



Healthcare Distribution Alliance

PATIENTS MOVE US.

September 6, 2022

BY ELECTRONIC FILING

<http://www.regulations.gov>, Docket No. FDA-2017-D-1956

Connie T. Jung, R.Ph., PhD
Senior Advisor for Policy
Office of Drug Security, Integrity, and
Recalls
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
connie.jung@fda.hhs.gov

Aaron Weisbuch
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Aaron.Weisbuch@fda.hhs.gov

**Re: Identifying Trading Partners Under the Drug Supply Chain Security Act;
Revised Draft Guidance for Industry, 87 Fed. Reg. 40254 (July 6, 2022), Docket
No. FDA-2017-D-1956**

Dear Dr. Jung and Mr. Wesibuch:

The Healthcare Distribution Alliance (“HDA”) thanks the Food and Drug Administration (“FDA”) for this opportunity to submit comments regarding the agency’s Revised Draft Guidance, *Identifying Trading Partners Under the Drug Supply Chain Security Act*, 87 Fed. Reg. 40254 (July 6, 2022), (“Revised Draft Guidance”). HDA thanks FDA for issuing the Revised Draft Guidance. We supported the first version of this guidance when it was issued in August 2017 and we again see much that we support in the Revised Draft Guidance.

1. About HDA

HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 180,000 pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated. Many of HDA’s members also operate third-party logistics providers (3PLs).

2. Discussion of the Revised Draft Guidance – General Principles

a. Conformity with the Licensure Rule

In the Revised Draft Guidance at lines 29-32, FDA notes that it is “currently drafting” the regulations that establish Federal standards for the licensing of wholesale drug distributors and third-party logistics providers (“3PLs”). These national standards have indeed now been proposed, Proposed Rule, *National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers*, 87 Fed. Reg. 6708 (Feb. 4, 2022) (“Licensure Rule”). Though it will be some time before these national standards are final, it appears the agency has sought to align the Revised Draft Guidance with the proposed Licensure Rule. We support that effort and believe this guidance, when final, should cross-reference the Licensure Rule. Where we have specific comments on an issue that is in both the Revised Draft Guidance and the Licensure Rule, we have similarly endeavored to align our recommendations.

b. Licensure and Reporting Requirements for 3PLs and Wholesale Distributors

Section II.C. of the Revised Draft Guidance describes the requirements § § 583, 584 and 503(e) of the Federal Food, Drug & Cosmetic Act (“FD&C Act”) impose upon wholesale distributors and 3PLs. We believe section II.C. is an accurate statement of the DSCSA as we understand it.

3. “Virtual” Trading Partners

An innovation of the DSCSA is that the statute regulates based upon what a trading partner is actually doing, as opposed to how a trading partner characterizes itself. The Revised Draft Guidance emphasizes this point: “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.” Revised Draft Guidance at lines 216-218. We support this recognition in the Revised Draft Guidance.

The DSCSA has only five categories of trading partners: manufacturer, repackager, wholesale distributor, 3PL, and dispenser. What that trading partner does with respect to a particular transaction determines what it is and what it must do under § 581 and § 582, respectively. Manufacturers, repackagers, and wholesale distributors all can operate under a “virtual” business model in which each meets its respective definition in § 581 but does not take physical possession of product.¹ This type of entity may also have a duly registered manufacturing or repackaging establishment or a licensed wholesale distributor facility – or it may not – but as to certain transactions, it directs the manufacture, repackaging, storage, shipment, purchase and/or sale of a product without physically handling it. Given the uncertainty that can arise with virtual entities,² we urge FDA to clarify in the final version of the Revised Draft Guidance that virtual manufacturers, repackagers, and wholesaler distributors under the DSCSA *are* (with some exceptions) manufacturers, repackagers, and wholesale distributors, are

¹ The DSCSA triggers obligations based upon changes in ownership, not possession. *See* definition of “transaction” at § 581(24).

² Some States have created a special licensure category for virtual manufacturers, virtual repackagers, and/or virtual distributors.

regulated as such, and can be an authorized trading partner, assuming the virtual entity meets the requirements otherwise applicable.

a. Virtual Manufacturers

Practically speaking, virtual manufacturers are addressed in § 581(10) and the Revised Draft Guidance, which recognize the very common business arrangement where the drug application or license holder relies upon a contract manufacturing organization (“CMO”) to manufacture the product. The virtual manufacturer owns the product manufactured but does not have a registered establishment under § 510 as to that product because it did not physically undertake its manufacture. The virtual manufacturer directs the CMO where it should send the manufactured product – a wholesale distributor or 3PL typically – and is responsible for assuring DSCSA transaction data requirements are met with the change in ownership. A private label distributor, discussed in III.A.4. of the Revised Draft Guidance would also be referred to as a “virtual manufacturer.”

