e., the parent has the power to control the business of
313 the subsidiary), and the situation described in paragraph (B) as describing a business relationship
314 where a third party controls the business of several entities, such as controlling both the parent
315 and the subsidiary. In other words, an *affiliate* is a business entity that legally controls another
316 business entity, directly or indirectly, or is controlled by another business entity; mere business
317 links or relationships are not sufficient to meet the definition of an affiliate.²⁴ Manufacturers and

²¹ A manufacturer that is an establishment that manufactures, prepares, propagates, compounds, or processes a drug must have a valid registration with FDA in accordance with section 510 of the FD&C Act to be considered an authorized trading partner. See section 581(2)(A) of the FD&C Act.

²² A drug is misbranded if, among other things, it is manufactured in an establishment not duly registered under section 510 of the FD&C Act (section 502(o) of the FD&C Act (21 U.S.C. 352(o)).

²³ While *co-licensed partner* is not defined in the FD&C Act, the term has been defined by various states to include a co-licensed marketing arrangement. See e.g., § 16.19.8.7(F) NMAC (which defines “Co-licensed partner or product” to mean “an instance where two or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with FDA’s implementation of the Drug Supply Chain Security Act (DSCSA)” and Md. Health. Occ. Code § 12-6c-01(d) (which defines “co-licensed partner” to mean “a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration’s implementation of the federal Prescription Drug Marketing Act.”

²⁴ This interpretation is consistent with the interpretation of *affiliate* previously described in FDA’s final rule “Foreign Establishment Registration and Listing” (66 FR 59138 at 59146, Nov. 27, 2001).

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318 their affiliates retain responsibility for carrying out the activities and requirements under section
319 582(b) of the FD&C Act. To be considered a manufacturer under the DSCSA, an affiliate of a
320 manufacturer as defined in 581(10)(A) or (B) of the FD&C Act must have received the product
321 directly from such a manufacturer.²⁵

322

323 4. Private Label Distributors

324

325 For DSCSA purposes, FDA generally considers a private label distributor to be an entity that
326 owns and distributes a manufactured product under its own label or trade name but does not
327 manufacture, repack, relabel, or salvage the product itself.²⁶

328

329 For purposes of the DSCSA, FDA generally considers private label distributors, who obtain a
330 manufactured product to market under their own label or trade name from an entity that holds an
331 approved application or license for such product, to be a co-licensed partner of the application or
332 license holder for a given product. As noted above, FDA interprets the term *co-licensed partner*
333 to mean one of two or more entities that have entered into a written agreement for the right to
334 engage in the marketing of a prescription drug.

335

336 FDA generally considers the term *co-licensed partner* to apply to private label distributors
337 because private label distributors are entities that enter into contractual agreements with
338 application holders and manufacturers for the right to engage in the marketing of a drug. In this
339 instance, the drug would be owned and marketed by the private label distributor under the label
340 or trade name of that private label distributor.

341

342 A private label distributor, who obtains product directly from an application holder or an affiliate
343 of that application holder, would generally be considered to be a manufacturer for purposes of
344 the DSCSA.²⁷

345

346 As a manufacturer for purposes of the DSCSA, a private label distributor is subject to all the
347 requirements for manufacturers in section 582 of the FD&C Act, including the product tracing,
348 product identifier, authorized trading partner, and verification requirements.

349

350 This is different from the definition of manufacturer under section 510 of the FD&C Act and 21
351 CFR part 207, which requires establishments that manufacture, prepare, propagate, compound, or
352 process drugs to register with the FDA. A private label distributor that does not manufacture,
353 repack, relabel, or salvage drugs should not register with FDA.²⁸ However, the product that the

²⁵ See section 581(10)(C) of the FD&C Act.

²⁶ This interpretation is consistent with the interpretation of *private label distributor* in 21 CFR 207.1.

²⁷ See section 581(10)(B) of the FD&C Act which defines a co-licensed partner of an application holder as a manufacturer for DSCSA purposes if the co-licensed partner receives the product directly from the manufacturer as defined in sections 581(10)(A) and (C) of the FD&C Act.

²⁸ See 21 CFR 207.17(b).

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354 private label distributor transfers to another trading partner must have been manufactured or
355 repackaged by an authorized entity that is registered under section 510 of the FD&C Act.²⁹

356
357 If an entity owns and distributes a manufactured product under a label or trade name that is not
358 its own, it may be engaged in wholesale distribution and subject to all the requirements for
359 wholesale distributors under the DSCSA unless the activity falls under one of the exclusions to
360 the definition of wholesale distribution enumerated in section 503(e)(4) of the FD&C Act.

361

362 5. Salvagers

363

364 FDA generally does not consider a salvager to be a manufacturer under the DSCSA. A *salvager*
365 is defined in 21 CFR 207.1 as a person who owns or operates an establishment that engages in
366 salvaging. Salvaging means the act of segregating out those finished drug products that may
367 have been subjected to improper storage conditions (such as extremes in temperature, humidity,
368 smoke, fumes, pressure, age, or radiation) for the purpose of returning the products that have
369 been deemed acceptable for distribution to the marketplace, and includes applying manufacturing
370 controls such as those required by current good manufacturing practice in 21 CFR parts 210 and
371 211.³⁰ Salvagers are required to register with FDA and report the National Drug Codes and lot
372 numbers for product they have determined can be sold or used.³¹ While FDA generally does not
373 consider salvagers to be manufacturers for the purposes of the DSCSA, other activities that a
374 salvager conducts may subject them to DSCSA requirements. For example:

375

376 • If a salvager conducts repackaging activities, they are also required to register under
377 section 510 and comply with repackager requirements under section 582(e) of the FD&C
378 Act (see section B below).

379

380 • If a salvager owns the drug products that have been salvaged, and sells salvaged products
381 to another trading partner, this activity is considered wholesale distribution unless the
382 activity falls under one of the exclusions to the definition of wholesale distribution
383 enumerated in section 503(e)(4) of the FD&C Act. Wholesale distributor product tracing
384 requirements under section 582(c) and licensing and reporting requirements under
385 sections 503(e) and 583 of the FD&C Act would apply (see section C below).

386

387 • If a salvager does not take ownership of the drug products, but takes direct possession³²
388 of the products and conducts activities on behalf of another trading partner to determine
389 if the products can be sold, FDA generally considers this as other logistic services and

²⁹ A manufacturer that is an establishment that manufactures, prepares, propagates, compounds, or processes a drug must have a valid registration with FDA in accordance with section 510 of the FD&C Act to be considered an authorized trading partner. See section 581(2)(A) of the FD&C Act. A repackager must have a valid registration with FDA in accordance with section 510 of the FD&C Act in order to be considered an authorized trading partner. See section 581(2)(A) of the FD&C Act.

³⁰ See 21 CFR 207.1.

³¹ See 21 CFR 207.17(a) and 21 CFR 207.54.

³² For the purposes of this guidance, FDA generally considers *direct possession* to mean having physical, direct contact with the product.

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390 3PL requirements for licensure and reporting under section 584 of the FD&C Act would
391 apply (see section D below).

392

393

B. Repackagers as Trading Partners Under the DSCSA

394

395 The DSCSA defines *repackager* in section 581(16) of the FD&C Act as “a person who owns or
396 operates an establishment that repacks and relabels a product or package for – (A) further sale; or
397 (B) distribution without a further transaction.” FDA generally considers entities engaged in
398 relabeling activities described in 21 CFR 207.1 to be repackagers under the DSCSA. Under
399 section 510 of the FD&C Act and 21 CFR part 207, with some limited exceptions, any person
400 who owns or operates any establishment that manufactures, prepares, propagates, compounds, or
401 processes drugs in the United States or that are offered for import into the United States must be
402 registered with the FDA.³³ This includes entities that repackage or otherwise change the
403 container, wrapper, or labeling of a drug in furtherance of the distribution of the drug.³⁴ Thus,
404 repackagers under the DSCSA must register in accordance with section 510 of the FD&C Act to
405 be considered authorized trading partners.

406

407 An entity that falls within the definition of repackager in section 581(16)(A) of the FD&C Act
408 who repacks and relabels a product or package “for further sale” must comply with all
409 requirements under section 582(e) of the FD&C Act. Repackagers defined under section
410 581(16)(B) of the FD&C Act who repackage and relabel product “for distribution without a
411 further transaction” must comply with only section 582(e)(1)(B)(ii) and (e)(3) of the FD&C
412 Act.³⁵

413

414 FDA generally does not consider a dispenser, specifically a pharmacy, that is solely engaged in
415 packaging and labeling drug product(s) for dispensing to an identified individual patient after the
416 receipt of a valid prescription for that patient (e.g., repackaging product into unit-dose packages
417 for administration to an identified individual patient), to be a repackager under the DSCSA.
418 Therefore, the requirements in section 582(e) of the FD&C Act would not apply.

419

420

C. WDDs as Trading Partners Under the DSCSA

421

422 The DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean “a
423 person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics
424 provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the
425 FD&C Act).”

426

427 Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)) defines *wholesale distribution* as
428 “distribution of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] to a
429 person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the
430 FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or patient,” but excludes

³³ 21 U.S.C. 360(b), (c), (d), and (i).

³⁴ 21 U.S.C. 360(a)(1).

³⁵ Section 582(e)(1) (except for 582(e)(1)(B)(ii)), (e)(2), (e)(3) and (e)(4) applies to repackagers defined under section 581(16)(A) of the FD&C Act, and only section 582(e)(1)(B)(ii) and (e)(3) applies to repackagers defined under section 581(16)(B) of the FD&C Act.

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431 several specific activities. An entity that falls within the definition of wholesale distributor in
432 section 581(29) of the FD&C Act must comply with the requirements under section 582(c) of the
433 FD&C Act.

434
435 One source of confusion is that the DSCSA provides a definition of wholesale distribution in
436 section 503(e) of the FD&C Act and a definition for wholesale distributor in section 581 of the
437 FD&C Act that differ from the respective definitions in the regulations promulgated pursuant to
438 sections 503(c), (d), and (e) of the FD&C Act, as enacted by the Prescription Drug Marketing
439 Act of 1987 (PDMA).³⁶ Several types of entities are not considered WDDs under the DSCSA
440 that were under these regulations. Many of these entities are now considered to be 3PLs under
441 the DSCSA and are discussed in the next section.

442
443 Another source of confusion stems from uncertainty as to whether a manufacturer can also be
444 licensed as a WDD. The definition of wholesale distribution, as set forth in section 503(e)(4) of
445 the FD&C Act, excludes the distribution of a manufacturer's own drug (section 503(e)(4)(H)).
446 As a result, if a manufacturer is only distributing its own drug, it would not be engaged in
447 wholesale distribution under the DSCSA and would not be required to comply with the licensure
448 and reporting requirements for WDDs under the DSCSA.

449
450 Generally, but with exclusions enumerated in section 503(e)(4), an entity engaged in the
451 distribution of a drug subject to section 503(b) of the FD&C Act (21 U.S.C. 353(b)), that the
452 entity did not manufacture, to someone other than a consumer or patient, is conducting wholesale
453 distribution and would be subject to all the WDD requirements under the DSCSA. FDA is
454 providing additional clarification on the applicability of some of the exclusions to wholesale
455 distribution as provided below.

456 457 *1. Distribution for Emergency Medical Reasons*

458
459 Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to
460 distribute a drug for emergency medical reasons, including a public health emergency (PHE)
461 declaration pursuant to section 319 of the Public Health Service Act, does not constitute
462 wholesale distribution.³⁷ FDA generally considers this exclusion to cover distribution activities
463 directly impacted by the PHE and distribution of products that are approved or authorized to
464 diagnose, cure, mitigate, treat, or prevent the basis of the PHE.³⁸ In addition, FDA generally
465 considers the following circumstances to constitute emergency medical reasons for purposes of
466 section 503(e)(4)(C) of the FD&C Act and therefore to be excluded from the definition of
467 wholesale distribution: (1) the distribution of a drug to a first responder or other authorized
468 individual administering prescription drugs to acutely ill or injured persons in an emergency
469 situation and outside a healthcare facility; and (2) the distribution of a drug to a long-term care

³⁶ Public Law 100-293; codified at 21 U.S.C. 321 *et seq.*

³⁷ Pursuant to section 503(e)(4)(C) of the FD&C Act, this exclusion from the definition of wholesale distribution does not include a drug shortage unless caused by a public health emergency.

³⁸ During the public health emergency, if an entity is engaged in activities that meet the definition of wholesale distribution but such activities are not for emergency medical reasons then that entity would be a wholesale distributor with respect to such activities and would need to comply with sections 503(e) and 582(c) of the FD&C Act for the distribution of the products involved.

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470 facility for use in emergency situations to treat acutely ill or injured persons during hours of the
471 day when necessary drugs cannot be obtained from a dispenser.

472
473 Because we generally would not consider these activities to fall within the definition of
474 wholesale distribution as defined in section 503(e)(4) of the FD&C Act, they do not subject an
475 entity to the wholesale distributor requirements under the DSCSA. With respect to the exclusion
476 related to first responders mentioned above, FDA considers this to be an emergency medical
477 reason only where the drug is to be administered to a patient who is in a current or active
478 “emergency situation.” This exclusion from the definition of wholesale distribution would not
479 apply in normal circumstances involving the replenishment of stock drugs, as there is no active
480 emergency in those situations. An entity distributing drugs to a first responder in the absence of
481 an emergency situation is subject to wholesale distributor requirements under the DSCSA.

2. Distribution for Office Use

482
483
484
485 Section 503(e)(4)(E) of the FD&C Act excludes “the distribution of minimal quantities of drug
486 by a licensed retail pharmacy to a licensed practitioner for office use” from the definition of
487 wholesale distribution. FDA has previously stated that it considers “minimal quantities” to mean
488 the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed
489 5 percent of the dollar volume of that retail pharmacy’s annual prescription drug sales.³⁹ FDA
490 generally intends to maintain its interpretation of what constitutes “minimal quantities.”
491 Furthermore, FDA generally considers “office use” to mean use by a licensed practitioner in the
492 usual course of professional practice and is not limited to use in a physician’s office, where the
493 licensed practitioner is lawfully authorized to prescribe or administer prescription drugs.

494
495 FDA generally does not consider a licensed retail pharmacy that sells drugs to a licensed
496 practitioner for office use in minimal quantities at or below such 5 percent threshold to be subject
497 to the wholesale distributor requirements under the DSCSA based on those sales alone; however,
498 the licensed retail pharmacy may still be considered a wholesale distributor based on other
499 activities it engages in that constitute wholesale distribution under section 503(e)(4) of the
500 FD&C Act.

3. Distribution of Drugs for Non-Human Research Purposes Only

501
502
503
504 For the purposes of DSCSA requirements, wholesale distribution is limited to include only
505 distribution of prescription drugs intended for use in humans.⁴⁰ Thus, the activities of the
506 purchaser or receiver of drugs for non-human research purposes only do not fall into activities of
507 a trading partner under the DSCSA and such purchaser or receiver would not be subject to
508 requirements under the DSCSA for those transactions. While DSCSA product tracing does not
509 apply, the receiver of drugs for non-human research purposes should maintain basic
510 recordkeeping in the event of a drug recall. Examples of non-human research include studies
511 conducted in animals only or in vitro studies. The seller of the drug may have DSCSA

³⁹ See the preamble to the final rule “Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures” (64 FR 67720 at 67748, Dec. 3, 1999).

⁴⁰ See section 503(e)(4) of the FD&C Act which references section 503(b) of the FD&C Act in the definition of *wholesale distribution*.

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512 obligations if they meet the definition of a trading partner and the drug meets the definition of
513 product under section 581 of the FD&C Act.

514
515 **4. *Distribution of Drugs for Research Purposes in Humans Under an IND***
516

517 Section 503(e)(4) of the FD&C Act defines *wholesale distribution* as a distribution to a person
518 “other than a consumer or patient.” FDA generally considers an investigator⁴¹ receiving drugs
519 for clinical research purposes to be a “consumer” if the studies are either under an investigational
520 new drug application (IND)⁴² or bioavailability or bioequivalence studies regulated under 21
521 CFR part 320.⁴³ In these situations, FDA generally would not consider the seller to be a WDD
522 within the meaning of the DSCSA, and the investigator, considered a “consumer,” would not be
523 considered a trading partner under the DSCSA. Accordingly, such investigator also would not
524 be subject to DSCSA requirements.⁴⁴ Drugs received by an investigator for clinical research
525 purposes should not re-enter the U.S. pharmaceutical supply chain.⁴⁵

526
527 **5. *Jobbers***
528

529 FDA generally considers a jobber to be a person or entity that owns or operates an establishment
530 that engages in wholesale distribution on a small scale or sells product solely to retailers and
531 institutions. Jobbers engage in wholesale distribution because they own and direct the sale or
532 distribution of product to, and receive product from, a person other than a consumer or patient,
533 and are not otherwise excluded from the definition under section 503(e)(4) of the FD&C Act.
534 Thus, FDA generally considers jobbers to be WDDs and subject to the requirements for WDDs
535 under the DSCSA.

536
537 **D. 3PLs as Trading Partners Under the DSCSA**
538

539 The DSCSA defines *3PLs* broadly to include any entity that provides or coordinates
540 warehousing, or other logistics services of a product in interstate commerce on behalf of a

⁴¹ For purposes of this draft guidance, the term *investigator* has the definition set forth in 21 CFR 312.3(b) and includes a sponsor-investigator as well as individuals and entities under the supervision of the “investigator.” See 21 CFR 312.61. See also 21 CFR 312.57(a) (describing a sponsor’s responsibility for maintaining a dequate records of the receipt, shipment, or other disposition of the investigational drug).

⁴² See 21 CFR part 312 (setting forth the requirements for an investigational new drug application).

⁴³ Bioavailability and bioequivalence studies submitted to FDA in an NDA, ANDA, or supplement to those applications, are required to be conducted consistent with the requirements of 21 CFR part 320. While some bioavailability and bioequivalence studies are conducted under an IND, many such studies are exempt from IND requirements. See 21 CFR 320.31.

⁴⁴ Prior to this distribution from the seller to the investigator, transfers of a drug that meets the definition of product under section 581 of the FD&C Act between trading partners may be subject to DSCSA requirements.

⁴⁵ FDA generally considers a product to be diverted, and therefore potentially suspect or illegitimate under sections 581(8) and 581(21) of the FD&C Act, if it is sold or dispensed to a consumer and then re-introduced into the U.S. pharmaceutical supply chain. See FDA’s draft guidance for industry *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act* (June 2021), which, when finalized, will represent the agency’s current thinking. We update guidances periodically. For the most recent version of a guidance, check the FDA Drugs guidance web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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541 manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the
542 product, nor have responsibility to direct the sale or disposition of the product.⁴⁶

543
544 There has been confusion as to what activities would be considered “other logistics services”
545 within the definition of 3PL. FDA generally considers *other logistics services* to mean services
546 provided by an entity that accepts or transfers direct possession of products from that entity’s
547 facility within the United States and its territories on behalf of a trading partner (i.e.,
548 manufacturer, repackager, WDD, or dispenser). FDA also generally considers other logistics
549 services to include services provided by an entity that accepts or transfers direct possession of
550 products from that entity’s facility within the United States and its territories on behalf of a
551 repackager of products for further sale or a repackager acting on behalf of a manufacturer, WDD,
552 or dispenser.

553
554 *Trading partner*, with respect to 3PLs, is defined in part as having direct possession of product.⁴⁷
555 Manufacturers, wholesale distributors, dispensers, and repackagers are required to conduct
556 transactions with “authorized trading partners,” therefore, 3PLs must be authorized, as defined in
557 section 581(2) of the FD&C Act, when working on behalf of manufacturers, wholesale
558 distributors, dispensers, and repackagers of product.⁴⁸

559
560 Furthermore, FDA generally considers the section 584 requirement that “each facility of such
561 [3PL]”⁴⁹ be licensed “in accordance with the regulations” to mean that 3PLs without a facility
562 are not required to be licensed. Section 584(d) of the FD&C Act provides that FDA will
563 establish licensure standards that centrally include requirements relating to storage of product.
564 These standards address issues with access and maintenance that presuppose the existence of a
565 physical facility wherein product is maintained.

566
567 Accordingly, FDA generally considers a *facility* to be an establishment, warehouse, structure, or
568 structures under common ownership at one general, permanent, physical location used to store or
569 handle prescription drug products. FDA would not generally consider a truck or shipping
570 container used to transport product to constitute a facility for purposes of the DSCSA because
571 such trucks or containers are not consistently located at one physical location and would not
572 sensibly be covered by the storage requirements specific to 3PL facility licensure. Likewise,
573 FDA would not generally consider an establishment, warehouse, or structure that is not used to
574 store or handle prescription drug products to constitute a facility for purposes of section 584 of
575 the FD&C Act.

1. Entities That Warehouse But Do Not Own or Direct the Sale or Disposition of Product

⁴⁶ See section 581(22) of the FD&C Act.

⁴⁷ See section 581(23)(B) of the FD&C Act.

⁴⁸ See section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1(b)(3), (c)(3), (d)(3) and (e)(3)).

⁴⁹ FDA interprets the language in section 584(a) of the FD&C Act, “facility of such third-party logistics provider,” to mean a facility owned, rented, or leased by the 3PL.

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580 FDA generally considers an entity that owns, rents, or leases a facility where it warehouses
581 product, but does not take ownership of, nor direct the sale or disposition of the product, to be a
582 3PL under the DSCSA. FDA would also generally consider an entity that owns, rents, or leases
583 a facility under common ownership or control with another trading partner, where it warehouses
584 product but does not take ownership of, nor direct the sale or disposition of the product, to be a
585 3PL under the DSCSA.

586
587
588

2. Brokers

589 FDA generally considers a *broker* to be a person or entity, who facilitates business transactions
590 between two other trading partners, but does not take ownership of the product nor direct the sale
591 or disposition of a product. A broker does not provide or coordinate warehousing and does not
592 accept or transfer direct possession of the product and, therefore, is not considered a 3PL under
593 the DSCSA. Thus, FDA generally would not consider the 3PL licensure requirements under the
594 DSCSA to cover brokers.

595
596 However, if an entity acts as a seller or buyer, or directs the sale, purchase, or trade of a product,
597 the broker becomes a principal party to the transaction and FDA generally considers such an
598 entity to be involved in directing the sale or disposition of the product. FDA generally does not
599 consider the lack of direct possession of the product as a sufficient reason to preserve broker
600 status because, as the seller or buyer, the person or entity is accepting or transferring ownership
601 of the product. Depending on the circumstances, FDA generally considers an entity engaged in
602 this activity to likely meet the definition of a manufacturer, WDD, repackager, or dispenser, who
603 would be required to meet all of the applicable requirements under the DSCSA.

604
605
606

3. Solution Providers

607 FDA generally considers a *solution provider* to be a person or entity that provides other entities
608 hardware, software, or systems solutions to help achieve compliance with the requirements under
609 the DSCSA. A solution provider does not take ownership of the product nor direct the sale or
610 disposition of a product. Furthermore, a solution provider does not provide or coordinate
611 warehousing and does not accept or transfer direct possession of the product and, therefore, FDA
612 generally would not consider such person or entity to be a 3PL under the DSCSA. Thus, FDA
613 would not generally consider the 3PL licensure requirements under the DSCSA to cover solution
614 providers.

615
616
617

4. Common Carriers

618 As it relates to the distribution of prescription drug products subject to the DSCSA, FDA
619 generally considers a *common carrier* to be an entity that solely provides transportation
620 services⁵⁰ but does not take ownership of the product nor direct the sale or disposition of the
621 product. Common carriers do not provide or coordinate warehousing for the products they

⁵⁰ Such transportation services may include the transport of product from one location to another, and cross-docking of product en route to its destination, but does not include the warehousing of a product that lacks an identified consignee or delivery destination.

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622 transport. Although common carriers accept and transfer direct possession of product, they do
623 not store and handle product at a facility, as defined above. Therefore, FDA would not generally
624 consider the services provided by common carriers to constitute other logistics services, and
625 FDA would not generally consider common carriers to be covered by the 3PL licensure
626 requirements under the DSCSA. The owner of the product would remain responsible for
627 compliance with any applicable storage and handling requirements and for the product's safety
628 and integrity during transit and should select common carriers that can provide appropriate
629 safeguards.

630

631

5. Logistics or Administrative Services Contractors

632

633 FDA is also aware that some entities that solely contract with trading partners to provide labor,
634 logistic, or administrative services in that trading partner's facility, but do not take ownership nor
635 direct the sale or disposition of product, have identified themselves as 3PLs. These entities do
636 not themselves provide or coordinate the warehousing of product; rather, the trading partner with
637 which the entity is contracting provides or coordinates the warehousing. Although such
638 contractors may accept and transfer direct possession of product, they do not store and maintain
639 product at their own facility, and thus would not meet the facility requirement of the other
640 logistics services definition above. Therefore, FDA would not generally consider such entities to
641 be 3PLs under the DSCSA. FDA expects the trading partner with which such a contractor is
642 contracting to be responsible for its activities. For example, if an entity is engaged in the
643 provision of its services as a contractor in a wholesale distribution facility that is not under
644 common ownership or control of the contractor and WDD, the contractor's activity would be
645 covered by the wholesaler's license and obligations for compliance.

646

647

6. Returns Processors and Reverse Logistics Providers

648

649 *A returns processor or reverse logistics provider* is defined in section 581(18) of the FD&C Act
650 as:

651

652 [A] person who owns or operates an establishment that disposes or otherwise
653 processes saleable or nonsaleable product received from an authorized trading partner
654 such that the product may be processed for credit to the purchaser, manufacturer, or seller
655 or disposed of for no further distribution.

656

657 FDA previously considered returns processors and reverse logistics providers to be 3PLs because
658 the definition at section 581(18) permitted these entities to handle saleable product. FDA has
659 received comments that some entities only handle products at the end of their lifecycle, either
660 returning nonsaleable products to the manufacturer for credit or dispositioning products for
661 destruction. FDA generally does not consider such entities to be 3PLs, as under these
662 circumstances, these products will not re-enter the supply chain. However, if an entity is
663 conducting activities for saleable returns that could put the product back into the pharmaceutical
664 supply chain by way of sale or transfer to a trading partner, it generally would be considered a
665 3PL, and 3PL requirements for licensure and reporting under section 584 of the FD&C Act
666 would apply. Additionally, if an entity takes ownership of the product or is responsible for
667 directing the sale or disposition of the product, FDA generally considers such entity to be

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668 engaged in wholesale distribution, subject to all the requirements for WDDs under the DSCSA.
669 Therefore, a returns processor or reverse logistics provider may be considered a 3PL, a WDD, or
670 neither depending on the activities it performs as described above.

671

672 **E. Dispensers as Trading Partners Under the DSCSA**

673

674 Section 581(3) of the FD&C Act states that *dispenser*:

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682

(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

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Under this definition, a *dispenser* is a pharmacy that does not act as a WDD, or any other person authorized to dispense or administer human prescription drugs. Furthermore, this definition redefines dispenser-affiliated warehouses and distribution centers as dispensers (these were previously considered to be WDDs under PDMA). Such warehouses and distribution centers are no longer considered WDDs, unless such facilities are also engaged in wholesale distribution activities.

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An entity that falls within the definition of dispenser in section 581(3) of the FD&C Act must comply with the requirements under section 582(d) of the FD&C Act. The statutory requirement for dispensers to exchange product tracing information became effective on July 1, 2015.

However, dispensers are not required to provide the product tracing information prior to, or at the time of, a transaction if the product is dispensed to a patient or if it is a sale by a dispenser to another dispenser to fulfill a “specific patient need.”⁵¹ The term *specific patient need* refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.⁵² This term 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.⁵³ Although a dispenser that sells a product to another dispenser to fulfill a specific patient need is not required to provide product tracing information, other requirements of section 582(d) of the FD&C Act may apply to the transferring and receiving pharmacies. Accordingly, such sales or transfers should be documented by each pharmacy in the normal course of business 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. To reiterate, a dispenser transferring product to another dispenser for a specific patient need is not required to provide product tracing information with the transfer. Transfers of product to another dispenser without a specific patient need may constitute wholesale distribution, and thus, the requirements for wholesale distributors in sections 582 and 583 of the FD&C Act may apply.

⁵¹ See section 582(d)(1)(A)(ii) of the FD&C Act.

⁵² See section 581(19) of the FD&C Act.

⁵³ *Id.*

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710 To be considered an authorized trading partner, a dispenser must have a valid license under State
711 law and accept or transfer direct ownership of a product from or to a manufacturer, repackager,
712 wholesale distributor, or dispenser.

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713 **Table 1. Summary of Authorized Trading Partners as Described in This Guidance**⁵⁴

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a <u>Trading Partner</u> When It	<u>Authorized</u> When It is
Manufacturer	<ul style="list-style-type: none"> • Manufactured the product • Approved application holder, or co-licensed partner of the approved application holder who obtained the product directly from a person described as a manufacturer under section 581(10) of the FD&C Act • Affiliate of manufacturer who obtained the product directly from a person described as a manufacturer under section 581(10) of the FD&C Act • Private label distributors who own and market a product under their own label 		<ul style="list-style-type: none"> • Salvagers as defined in 21 CFR 207.1 	<ul style="list-style-type: none"> • Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> • Registered with FDA in accordance with section 510 of the FD&C Act • Compliant with its obligations under section 510 of the FD&C Act • Compliant with its obligations under section 510 of the FD&C Act, if applicable. • Compliant with its obligations under section 510 of the FD&C Act

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⁵⁴ For discussion of the entities identified in this table, see section III., above.

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Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It is
Repackager	<ul style="list-style-type: none"> Owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction 		<ul style="list-style-type: none"> A dispenser, specifically a pharmacy, that is solely engaged in packaging and labeling a product for dispensing to an identified individual patient pursuant to a valid prescription 	<ul style="list-style-type: none"> Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> Registered with FDA in accordance with section 510 of the FD&C Act
Wholesale Distributor	<ul style="list-style-type: none"> Engaged in distribution of a drug to, or receipt of a drug by, a person other than a consumer or patient, with certain exceptions 	<ul style="list-style-type: none"> Jobbers, i.e., those engaged in wholesale distribution on a small scale or that sell product solely to retailers and institutions; dispensers who transfer product to another dispenser without a specific patient need 	<ul style="list-style-type: none"> A manufacturer distributing its own drug; a manufacturer’s co-licensed partner; a 3PL; a repackager; a dispenser; a dispenser-affiliated warehouse or distribution center; a dispenser who transfers product to another dispenser for a specific patient need; and other entities engaged in the distribution or receipt of a drug that falls under an exclusion from “wholesale distribution” pursuant to section 503(e)(4) of the FD&C Act, including but not limited to: emergency medical reasons; office 	<ul style="list-style-type: none"> Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> Has a valid license under State law or section 583 of the FD&C Act, in accordance with 582(a)(6) of the FD&C Act; in compliance with reporting requirements under section 503(e) of the FD&C Act

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Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It is
			use; non-human research, or research in humans under an IND		
3PL	<ul style="list-style-type: none"> Provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product 	<ul style="list-style-type: none"> Returns processors or reverse logistics providers conducting activities for saleable returns that put the product back into the pharmaceutical supply chain by way of sale or transfer to a trading partner 	<ul style="list-style-type: none"> Brokers, solution providers, common carriers, logistics or administrative services contractors, entities that only return nonsaleable product to the manufacturer for credit or disposition the product for destruction 	<ul style="list-style-type: none"> Accepts or transfers direct possession of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> Has a valid license under State law or section 584(a)(1) of the FD&C Act, in accordance with 582(a)(7) of the FD&C Act; in compliance with licensure reporting requirements under section 584(b) of the FD&C Act
Dispenser	<ul style="list-style-type: none"> Retail pharmacy, hospital pharmacy, or group of chain pharmacies under common ownership and control that do not act as a wholesale distributor 		<ul style="list-style-type: none"> Person who only dispenses products to be used in animals in accordance with section 512(a)(5) of the FD&C Act 	<ul style="list-style-type: none"> Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> Has a valid license under State law

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Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a Trading Partner When It	Entity is Authorized When It is
Dispenser	<ul style="list-style-type: none"> • Person authorized by law to dispense or administer prescription drugs • Affiliated warehouses or distribution centers of a dispenser under common ownership and control that do not act as a wholesale distributor 		<ul style="list-style-type: none"> • Person who only dispenses products to be used in animals in accordance with section 512(a)(5) of the FD&C Act 	<ul style="list-style-type: none"> • Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser 	<ul style="list-style-type: none"> • Has a valid license under State law

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