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DRAFT GUIDANCE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

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TABLE OF CONTENTS

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

The Food and Drug Administration (FDA or Agency) is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA).[2] This guidance revises the Agency's draft guidance for industry *Identifying Trading Partners Under the Drug Supply Chain Security Act* (August 2017) to address the status of some entities as trading partners (e.g., private-label distributors, salvagers, and returns processors and reverse logistics providers), provide clarification on certain drug distribution scenarios, and address the interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which discusses third-party logistics providers (3PL) licensure status prior to the effective date of the forthcoming regulations establishing licensure standards. The DSCSA establishes product tracing requirements for certain trading partners in the drug supply chain, including manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA also requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must meet the applicable requirements for being "authorized trading partners."[3] Additionally, the DSCSA requires FDA to issue regulations that establish Federal standards for the licensing of wholesale drug distributors[4] (WDDs) and 3PLs. The Agency is currently drafting these regulations. This guidance, when finalized, will explain FDA's current thinking on how certain DSCSA requirements apply to entities that are considered trading partners in the drug supply chain.

[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.

This guidance is intended to: (1) assist industry and State and local governments in understanding the applicability of DSCSA requirements to the various types of entities that take part in the distribution of prescription drugs in the United States[5]; and (2) help clarify for industry whether they are engaged in activities that require licensure and annual reporting, as well as other requirements related to being an authorized trading partner in the drug supply chain. The guidance does not address all requirements described in the DSCSA but is limited to describing the activities that would determine what type of trading partner an entity may be and the applicable requirements under the DSCSA.

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

II. BACKGROUND

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

A. Definitions of Drug Supply Chain Entities Under the DSCSA

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

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

> [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).

[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.

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

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

> (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).

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

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

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

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

> [A]n entity that 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 has responsibility to direct the sale or disposition of the product.

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

B. Authorized Trading Partners Under the DSCSA

The DSCSA restricts access to the distribution system for prescription drug products by 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)).

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

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

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

- Similarly, to be considered an authorized trading partner, a 3PL must have a valid license under State law or section 584(a)(1) of the FD&C Act, in accordance with section 582(a)(7) of the FD&C Act, comply with the licensure reporting requirements under section 584(b) of the FD&C Act (21 U.S.C. 360eee-3(b)), and accept or transfer direct possession of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser.

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

C. Licensure and Reporting Requirements for WDDs and 3PLs

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

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

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

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

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

> Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor licensing regulations under section 583, the term 'licensed' or 'authorized', as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law.[15]

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

> Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.[16]

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

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[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."

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

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

III. IDENTIFYING WHO IS A TRADING PARTNER

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

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

> . . . manufacturers; repackers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.[18]

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

[17] See https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.
[18] 21 CFR 203.3(dd) (1999).

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 confusion[19] 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).

the FD&C Act in order to be considered authorized trading partners, they still must comply with all other relevant obligations under the DSCSA. For example, the NDA-, BLA-, or ANDA-holder, or co-licensed partner should ensure that the product it transfers to another trading partner was manufactured by an authorized[21] entity that is registered under section 510 of the FD&C Act.[22] We note, however, that any person who owns or operates any establishment manufacturing, preparing, propagating, compounding, or processing drugs in the United States, or that are offered for import into the United States, must have a valid registration in accordance with section 510 to comply with the FD&C Act.

For purposes of the DSCSA, FDA interprets the term *co-licensed partner* of a manufacturer, referenced in section 581(10)(B) of the FD&C Act, to mean one of two or more entities that have entered into a written agreement for the right to engage in the marketing of a prescription drug. While the term *co-licensed partner* is not defined in the FD&C Act, the Agency believes this 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)

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

> [A] business entity that has a relationship with a second business entity if, directly or indirectly—
>
> (A) one business entity controls, or has the power to control, the other business entity; or
>
> (B) a third party controls, or has the power to control, both of the business entities.

FDA generally considers the situation described in paragraph (A) to be similar to a parent/subsidiary business relationship (i.e., the parent has the power to control the business of the subsidiary), and the situation described in paragraph (B) as describing a business relationship where a third party controls the business of several entities, such as controlling both the parent and the subsidiary. In other words, an *affiliate* is a business entity that legally controls another business entity, directly or indirectly, or is controlled by another business entity; mere business 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).

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

4. Private Label Distributors

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

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

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

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

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

This is different from the definition of manufacturer under section 510 of the FD&C Act and 21 CFR part 207, which requires establishments that manufacture, prepare, propagate, compound, or process drugs to register with the FDA. A private label distributor that does not manufacture, 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).

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

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

5. Salvagers

FDA generally does not consider a salvager to be a manufacturer under the DSCSA. A *salvager* is defined in 21 CFR 207.1 as a person who owns or operates an establishment that engages in salvaging. Salvaging means the act of segregating out those finished drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products that have been deemed acceptable for distribution to the marketplace, and includes applying manufacturing controls such as those required by current good manufacturing practice in 21 CFR parts 210 and 211.[30] Salvagers are required to register with FDA and report the National Drug Codes and lot numbers for product they have determined can be sold or used.[31] While FDA generally does not consider salvagers to be manufacturers for the purposes of the DSCSA, other activities that a salvager conducts may subject them to DSCSA requirements. For example:

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

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

- If a salvager does not take ownership of the drug products, but takes direct possession[32] of the products and conducts activities on behalf of another trading partner to determine 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.

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

B. Repackagers as Trading Partners Under the DSCSA

The DSCSA defines *repackager* in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction." FDA generally considers entities engaged in relabeling activities described in 21 CFR 207.1 to be repackagers under the DSCSA. Under section 510 of the FD&C Act and 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.[33] This includes entities that repackage or otherwise change the container, wrapper, or labeling of a drug in furtherance of the distribution of the drug.[34] Thus, repackagers under the DSCSA must register in accordance with section 510 of the FD&C Act to be considered authorized trading partners.

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

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

C. WDDs as Trading Partners Under the DSCSA

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

Section 503(e)(4) of the FD&C Act (21 U.S.C. 353(e)(4)) defines *wholesale distribution* as "distribution of a drug subject to [section 503(b) of the FD&C Act (21 U.S.C. 353(b))] to a person other than a consumer or patient, or receipt of a drug subject to [section 503(b) of the 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.

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

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

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

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

1. Distribution for Emergency Medical Reasons

Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency (PHE) declaration pursuant to section 319 of the Public Health Service Act, does not constitute wholesale distribution.[37] FDA generally considers this exclusion to cover distribution activities directly impacted by the PHE and distribution of products that are approved or authorized to diagnose, cure, mitigate, treat, or prevent the basis of the PHE.[38] In addition, FDA generally considers the following circumstances to constitute emergency medical reasons for purposes of section 503(e)(4)(C) of the FD&C Act and therefore to be excluded from the definition of wholesale distribution: (1) the distribution of a drug to a first responder or other authorized individual administering prescription drugs to acutely ill or injured persons in an emergency 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.

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

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

2. Distribution for Office Use

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

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

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

For the purposes of DSCSA requirements, wholesale distribution is limited to include only distribution of prescription drugs intended for use in humans.[40] Thus, the activities of the purchaser or receiver of drugs for non-human research purposes only do not fall into activities of a trading partner under the DSCSA and such purchaser or receiver would not be subject to requirements under the DSCSA for those transactions. While DSCSA product tracing does not apply, the receiver of drugs for non-human research purposes should maintain basic recordkeeping in the event of a drug recall. Examples of non-human research include studies 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*.

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

4. Distribution of Drugs for Research Purposes in Humans Under an IND

Section 503(e)(4) of the FD&C Act defines *wholesale distribution* as a distribution to a person "other than a consumer or patient." FDA generally considers an investigator[41] receiving drugs for clinical research purposes to be a "consumer" if the studies are either under an investigational new drug application (IND)[42] or bioavailability or bioequivalence studies regulated under 21 CFR part 320.[43] In these situations, FDA generally would not consider the seller to be a WDD within the meaning of the DSCSA, and the investigator, considered a "consumer," would not be considered a trading partner under the DSCSA. Accordingly, such investigator also would not be subject to DSCSA requirements.[44] Drugs received by an investigator for clinical research purposes should not re-enter the U.S. pharmaceutical supply chain.[45]

5. Jobbers

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

D. 3PLs as Trading Partners Under the DSCSA

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

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[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 adequate 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.

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.[46]

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

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

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

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

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

2. Brokers

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

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

3. Solution Providers

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

4. Common Carriers

As it relates to the distribution of prescription drug products subject to the DSCSA, FDA generally considers a *common carrier* to be an entity that solely provides transportation services[50] but does not take ownership of the product nor direct the sale or disposition of the 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.

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

5. Logistics or Administrative Services Contractors

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

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

E. Dispensers as Trading Partners Under the 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 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).

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.

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.

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

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 Trading Partner When It	Entity is Authorized When It is
Manufacturer	• 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		• Salvagers as defined in 21 CFR 207.1	• 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 • 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

continued

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

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	• Owns 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
Wholesale Distributor	• 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.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	• 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	• 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; in compliance with reporting requirements under section 503(e) of the FD&C Act

continued

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	• 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	• 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	• 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	• 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; in compliance with licensure reporting requirements under section 584(b) of the FD&C Act
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) of the FD&C Act	• 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

continued

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	• 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		• Person who only dispenses products to be used in animals in accordance with section 512(a)(5) of the FD&C Act	• 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

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