Though the Revised Draft Guidance does not use the term, we believe it adequately describes and covers the activity of a “virtual manufacturer.” For clarity and to offer guidance to regulators and trading partners, we ask that FDA specifically state in the final version of the Revised Draft Guidance that, for DSCSA purposes, a virtual manufacturer is a manufacturer. Suggested language might be the following after line 263, with additions in **blue bold**:

An entity that meets the definition of “manufacturer” in Section 581(10) but that does not physically produce the products (and thus cannot register its establishment under § 510), whether or not it takes physical possession of the product after manufacture, will be considered by FDA to be a “virtual manufacturer.” FDA deems “virtual manufacturers” to be “manufacturers” (for DSCSA purposes) regardless of whether they physically handle product. Such trading partners are subject to all the applicable requirements for manufacturers in section 582 of the FD&C Act, including the product tracing, product identifier, authorized trading partner, and verification requirements. A virtual manufacturer would need to comply only with those requirements applicable to an establishment that does not actually manufacture products.

b. Repackagers as Trading Partners

In our 2017 comment, we asked that FDA address the issue of “virtual” repackagers. The Revised Draft Guidance did not do so and we respectfully repeat the request.

The “repackager” definition in § 581(16) begins by stating that a repackager is “a person who owns or operates an establishment that repacks and relabels a product or package...” Like a manufacturer, a repackager is authorized if it is registered under § 510. § 581(2)(A). Thus, repackager arrangements will pose the same challenges as the manufacturer arrangements discussed above and in section III.A. of the Revised Draft Guidance. That is, if an entity contracts with an FDA-registered establishment to have its products repackaged (*i.e.*, uses a contract repackager), the entity directing but not actually doing the repackaging is not required (nor eligible) to be registered as a repackager, under

§ 510. Unlike the manufacturer discussion in lines 226-237, however, the repackager discussion in section III.B. of the Draft Guidance does not address how a repackager can be authorized when it cannot be registered because it is not actually performing the repackaging or relabeling.

We suggest the following clarification, to be inserted after line 418, with additions in **blue bold**:

An entity that meets the definition of “repackager” in Section 581(16) but that does not physically repackage the products (and thus cannot register its establishment under § 510), whether or not it takes physical possession of the product after repackaging, will be considered by FDA to be a “virtual repackager.” FDA deems “virtual repackagers” to be “repackagers” (for DSCSA purposes) regardless of whether they physically handle product. Such trading partners are subject to all applicable requirements for repackagers in section 582 of the FD&C Act, including the product tracing, product identifier, authorized trading partner, and verification requirements. A virtual repackager would need to comply only with those requirements applicable to an establishment that does not actually repackage products.

If an entity that directs repackaging but does not actually undertake such activities itself is *not* deemed to be a repackager under the DSCSA, we are uncertain what it would be and ask the agency for clarification on this issue.

Repackagers are also faced with the same difficulties as manufacturers in demonstrating that they are authorized when they are not, themselves, undertaking the repackaging of a product at a facility registered under § 510 of the FD&C Act. We suggest the following to replace lines 403-405 to align the repackaging provisions of the Revised Draft Guidance with section III.A. applicable to manufacturers, with deletion in ~~red strikeout~~ and additions in **blue bold**.

~~Thus, repackagers under the DSCSA must register in accordance with section 510 of the FD&C Act to be considered authorized trading partners.~~

A repackager will be deemed to be an authorized trading partner with respect to a product if it:
(A) is registered in accordance with section 510 of the FD&C Act; or
(B) arranges for the product to be repackaged by an establishment described in subparagraph (A).

c. Virtual Wholesale Distributors

A “wholesale distributor” is an entity that engages in wholesale distribution, which means it is not a manufacturer or repackager as defined in § 581(10) and § 581(16), respectively, and, with some exceptions, purchases and sells prescription drugs to persons other than consumers and patients.³ The FD&C Act does not require that a wholesale distributor ever take physical

³ See Revised Draft Guidance at lines 422-433; § 581(29) (definition of “wholesale distributor”), § 503(e)(4) (definition of “wholesale distribution”).

possession of a product – it must only own the product, not be a manufacturer or repackager, and not be distributing the product to a consumer or patient. We believe that the existing definitions of “wholesale distributor” and “wholesale distribution” include both wholesale distributors that take physical possession of prescription drugs and “virtual” wholesale distributors that do not. Such “virtual” wholesale distributors rely upon other entities, such as 3PLs, to provide logistical services, including taking physical possession, but never ownership, of prescription drugs.⁴ However, they are still engaged in wholesale distribution as defined in the FD&C Act.

We suggest the following clarification, to be inserted after line 455, with additions in **blue bold**:

An entity that meets the definition of “wholesale distributor” in Section 581(29) but does not take physical possession of the product will be considered by FDA to be a “virtual wholesale distributor.” FDA deems “virtual wholesale distributors” to be “wholesale distributors” (for DSCSA purposes) even if they do not physically handle the product that they own. Such trading partners are subject to all applicable requirements for wholesale distributors in section 582 of the FD&C Act, including the product tracing, authorized trading partner, and verification requirements. A virtual wholesale distributor would need to comply only with those requirements applicable to a facility that does not take physical possession of products. For example, a virtual wholesale distributor would not be expected to have the security systems necessary for the physical protection of prescription drugs or to have processes around maintenance of refrigerators and freezers for storing products that must be stored at cold temperatures. To the extent a “virtual distributor” uses a contractor to carry out any of its duties, it would need to comply with § 205.26(c).

4. Manufacturers as Trading Partners

a. Affiliates

As part of their DSCSA obligations, HDA members need to be able to ensure that their manufacturer suppliers are authorized. Section III.A. of the Revised Draft Guidance advises on numerous manufacturing arrangements and scenarios, including manufacturers with their own establishments, application and license holders with a co-licensed partner that manufactures the product, and affiliates. We support the additional clarity the Revised Draft Guidance provides.

We repeat a request from our 2017 comment to the original version of this guidance⁵ where we asked that FDA provide further clarification regarding “affiliates” of manufacturers as

⁴ In the Licensure Rule proposed § 205.26(c) would impose responsibilities upon a wholesale distributor that contracted out any of its duties: “If a wholesale distributor uses a contractor to carry out any of its duties, the wholesale distributor remains responsible for compliance with this subpart and must ensure that the contractor abides by the applicable written policies and procedures.”

⁵ FDA first issued this guidance in draft in 2017, 82 Fed. Reg. 40159 (Aug. 24, 2017), Dkt. No. FDA-2017-D-1956. HDA submitted comments on that draft, available [here](#).

defined in § 581(10). Affiliates of manufacturers are deemed to be manufacturers under § 581(10). Section § 581(10)(C) provides that, to be an affiliate of a manufacturer, the affiliate must “receive” the product from the application holder, its co-licensed partner, or another affiliate of the manufacturer. We were concerned in 2017 that the word “receive” might be interpreted to require an affiliate to take physical possession and custody of the product when an affiliate could own a product without ever having had physical possession of it. For example, the affiliate of the drug’s application holder could acquire ownership of a product and direct its delivery to the affiliate’s 3PL for subsequent distribution. We believe the affiliate should be deemed a “manufacturer” under the DSCSA because it technically received the product, though not physically, and then directed its distribution.

The Revised Draft Guidance repeats the same “receive” language from the 2017 guidance, without change. *See* lines 319-321. It is possible that the use of this “receive” language is an artifact of the Prescription Drug Marketing Act and pre-DSCSA requirements that focused upon locations of products and physical possession rather ownership of products. Of course, the DSCSA’s focus is not upon changes in physical possession, but changes of ownership in covered transactions.⁶

We ask that the agency clarify that “receive” in § 581(10)(C) *does not* require the manufacturer’s affiliate to physically take possession of product. Rather, and consistent with the DSCSA, “receive” should mean that the manufacturer’s affiliate has received or receives *ownership* of the product. “Receive” should not be limited to physical custody and should encompass any business arrangement in which an affiliate sources or otherwise obtains a product from its affiliated manufacturer.

b. Private Label Distributors

The Revised Draft Guidance states at lines 342-348 that “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.” While the actual business arrangement might vary, we agree with the Revised Draft Guidance that, generally, private label distributors are manufacturers under the DSCSA and would be regulated as such.

5. Wholesale Distributors as Trading Partners

Section III.C. of the Revised Draft Guidance sets out what is and is not wholesale distribution. We generally agree with the Revised Draft Guidance and offer comments only on a few aspects of section III.C where we believe additional expansion or clarification may be useful.

a. Distribution by Manufacturer or Repackager of its Own Products

At lines 443-448, the Revised Draft Guidance emphasizes that, pursuant to § 503(e)(4)(H), manufacturers distributing their own products are not wholesale distributors. We agree that this very important restatement of the law should be included in the final guidance.

⁶ § 581(24) (definition of “transaction” “means the transfer of product between persons in which a change of ownership occurs”).

There is a similar exception for repackagers, however, that is not included in the Revised Draft Guidance. Section 503(e)(4)(K) provides that repackagers distributing their own products are also not engaged in wholesale distribution. We recommend that the final guidance make clear that repackagers may also distribute their own products without being classified as wholesale distributors. We suggest the following language be added, modeled on lines 443-448, with additions in **blue bold**:

As set forth in § 503(e)(4)(K), if a repackager 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.

There is also persistent confusion regarding whether “virtual” manufacturers and repackagers may distribute their own products without being categorized as a wholesale distributor. As discussed above, assuming that a manufacturer or repackager otherwise meets the respective definitions in § 581(10) and § 581(16), they *are* manufacturers and repackagers, respectively, even if they do not physically handle the product they own. Such entities do not meet the definition of “wholesale distributor” and are not engaged in “wholesale distribution” as those terms are defined. We suggest the following clarifying language after line 455, with additions in **blue bold**:

A “virtual” manufacturer or “virtual” repackager that directs the distribution of its own drug regardless of whether it takes physical possession of its own drug is not 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. Such trading partners are subject to all applicable requirements for manufacturers and repackagers in section 582 of the FD&C Act, including the product tracing, authorized trading partner, product identifier, and verification requirements. A virtual manufacturer or repackager would need to comply only with those requirements applicable to an establishment that does not physically manufacture or repackage products.

The above notwithstanding, we note that a virtual manufacturer or repackager may sometimes take physical possession of the product that was manufactured or repackaged on its behalf by a § 510-registered manufacturing or repackaging establishment. The virtual manufacturer or repackager may then direct a 3PL to distribute the product on its behalf, or it may sell the product to a customer. We do not believe this physical possession changes the trading partner status of a virtual manufacturer or virtual repackager to that of a wholesale distributor given that the virtual manufacturer or virtual repackager is directing distribution only of its own product. We ask that FDA include this clarification in the final guidance.

b. Minimal quantities for office use

The Revised Draft Guidance provides that the agency “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.” Revised Draft Guidance at lines 495-500. FDA adopted the same definition in the Licensure Rule in proposed § 205.3(h). We supported this definition in our comment to the Licensure Rule and support it here.

In our Licensure Rule comments, we also suggested that the agency describe and abbreviate the “5% rule” differently as it is often confused with the DEA “5% rule,” 21 C.F.R. § 1307.11, which permits a practitioner who is registered to dispense limited amounts of controlled substances to another practitioner under certain conditions.⁷ Additionally, many States have their own versions of a “5% rule,” that exempt various dispenser activities from wholesale distribution licensure requirements. We believe continued use of the same term could lead trading partners to believe that these individual State “5% rules” remain in effect and have been endorsed by FDA when they are, in fact, preempted under § 585 if inconsistent with § 581, § 582, and/or the Licensure Rule (once finalized). We suggest referring to this important limitation as “the minimal quantities rule” or “rule on the limit on sales for office use” rather than as the “5% rule.”

The preamble to the Licensure Rule also addresses how it is not wholesale distribution if a pharmacy’s “sales and trades” to another pharmacy are to fulfill a specific patient need. 87 Fed. Reg. at 6714. We suggest the final guidance specifically address the DSCSA requirements for dispenser borrows, loans, and trades.

HDA agrees with the Draft Guidance’s statement that “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.” We encourage FDA to also emphasize that, if an entity is engaging in wholesale distribution it must meet *all* applicable requirements under the final Licensure Rule *and* § 582. To help avoid ambiguity and possible differences in interpretation, we also encourage FDA to include examples of what is required of wholesale distributors under § 582, such as the requirements for receiving, providing, and maintaining electronic, interoperable transaction data.

c. Distribution for Research Uses

We appreciate FDA’s efforts to clarify that drugs distributed for use in clinical trials and for research purposes are not wholesale distribution. The Revised Draft Guidance explains that “FDA generally considers an investigator receiving drugs for clinical research purposes to be a

⁷ The DEA “5% rule” is based on the “total number of dosage units of all controlled substances ... dispensed...” whereas the FDA “5% rule” is based on “the total annual dollar volume of prescription drug sales...” These are two very different measures of sales volumes that we believe could easily be confused.

‘consumer’ if the studies are either under an investigational new drug application (IND) or bioavailability or bioequivalence studies regulated under 21 CFR part 320.” Revised Draft Guidance at lines 517-521 (footnotes omitted). As § 503(e)(4) defines wholesale distribution as a distribution to a person “other than a consumer or patient,” sales to an investigator do not constitute wholesale distribution.

FDA adopted similar reasoning in the Licensure Rule in proposed § 205.3(j), the definition of “other than a consumer or patient.” Proposed § 205.3(j)(3) states that

(j) *Other than a consumer or patient* means the person receiving the drug is not:

...

(3) The clinical investigator, as defined in § 312.3(b) of this chapter.

We believe that the Revised Draft Guidance would be clearer if it more closely followed the format and language of the Licensure Rule. Additionally, we believe the Revised Draft Guidance should clarify that distributions to both investigators *and* clinical trial sites are not “to a person other than a consumer or patient.” Because we believe uncertainty continues to persist around the practice, we ask that the Revised Draft Guidance also clarify that distributions of both the investigational new drug and any approved comparator are outside the definition of wholesale distribution when the distribution is to an investigator or to a clinical trial site. We suggest editorial changes consistent with our comment on the Licensure Rule that are intended to clarify this important exception to wholesale distribution.

We recognize that the Revised Draft Guidance deems clinical trial sites and investigators as akin to “consumers” for purposes of distributions to them. We are concerned, however, that this interpretation could lead to a conclusion that licensed wholesale distributors that sell to these entities are “dispensers” and so must be licensed as such. This is, of course, not the case, and we ask that the agency specifically state that a licensed wholesale distributor that sells drugs for clinical research to an investigator or clinical trial site is not a dispenser.

We suggest the following changes to lines 517-525 of the Revised Draft Guidance, with footnotes omitted, additions in **blue bold** and strikeouts in ~~red~~:

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 **or clinical trial site** receiving **investigational new or approved** drugs for clinical research purposes to be a “consumer” if the studies are either under an investigational new drug application (IND) or bioavailability or bioequivalence studies regulated under 21 CFR part 320.

In these situations, FDA generally would not consider the seller to be **engaged in wholesale distribution** ~~a WDD~~ within the meaning of the DSCSA. **FDA generally would also consider the investigator or clinical trial site to be ;** ~~considered~~ a “consumer.” ~~;~~ ~~would not be considered a trading partner under the DSCSA.~~ Accordingly, such investigator **or clinical trial site would not be considered a trading partner and also** would not be subject to DSCSA

requirements. Drugs received by an investigator **or clinical trial site** for clinical research purposes should not re-enter the U.S. pharmaceutical supply chain. **A licensed wholesale distributor is permitted to sell drugs for clinical research purposes and FDA would not consider them to be a dispenser.**

6. 3PL as Trading Partner

The Revised Draft Guidance explains what is and is not a 3PL. As with the discussion of wholesale distributors, we generally agree with the Revised Draft Guidance and offer comments only on a few aspects of section III.D where we believe additional expansion or clarification may be useful.

a. Other Logistics Services

Lines 544-552 discuss what activities would be considered “other logistics services” within the definition of 3PL:

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. [emphasis supplied]

We support this definition in the Revised Draft Guidance as it addresses the omission of repackagers from the statutory definition of entities that 3PLs provide warehousing and other logistics services to in § 581(22). The Revised Draft Guidance also recognizes that a repackager uses a 3PL both for the repackager’s own purposes, and when the repackager is acting on behalf of another trading partner.

The Revised Draft Guidance definition, however, differs from the definition of “other logistics services” in § 205.3(i) of the Licensure Rule. Proposed § 205.3(i) states:

(i) *Other logistics services* include services provided by entities that accept or transfer direct possession of products from that entity’s facility within the United States and its territories on behalf of a trading partner (e.g., manufacturer, wholesale distributor, dispenser) but that do not take ownership of the product nor have the responsibility to direct a product’s sale or disposition. ‘Other logistics services’ also means services undertaken with respect to a product for a repackager acting on behalf of a manufacturer, wholesale distributor, or dispenser.

A key difference between the Revised Draft Guidance and the proposed § 205.3(i) in the Licensure Rule is that the Revised Draft Guidance includes “repackager” with manufacturer, wholesale distributor and dispenser in the parenthetical. We believe that the Revised Draft Guidance offers the better description of the services a 3PL provides to a repackager and we recommend that § 205.3(i) in the Licensure Rule conform to it.

To further clarify the role of a 3PL, we suggest adding the following (in **blue bold**) to the final version of the Revised Draft Guidance. This insert was included in proposed § 205.3(i) of the Licensure Rule:

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) **but that do not take ownership of the product nor have the responsibility to direct a product’s sale or disposition.** 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.

b. “Transactions with other trading partners”

Lines 554-558 state the following (footnotes omitted, emphasis in original):

Trading partner, with respect to 3PLs, is defined in part as having direct possession of product. 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.

We are concerned with the implication in the above language that manufacturers, wholesale distributors, dispensers and repackagers are conducting “transactions” with 3PLs when they, in fact are not. Indeed, if it were a transaction, the 3PL would no longer be a 3PL because it was engaged in a change of ownership and had become the owner of the product. We suggest deleting the second line of the above paragraph so that it reads:

Trading partner, with respect to 3PLs, is defined in part as having direct possession of product, **but not ownership of it.** ~~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.

c. Warehousing and Common Carriers

Lines 616-629 explain why common carriers are not 3PLs (footnotes omitted):

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 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 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.

We generally agree with this explanation and thank FDA for its inclusion. We believe another important distinction is that 3PLs and wholesale distributors warehouse products, whereas common carriers and other transportation and logistics entities do not. Warehousing is typically understood to mean *storing* physical inventory for sale or distribution. Though common carriers and other entities may have warehouse-like transportation hubs and facilities, products are only moving through them during the shipping and delivery process; products are not being stored, as they would be with a 3PL or wholesale distributor. We suggest adding the following to the discussion of common carrier in section III.D.4., additions in **blue bold**:

Common carriers may have transportation hubs and other physical facilities, but they do not warehouse products, in contrast to 3PLs and wholesale distributors.

7. Dispenser as Trading Partner

We support section III.E. regarding dispensers. As discussed above, we suggest that the Revised Draft Guidance address the DSCSA requirements for dispenser borrows, loans, and trades. We also recommend that section III.E. emphasize that, if a dispenser engages in wholesale distribution, it must be licensed as a wholesale distributor and meet all other requirements applicable to wholesale distributors under § 581- § 583 and § 503(e) and the Licensure Rule (once final), including receiving, providing, and maintaining electronic, interoperable transaction data.

The Revised Draft Guidance does not describe one instance in which a dispenser may transfer ownership of a product without providing transaction data and being licensed as a wholesale distributor – when it returns a product to the wholesale distributor it bought that product from.

We discussed this returns issue in our comment on the Draft Guidance, *Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs*, 87 Fed. Reg. 13738 (March 10, 2022) (“Verification Systems Draft Guidance”). The last sentence of the Verification Systems Draft Guidance, at lines 612-614, states: “Until November 27, 2023, a dispenser may return product to the trading partner it purchased the product from without providing the related transaction history, transaction information, and transaction statement.” This sentence is supported by Footnote 72 which cites to § 582(d)(1)(C)(i) – “A dispenser may return product to the trading partner from which the dispenser obtained the product without providing [transaction information, transaction statement, or transaction history] required under subparagraph (A).” Footnote 72 also cites to § 582(k)(2) which provides that § 582(d)(1)(C)(i) sunsets on November 27, 2023.

This sentence has led to some concern among stakeholders that, after November 27, 2023, FDA assumes that dispensers must begin providing to their wholesale distributor the transaction data for each saleable return (returns being limited to those products the dispenser purchased from that wholesale distributor, § 581(17)). Though not cited in the Verification Systems Draft Guidance, § 582(d)(1)(A)(ii) makes clear that the dispenser does not have to provide transaction data for this saleable return:

A dispenser ... prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (*but not including dispensing to a patient or returns*) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; ... (emphasis supplied)

Section 582(d)(1)(A)(ii) does not sunset.

In our comments on the Verification Systems Draft Guidance we asked FDA to clarify that, where the dispenser is returning product to the wholesale distributor it purchased the product from, the dispenser does not need to provide transaction data to the wholesale distributor, even though a change of ownership is occurring. We ask that FDA include that exception here in the final version of the Revised Draft Guidance as well.

* * *

HDA thanks FDA for this opportunity to comment on the Revised Draft Guidance and we urge its swift finalization and release.

If you have any questions, please contact me at 703-885-0240 or aducca@hda.org.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs