
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DRAFT GUIDANCE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)**

**August 2017
Procedural**

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1 **Identifying Trading Partners Under the Drug Supply Chain**
2 **Security Act**
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6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug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 and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
11

12
13
14
15 **I. INTRODUCTION**
16

17 The Food and Drug Administration (FDA or the Agency) is issuing this guidance to assist
18 industry and State and local governments in understanding how to categorize the entities in the
19 drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA).² DSCSA
20 establishes product tracing requirements for certain trading partners in the drug supply chain,
21 including manufacturers, repackagers, wholesale distributors, and dispensers. DSCSA also
22 requires that trading partners of manufacturers, wholesale distributors, dispensers, and
23 repackagers must meet the applicable requirements for being “authorized trading partners.”³
24 DSCSA also requires FDA to issue regulations that establish Federal standards for the licensing
25 of wholesale drug distributors (WDDs) and third-party logistics providers (3PLs). The Agency
26 is currently drafting these regulations. This guidance, when finalized, will explain FDA’s
27 current thinking on how licensing and certain other requirements apply to entities that may be
28 considered trading partners in the drug supply chain.
29

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

¹ This guidance has been prepared by the Division of Drug Supply Chain Integrity 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 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 Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 353(e), 360eee, and 360eee-3).

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

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

II. BACKGROUND

46
47
48 On November 27, 2013, DSCSA was signed into law. It outlines new requirements to develop
49 and enhance drug distribution security by 2023. In part, these changes include defining the types
50 of entities in the drug supply chain (i.e., manufacturers, repackagers, wholesale distributors,
51 3PLs, and dispensers), requiring that the trading partners of manufacturers, repackagers,
52 wholesale distributors, and dispensers meet the applicable requirements to be *authorized* trading
53 partners, and establishing national standards for the licensing of WDDs and 3PLs.
54

A. Definitions of Drug Supply Chain Entities Under DSCSA

55
56
57 DSCSA identifies and defines five types of entities in the prescription drug supply chain:
58 manufacturers, repackagers, dispensers, wholesale distributors, and 3PLs. DSCSA defines these
59 entities in section 581 of the FD&C Act (21 U.S.C. 360eee).
60

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

62
63 [W]ith respect to a product -- (A) a person that holds an application approved under
64 section 505 or a license issued under section 351 of the Public Health Service Act for
65 such product, or if such product is not the subject of an approved application or license,
66 the person who manufactured the product; (B) a co-licensed partner of the person
67 described in subparagraph (A) that obtains the product directly from a person described
68 in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described
69 in subparagraph (A) or (B) that receives the product directly from a person described in
70 this subparagraph or subparagraph (A) or (B).
71

72 Section 581(16) of the FD&C Act defines a *repackager* to mean “a person who owns or operates
73 an establishment that repacks and relabels a product or package for – (A) further sale; or (B)
74 distribution without a further transaction.”
75

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

77
78 (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under
79 common ownership and control that do not act as a wholesale distributor, or any other
80 person authorized by law to dispense or administer prescription drugs, and the affiliated
81 warehouses or distribution centers of such entities under common ownership and control
82 that do not act as a wholesale distributor; and (B) does not include a person who
83 dispenses only products to be used in animals in accordance with section 512(a)(5).
84

85 DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean “a person
86 (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider,

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87 or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C
88 Act, as amended by [DSCSA]).” Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4))
89 defines *wholesale distribution* as “distribution of a drug subject to [section 503(b) of the FD&C
90 Act (21 U.S.C. 353(b))] to a person other than a consumer or patient, or receipt of a drug subject
91 to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or
92 patient,” but exempts several specific activities.

93

94 DSCSA adds *third-party logistics providers (3PLs)* as a new entity in the drug supply chain,⁴
95 and requires 3PL facilities to be licensed and regulated separately from wholesale distributors.⁵
96 DSCSA defines a *3PL* in section 581(22) of the FD&C Act to mean:

97

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

102

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

106

B. Authorized Trading Partners Under DSCSA

107

108
109 DSCSA restricts access to the distribution system for prescription drug products by requiring
110 trading partners of manufacturers, wholesale distributors, dispensers, and repackagers meet the
111 applicable requirements for being authorized trading partners.⁶ DSCSA includes definitions for
112 *authorized*⁷ and *trading partner*⁸ with respect to each entity in the drug supply chain as follows:

113

114 • To be considered an authorized trading partner, a *manufacturer* or *repackager* must have
115 a valid registration in accordance with section 510 of the FD&C Act and accept or
116 transfer direct ownership of a product from or to a manufacturer, repackager, wholesale
117 distributor, or dispenser.

118

119 • To be considered an authorized trading partner, a *wholesale distributor* must have a valid
120 license under State law or section 583 of the FD&C Act, in accordance with section
121 582(a)(6) of the FD&C Act, comply with the licensure reporting requirements in section
122 503(e) of the FD&C Act, as amended by DSCSA, and accept or transfer direct ownership
123 of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

124

125 • Similarly, to be considered an authorized trading partner, a *3PL* must have a valid license
126 under State law or section 584(a)(1) of the FD&C Act, in accordance with section

⁴ Section 581(22) of the FD&C Act.

⁵ See section 585(b)(2) of the FD&C Act (21 U.S.C. 360eee-4).

⁶ See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1).

⁷ See section 581(2) of the FD&C Act.

⁸ See section 581(23) of the FD&C Act.

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127 582(a)(7) of the FD&C Act, comply with the licensure reporting requirements under
128 section 584(b) of the FD&C Act (21 U.S.C. 360eee-3), and accept or transfer direct
129 possession of a product from or to a manufacturer, repackager, wholesale distributor, or
130 dispenser.

- 131
- 132 • A *dispenser* must have a valid license under State law and accept or transfer direct
133 ownership of a product from or to a manufacturer, repackager, wholesale distributor, or
134 dispenser.

C. Licensure and Reporting Requirements for WDDs and 3PLs

135

136 DSCSA also establishes new licensure and reporting requirements for wholesale distributors and
137 third-party logistics providers.

138

139 Section 503(e) of the FD&C Act (as amended by DSCSA) establishes licensure requirements
140 and adds reporting requirements for WDDs. Specifically, section 503(e)(1) prohibits a person
141 from engaging in wholesale distribution of prescription drugs in any State unless such person is
142 licensed by the State from which the drug is distributed, or by FDA if such State from which the
143 drug is distributed has not established a licensure requirement. Furthermore, under certain
144 circumstances,⁹ such person must also be licensed by the State into which the drug is distributed.
145 Section 503(e)(2) of the FD&C Act requires WDDs to report certain information to FDA on an
146 annual basis, including State licensure information for each license, the name and address of
147 each licensed facility, and any significant disciplinary actions taken by a State or the Federal
148 government.¹⁰

149

150 DSCSA adds section 584 to the FD&C Act; the section sets forth requirements for licensure and
151 reporting by 3PL facilities. Specifically, section 584(a) prohibits a 3PL in any State from
152 conducting activities in any State unless each facility of the 3PL is licensed by the State from
153 which the drug is distributed by the 3PL, or by FDA if the State from which the drug is
154 distributed by the 3PL has not established a licensure requirement. Furthermore, under certain
155 circumstances,¹¹ the 3PL must also be licensed by the State into which the drug is distributed.
156 Section 584(b) of the FD&C Act requires 3PL facilities to report certain information to FDA,
157 including State licensure information for each facility and the name and address of each facility.

III. IDENTIFYING WHO IS A TRADING PARTNER

160

161

162

⁹ See section 503(e)(1)(A)(ii) – in relevant part, “if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.”

¹⁰ More information about reporting is on the Wholesale Distributor and Third-Party logistics Providers Reporting web page (<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm>).

¹¹ See section 584(a)(2) – 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.”

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164 FDA has received comments and inquiries about which entities meet the definitions of the
165 various trading partners. Whether an entity meets the statutory definition of a particular trading
166 partner that would trigger the applicable requirements depends on the activities in which it
167 engages. This may be particularly applicable to entities, such as private-label distributors,¹² who
168 may have a variety of business models and may meet the definitions of a variety of trading
169 partners. Please see the discussion below for each type of trading partner for more information.
170

171 There has also been confusion about how the definitions of *wholesale distributor* and *wholesale*
172 *distribution* changed upon enactment of the DSCSA. Regulations enacted prior to DSCSA
173 defined the term *wholesale distributor* to include manufacturers; repackers; own-label
174 distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers'
175 and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;
176 independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.¹³
177 Some of these listed entities are not included as wholesale distributors in the DSCSA.
178

179 In addition, section 581 of the FD&C Act defines different types of trading partners in the drug
180 supply chain, including manufacturers, repackagers, WDDs, 3PLs, and dispensers. Neither
181 section 503(e) nor section 581 of the FD&C Act lists the other types of entities included in the
182 regulations discussed above, at 21 CFR 203.3(dd). Consequently, several types of activities that
183 may fall within the definition of wholesale distribution under 21 CFR part 203 are not directly
184 addressed by the statutory definition of wholesale distribution in section 503(e) of the FD&C
185 Act, as amended by DSCSA. This may leave questions regarding the status of certain entities
186 under the DSCSA. For example, there has been confusion as to whether DSCSA licensure and
187 reporting requirements apply to certain types of entities, such as but not limited to jobbers,
188 brokers, and certain contractors and solution providers. To address some of the confusion
189 expressed by industry and the States, FDA is providing its current thinking on each of the trading
190 partners.
191

A. Manufacturers as Trading Partners Under DSCSA

192
193 DSCSA defines a *manufacturer* in section 581(10) of the FD&C Act as:

194
195 [W]ith respect to a product -- (A) a person that holds an application approved under
196 section 505 or a license issued under section 351 of the Public Health Service Act for
197 such product, or if such product is not the subject of an approved application or license,
198 the person who manufactured the product; (B) a co-licensed partner of the person
199 described in subparagraph (A) that obtains the product directly from a person described
200 in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described
201 in subparagraph (A) or (B) that receives the product directly from a person described in
202 this subparagraph or subparagraph (A) or (B).
203
204

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

¹² 21 CFR 207.1 (2016).

¹³ 21 CFR 203.3(dd) (1999).

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207
208 FDA has received comments and inquiries about how to determine whether a manufacturer is an
209 authorized trading partner. FDA believes that most of the confusion¹⁴ is related to the inclusion
210 of entities that hold drug approvals (aka NDA-, BLA-, or ANDA-holders¹⁵), co-licensed
211 partners, and affiliates of such entities in the definition of *manufacturer* in section 581(10) of the
212 FD&C Act, and the interaction of this definition with the requirement to register under section
213 510 of the FD&C Act to be “authorized” according to section 581(2).

1. Manufacturing Establishments

214
215
216 Under section 510 of the FD&C Act, and part 207 (21 CFR part 207), with some limited
217 exceptions, any person who owns or operates any establishment that manufactures, prepares,
218 propagates, compounds, or processes drugs in the United States, or that are offered for import
219 into the United States, must be registered with the FDA.¹⁶ Thus, under section 581(2)(A), such
220 manufacturer establishments must be registered in accordance with section 510 of the FD&C Act
221 to be considered an authorized trading partner.
222

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

223
224
225 An NDA-, BLA-, or ANDA-holder or co-licensed partner of a manufacturer might not engage in
226 the manufacturing, preparation, propagation, compounding, or processing of a drug, but could
227 still meet the definition of manufacturer in section 581(10) in the FD&C Act. There has been
228 confusion as to whether such manufacturers should register under section 510 of the FD&C Act
229 to be considered an authorized trading partner. FDA believes such an entity would be an
230 authorized trading partner without being registered under section 510 so long as the NDA-,
231 BLA-, or ANDA-holder, or co-licensed partner is compliant with its obligations under section
232 510 of the FD&C Act and with any other obligations under the DSCSA. We note, however, that
233 any person who owns or operates any establishment manufacturing, preparing, propagating,
234 compounding, or processing drugs in the United States, or that are offered for import into the
235 United States, must have a valid registration in accordance with section 510 to comply with the
236 FD&C Act.
237

3. Affiliate of a Manufacturer (Section 581(10)(C))

238
239 *Affiliate* is defined in section 581(1) of the FD&C Act as:
240

241
242 [A] business entity that has a relationship with a second business entity if, directly or
243 indirectly—

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

246 (B) a third party controls, or has the power to control, both of the business entities.
247

¹⁴ 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 DSCSA.

¹⁵ This refers to holders of an approved new drug application (NDA), biologics license application (BLA), or abbreviated new drug application (ANDA).

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

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248
249 FDA considers the situation described in paragraph (A) to be similar to a parent/subsidiary
250 business relationship (i.e., the parent has the power to control the business of the subsidiary).
251 FDA considers the situation described in paragraph (B) as describing a business relationship
252 where a third party controls the business of several entities, such as controlling both the parent
253 and the subsidiary. In other words, an *affiliate* is a business entity that legally controls another
254 business entity, directly or indirectly, or is controlled by another business entity; mere business
255 links or relationships are not sufficient to meet the definition of an *affiliate*.¹⁷ Manufacturers and
256 their affiliates retain responsibility for carrying out the activities and requirements under section
257 582(b) of the FD&C Act. To be considered a manufacturer under DSCSA, an affiliate of a
258 manufacturer as defined in 581(10)(A) or (B) of the FD&C Act must have received the product
259 directly from such a manufacturer.¹⁸

260

B. Repackagers as Trading Partners Under DSCSA

261

262
263 DSCSA defines *repackager* in section 581(16) of the FD&C Act as “a person who owns or
264 operates an establishment that repacks and relabels a product or package for – (A) further sale; or
265 (B) distribution without a further transaction.” Under section 510 of the FD&C Act, and under
266 part 207, with some limited exceptions, any person who owns or operates any establishment that
267 manufactures, prepares, propagates, compounds, or processes drugs in the United States or that
268 are offered for import into the United States must be registered with the FDA.¹⁹ This includes
269 repackagers of drugs.²⁰ Thus, such repackager establishments must be registered in accordance
270 with section 510 to be considered authorized trading partners.

271

272 An entity that falls within the definition of *repackager* in section 581(16) of the FD&C Act must
273 comply with the requirements under section 582(e) of the FD&C Act. However, FDA does not
274 consider a dispenser, specifically a pharmacy, that is solely engaged in packaging and labeling
275 drug product(s) for dispensing to an identified individual patient after the receipt of a valid
276 prescription for that patient (e.g., repackaging product into unit-dose packages for administration
277 to an identified individual patient), to be a repackager under DSCSA. Therefore, the
278 requirements in section 582(e) of the FD&C Act would not apply.

279

C. WDDs as Trading Partners Under DSCSA

280

281
282 DSCSA defines *wholesale distributor* in section 581(29) of the FD&C Act to mean “a person
283 (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider,
284 or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C
285 Act, as amended by [DSCSA]).” Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4))
286 defines *wholesale distribution* as “distribution of a drug subject to [section 503(b) of the FD&C
287 Act (21 U.S.C. 353(b))] to a person other than a consumer or patient, or receipt of a drug subject

¹⁷ This interpretation is consistent with the interpretation of *affiliate* previously described in 66 FR 59138 at 59146 (November 27, 2001).

¹⁸ See section 581(10)(C) of the FD&C Act.

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

²⁰ 21 U.S.C. 360(a)(1).

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288 to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] by a person other than the consumer or
289 patient,” but exempts several specific activities. An entity that falls within the definition of
290 *wholesale distributor* in section 581(29) of the FD&C Act must comply with the requirements
291 under section 582(c) of the FD&C Act.

292
293 FDA has received comments and inquiries about how to determine whether a WDD is an
294 authorized trading partner. Comments have stated that one source of confusion is that DSCSA
295 provides a definition of *wholesale distribution* in section 503(e) of the FD&C Act and a
296 definition for *wholesale distributor* in section 581 of the FD&C Act that differ from the
297 respective definitions in the regulations promulgated pursuant to sections 503(c), (d), and (e) of
298 the FD&C Act, as enacted by the Prescription Drug Marketing Act of 1987 (PDMA).²¹ Several
299 types of entities are not considered to be WDDs under DSCSA that were under these regulations.
300 Many of these entities are now considered to be 3PLs under DSCSA, and are discussed in the
301 next section.

302
303 Another source of confusion stems from uncertainty as to whether a manufacturer can also be
304 licensed as a WDD. The definition of *wholesale distribution*, as set forth in section 503(e)(4) of
305 the FD&C Act, as amended by DSCSA, excludes the distribution of a manufacturer’s own drug
306 (section 503(e)(4)(H)). As a result, if a manufacturer is only distributing its own drug, it would
307 not be engaged in wholesale distribution under DSCSA, and would not be required to comply
308 with the licensure and reporting requirements for WDDs under DSCSA.

309
310 Generally, but with exclusions enumerated in section 503(e)(4), an entity engaged in the
311 distribution of a drug subject to section 503(b) of the FD&C Act (21 U.S.C. 353(b)) to someone
312 other than a consumer or patient and that the entity did not manufacture, would be engaged in
313 wholesale distribution and subject to all the WDD requirements under DSCSA.

314
315 **Jobbers:** FDA considers a *jobber* to be a person or entity that owns or operates an establishment
316 that engages in wholesale distribution on a small scale, or sells product solely to retailers and
317 institutions. Jobbers engage in *wholesale distribution* because they own and direct the sale or
318 distribution of product to, and receive product from, a person other than a consumer or patient,
319 and are not otherwise excluded from the definition under section 503(e)(4) of the FD&C Act.
320 Jobbers are thus considered WDDs and are subject to the requirements for WDDs under DSCSA.

D. 3PLs as Trading Partners Under DSCSA

321
322
323 DSCSA defines *3PLs* broadly to include any entity that provides or coordinates warehousing, or
324 other logistics services of a product in interstate commerce on behalf of a manufacturer,
325 wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor
326 have responsibility to direct the sale or disposition of the product.²²

327
328
329 There has been confusion as to what activities would be considered “other logistics services”
330 within the definition of *3PL*. FDA’s current thinking is that *other logistics services* means

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

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

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331 services provided by entities that accept or transfer direct possession²³ of products from that
332 entity's facility within the United States and its territories on behalf of a trading partner (i.e.,
333 manufacturer, repackager, WDD, or dispenser). FDA also considers "other logistics services" to
334 include services provided by entities that accept or transfer direct possession of products from
335 that entity's facility within the United States and its territories on behalf of a repackager of
336 products for further sale or a repackager acting on behalf of a manufacturer, WDD, or dispenser.
337

338 *Trading partner*, with respect to 3PLs, is defined in part as having direct possession of
339 product.²⁴ Those 3PLs that do not accept or transfer direct possession of product are thus not
340 considered trading partners. Therefore, the "authorized trading partner" provisions of section
341 582 of the FD&C Act would not apply when manufacturers, wholesale distributors, dispensers,
342 and repackagers engage 3PLs who are not trading partners.²⁵
343

344 Furthermore, FDA considers the section 584 requirement that "each facility of such [3PL]"²⁶ be
345 licensed "in accordance with the regulations" to mean that 3PLs without a facility are not
346 required to be licensed. Section 584 provides that FDA will establish licensure standards that
347 centrally include requirements relating to storage of product. These standards address issues
348 with access and maintenance that presuppose the existence of a physical facility wherein product
349 is maintained.
350

351 Accordingly, FDA considers a *facility* to be an establishment, warehouse, structure, or structures
352 under common ownership at one general, permanent, physical location used to store or handle
353 prescription drug products. FDA would not consider a truck or shipping container used to
354 transport product to constitute a facility for purposes of DSCSA because such trucks or
355 containers are not consistently located at one physical location and would not sensibly be
356 covered by the storage requirements specific to 3PL facility licensure. Likewise, FDA would not
357 consider an establishment, warehouse, or structure that is not used to store or handle prescription
358 drug products to constitute a facility for purposes of section 584.
359

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

360
361
362
363 An entity that owns, rents, or leases a facility where it warehouses product, but does not take
364 ownership of, nor direct the sale or disposition of the product, is a 3PL under DSCSA. An entity
365 that owns, rents, or leases a facility under common ownership or control with another trading
366 partner, where it warehouses product but does not take ownership of, nor direct the sale or
367 disposition of the product, is also a 3PL under DSCSA. These entities could be engaged in
368 activities that include storage of products distributed by *consignment*.²⁷
369

²³ FDA considers *direct possession* to mean having physical, direct contact with the product.

²⁴ See section 581(23)(B) of the FD&C Act.

²⁵ See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act (21 U.S.C. 360eee-1).

²⁶ 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.

²⁷ FDA's current understanding of *consignment* involves the sale of a product by the manufacturer directly to the consumer where the product is stored and shipped by an entity on behalf of the manufacturer.

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370 2. *Brokers*

371
372 FDA considers a *broker* to be a person or entity, who facilitates business transactions between
373 two other trading partners, but does not take ownership of the product nor direct the sale or
374 disposition of a product. A broker does not provide or coordinate warehousing and does not
375 accept or transfer direct possession of the product and, therefore, is not considered a 3PL under
376 DSCSA. Thus, FDA generally would not consider the 3PL licensure requirements under
377 DSCSA to cover brokers.

378
379 However, if a person or entity acts as a seller or buyer, or directs the sale, purchase, or trade of a
380 product, such person or entity is a principal party to the transaction and is considered to be
381 involved in directing the sale or disposition of the product. FDA does not consider the lack of
382 direct possession of the product as a sufficient reason to preserve broker status because, as the
383 seller or buyer, the person or entity is accepting or transferring ownership of the product. A
384 person or entity engaged in this activity would not be considered a broker, but would likely meet
385 the definition of a manufacturer, WDD, repackager, or dispenser, depending on the
386 circumstances, and would be required to meet all of the applicable requirements under DSCSA.

387 388 3. *Solution Providers*

389
390 FDA considers a *solution provider* to be a person or entity that provides other entities hardware,
391 software, or systems solutions to help achieve compliance with the requirements under DSCSA.
392 A solution provider does not take ownership of the product nor direct the sale or disposition of a
393 product. Furthermore, a solution provider does not provide or coordinate warehousing and does
394 not accept or transfer direct possession of the product and, therefore, is not considered a 3PL
395 under DSCSA. Thus, FDA would not consider the 3PL licensure requirements under DSCSA to
396 cover solution providers.

397 398 4. *Common Carriers*

399
400 As it relates to the distribution of prescription drug products subject to DSCSA, FDA considers a
401 *common carrier* to be an entity that solely provides transportation services,²⁸ but does not take
402 ownership of the product nor direct the sale or disposition of the product. Common carriers do
403 not provide or coordinate warehousing for the products they transport. Although common
404 carriers accept and transfer direct possession of product, they do not store and handle product
405 from a facility, as defined above. Therefore, FDA would not consider the services provided by
406 common carriers to constitute other logistics services, and FDA would not consider common
407 carriers to be covered by the 3PL licensure requirements under DSCSA. The owner of the
408 product would remain responsible for compliance with any applicable storage and handling
409 requirements and for the product's safety and integrity during transit, and should select common
410 carriers that can provide appropriate safeguards.

411

²⁸ 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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5. Logistics or Administrative Services Contractors

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

6. Returns Processors and Reverse Logistics Providers

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

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

FDA considers *returns processors* and *reverse logistics providers* to be 3PLs because they are entities that provide *other logistics services* on behalf of other trading partners in a facility the returns processor or reverse logistics provider owns, rents, or leases, and they do not take ownership of nor direct the sale or disposition of the product. As indicated in the definition, such entities may execute the dispositioning of product, whether it is as a return, recall, or for disposal, but they are not responsible for directing whether the product is to be sold or dispositioned. This activity may include activity that has been referred to as "reverse distribution." However, if an entity takes ownership of the returned or dispositioned product or is responsible for directing the sale or disposition of the product, such entity does not meet the definition of a returns processor or reverse logistics provider, but rather is engaged in wholesale distribution, subject to all the requirements for WDDs under DSCSA.

E. Dispensers as Trading Partners Under DSCSA

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

(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

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458 that do not act as a wholesale distributor; and (B) does not include a person who
459 dispenses only products to be used in animals in accordance with section 512(a)(5).

460
461 Under this definition, a dispenser is a pharmacy that does not act as a WDD, or any other person
462 authorized to dispense or administer human prescription drugs. Furthermore, this definition
463 redefines dispenser-affiliated warehouses and distribution centers as dispensers (these were
464 previously considered to be WDDs under PDMA). Such warehouses and distribution centers are
465 no longer considered WDDs, unless such facilities are also engaged in wholesale distribution
466 activities.

467
468 An entity that falls within the definition of *dispenser* in section 581(3) of the FD&C Act must
469 comply with the requirements under section 582(d) of the FD&C Act. The statutory requirement
470 for dispensers to exchange product tracing information became effective on July 1, 2015.²⁹
471 However, dispensers are not required to provide the product tracing information prior to, or at
472 the time of, a transaction if the product is dispensed to a patient or if it is a sale by a dispenser to
473 another dispenser to fulfill a “specific patient need.”^{30,31} The term *specific patient need* refers to
474 the transfer of a product from one pharmacy to another to fill a prescription for an identified
475 patient. This term does not include the transfer of a product from one pharmacy to another for
476 the purpose of increasing or replenishing stock in anticipation of a potential need.³² Although a
477 dispenser that sells a product to another dispenser to fulfill a specific patient need is not required
478 to provide product tracing information, other requirements of section 582(d) and the FD&C Act
479 may apply to the transferring and receiving pharmacies. Accordingly, such sales or transfers
480 should be documented by each pharmacy in a manner that would facilitate appropriate actions by
481 the pharmacy in the event of an investigation of suspect or illegitimate product, recall, or
482 notification of illegitimate product. Transfers of product to another dispenser without a specific
483 patient need may constitute wholesale distribution, subject to the requirements for wholesale
484 distributors in sections 503(e), 582, and 583 of the FD&C Act.

485
486 To be considered an authorized trading partner, a *dispenser* must have a valid license under State
487 law and accept or transfer direct ownership of a product from or to a manufacturer, repackager,
488 wholesale distributor, or dispenser.
489

²⁹ FDA issued guidance explaining that the Agency did not intend to object to the failure to comply with certain requirements of section 582(d) of the FD&C Act, relating to the exchange of product tracing information before March 1, 2016. See FDA guidance for industry *DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy (Revised)*. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

³⁰ See section 582(d)(1)(A)(ii) of the FD&C Act.

³¹ The term *specific patient need* is defined in section 581(19) of the FD&C Act.

³² *Id.*

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490 Table 1. Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a <u>Trading Partner</u> When It	Entity is <u>Authorized</u> When It is
Manufacturer	Manufactured the product			Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Registered with FDA in accordance with section 510 of the FD&C Act
	Approved application holder, or co-licensed partner of the approved application holder who obtained the product directly from the application holder or person who manufactured the product				Compliant with its obligations under section 510 of the FD&C Act
	Affiliate ¹ of manufacturer who obtained the product directly from the application holder or person who manufactured the product				Compliant with its obligations under section 510 of the FD&C Act
Repackager	Owens or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction		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	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Registered with FDA in accordance with section 510 of the FD&C Act

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491 Table 1 (cont'd). Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a <u>Trading Partner</u> When It	Entity is <u>Authorized</u> When It/It is
Wholesale Distributor²	Engaged in distribution of a drug to, or receipt of a drug by, a person other than a consumer or patient, with certain exceptions	Jobbers, <i>i.e.</i> , 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	A manufacturer distributing its own drug; a manufacturer's co-licensed partner, a 3PL, a repackager, entities excluded from "wholesale distribution" pursuant to section 503(e)(4), a dispenser, a dispenser-affiliated warehouse or distribution center, or a dispenser who transfers product to another dispenser for a specific patient need	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	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, as amended by DSCSA; in compliance with reporting requirements under section 503(e)
3PL	Provides or coordinates warehousing or other logistics services with regard to 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	Returns processors or reverse logistics providers ³ that do not take ownership of the product and are not responsible for directing the sale or disposition of the product	Brokers, ⁴ solution providers, ⁵ common carriers, ⁶ logistics or administrative services contractors ⁷	Accepts or transfers direct possession of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	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, as amended by DSCSA; in compliance with reporting requirements under section 584(b)

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493 Table 1 (cont'd). Summary of Authorized Trading Partners*

Entity Type	Description of Activity	Other Entities Included	Entities Generally Not Included	Entity is a <u>Trading Partner</u> When It	Entity is <u>Authorized</u> When It
Dispenser	Retail pharmacy, hospital pharmacy, or group of chain pharmacies under common ownership and control that do not act as a wholesale distributor		Person who only dispenses products to be used in animals in accordance with section 512(a)(5)	Accepts or transfers direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser	Has a valid license under state law
	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				

494 * Content in merged cells applies to all the rows that run across those merged cells for each entity type.

495 ¹ See §581(1) of the FD&C Act.

496 ² See discussion in section III.C. above, pp. 7-8.

497 ³ See §581(18) of the FD&C Act, and discussion in section III.D.6. above, p. 11.

498 ⁴ See discussion in section III.D.2. above, pp. 9-10.

499 ⁵ See discussion in section III.D.3. above, p. 10.

500 ⁶ See discussion in section III.D.4. above, p. 10.

501 ⁷ See discussion in section III.D.5. above, pp. 10-11.