
Dear Dr. Jung:


HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 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.

HDA thanks FDA for issuing the Draft Guidance and the clarity it is intended to bring regarding definitions of trading partners. HDA agrees with and supports much of the Draft Guidance. In the discussion below, we note our support for specific provisions where we believe the Draft Guidance is especially helpful. In a few instances, we request clarification or recommend modifications.
I. Discussion of third party logistics providers (3PLs) in Sections II.B. and III.D.

In lines 125-127, FDA states that to be considered an authorized trading partner, a 3PL must, among other things, have a valid license under state law or § 584(a)(1), in accordance with § 582(a)(7). In order to minimize the risk of confusion for state law enforcement, we ask that FDA specifically acknowledge that 3PLs are deemed authorized until FDA issues licensure standards. See § 582(a)(7).

We also thank FDA for the thoughtful analysis of 3PLs in Section III.D. and lines 324-358 of the Draft Guidance. We support this Section and recommend no changes to it.

II. Discussion in Section III, regarding identifying who is a trading partner.

A. HDA strongly supports FDA’s statement in lines 165-167.

In lines 165-167, FDA states:

Whether an entity meets the statutory definition of a particular trading partner that would trigger the applicable requirements depends on the activities in which it engages.

In the experience of wholesale distributors, confusion persists, particularly among some dispensers and state licensing authorities, regarding the significance of the definitions in the DSCSA. HDA strongly supports the language quoted above, but suggests strengthening the language to emphasize that a trading partner’s status depends on what it does in a transaction, and that this analysis must be done on a product-by-product and transaction-by-transaction basis. For example, if a company that traditionally has operated as a wholesale distributor does not take ownership of a new line of product that it ships from its distribution center, then the entity would be considered a 3PL as to those products and must also be licensed as a 3PL. Similarly, if an entity that historically has operated as a dispenser sells a product to a wholesale distributor, it has engaged in a transaction as a wholesale distributor and must be licensed as such in order to lawfully engage in that transaction.

B. HDA strongly supports FDA’s discussion of wholesale distributors in lines 171-179.

FDA explains that there has been confusion regarding the applicability of the very broad definition of “wholesale distribution” in 21 C.F.R. § 203.3(dd) (implementing the Prescription Drug Marketing Act of 1987 (PDMA)) and whether entities such as brokers and solution providers are wholesale distributors. We appreciate and support FDA’s clarification that the DSCSA definitions of wholesale distributor and wholesale distribution in § 581 and § 503(e) determine DSCSA applicability and compliance requirements, including requirements associated with product distribution, licensure and reporting. We further suggest revision of 21 C.F.R. Part 203 to reflect enactment of the DSCSA.

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1 All citations are to relevant sections of the Federal Food, Drug and Cosmetic Act or “FD&C Act”.
2 Public Law 100-293.
III. Discussion in Section III.A., regarding manufacturers as trading partners.

A. HDA appreciates FDA’s efforts to explain application holders’ status as authorized trading partners in lines 226-237, but believes additional clarity would be useful.

We appreciate FDA’s recognition of the lack of alignment between § 510 of the FDC Act regarding when a manufacturer is required to register and the DSCSA’s definition of “manufacturer” in § 581(10). FDA recognizes that, under certain circumstances, a drug-application holder that meets the definition of “manufacturer” under the DSCSA (§ 581(10)) might not engage in the type of manufacturing activities that would allow it to register under § 510 (e.g., it uses a contract manufacturer to produce the drug) and so would not be able to meet the DSCSA’s definition of “authorized” (§ 581(2)).

FDA seeks to resolve this confusion by stating that:

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 and with any other obligations under the DSCSA.

Draft Guidance at lines 231-233.

However, we note that an application holder in this scenario could not be “compliant with its obligations under section 510” because it has no obligations under § 510. For clarity, we recommend lines 231-233 be revised as follows:

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 and with any other obligations under the DSCSA.

Similar language also appears in column 3 on page 13 of the Draft Guidance and we recommend amending that text to be consistent with the above suggestion.

We suggest the additional clarification that the application holder or its co-licensed partner would be authorized only if the drugs were manufactured by an entity that is registered under § 510.

B. HDA believes further clarification in line 258 regarding affiliates of manufacturers would be useful.

In lines 257-258, the Draft Guidance explains that the definition of “manufacturer” in § 581(10) provides that an affiliate of a manufacturer must “receive” product from the manufacturer—that is, the application holder, its co-licensed partner, or another affiliate of the manufacturer. We are concerned that the word “receive” might be interpreted to require an affiliate to have physical custody
of the product. However, it is possible for an affiliate to “own” a product without ever having had physical possession. For example, if the affiliate of an application holder acquires title to a product, yet the product is delivered to the affiliate’s 3PL for subsequent distribution, the affiliate should be deemed a “manufacturer” under the DSCSA despite having not physically received the product.

We ask that the Agency clarify that in this context, “receive” in § 581(10) is not limited to physical custody and encompasses any other business arrangement in which an affiliate sources or otherwise obtains a product from its affiliated manufacturer.

IV. Discussion in Section III.B., regarding repackers as trading partners.

The “repackager” definition in § 581(16) begins by stating 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, discussed in lines 263-278, pose the same difficulties as those with manufacturers discussed above in Section III.A. 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 performing the repackaging or relabeling.

We suggest the following insertion after line 271 to provide a clarification. The insertion is modeled on the language in lines 226-233:

FDA deems a trading partner to be a repackager when it directs a product that it owns to an FDA-registered establishment for repackaging and/or relabeling, and does not repackage or relabel the product itself. This repackager also would be an authorized trading partner without being registered under section 510 so long as it is compliant with its other obligations under the DSCSA.

We believe the above language aligns with the definition of “repackager” in § 581(16) because the “operation” of a repackaging establishment could encompass a trading partner directing its products to an establishment contracted for repackaging and relabeling services. Note that we suggest in the above insert that the repackager must direct the product to a repackaging establishment registered under § 510.

Column 3 on page 13 of the Draft Guidance also states that a repackager must be registered in accordance with § 510. This language would need to be revised if FDA, as requested above, recognizes that a repackager that directs a product it owns to an FDA-registered establishment for repackaging and relabeling can be an authorized trading partner even though it does not repackage or relabel the product itself.
If FDA chooses not to accept our proposal, we request that the Agency address how such entities would be regulated under the DSCSA. They certainly would not meet the definition of “manufacturer,” nor would the definition of “wholesale distributor” seem appropriate.

V. Discussion in Section III.C., regarding wholesale distributors as trading partners.

HDA supports the views expressed in Section III.C. of the Draft Guidance. We note that manufacturers have been required in some states to obtain wholesale distributor licenses when distributing their own products. We, therefore, appreciate FDA noting that, under § 503(e)(4)(H), “if a manufacturer is only distributing its own drug, it would not be engaged in wholesale distribution under DSCSA, and would not be required to comply with the licensure and reporting requirements for [wholesale distributors] under DSCSA.” Draft Guidance at lines 306-308.

We also support FDA’s discussion that, unless subject to an exception in § 503(e)(4), any entity (other than a manufacturer) that distributes a drug to someone other than a consumer or patient is engaged in wholesale distribution. Draft Guidance at lines 310-313. Some state regulatory authorities and dispensers continue to be confused regarding what constitutes wholesale distribution and the limited exceptions to the definition in § 503(e)(4). We urge FDA to communicate explicitly and directly to state regulators and the dispenser community regarding the types of transactions that constitute wholesale distribution and the associated requirements – including licensure as a wholesale distributor – when engaging in such transactions.

VI. HDA does not believe that FDA can or should regulate via a draft guidance, for the first time, that reverse logistics providers/returns processors are 3PLs under the DSCSA and asks FDA to clarify lines 430-448, and amend Table 1.

The Draft Guidance states:

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 considers returns processors and reverse logistics providers to be 3PLs because they are entities that provide other logistics services on behalf of other trading partners in a facility the returns processor or reverse logistics provider

3 We believe this position aligns with the Guidance for Industry: Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act, Compliance Policy (Feb. 2017).
owns, rents, or leases, and they do not take ownership of nor direct the sale or disposition of the product.

Draft Guidance at lines 430-441.

HDA associate members include many returns processors and reverse logistics providers (collectively “returns processors”). In consultation with them and our primary wholesale distributor members (who ship product returns to returns processors), we offer brief comments on why we do not believe imposing DSCSA requirements upon returns processors as 3PLs for the first time via the Draft Guidance is appropriate. We urge FDA to issue a clarifying statement as soon as possible to avoid the significant confusion this designation may cause in the supply chain and with state regulators.

A. Returns processors have an important, unique role in the supply chain that is distinct from others, including 3PLs.

A necessary consequence of millions of units of pharmaceuticals rapidly moving forward in the supply chain every day is that a small percentage of those units will not be dispensed or administered to patients and will need to be returned for disposition and credit from the manufacturer issued to the wholesale distributor who bought them. Pharmaceutical returns processors play a unique and critical role in the safe and secure management of these products. Returns processors are appropriately permitted under state laws to gather and evaluate products in centralized, secure locations. These permitting requirements vary by state.

Returns processors manage the end of a single product unit’s life cycle in the pharmaceutical supply chain. As the Draft Guidance notes, correctly, returns processors do not take title to products. They are acting on behalf of manufacturers, wholesale distributors, and dispensers to aid in credit determinations and help determine and accomplish the product’s appropriate, safe and secure disposition. Returns processors also assist in regulatory actions and law enforcement by processing drugs removed from distribution due to recalls, and other regulatory and legal activities.

Most fundamentally, returns processors are unlike the trading partners described in the DSCSA. Trading partners are dedicated to moving products forward for dispensing and administration to patients. Returns processors’ activities come at the end, when the product is no longer retained for distribution or dispensing and is safely removed from the supply chain.

B. We do not believe returns processors should be regulated for the first time via the Draft Guidance.

Though neither 3PLs nor returns processors take title to products, their functions in the supply chain are fundamentally different – and these are differences the DSCSA itself recognizes. Congress defined each entity separately. In comparison to a 3PL, which “provides or coordinates warehousing, or other logistics services of a product in interstate commerce” (§ 581(22)), a returns processor “dispositions or otherwise processes” products so that “the product may be processed for credit” or “disposed of for no further distribution” (§ 581(18)). Nor does the DSCSA intend for returns processors to comply with the full set of obligations
imposed upon 3PLs. In the many federal requirements now applicable to 3PLs (authorized trading partner status (§ 581(2),(23)), licensure (§ 584(a)), reporting of licensure status to FDA (§ 584(b)), the DSCSA does not appear to indicate any intention to mandate that returns processors also comply with these requirements. Some of the licensure standards for 3PLs in § 584 also do not appear to apply to returns processors, such as the assumptions that product is being distributed for further use, rather than only for credit assessment and/or disposition.

Until FDA released the Draft Guidance, there has been no indication that returns processors are subject to the full set of DSCSA requirements applicable to 3PLs, particularly as Congress defined and placed returns processors in a category that is distinct from 3PLs.

Though a draft guidance is not binding and only reflects the Agency’s current thinking, this sudden declaration that returns processors are 3PLs under the DSCSA has potentially serious legal repercussions. Returns processors have, to date, been operating in compliance with applicable law. Under the Draft Guidance, it is unclear if they should now scramble to obtain 3PL licenses, submit 3PL licensure information to FDA, and otherwise comply with the DSCSA when, heretofore, the only provision impacting them was that nonsaleable returns did not need transaction data (see, e.g., § 582(b)(4)(F), § 582(c)(1)(B)(ii)). Further, state regulators will likely look upon the Draft Guidance as a persuasive, and even definitive, interpretation of the DSCSA and may move to impose new requirements upon returns processors.

Given all the above, and in support of our returns processor members, HDA recommends the following to FDA:

1) FDA should immediately clarify that, at this time, it does not intend to require returns processors to meet all the requirements for 3PLs under the DSCSA. FDA should also revise lines 430-448 of the Draft Guidance and amend Table 1 accordingly.
2) Rather than making this dramatic change via a draft guidance, HDA believes it would be beneficial, appropriate, and necessary, for FDA to first offer an opportunity for public comment on the full set of issues and analyses associated with returns processors in the pharmaceutical supply chain, including but not limited to, the DSCSA requirements, the impacts on small businesses under the Regulatory Flexibility Act and the paperwork burden as under the Paperwork Reduction Act.
3) Should FDA ultimately conclude that returns processors should be regulated as 3PLs, FDA would need to address the unique status of returns processors in the forthcoming 3PL licensure standards regulations. Specifically, as long as a returns processor only handles products intended for credit determination and disposition, many of the requirements that would otherwise apply to 3PLs should not be applicable to returns processors.

VII. Discussion of Section III.E., regarding dispensers as trading partners.

HDA supports FDA’s explanation of the DSCSA’s clear distinctions between dispensers and wholesale distributors. We also appreciate FDA’s reminder to stakeholders that the PDMA definitions of dispenser-affiliated warehouses and distribution centers no longer apply. Further, under
the DSCSA, such facilities would be considered dispensers, not wholesale distributors, unless engaged in wholesale distribution. Draft Guidance at lines 461-466.

HDA is also aware that confusion persists regarding the types of exchanges that constitute a change of ownership, and when such changes constitute wholesale distribution, thus triggering wholesale distributor licensure and other requirements. We encourage FDA to continue efforts to clarify these concepts and how the various DSCSA requirements apply under each circumstance.

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HDA thanks FDA for this opportunity to provide comments and suggestions on FDA’s publication of the Draft Guidance on Identifying Trading Partners under the Drug Supply Chain Security Act. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs