Healthcare Distribution Alliance

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Re: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, Proposed Rule, 87 Fed. Reg. 6708 (Feb. 4, 2022), Docket No. FDA-2020-N-1663

Dear Dr. Jung and Mr. Weisbuch:

The Healthcare Distribution Alliance (HDA) thanks the Food and Drug Administration (FDA) for this opportunity to submit comments regarding the agency's Proposed Rule, *National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers*, 87 Fed. Reg. 6708 (Feb. 4, 2022) ("proposed rule" or "licensure rule"). We greatly appreciate the agency's efforts to propose national standards for licensure of pharmaceutical wholesale distributors and third-party logistics providers (3PLs). We recognize the work the proposed rule represents and look forward to working with FDA to implement a national uniform system for licensure of wholesale distributors and 3PLs as envisioned in the Drug Supply Chain Security Act (DSCSA).

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 prescription drug wholesale distributor members also have separate third-party logistics provider (3PL) businesses.

Introduction

HDA represents the entities most impacted by the proposed rule – the wholesale distributors and 3PLs that will have to comply with these national standards. Our members are currently licensed under the fifty-state patchwork of licensure requirements that the DSCSA was enacted to eliminate and HDA was a strong advocate of including stronger, uniform licensure requirements in the law. We have closely examined the proposed rule and considered, for each provision, if it comports with current practice for both the regulated and regulator and, if it does not, whether it is consistent with DSCSA and, if so, whether we deem it achievable with a commitment of time and resources. We further considered whether each provision of the proposed rule furthers the intended purpose of making the pharmaceutical supply chain more secure.

Our detailed comments are presented in three parts:

- This cover letter, which addresses certain larger and/or complex issues best presented in a prose format;
- HDA's analysis of preemption under § 585(b) (HDA Preemption Analysis) (see **Attachment 1**); and,
- A chart, organized by section of the proposed rule, with specific comments, and with suggested editorial changes and additions (see **Attachment 2**). In the chart, we provide a 3-column presentation:
    - column 1 - citation to the relevant provision(s);
    - column 2 - comments and/or discussion of that provision; and,
    - column 3 - suggested edits to the relevant provision(s), with **additions in blue bold** and ~~strikeouts in red~~.

  To facilitate the agency's review of our extensive comments and suggested editorial changes to the proposed rule, we provide our chart in rich text format (RTF) and portable document format (PDF).

While the overall length of our comment, including the attached detailed chart, might convey an impression of profound disagreement with the proposed rule, that is not the case. Our own model rules were one of the sources FDA used in drafting and we support much of the proposed rule. That we omit discussion of particular sections of the proposed rule in the attached chart does not mean that we do not support them.

One reason for the length of our comments is the numerous instances in which the 3PL and wholesale distributor provisions address the same substantive area but are not parallel and we could not discern a statutory basis for the difference. We believe compliance will be more smoothly accomplished, with a better understanding of responsibilities and requirements, if the two sections are as closely aligned as possible and so do not convey the perception that they impose different requirements. Seemingly minor differences may distract both the regulated and regulator with whether the difference is meaningful and intended, mandated by differences in the DSCSA, or simply a drafting artifact. The differences may also result in additional complications for States performing their role(s) in implementation. For example, State regulatory authorities may take longer to evaluate the information provided in each type of license application or may need to conduct more complex and lengthy State inspector training programs to understand the differences. Thus, the variability in requirements for the two types of entities, i.e., 3PLs and Wholesale Distributors, raises the potential for the States to experience greater costs and/or delays as they strive to implement the final rule's requirements.

Consequently, we have compared each wholesale distributor requirement to the analogous 3PL section and, where the differences do not appear rooted in statute, we seek to align the two provisions. Our suggestions in these instances should not be construed as disagreement with the proposed rule necessarily, but with our belief that the 3PL and wholesale distributor provisions should be parallel wherever possible.

Below we address the following:

1. The DSCSA Section 585 and preemption[1]
2. The need for clear guidance to State licensing authorities
3. The importance of licensure of wholesale distributor ***facilities***
4. The difficulties posed by the "unfit for distribution" principle in the proposed rule
5. A response to certain concerns we understand have been raised by some States' licensing authorities

1. The DSCSA Section 585 and Preemption

Section 585(b)(1) expressly preempts State and local requirements with respect to the licensure of wholesale distributors and 3PLs. In the preamble to the proposed rule, FDA states that it "interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the [Federal, Food, Drug and Cosmetic] FD&C Act. In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted." 87 Fed. Reg. at 6735. FDA included HDA's previous legal analysis of § 585 preemption as a reference in the preamble; our 2015 comment is included as Reference 5 to this proposed rule and is available here.

We strongly concur with FDA's interpretation and believe it comports with the plain language of the law, recent case law, and the intent of Congress. However, we understand some stakeholders disagree with the agency's position or are uncertain as to the scope of the DSCSA's preemption of State licensure requirements. We have, therefore, taken this opportunity to update our 2015 preemption analysis to include recent case law and these proposed rules. HDA's *Analysis of Preemption of State and Local Licensure Requirements With Respect to Licensure of Wholesale Distributors and Third-Party Logistics Providers in § 585(b) of the Federal, Food, Drug and Cosmetic Act* is included as Attachment 1.

2. The Need for Clear Guidance to State Licensing Authorities

In several instances, the agency expresses in vague terms the requirements the licensure rule imposes upon licensing authorities. For instance, "While § 205.6 is only applicable to 3PLs obtaining a license from FDA, FDA suggests that States implement similar procedures." 87 Fed. Reg. at 6717. Similarly, 87 Fed. Reg. at 6724 states, "While this section is only applicable to wholesale distributors obtaining a license from FDA, FDA suggests States implement similar procedures to ensure that all

[1] As mentioned above, the more detailed HDA Preemption Analysis is provided as a separate document, Attachment 1.

wholesale distributor licenses issued are consistent with the proposed regulation pursuant to section 503(e)(1)(B) of the FD&C Act."

We do not believe the adoption of the federal standards should be a "suggestion" for States to adopt "similar" standards. Rather, and as we present in the HDA Preemption Analysis, preemption dictates that States should implement ***the same*** procedures and requirements. *See* 87 Fed. Reg. at 6735 (State requirements must be "the same as Federal requirements"). Moreover, we believe these and any other qualified or equivocal suggestions in the preamble are more likely to confuse licensing authorities who are looking for guidance from the agency on what they are supposed to do with this new regime. The licensing rule should explain how States should implement these new national standards. To address this point, we suggest an addition to the proposed rule § 205.2 – ***Purpose***, to provide this instruction (also provided in section 2, Attachment 2, i.e., our accompanying chart):

> **§ 205.2 Purpose.**
>
> **(a)** The purpose of this part is to establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including a process for the revocation, reissuance, and renewal of such licenses. This part also establishes the process and standards the Food and Drug Administration will use to approve third-party organizations to evaluate the qualifications of 3PLs for licensure and conduct inspections of wholesale distributor facilities.
> **(b) Section 585 of the FD&C Act requires national uniformity for the licensure of 3PLs and prescription drug wholesale distributors. To the extent that a State establishes its own licensure standards, the State (including the licensing authority) must adopt these standards, terms, and conditions in their entirety without change.**

Moreover, recommendations in the preamble that States adopt requirements "similar" to the national standards should be changed to mandatory language, *e.g.*, "While this section is only applicable to wholesale distributors obtaining a license from FDA, ~~FDA suggests~~ States **must** implement ~~similar~~ **the same** procedures to ensure that all wholesale distributor licenses issued are consistent with the proposed regulation pursuant to section 503(e)(1)(B) of the FD&C Act." 87 Fed. Reg. at 6724.

In a recent final rule, FDA provided a preemption roadmap for States in new 21 C.F.R. § 800.30(h). *See* Final Rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 87 Fed. Reg. 50698, 50736-38 (August 17, 2022) (OTC Hearing Aid Rule). The final rule, and the proposed rule before it (86 Fed. Reg. 58150 (Oct. 20, 2021)), contained numerous examples of State requirements that were, and were not, preempted. In the final rule, the agency also provided resources for States and localities to use when seeking guidance on which requirements were preempted. The agency stated: "State or localities that have questions about preemption may contact the Center for Devices and Radiological Health (CDRH)'s Ombudsman at cdrhombudsman@fda.hhs.gov or FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov." 87 Fed. Reg. at 50737. We believe such support could be useful in implementation of the final licensure rule.

3. The Importance of the Licensure of Wholesale Distributor Facilities

Proposed rule § 205.20 states:

> (a) No wholesale distributor may engage in wholesale distribution of a prescription drug unless the **person** is licensed:
>
> > (1) By the State from which the drug is distributed; or
> > (2) If the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and
> > (3) If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.
>
> [emphasis supplied]

Thus, the proposed rule provides that no wholesale distributor may engage in wholesale distribution unless the "person" is licensed." The 3PL provision, in contrast, in proposed § 205.4(a), requires that each "facility" be licensed.

We believe this situation is arising from ambiguity in the FD&C Act which refers to license of a "person" engaged in wholesale distribution (*see, e.g.,* § 583 and § 503(e)), with a potential implication that a wholesale distribution facility does not have to hold a license but only be inspected. Requiring only a "person" engaged in wholesale distribution to be licensed could be read as permitting a single, corporate entity-wide license that covers each and all of a corporation's facilities.

However, HDA's wholesale distributor members do not believe this is a sound interpretation of the DSCSA's requirements, even if it could dramatically reduce their licensure burdens. We believe supply chain security depends upon each, individual, wholesale distribution facility being licensed. This is the current regime in every State, and we do not believe the DSCSA was intended to lessen or eliminate this oversight, but only to assure that State and federal standards for that oversight be the same. Not requiring a wholesale distributor facility to be licensed, as 3PL facilities must be, in our view represents a potentially significant gap in security and accountability.

We urge FDA to clarify, in § 205.20 and elsewhere in the licensure rule[2] that there must a license for ***each*** facility engaged in wholesale distribution, including virtual wholesale distributors.

> Proposed § 205.20(a)
>
> (a) No ~~wholesale distributor~~ **entity** may engage in wholesale distribution of a prescription drug **from a facility** unless ~~the person~~ **the facility** is licensed:
>
> > (1) By the State **in which the facility is located** ~~from which the drug is distributed~~; or

[2] In our attached chart, Attachment 2, we recommend changes in numerous places to clarify that wholesale distributor facilities must be identified in applications, inspected, and licensed and that a license should not be issued to a single corporate "person" engaged in wholesale distribution. *See, e.g.,* section 11, *Submission of Licensure Application General Requirements Wholesale Distributors, Proposed § 205.22*.

(2) If the State **in which the facility is located** ~~from which the drug is distributed~~ has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and
(3) If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.

Although we believe that the DSCSA did not intend to eliminate the current scheme of facility licensure for wholesale distributors, wholesale distributors also operate "virtual" models where a wholesale distributor takes ownership, but not physical possession, of a product. 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 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. Wholesale distributors include those that take both ownership ***and*** physical possession of prescription drugs and those that take ownership ***but not*** physical possession. Such "virtual" wholesale distributors commonly rely upon other entities, such as 3PLs, to provide logistical services.[4]

Regardless of whether an entity engaged in wholesale distribution takes physical possession of product it owns or relies upon others to do so, it ***is*** a wholesale distributor, is covered and regulated by all applicable provisions of the FD&C Act and this licensure rule, and must be licensed under these national standards.[5] The only relevant distinction between a wholesale distributor that physically handles products it owns and one that does not is that, of course, a virtual wholesale distributor would need to comply only with those requirements applicable to a facility that does not take physical possession of products. A "virtual" wholesale distributor would not, for instance, be expected to have the security systems, equipment, and processes that are 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.

We suggest the following to clarify the status and obligations of virtual wholesale distributors.

New 205.__

To the extent that an entity engaged in wholesale distribution takes ownership but not physical possession of prescription drugs, it is a

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[3] *See, e.g.,* Identifying Trading Partners Under the Drug Supply Chain Security Act Revised Draft Guidance for Industry (July 2022) (available here) at lines 69-116 (citing § 581(10) (definition of manufacturer), § 581(16) (definition of repackager), § 581(3) (definition of dispenser), § 581(29) (definition of wholesale distributor), § 581(22) (definition of 3PL)). See also § 503(e)(4) (definition of "wholesale distribution").
[4] Pursuant to proposed § 205.26(c), "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] We believe State requirements would be preempted if they regulate "virtual wholesale distributors" as distinct from wholesaler distributors that take possession of the products they own. All wholesale distributors would be subject to these national standards and any different State requirements would be preempted.

> **wholesale distributor and must comply with all requirements of this part applicable to such an entity, including being appropriately licensed under these national standards. A wholesale distributor that does not take physical possession of the product that it owns would need to comply only with those requirements applicable to a facility that does not take physical possession of products, and, to the extent it uses a contractor to carry out any of its duties, would need to comply with § 205.26(c).**

4. The Difficulties Posed by the *Unfit for Distribution* Principle in the Proposed Rule

The definition of *unfit for distribution*, proposed § 205.3(m), is a very important concept in the proposed rule:

> (m) *Unfit for distribution* means a prescription drug that has been identified as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act. This includes prescription drugs identified as suspect or illegitimate pursuant to section 582(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(c)); adulterated pursuant to section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), including drugs rendered nonsaleable because conditions such as return, recall, damage, or expiry cast doubt on the drug's safety, identity, strength, quality, or purity; or misbranded pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Requirements around the identification and handling of unfit products (for 3PLs) and unfit prescription drugs (for wholesale distributors) appear throughout the proposed rule. *See, e.g.*, proposed § 205.10(c)(2) and § 205.26(b)(1)(vi) (separation of products by 3PLs and wholesale distributors); proposed § 205.12(c)(1) and § 205.26(c)(4) (inbound and outbound shipping container inspection for 3PLs and shipping container examination for wholesale distributors); proposed § 205.26(c)(5)(i) and § 205.12(c)(4) (inventory management for 3PLs and wholesale distributors). Because "unfit for distribution" is so central to the licensure rule, we believe there must be a very clear, precise definition of the term so that compliance with requirements associated with such products/drugs is achievable given that wholesale distributors and 3PLs have very limited visibility into the many things that might result in a product meeting this definition of "unfit for distribution."

We appreciate that the proposed definition of "unfit for distribution" recognizes the distinction between suspect and illegitimate products under §§ 581 and 582 and products that, though they are unfit for distribution, are not suspect or illegitimate. We thank FDA for recognizing this principle.

However, the definition in proposed § 205.3(m) is otherwise overbroad, particularly given the many instances where the proposed rule links legal requirements to products that are or may be "unfit for distribution." We are very concerned with a definition that bluntly declares that any product in violation of the misbranding provisions of the FD&C Act, for example, is necessarily unfit for distribution. Very minor non-compliance, such as what would arise from minor packaging or labeling anomalies, would, under this definition, render such products unfit for distribution even though they are still safe for their intended use, pure, and held under appropriate conditions to maintain their integrity and strength.

More concerning is that in many and perhaps most instances, a wholesale distributor or 3PL would not know or even be able to detect most of the deficiencies that would render a product unfit for

distribution under this definition. Only the most obvious problems would be discernable to a 3PL or wholesale distributor, such as if a product has plainly visible damage or is expired, or if the 3PL or wholesale distributor has received a notification from a trading partner or government authority that the product is suspect or illegitimate, adulterated, misbranded, or being recalled, or otherwise not fit for distribution.

We appreciate that the definition in proposed § 205.3(m) does attempt to limit its scope with the first sentence, clarifying that "unfit for distribution" "means a prescription drug ***that has been identified*** as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act" (emphasis supplied). However, this qualifier does not go far enough as it is very possible that another trading partner or governmental entity has identified a product as unfit for distribution but has not communicated that information to the 3PL or wholesale distributor.

We therefore ask for more clarity around "that has been identified" and that this important qualifier be included in relevant parts of the licensure rule that link responsibilities with unfit product. Without further qualification and consistent use of this qualifier throughout the licensure rule, wholesale distributors and 3PLs could otherwise be responsible for products they had no way of knowing were unfit. An aggressive interpretation could also result in conservative actions, including the removal from distribution – and potential shortage – of products that are otherwise completely fit for distribution and safe for patient use.

As reflected in the attached chart of comments (Attachment 2), where a wholesale distributor or 3PL must undertake certain actions regarding product that is unfit for distribution (*e.g.*, an inspection of outbound product/prescription drugs), we recommend edits to the proposed rule[6] to clarify that these obligations apply only when the 3PL or wholesale distributor has either: (1) itself identified a product/prescription drug as unfit for distribution, or, (2) has received a notice from a trading partner or other entity, such as FDA or a State licensing authority, that a product/prescription drug is unfit for distribution. In this way, a 3PL or wholesale distributor is not responsible for taking (or not taking) prescribed actions for products or prescription drugs that it has no way of knowing are unfit for distribution.

5. Concerns Raised By State Regulators

We are aware of concerns raised by some State licensing authorities regarding aspects of the licensure rule. We respond to some of those concerns we have learned of below:

- We understand some licensing authorities have objected to FDA's interpretation of § 585(b)(1). As discussed in the HDA Preemption Analysis attached to this submission, we support FDA's position that States may not establish or continue licensure requirements for 3PLs or wholesale distributors unless those State requirements are the same as Federal requirements. 87 Fed. Reg. at 6735. This position is supported by the plain language of the

[6] In our attached chart, Attachment 2, we recommend changes to several parts of the proposed rule to clarify that "unfit for distribution" obligations arise from products identified by the 3PL or wholesale distributor as unfit for distribution. *See, e.g.*, section 14, Separation of Saleable and Unsaleable Products for 3PLs, Proposed § 205.10(c)(2), and Separation of Prescription Drugs for Wholesale Distributors, Proposed § 205.26(b)(1)(vi); section 22, Inspection & Handling of Inbound & Outbound Shipments for 3PLs, Proposed Rule § 205.12(c)(1), and Examination of Shipping Containers for Wholesale Distributors, Proposed Rule § 205.26(c)(4).

law, decades of Supreme Court cases interpreting the preemptive phrases in § 585(b)(1), the recent case law, and legislative history.

- We believe certain State authorities have objected to FDA licensure of out-of-state 3PLs because the State would not then be able to require the out-of-state 3PL to obtain a license to ship product into the State. This provision in the licensure rule is dictated by § 584(a)(2) and a different outcome would require a legislative change.

- State licensing authorities have raised concerns about the use, qualifications, and ethics of approved third-party organizations (referred to in the licensure rule as "AOs") to conduct inspections. We do not read the licensure rule as requiring a State to use AOs to conduct inspections or review 3PL license applications if it does not wish to do so. Other States have already outsourced their inspectional duties to third parties. Wholesale distributors have found these inspections very comprehensive. We agree that there should be robust rules around AO inspectors and inspection programs to prevent them from profiting from an inspectional outcome and believe all compensation should be handled by the licensing authority that retains AOs, rather than the regulated entity, to avoid any appearance of impropriety. We address these and other AO points in our chart, Attachment 2, in section 51.

- We understand that State authorities may be concerned with the co-located facility requirements in the proposed rule. The proposed rule permits separate licensees at a single location, *e.g.*, co-location of a 3PL and a wholesale distributor within the same building. We agree that the products of different licensees at the same location should be maintained separately, with each entity maintaining a separate inventory, whether physically or electronically. We explain in our comment that, though co-located businesses should generally maintain "separate" systems and processes, sharing some common, company-wide systems should be permissible. It can be beneficial to both organizations' efficiency, continuity, and security if they can maintain certain common, company-wide programs and systems, such as a shared enterprise resource planning (ERP) system[7] and/or inventory management system (though we agree that separate inventory, whether physically or electronically, should be maintained). We discuss this issue in our chart, Attachment 2, section 8, co-location of 3PLs and wholesale distributors.

- The proposed rule permits structures at the same physical location to hold one license under some circumstances. Proposed § 205.3(f) defines "facility" as "an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used for distribution, including storage and handling, of prescription drugs." We support this definition and do not believe that the proposed rule would require a single operation, under a single corporate entity and management, such as a wholesale distributor with several buildings on a single campus, to obtain a separate facility license for each building on the campus. To the extent that a State requirement would require separate licenses for each building under common ownership at one general, permanent, physical location, such a State requirement would be preempted. *See* HDA Preemption Analysis.

- The DSCSA is clear that a facility's designated representative/facility manager – and no one else – must undergo fingerprinting, and background check (sections 583(b)(4) and 584(d)(4)(F)). We do not believe that licensing authorities may expand fingerprinting and

[7] Enterprise resource planning (ERP) systems allow companies to manage and integrate certain business processes, such as planning, sales, marketing, finance, and human resources.

criminal background checks for persons beyond designated representatives/facility managers as such requirements are different from these national standards and preempted under § 585(b)(1). *See* HDA Preemption Analysis for more discussion of this issue.

- We understand that some States are concerned with the proposed rule's various provisions regarding dispenser sales activities, including distributions: within affiliates; in public health emergencies; of "minimal quantities" for office use; and among healthcare entities under common control. There are similar concerns with distributions of various medical products that do not, under the proposed rule, constitute "wholesale distribution." We believe that these exceptions to and definitions of "wholesale distribution" are all derived from the FD&C Act itself, including in § 503(e) and/or in definitions in § 581. The extent to which these State requirements are preempted is discussed in the HDA Preemption Analysis. Changing these requirements would require changing the law. We strongly support the overall requirement that an entity must be properly licensed for the activity it is engaged in.

- We understand that some State regulators are concerned that dispensers will be unable to continue returning drugs to a wholesale distributor and whether there are sufficient protections around this process. Handling saleable and nonsaleable returns is addressed extensively in § 581 and § 582 as part of the DSCSA's tracing requirements. *See, e.g.,* § 581(17), definition of return; § 582(g)(1)(F) (each person accepting a saleable return must associate the return with TI and TS associated with that product); § 582(c)(4)(D) (wholesale distributor must verify returns it intends to resell). Section 582(d)(1)(C)(ii) permits a dispenser to return a product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing transaction data and without being licensed as a wholesale distributor.[8]

- We agree with the concerns of some State licensing authorities regarding the transition to the licensure rules once they are final. Among other things, we believe there will be significant effort required to process license applications and inspect facilities. We extensively discuss our recommendations to ease the transition burden in Attachment 2, our chart containing detailed comments in section 4, Transitioning Existing State Licenses to Federal Standards; section 37, Inspections Generally for 3PLs, Proposed Rule § 205.16(a), and for Wholesale Distributors, Proposed § 205.28(a); section 42, License Renewal for 3PLs, Proposed Rule § 205.8, and for Wholesale Distributors, Proposed Rule §§ 205.20(b) & 205.22(d). Our key points include:

    - Many States have set a uniform license renewal date for all facilities licensed in the State. Other States renew from the date of first issuance of each license as proposed in the rule. We support continuing this approach and believe that States should have the flexibility to set and maintain their own renewal dates so that not all licenses in all 50 States expire on the same calendar day. This would be very burdensome for both license holders and for State licensing authorities. Further, we believe obtaining timely inspections would be very difficult. We strongly urge FDA to permit States to set a renewal date that is most convenient for the management of their own resources.

    - We do not believe that all licenses should be required to be renewed in accordance with the national standards of the licensure rule on or by a single day two years after

[8] As part of product tracing, the saleable returns requirements of § 581 and saleable returns requirements of § 581 and § 582 preempt any State requirements under § 585(a).

the effective date of the final rule – we believe it would be very difficult for both regulated and regulator to accomplish all license renewals and needed inspections on a single day, even with two years to prepare. Rather, we recommend that, once the licensure rule is final and effective, existing licenses should be permitted to continue through to their natural renewal date and that any required inspections occur in conjunction with that natural renewal. This approach would avoid creating a situation in which all licenses nationwide would need to be renewed on the same day under these new national standards.

* * *

6. Conclusion

National uniformity in licensure requirements was a central tenet of the DSCSA. Congress determined that one critical component of better securing the pharmaceutical supply chain was to raise the overall level of requirements applicable to those that wholesale, warehouse, and distribute prescription drugs. The patchwork of State licensure laws that existed prior to the DSCSA's enactment in 2013 was deemed to be a contributing factor to the introduction of illegitimate products into the U.S. market. The proposed rule, when finalized, is a critical component in fortifying the pharmaceutical supply chain against wrongdoers.

We thank FDA for its work on the licensure rule. We urge its finalization as soon as possible though we recognize that the scope of changes requested by stakeholders and regulators may necessitate the reissuance of the proposed rule or parts of the proposed rule for additional comment. As the trade association representing the industry sector most impacted by the proposed rule, we welcome the opportunity for further discussion with the agency. However, if the Agency does find it necessary to repropose the rule, we urge doing so as expeditiously as possible.

Sincerely,

Anita T. Ducca

Anita T. Ducca
Senior Vice President, Regulatory Affairs

cc: Leigh Verbois, Director, Office of Drug Security, Integrity, and Response, Office of Compliance

Attachments:
1. Healthcare Distribution Alliance Analysis of Preemption of State and Local Licensure Requirements With Respect to Licensure of Wholesale Distributors and Third-Party Logistics Providers in § 585(b) of the Federal, Food, Drug and Cosmetic Act.
2. Comments of the Healthcare Distribution Alliance (HDA) on the Proposed Rule: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Providers in RTF and PDF formats.

Healthcare Distribution Alliance

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ATTACHMENT 1

Healthcare Distribution Alliance Analysis Of Preemption Of State And Local Licensure Requirements With Respect To Licensure Of Wholesale Distributors And Third-Party Logistics Providers In § 585(b) Of The Federal, Food, Drug And Cosmetic Act

Comments on, and Submitted to, Docket No. FDA-2020-N-1663
National Standards for the Licensure of
Wholesale Drug Distributors and Third-Party Logistics Providers, Proposed Rule, on
September 6, 2022
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Our detailed comments to the licensure rule are presented in three parts:

(1) The cover letter, which addresses certain larger issues best presented in a prose format;
(2) This analysis of preemption under § 585(b) (HDA Preemption Analysis) (Attachment 1); and
(3) A chart, organized by section of the proposed rule, with comments on, and suggested specific editorial changes and additions to, the included sections. (Attachment 2).

Section 585(b)(1) expressly preempts State and local requirements with respect to the licensure of wholesale distributors and 3PLs. In the preamble to the licensure rule, FDA states that it "interprets section 585(b)(1) of the [Federal Food, Drug and Cosmetic Act] FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or [wholesale drug distribution] WDD licensure that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the FD&C Act. In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted." 87 Fed. Reg. at 6735.

In the discussion here, we explain how FDA's interpretation comports with the plain language of the law, recent case law, and the intent of Congress.

1. Introduction And Background On Preemption In Statute, Guidance, And The Proposed Rule

Section 585 of the FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA)[1] is entitled ***Uniform national policy***. Section 585 states in relevant part:

> (a) PRODUCT TRACING AND OTHER REQUIREMENTS.— Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—
>
> (1) any waiver, exception, or exemption pursuant to section 581 or 582; or
> (2) any restrictions specified in section 582.
>
> (b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—
> (1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

FDA first interpreted § 585 in a Draft Guidance, *The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers* (2014 Preemption Draft Guidance), 79 Fed. Reg. 60853 (Oct. 8, 2014).[2] The 2014 Preemption Draft Guidance stated at lines 131-136 (footnotes omitted) that "Beginning on November 27, 2013, … States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law." There was a similar provision at lines 179-184 for 3PLs.

FDA altered this interpretation of the 2014 Preemption Draft Guidance in the preamble to the licensure rule:

> FDA interprets section 585(b)(1) of the FD&C Act as preempting States and localities from establishing or continuing requirements for 3PL or WDD licensure

[1] The Drug Supply Chain Security Act (DSCSA) was Title II of the Drug Quality and Security Act (DQSA), Public L. No. 113-54, signed into law on November 27, 2013.
[2] The 2014 Preemption Draft Guidance is posted to Dkt. No. FDA-2014-D-1411, available here.

> that are different from the standards and requirements applicable under sections 584 and amended 503(e) of the FD&C Act. ***In other words, States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted.***
> …
> ***FDA has reconsidered its earlier proposed interpretation and determined that its current interpretation – that the Federal requirements will establish both a "floor" and a 'ceiling' – is more consistent with the language of the statute, Congressional purpose, and policy considerations.*** Section 585(b)(1) provides for the preemption of any state requirements that are, among other things, 'inconsistent with' or 'covered by' Federal requirements – which suggests both a floor and a ceiling.

87 Fed. Reg. at 6735 (emphasis supplied).

Concurrent with the release of the proposed rule, the agency released a final version of the 2014 Preemption Draft Guidance, *Drug Product Tracing: The Effect of Section 585 of the FD&C Act Questions and Answers* (2022 Preemption Final Guidance) (Feb. 2022) available here. The 2022 Preemption Final Guidance omits the entirety of the preemption discussion under § 585(b) and interprets only § 585(a).

We strongly concur with FDA's conclusions regarding preemption and thank the agency for this change in its interpretation of § 585(b)(1).

2. Section 585(b)(1) Preemption Should Be Its Own Section Of The Proposed Rule (Once Finalized), Not In The Preamble Alone

We recommend that the agency's position on preemption be added to the text of the rule. The only guidance on § 585 preemption FDA has issued now omits § 585(b) entirely. After a few very brief mentions of provisions that are preempted, the only substantive discussion of § 585(b) is relegated to a discussion beginning the 28th page of the proposed rule in the preamble, 68 Fed. Reg. at 6735, and extending briefly to the next page.

FDA included an express preemption provision in new 21 C.F.R. § 800.30(h), in the Final Rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (OTC Hearing Aid Rule) 87 Fed. Reg. 50698 (Aug. 17, 2022). While the reasoning was, in part, because the applicable preemption provisions did not appear in the FD&C Act, the agency also stated that codifying them in the OTC Hearing Aid Rule would "assist stakeholders in understanding the legal framework" that governed OTC hearing aids. 86 Fed. Reg. 58150, 58166 (Oct. 20, 2021).

The same rationale would apply to the licensure rule. This important provision should be added as a new section in Part 205 that is clear and easy to find. This new section should also provide explicit instruction on how States should adopt and implement the uniform licensure standards.

There are two related issues that we also recommend be addressed in this important new section.

- There continues to be confusion regarding 3PLs and manufacturers being regulated as wholesale distributors. Though the DSCSA expressly prohibits the regulation of 3PLs as wholesale distributors,[3] some States continue to require wholesale distributor licenses for 3PLs. Some States also require manufacturers to be licensed as wholesale distributors when distributing their own products, though the DSCSA expressly exempts this activity from the definition of "wholesale distribution."[4] The Revised Draft Guidance, *Identifying Trading Partners Under the Drug Supply Chain Security Act* (July 2022) (Trading Partner Revised Guidance) (available here) contains useful clarifications on both issues. However, we believe that expressly including these clarifications in a new regulation specific to preemption would further Congressionally mandated uniformity.

- Similarly, we believe this clarification that manufacturers are not wholesale distributors if distributing their own products should be expressly extended to repackagers, including virtual repackagers. Section 503(e)(4)(K) states that repackagers distributing their own products are exempt from the definition of "wholesale distribution." Like manufacturers, when distributing their own product, repackagers may not be classified as wholesale distributors under State requirements and the licensure rule should make this clear.

We suggest incorporating the following new section which is also included in our accompanying chart in section 1, Attachment 2.

> § 205. __ Scope of Preemption.
>
> (a) The DSCSA prohibits any State from establishing or continuing any standards, requirements, or regulations with respect to third-party logistics provider or wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of this part and the FD&C Act.
>
> (b) FDA interprets the national uniformity provisions of the FD&C Act as mandating that there be national uniformity in the standards, requirements, and regulations for the licensure of third-party logistics providers.
>
> (c) FDA interprets the national uniformity provisions of the FD& C Act as mandating that there be national uniformity in the standards, requirements, and regulations for the licensure of wholesale distributors, including virtual wholesale distributors.
>
> (d) Any standards, requirements, or regulations a State licensing authority adopts for licensure of third-party logistics providers or wholesale distributors must include all the requirements of this part without change or addition. No State standard, requirement, or regulation with respect to licensure of third-party logistics providers or wholesale distributors may impose requirements exceeding what the standards of this part impose.

[3] *See* § 581(29), § 585(b)(2) and § 503(e)(5) (3PLs are not wholesale distributors).
[4] *See* § 503(e)(4)(H).

> (e) All approved third-party organizations must adhere to the standards, requirements, and regulations of the FD&C Act and this part. No approved third-party organization standard or requirement associated with the licensure or inspection of a facility of a third-party logistics provider or inspection of a wholesale distributor may impose requirements exceeding what the standards of the Act and this part impose.
>
> (f) No licensing authority shall license or otherwise regulate third-party logistics providers as wholesale distributors.
>
> (g) No licensing authority shall license or otherwise regulate a manufacturer or repackager, including the manufacturer's or repackager's affiliates and co-licensed partners, as a wholesale distributor where the manufacturer or repackager is distributing only products for which it is the manufacturer or repackager.
>
> 205.__ Separate Accreditation Not Permitted.
>
> A licensing authority may not require a wholesale distributor or 3PL to obtain a certification or accreditation by a third party as a condition of licensure. A licensing authority may, as set forth in this part, use an approved third-party organization to conduct inspections of wholesale distributors and 3PLs, to review the license applications of 3PLs, and to make recommendations for licensure of 3PLs.

3. We Believe § 585(b)(1), Like § 585(a), Was Effective On November 27, 2013

The proposed rule states that these national standards will only preempt State and local licensure requirements once this regulation is finalized. *See* 78 Fed. Reg. at 6735. The preamble argues that § 585(b)(1) has no "current application" because preemption "applies only to state requirements that are inconsistent with the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act." 87 Fed. Reg. at 6735. "Those national standards will be established by this regulation, ***once finalized and effective***." 87 Fed. Reg. at 6735 (emphasis supplied).

We disagree. Section 585(b)(1) states, "***Beginning on the date of enactment of the [DSCSA],*** no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) … or section 584..." (emphasis supplied). The plain and unequivocal meaning of Congress was that all State requirements, regulations, and standards were preempted beginning November 27, 2013 by the standards and requirements of § 503(e) and § 584.

Moreover, it is "standards ***and requirements***" applicable under § 503(e) and § 584 that preempt State and local standards, requirements, and regulations. The ***requirements*** in the DSCSA in § 503 and § 584 also preempt State law, regardless of the necessity of also issuing these standards. We do not believe, as the preamble suggests, that the supply chain would be unprotected with a 2013

effective date for preemption. During the pendency of this rulemaking, the federal requirements in §§ 581-585 and § 503 and State requirements compliant with them continue, as they have, since November 27, 2013.

That § 585(b) is now not effective until likely a decade or longer than Congress had intended also represents a reversal of the FDA's previous position, articulated since the 2014 Preemption Draft Guidance. As quoted above, the 2014 Preemption Draft Guidance has stated since its promulgation over seven years ago, that § 585(b) was effective "***Beginning on November 27, 2013***…" (emphasis supplied).

4. Section 585(b)(1) Establishes Standards With Respect To Wholesale Distributor And 3PL Licensure That States Must Adopt And May Not Enlarge

We strongly endorse the agency's conclusion in the proposed rule that, under § 585(b)(1), "States and local governments may not establish or continue licensure requirements for 3PLs or WDDs unless those State requirements are the same as Federal requirements; different requirements are preempted." 87 Fed. Reg. at 6735. HDA's previous legal analysis of § 585 preemption submitted to FDA in 2015 advocated this view; our 2015 comment is included as Reference 5 to this proposed rule and is available here.

We believe FDA's interpretation of § 585(b)(1) comports with the plain language of the law, recent case law, and the intent of Congress. However, we understand some stakeholders disagree with the agency's position or are uncertain as to the scope of the DSCSA's preemption of State licensure requirements. We have, therefore, taken this opportunity to revisit our 2015 preemption analysis and update it to reflect recent case law and these proposed rules.

a. Congress Mandated National Uniformity For Wholesale Distributor And 3PL Licensure And Preempted State Requirements To Achieve It

The DSCSA is intended to bring national uniformity to wholesale distributor and 3PL licensure. Sections 583 and 584 are titled, respectively, "National standards for prescription drug wholesale distributors" and "National standards for third-party logistics providers." Section 585 is entitled "Uniform national policy." Wholesale distributor and 3PL licensing cannot be "uniform" if every State is free to impose different licensure requirements.

b. Interpretations Of Key Terms In § 585(B)(1) Determine The Scope Of State Licensure Law The DSCSA Preempts

Where, as here, Congress has expressly superseded State law by statute, the "task is to 'identify the domain expressly pre-empted.'" *Dan's City Used Cars, Inc. v. Pelkey*, 133 S.Ct. 1769, 1778 (2013) (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001)). Though "a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008).

To conduct this analysis, we must begin with the language of § 585(b)(1). As "the statute [the DSCSA] contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of

Congress' pre-emptive intent." *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (quoted in *Chamber of Commerce v. Whiting*, 563 U.S. 582, 594 (2011)). "The best evidence of [Congress'] purpose is the statutory text adopted by both Houses of Congress and submitted to the President." *West Virginia Univ. Hospitals, Inc.* v. *Casey*, 499 U. S. 83, 98 (1991) (superseded by statute on other grounds).[5] *See also Puerto Rico v. Franklin Cal. Tax-Free Trust*, 579 U.S. 115, 125 (2016) (where "the statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." (citations and internal quotations omitted)).

All the key terms in § 585(b)(1) have been used in the preemption provisions of federal statutes for decades and have been repeatedly interpreted by U.S. Courts of Appeals and the U.S. Supreme Court. These prior judicial interpretations of similar preemption clauses must guide the interpretation of §585(b)(1) as "repetition of the same language in a new statute indicates, as a general matter, the [congressional] intent to incorporate its judicial interpretations as well." *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85 (2006) (internal quotations and citations omitted).

Below, we address relevant authority interpreting the key preemptive phrases of § 585(b)(1):

- "With respect to" wholesale prescription drug distributor or 3PL licensure
- "Inconsistent with" and "less stringent than"
- "Directly related to"
- "Covered by"

In the OTC Hearing Aid Rule, FDA looked at the ordinary dictionary meanings of terms used in the preemption clause it was interpreting, the context of the law, including its objectives, and the specific facts, such as the specific language of the State or local requirements being preempted and whether the State or local requirement has an impermissible effect on the preempted activity regulated under federal law. 87 Fed. Reg. at 50736. The analysis below is consistent with the analysis the agency undertook in the OTC Hearing Aid Rule.[6]

i. The meaning of "with respect to … licensure"

Parameters around § 585(b)(1)'s displacement of State licensure law are found in the first clause, "no State ... may establish or continue any standards, requirements, or regulations ***with respect to*** wholesale prescription drug distributor or third-party logistics provider ***licensure***…"

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[5] "In statutory interpretation disputes, a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law itself. … Where, as here, that examination yields a clear answer, judges must stop." *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019) (internal citations omitted).

[6] As the FDA concluded in the OTC Hearing Aid Rule and its analysis of preemption under the FDA Reauthorization Act (FDARA), we do not believe that the "presumption against preemption" is applicable to the DSCSA and § 585. "FDA intends to assess preemption consistent with the statutory language of section 709(b)(4) of FDARA for State or local requirements that fall within this provision. We believe this approach to assessing preemption is consistent with the Supreme Court's approach to Federal preemption. *See, e.g., Puerto Rico*, 579 U.S. at 125 (explaining that 'because the statute contains an express preemption clause, we do not invoke any presumption against preemption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.' (citations and internal quotations omitted))." 87 Fed. Reg. at 50736-37.

(emphasis supplied). "With respect to" is a frequently interpreted term in preemption analysis. Its use in § 585 establishes that the DSCSA preempts State requirements that "concern" licensure and that § 585(b)(1) does not preempt laws that have only an indirect connection to licensure. *See Dan's City Used Cars, Inc.*, 133 S. Ct. at 1778-79. *See also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996) (to be preempted, State requirements must be "with respect to medical devices and different from, or in addition to, federal requirements").

Thus, to be preempted, a State requirement must "concern" and have a direct connection to the licensure of wholesale distributors or 3PLs. Any State requirements of "general applicability" likely would not be preempted by § 585(b)(1) so long as they are not specific to wholesale distributor or 3PL licensure. *See* OTC Hearing Aid Rule, 87 Fed. Reg. at 50736; *Medtronic*, 518 U.S. at 499-500.

ii. The meaning of "inconsistent with" and "less stringent than"

The terms "inconsistent with" and "less stringent than" in § 585(b)(1) establish the so-called "floor" or minimum standards and are not broadly preemptive. *See Jones v. Rath Packing Co.*, 430 U.S. 519, 540 (1977) (explaining that a federal statute that prohibits "inconsistent" State laws allows State requirements to go further than a federal statute if compliance with both is possible).

We interpret "inconsistent with" or "less stringent" in § 585(b)(1) as requiring States to adopt, at a minimum, the requirements of the federal licensure rule. Section 585(b)(1), however, does not stop with these terms. Congress added two additional phrases that significantly expand the preemptive reach of § 585(b)(1) – "directly related to" and "covered by."

iii. The meaning of "directly related to"

We are not aware of any statute which provides, as the DSCSA does, for federal preemption of State laws that are "***directly*** related to" federal requirements. There is significant case law interpreting the phrase "that relate to" and "related to" as being broadly preemptive. The Employee Retirement Income Security Act of 1974 (ERISA) "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). Additionally, in the Airline Deregulation Act (ADA), Congress preempted state laws "related to a price, route, or service of an air carrier." 49 U.S.C. § 41713(b)(1). Two years later, Congress used the ADA model to preempt state laws in the Federal Aviation Administration Authorization Act of 1994 (FAAAA) "related to a price, route, or service of any motor carrier . . . with respect to the transportation of property." 9 U.S.C. §14501(c)(1).

The Supreme Court decided that a State law "relates to" an ERISA employee benefit plan, and so is preempted, if it makes a "reference to" or has a "connection with" or is "in reference to" employee benefit plans. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983). This "relate to" preemption provision in ERISA "displace[s] all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements." *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 829-30 (1988) (quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 739 (1985)).

Interpretations of "related to" preemption under the ADA and the FAAAA use the same "reference to" or "connection with" test. In *Morales v. Trans World Airlines, Inc*., 504 U.S. 374, 384 (1992), the Supreme Court interpreted the ADA preemption clause:

> For purposes of the present case, the key phrase, obviously, is "relating to." The ordinary meaning of these words is a broad one—"to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with," Black's Law Dictionary 1158 (5th ed. 1979)—***and the words thus express a broad pre-emptive purpose***.

Morales, 504 U.S. at 383 (emphasis supplied).

The "relating to" language in the ADA preemption clause means "having a connection with, or reference to, airline 'rates, routes, or services.'" 504 U.S. at 384. The challenged guidelines in the case were preempted in part because they had a "forbidden significant effect" on prices, routes, or services. *Id*. at 388. If the connection to an airline's prices, routes, and services is "tenuous, remote, or peripheral," ADA preemption would not attach. *Id.* at 390. *See also Rowe v. New Hampshire Motor Transp.*, 552 U.S. 364, 371 (2008) (State laws with only a "tenuous, remote, or peripheral" effect on rates, routes, or services are not preempted.). Similarly, in interpreting the FAAAA, the Supreme Court stated that the "phrase 'related to' … embraces state laws 'having a connection with or reference to' carrier 'rates, routes, or services,' whether directly or indirectly" with respect to transportation. *Dan's City Used Cars,* 133 S. Ct. at 1778 (quoting *Morales*, 504 U.S. at 384).

The word "directly" modifies "related to" in the DSCSA and does not make the same modification in ERISA, the ADA, or FAAAA. A court would, therefore, determine the meaning and qualifying impact of "directly" upon "related to" preemption. To do so, courts would turn to ordinary definitions of the word "directly" found in dictionaries and legal treatises. *See CSX Transp.,* 507 U.S. at 664-65 (relying upon *Webster's Third New International Dictionary* for the definition of "covering"); *Shaw*, 463 U.S. at 97 n.16 (relying upon *Black's Law Dictionary* for the definition of "relate"). The Supreme Court looked to the *Oxford English Dictionary* and *Black's Law Dictionary* for the meaning of ordinary words in *Puerto Rico*, 36 S.Ct. at 1947. *See also Food Marketing Institute*, 139 S. Ct. at 2363 (common dictionary meanings of "confidential").

Black's Law Dictionary defines "directly" as:

1. In a straightforward manner.
2. In a straight line or course.
3. Immediately.

Black's Law Dictionary (11th ed. 2019).

Merriam-Webster defines "directly" as "in a direct manner; in immediate physical contact; in the manner of direct variation." *Merriam-Webster.com Dictionary*.[7]

Based upon these common, dictionary definitions, the word "directly" would modify, to some extent, the broad "related to" preemption in § 585(b)(1). We believe any State requirements with a straightforward, immediate, or direct connection with or to the DSCSA's wholesale distributor or 3PL licensure standards would be preempted under § 585(b)(1). State requirements with a tenuous, remote, or peripheral effect upon the DSCSA's wholesale distributor or 3PL licensure standards would not be preempted.

[7] FDA also used this same dictionary source in interpreting the FDARA preemption clause and the meaning of "restrict or interfere" in the OTC Hearing Aid Rule. 87 Fed. Reg. at 50736.

iv. The meaning of "covered by"

A phrase similar to "covered by" appears in several federal statutes and has been interpreted by courts, including the Supreme Court, to be broadly preemptive, although not as broad as "related to" preemption.

In *CSX Transp., Inc. v. Easterwood,* 507 U.S. 658 (1993), the Supreme Court interpreted the preemption language in the Federal Railroad Safety Act (FRSA) which, at the time the case was decided, permitted the States to "adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety until such time as the Secretary has adopted a rule, regulation, order, or standard ***covering*** the subject matter of such State requirement." 45 U.S.C. § 434, *amended by* 49 U.S.C. § 20106(a)(2) (emphasis supplied).[8] One issue in *Easterwood* was whether FRSA regulations regarding maximum train speeds preempted a State law personal injury negligence claim. Even though the train at issue in the case was traveling below and complying with the federal maximum of 60 miles per hour, the petitioner attempted to hold CSX Transportation to a more stringent standard by arguing that the railroad breached its common-law duty to operate its train at a moderate and safe rate of speed.

The Supreme Court determined federal requirements covered and so preempted State requirements if they "comprised," "included," or "embraced" the State requirements, or if the State requirement was "substantially subsumed by" the federal requirement. *Easterwood*, 507 U.S. at 664-65. *Accord Shanklin*, 529 U.S. at 352-353 Within this purview, the "covering" language "must be read as not only establishing a ceiling but also precluding additional state regulation of the sort which respondent seeks to impose on petitioner." *Easterwood*, 507 U.S. at 674. In this case, the federal train maximum-speed regulations "substantially subsumed" and therefore "covered" the subject of train speeds because they comprehensively regulated that issue, thereby precluding and preempting additional State regulations.

The Second Circuit, relying upon *Easterwood* and *Shanklin*, undertook a detailed analysis of "covering the subject matter" preemption language found in the Federal Aviation Administration's (FAA) implementing regulations to the Federal Aviation Act's drug testing requirements. *Drake v. Lab. Corp. of Am. Holdings*, 458 F.3d 48 (2d Cir. 2006). A State requirement is preempted if the "intersection" between the State and Federal requirements is "substantial." *Id.* at 60. If State law "regulates conduct that is addressed by a specific provision of the FAA regulations, it is preempted." *Id.* at 63. Further, because of the FAA's interest in "consistency and uniformity" in drug testing, a State "cannot enlarge or enhance" its requirements "to impose burdens more onerous than those of the federal requirements on matters addressed by the federal regulations." *Id.* at 65 (citing *American Airlines, Inc. v. Wolens*, 513 U.S. 219, 233 (1995) (internal quotations omitted)).

Under this line of case law, § 585(b)(1) would preempt any State requirement that is substantially subsumed by the licensure rule and applicable requirements §§ 503(e) and 584, or any State requirement that seeks to enhance, enlarge, or impose greater burdens that those of the licensure rule and §§ 503(e) and 584.

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[8] Although Congress superseded and amended § 434, the "covering" language remained and the Supreme Court relied upon *Easterwood* when it interpreted preemption under the FRSA in in *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344 (2000).

5. A Recent Court Case Supports This Interpretation Of § 585(b)(1)

Though not referenced in the preamble to the proposed rule, federal courts have, very recently, acknowledged the preemptive scope of § 585(b)(1). In *Matrix Distributors, Inc., v. NABP*, Civ., 2020 WL 7090688 (D.N.J.) (Slip Op. Dec. 4, 2020),[9] the district court described the preemptive effect of the DSCSA in broad terms:

> Congress enacted the DSCSA to create a "[u]niform national policy" for drug supply chain regulation, 21 U.S.C. § 360eee-4 (section title), and fix the supply chain's vulnerability to counterfeit drugs—a vulnerability which, according to Congress, "exists, in large part, due to a patchwork of inconsistent State regulations"…. That purpose would be undermined if states could too easily circumvent the statute and re-institute the regulatory patchwork by outsourcing regulation to private actors.

2020 WL 7090688 at *9 (quoting H.R. Rep. 113-93, at 24 (2013) which the court mistakenly refers to as H.R. Rep. 113-83).

In *Matrix Distributors*, the district court heard arguments on how the requirements of the Verified-Accredited Wholesale Distributor (VAWD) program of the National Association of Boards of Pharmacy (NABP)[10] allegedly were preempted by § 585(b)(1). The court did not reach this precise issue because the court found that the private parties in the action – NABP and a prescription benefit manager – were not, under the facts present in the case, a State authority and neither party was acting on behalf of a State authority when imposing a VAWD requirement upon a pharmaceutical wholesale distributor. However, the court cautioned that, had a State been acting to impose VAWD requirements upon a wholesale distributor, the result might have been different:

> Consider, for example, a hypothetical case in which the board of pharmacy in Rhode Island adopted the VAWD requirement and a distributor, assuming it had standing, challenged Rhode Island's incorporation and enforcement of that requirement. Or consider another hypothetical case in which Rhode Island delegated its regulatory powers over distributors to the VAWD program. In either case, we might more easily find that the authority of Rhode Island was being exercised.

2020 WL 7090688 at *10.[11] In such a case, if a State licensing authority had sought to impose a VAWD requirement on a wholesale distributor, or if NABP had been acting on the State's behalf to impose such a requirement, the court would then examine whether the State requirement is preempted by § 585(b)(1) because it undermined the uniformity the DSCSA was enacted to avoid.

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[9] *Affirmed in part, reversed in part on other grounds*, 34 F.4th 190 (3rd Cir. 2022).

[10] NABP is a national trade organization representing State Boards of Pharmacy. Those State Boards regulate the practice of pharmacy in a State and many also regulate and license wholesale distributors and 3PLs.

[11] FDA came to a similar conclusion in the OTC Hearing Aid Rule: "As we explained in the proposal, under section 709(b)(4) of FDARA, a State or local government cannot require persons engaged in commercial activity involving OTC hearing aids to undertake special licensing or equivalent activities solely on that basis (see 86 FR 58150 at 58158)." 87 Fed. Reg. at 50739.

The Third Circuit affirmed in part on other grounds and reversed in part the judgment of the district court and did not disturb or reach the district court's discussion of the DSCSA's uniform national regulation of wholesale distributors. 34 F.4th 190 (3rd Cir. 2022).

6. Congress Wrote What It Intended

In § 585(b)(1), Congress's intention of creating uniform federal licensure standards for licensure is clear, detailed, and specific. Recourse to legislative history is, therefore, unnecessary. *See Darby v. Cisneros*, 509 U.S. 137, 147 (1993) ("Recourse to the legislative history … is unnecessary in light of the plain meaning of the statutory text."); *Food Marketing Institute*, 139 S. Ct. at 2364 (Courts should never allow "legislative history … to be used to 'muddy' the meaning of 'clear statutory language" (internal quotations and citations omitted)). However, the legislative history of the DSCSA confirms that Congress intended national uniformity in licensure with federal and state requirements being the same.[12]

As explained by Representative Fred Upton, ***the sponsor*** of H.R. 3204 which would become the enacted public law, the DSCSA would "[c]reate floor and ceiling licensure standards for wholesale distributors and 3PLs while preserving state authority for licensure issuance and fee collection." *H.R. 3204, The Drug Quality and Security Act* (Sept. 27, 2013).[13]

We believe that recourse to legislative history is neither necessary nor a particularly favored approach given the express preemption of § 585(b)(1) that is informed by the decades of Court opinion described previously that interpret the terms Congress used in the DSCSA. Congress could not have been plainer in its intent given that Sections 583, 584 and 585 are titled, respectively, ***National standards for prescription drug wholesale distributors***, ***National standards for third-party logistics providers***, and ***Uniform national policy***. There is ample support for the incontrovertible conclusion that the DSCSA establishes a uniform system for licensure of wholesale distributors and 3PLs that was intended by Congress to preempt State licensure requirements.

7. The Scope Of § 585(b) – Identifying What Is And Is Not Preempted

a. What Is Preempted

Based upon the foregoing, any and all of the following State 3PL and wholesale distributor licensure requirements would be preempted as they are all specifically identified in § 583 and § 584

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[12] We do not believe the Supreme Court's recent requirement, articulated in *West Virginia v. EPA*, 597 U.S. __ (June 30, 2022), is relevant here. In that case, the Supreme Court stated that there may need to be "clear Congressional authorization" where an agency undertakes a rulemaking involving "major questions." In the DSCSA, such "clear Congressional authorization" is in the statute itself – Congress expressly ordered uniform national standards in §§ 583 and 584 and preempted State requirements in § 585.

[13] Insisting, as we believe some commentators have, that legislative history establishes that § 585(b) sets only a floor of minimum regulation ignores the plain language of the law. Section 585(b) provides that not only are State requirements that are "less stringent than" or "inconsistent" with these national standards preempted, State requirements that are "directly related to" or "covered by" these national standards are also preempted. Also, we believe that some earlier, not enacted, versions of § 585(b) introduced in Congress (*e.g.*, S.957 and S.959) did limit preemption to only State licensure requirements less stringent than the federal standards – these bills and their narrow preemption did not, of course, become law.

and so are covered by or directly related to the requirements of § 583 and § 584 and these standards which are implementing those requirements.

- For wholesale distributors under § 583(b)(1)-(7), State requirements regarding the following are preempted:

    - The storage and handling of prescription drugs (proposed § 205.26);
    - Facility requirements (proposed § 205.26(b));
    - Records (proposed § 205.27);
    - Bond (proposed § 205.21);
    - Requirements for facility managers, designated representatives, and key personnel (proposed § 205.25);
    - Who must undergo criminal background checks and submit fingerprints (proposed § 205.25);
    - Inspection criteria (proposed § 205.28); and,
    - Prohibitions upon who may receive and maintain a license (proposed § 205.22).

- For 3PLs under § 584(d)(2), State requirements regarding the following are preempted:

    - Storage practices, suitability of warehouse space, and security (proposed § 205.10);
    - Written policies and procedures (proposed § 205.12) regarding:
        - Receipt, security, storage, inventory, shipment, and distribution of product, identify, record, and report confirmed losses or thefts (proposed § 205.12(a)(1)(i), (c));
        - Errors and inaccuracies in inventories (proposed § 205.12(c)(4));
        - Support for manufacturer recalls (proposed § 205.12(d));
        - Personnel (proposed § 205.12(b));
        - Planning for a reasonably foreseeable crisis affecting security or operation (proposed § 205.12(e));
        - Segregation and disposition of expired product, handling of products unfit for distribution (proposed § 205.12(c),(f);
        - Tracing receipt and outbound distribution of a product (proposed § 205.12(c)(4));
        - Quarantine or destruction/disposition of suspect and illegitimate product when so directed (proposed § 205.12(g),(h)); and
    - Inspection criteria (proposed § 205.16);
    - Recordkeeping and document maintenance (proposed § 205.13); and,
    - Requirements for facility managers and designated representatives (proposed § 205.11).

The following are other specific examples of State requirements we believe these federal licensure standards preempt:

- State authorities would not be able to deviate from the licensure rule's definitions of what constitutes "wholesale distribution" (proposed § 205.3(n)) or "other logistics services" (proposed 21 C.F.R. § 205.3(i) as these definitions are "directly related" to whether an entity must be licensed as a wholesale distributor (proposed § 205.20 – requirements that wholesale distributors be licensed) or 3PL (proposed § 205.4 – requirements that 3PLs be licensed).

- State authorities could not permit lesser or more expansive requirements as to records, including what records a wholesale distributor or 3PL must maintain or the length of time those records must be maintained because records requirements and retention are "directly related" to and "covered by" the recordkeeping and document maintenance requirements in proposed § 205.27 (wholesale distributors) and proposed § 205.13 (3PLs).

- The Drug Distributor Accreditation (formerly VAWD) mandated in the States of Indiana, North Dakota, Wyoming, and Iowa[14] as a condition of state licensure is preempted because this separate accreditation is subsumed and covered by the DSCSA's inspection and licensure requirements. Third-party approved organizations (AOs) have authority under the DSCSA and the implementing licensure rule only to inspect wholesale distributors and 3PLs (proposed § 205.31 and § 205.17) and to review 3PL licensure applications (proposed § 205.17). No authority is granted to these organizations to approve or accredit wholesale distributors or 3PLs. Nor is any authority granted to the State to require a separate accreditation as a condition of licensure. Any attempt by a State to require such third-party accreditations as a condition of licensure would be preempted. FDA specifically rejected this type of "special" licensing in the OTC Hearing Aid Rule. 87 Fed. Reg. at 50739 ("a State or local government cannot require persons engaged in commercial activity involving OTC hearing aids to undertake special licensing or equivalent activities solely on that basis (see 86 FR 58150 at 58158)."

- While a State authority must inspect wholesale distributors and 3PLs – or have an AO inspect on the State's behalf – States and AOs both must apply only these federal licensure standards during that inspection. No State, whether on its own or through a third-party AO, may enhance, enlarge, or impose greater burdens than those of the licensure rule. Given that the DSCSA imposes national uniformity, the imposition of different standards during inspections would effectively re-institute the State regulatory patchwork eliminated in the law.[15]

- The licensure standards in proposed § 205.11 and proposed § 205.25 set out the requirements for the designated representative/facility manager for 3PLs and wholesale distributors and the requirements for all key personnel. Sections 583 and 584 specify that only the designated representative/facility manager must have a criminal background check and be fingerprinted and proposed § 205.11 and proposed § 205.25 would implement these requirements. This means that States could not require other persons to be fingerprinted or to submit to a criminal background check. Similarly, State authorities can no longer require that facility managers and designated representatives take tests as a condition of licensure as such requirements are neither in the law nor in proposed § 205.11 and proposed § 205.25 which implement § 583 and § 584.

- The licensure standards in proposed § 205.7 and § 205.24 set out what changes in entity ownership (defined in proposed § 205.3(b)) would trigger the submission of an application for a new license and how and when the license holder must make that submission. A State authority could not use a different definition of change in entity ownership and could

[14] *See* NABP website here. Maryland and Oregon have a "reciprocity" program and will require NABP accreditation if a wholesale distributor is not licensed in certain States.
[15] *See Matrix Distributors, Inc., v. NABP*, Civ., 2020 WL 7090688 at *9-10.

not require the submission of the application on a different timetable than what is set out in the federal rule.

Permitting State requirements to persist that are different from these federal licensure standards would perpetuate the patchwork of inconsistent and variable requirements that disrupt the national uniformity Congress enacted in the DSCSA.

In addition to our recommendation that the agency's position on preemption be added to the text of the proposed rule (*See* section 1 above and section 1 of our chart, Attachment 2), we urge FDA to explain in more detail which State requirements are preempted and to give examples and further guidance given the persistent confusion.

b. What Is Not Preempted

The DSCSA includes savings clauses that preserve the ability of States to impose requirements not concerned with licensure. *See* §§ 585(b)(4), (c). Section 585(b)(1) only preempts State standards, requirements, or regulations with respect to, that is, concern, wholesale prescription drug distributor or 3PL licensure. *See, e.g., Dan's City Used Cars*, 133 S. Ct. at 1778-1779. A State requirement is not preempted if it is not directly related to or not covered by these standards.

We believe the following are examples of State authority unaffected by and not preempted by § 585:

- State-controlled substances requirements, including requirements for facilities to be registered under State law to handle controlled substances;
- State prescription drug monitoring programs;
- State and local hazardous waste, extended producer responsibility and environmental stewardship laws,[16] and other environmental requirements; and,
- Collection of licensure fees.

Many States have licensure requirements for entities that handle medical products but are not engaged in wholesale distribution or 3PL activities as defined and addressed in § 503(e), § 583, § 584, and these national standards. These entities include pharmacies, returns processors, reverse logistics providers, retailers, transportation companies, and waste management companies as well as wholesale distributors that distribute medical gases, medical devices, non-prescription drugs, or medical foods. We believe these types of State licensure requirements would only be preempted to the extent that a regulated entity is engaged in wholesale distribution or 3PL activities that brings that entity within the scope of these licensure rules. We encourage regulatory authorities to consider aligning those separate licensing requirements to these national standards. Further, we suggest that State authorities consider deeming an entity to be licensed for purposes of wholesale distribution of other medical products so long as that entity is licensed under these national standards for wholesale distribution of prescription drugs.[17]

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[16] Extended producer responsibility and stewardship laws refer to requirements in States and localities that manufacturers and others become responsible for management of their own discarded products and packaging rather than having that waste enter municipal systems.

[17] We believe the OTC Hearing Aid Rule may offer additional analysis of the scope of State requirements that are not preempted, including requirements not deemed specific to commercial activity in hearing aids (87 Fed. Reg. at 50739) and generally applicable requirements (87 Fed. Reg. at 50736).

Additionally, § 585(b) specifically preserves the ability of a State to bring enforcement actions for violation of licensure requirements:

> (4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—
>
> (A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;
> (B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;
> (C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and
> (D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

We believe that State authorities have been uncertain as to whether they still have a role in enforcement and, if so, under what legal requirements and authority. While § 585(b)(4) addresses State enforcement of State-enacted versions of these standards, we believe it would be helpful for FDA to provide further guidance in this area.

* * *

FDA concludes that § 585(b)(1) forbids States and local governments from establishing or continuing licensure requirements for 3PLs or wholesale distributors that are different from these national standards. 87 Fed. Reg. at 6735. The plain language of § 585(b)(1), case law interpreting the words used in § 585(b)(1), and statements by the DSCSA's congressional sponsor accompanying the bill all support this conclusion. State requirements with respect to licensure of wholesale distributors and 3PLs are preempted.

ATTACHMENT 2

Comment by the Healthcare Distribution Alliance (HDA) on

National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

Proposed Rule, 87 Fed. Reg. 6708 (Feb. 4, 2022)

September 6, 2022

Notes:

- This chart is organized by section of the proposed rule with suggested specific editorial changes and additions. The chart is in a 3-column presentation:
  - Column 1 - citation to the relevant page of the preamble or provision(s);
  - Column 2 - discussion of and/or comments on that provision; and,
  - Column 3 - suggested edits to the relevant provision(s), with **additions in blue bold** and ~~deletions in red strikeout~~.
- To facilitate the agency's review of our suggested editorial changes to the rule, we also provide our chart in rich text format (RTF) and portable document format (PDF).
- In addition to this chart, we also have submitted a cover letter with additional and supportive comments and the separate, Attachment 1, HDA *Analysis of Preemption of State and Local Licensure Requirements* ("HDA Preemption Analysis").
- We refer throughout this document to changes we recommend to the "proposed rule," though, technically, these are changes we recommend be incorporated into the "final" rule the Food and Drug Administration ("FDA") will ultimately issue.

1. Preemption

Cite to Preamble or Proposed Rule	HDA Comments	HDA's Recommended Changes
6709, 6735	We strongly concur with FDA's conclusions regarding preemption and thank the agency for this change in interpretation of § 585(b). We believe the agency's change of position comports with the plain language of the law, legal precedent, and the intent of Congress. This conclusion is supported, most recently, by *Matrix Distributors, Inc., v. NABP*, 2020 WL 7090688 (D.N.J.) (Dec. 4, 2020), *aff'd in part, rev'd in part on other grounds*, 34 F.4th 190 (3rd Cir. 2022). The district court stated: "Congress enacted the DSCSA to create a '[u]niform national policy' for drug supply chain regulation … and fix the supply chain's vulnerability to counterfeit drugs – a vulnerability which, according to Congress, 'exists, in large part, due to a patchwork of inconsistent State regulations,' …. That purpose would be undermined if states could too easily circumvent the statute and re-institute the regulatory patchwork by outsourcing regulation to private actors."	New § 205. __ *Scope of Preemption*. **(a) The DSCSA prohibits any State from establishing or continuing any standards, requirements, or regulations with respect to third-party logistics provider or wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of this part and the FD&C Act.** **(b) FDA interprets the national uniformity provisions of the FD&C Act as mandating that there be national uniformity in the standards, requirements, and**

	In the HDA Preemption Analysis, Attachment 1, we explain the legal bases for our conclusions regarding preemption and the scope of State law displaced. In addition to the preamble discussion, and as we address in the HDA Preemption Analysis, we recommend that the agency's position on preemption be set forth in the text of the proposed rule and that it be especially clear so that States can be guided adequately. We recommend a new section in Part 205 that provides explicit instruction on what is and is not preempted and how States may adopt and implement the uniform licensure standards. This approach is consistent with the preemption roadmap FDA recently set out in the Final Rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 87 Fed. Reg. 50698 (August 17, 2022) and the proposed rule before it, 86 Fed. Reg. 58150 (Oct. 20, 2021). The Federal Food, Drug and Cosmetic Act is abbreviated as it is presented in the proposed rule, "FD&C Act."	**regulations for the licensure of third-party logistics providers.** **(c) FDA interprets the national uniformity provisions of the FD&C Act as mandating that there be national uniformity in the standards, requirements, and regulations for the licensure of wholesale distributors, including virtual wholesale distributors.** **(d) Any standards, requirements, or regulations a State licensing authority adopts for licensure of third-party logistics providers or wholesale distributors must include all the requirements of this part without change or addition. No State standard, requirement, or regulation with respect to licensure of third-party logistics providers or wholesale distributors may impose requirements exceeding what the standards of this part impose.** **(e) All approved third-party organizations must adhere to the standards, requirements, and regulations of the FD&C Act and this part. No approved third-party organization standard or requirement associated with the licensure or inspection of a facility of a third-party logistics provider or inspection of a wholesale distributor may impose requirements exceeding what the standards of the Act and this part impose.** **(f) No licensing authority shall license or otherwise regulate third-party logistics providers as wholesale distributors.** **(g) No licensing authority shall license or otherwise regulate a manufacturer or repackager, including the manufacturer's or repackager's affiliates and co-licensed partners, as a wholesale distributor where the manufacturer or repackager is distributing only products for which it is the manufacturer or repackager.**

2. Instructions to the States

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
6717, 6722, 6724, 6730	In numerous places in the preamble, including, but not limited to 87 Fed. Reg. at 6717, 6722, 6724, 6730, FDA "suggests" that States adopt requirements that are similar to the national standards. We believe preemption dictates that States ***must*** implement ***the same*** requirements as these national standards. We recommend that any optional "suggestions" in the preamble be changed to clear directions. The final rule should explain both ***what*** is preempted and ***how*** States should implement these new national standards. Both are addressed briefly in section 1 above, in our cover letter, and in the HDA Preemption Analysis. We suggest an addition to **Proposed § 205.2 Purpose** to provide this instruction. We also address the need for explicit instructions to the States in our cover letter.	Anywhere in the preamble where FDA "suggests" States should adopt requirements "similar" to the national standards should be changed to mandatory language, *e.g.*, "While this section is only applicable to wholesale distributors obtaining a license from FDA, ~~FDA suggests~~ States **must** implement ~~similar~~ **the same** procedures to ensure that all wholesale distributor licenses issued are consistent with the proposed [final] regulation pursuant to section 503(e)(1)(B) of the FD&C Act." 87 Fed. Reg. at 6724. --- New § 205.2 *Purpose* **(a)** The purpose of this part is to establish standards, terms, and conditions for the licensing of 3PLs and prescription drug wholesale distributors by State or Federal licensing authorities, including a process for the revocation, reissuance, and renewal of such licenses. This part also establishes the process and standards the Food and Drug Administration will use to approve third-party organizations to evaluate the qualifications of 3PLs for licensure and conduct inspections of wholesale distributor facilities. **(b) Section 585 of the FD&C Act requires national uniformity for the licensure of 3PLs and prescription drug wholesale distributors. To the extent that a State establishes its own licensure standards, the State (including the licensing authority) must adopt these standards, terms, and conditions in their entirety without change.**

3. Effective Dates

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
6731	FDA proposes to align the effective dates of the Proposed Rule so that the requirements for both wholesale distributors and 3PLs are effective two years after the final regulation is published. We support this alignment.	We support this proposal.

4. Transitioning Existing State Licenses to Align with Federal Standards

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
6717	FDA is proposing that every 3PL must obtain a new license and that both 3PLs and wholesale distributors be inspected before the new license, compliant with this rule, can be issued. We believe these new inspection and licensure requirements will pose enormous burdens upon States. As we discuss further in section 37 below regarding proposed § 205.16(a) (*inspections for 3PLs*) and proposed § 205.28(a) (*inspections for wholesale distributors*), we recommend the "grandfathering" of existing licenses to partially ease this burden. We recommend permitting these requirements to be phased in for each existing 3PL and wholesale distributor license at its natural renewal, as a far less burdensome alternative to all existing licenses expiring 2 years from the date these requirements go into effect. We also suggest that the agency work with State licensing authorities and other appropriate stakeholders regarding an ordered transition to these national standards. Guidance could address issues such as prioritization of and timelines for changes in existing requirements, where grandfathering of existing licenses and inspections may be reasonably relied upon, implementation of new processes around the conduct of inspections and licensure denials, revocations, and suspensions, and education on the standards.	*See* discussion in section 37 below and proposed new regulation, 205. __ *Applicability to existing facility licenses*.

5. Definitions, What Is And Is Not Wholesale Distribution, *Proposed § 205.3*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
Definitions; § 205.3(n), *definition of "wholesale distribution"*	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. (*See, e.g.,* § 581(24)(A) (*definition of "transaction" as a change of ownership*); Identifying Trading Partners Under the Drug Supply Chain Security Act Revised Draft Guidance for Industry (July 2022) (Revised Trading Partner Draft Guidance) (*definitions of trading partners*) (available here); § 503(e)(4) (*definition of "wholesale distribution"*). The FD&C Act does not require that a wholesale distributor ever take physical 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. Under these legal requirements and definitions, wholesale distributors include both those that take ownership ***and*** physical possession of prescription drugs and those that take ownership ***but not*** physical possession. Such "virtual" wholesale distributors commonly rely upon other entities, such as 3PLs, to provide logistical services for the prescription drugs that the wholesale distributor owns but does not handle. Regardless of whether an entity engaged in wholesale distribution takes physical possession of a product it owns or relies upon others to do so, it ***is*** a wholesale distributor, is covered and regulated by all applicable provisions of the FD&C Act and this licensure rule, and must be licensed under these national standards. The only relevant distinction between a wholesale distributor that physically handles products it owns and one that does not is that, of course, a "virtual" wholesale distributor would need to comply only with those requirements applicable to a facility that does not take physical possession of products. A "virtual" wholesale distributor would not, for instance, be expected to have the security systems, equipment, and processes that are necessary for the physical protection of prescription drugs or to have processes around the maintenance of refrigerators and freezers for storing products that must be stored at cold temperatures. As some States license "virtual" wholesale distributors under separate schemes that are different from those applicable to wholesale distributors that take physical possession of products, we ask FDA to clarify in the licensure rule that both types of entities are engaged in wholesale distribution and are subject to these national standards of the licensure rule. We believe State requirements would be	New § 205. __ *Wholesale Distribution* **To the extent that an entity engaged in wholesale distribution takes ownership but not physical possession of prescription drugs, it is a wholesale distributor and must comply with all requirements of this part applicable to such an entity, including being appropriately licensed under these national standards. A wholesale distributor that does not take physical possession of the product that it owns would need to comply only with those requirements applicable to a facility that does not take physical possession of products, and, to the extent that it uses a contractor to carry out any of its duties, would need to comply with § 205.26(c).**

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
	preempted if they regulate "virtual wholesale distributors" as distinct from wholesale distributors that take possession of the products they own. To the extent a wholesale distributor relies upon other entities for logistical services, proposed § 205.26(c) would apply, "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."	
Definitions; § 205.3(h) (*definition of "minimal quantities"*); § 205.3(n)(5) (*definition of "wholesale distribution" and exceptions*)	We strongly support the proposed definition of "minimal quantities" for office use as no more than 5% of pharmacy sales in proposed § 205.3(h). We believe this definition will be enormously helpful in clarifying what does and does not constitute wholesale distribution (proposed § 205.3(n)(5)). In our comments to the Revised Trading Partner Draft Guidance and here, we suggest 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 registered practitioner to dispense limited amounts of controlled substances to another practitioner under certain conditions. Also, the DEA "5% rule" is based on the total number of dosage units of all controlled substances dispensed whereas the proposed minimal quantities "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. 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 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 these national standards. We suggest referring to this important limitation as "the minimal quantities rule" or "rule on the limit on sales for office use." The preamble cautions that a pharmacy's "sales or trades" are wholesale distribution unless to fulfill a specific patient need. 87 Fed. Reg. at 6714. We believe this important clarification should be expressly added to the definition of "wholesale distribution" in proposed § 205.3(n) or otherwise made clear in a new section of the regulation, and/or through specific examples in the final rule. This clarification of what constitutes wholesale distribution should also expressly add so-called "borrow and loan" arrangements among pharmacies. We believe there is a pervasive misperception that these practices do not constitute wholesale distribution. For any descriptions of what constitutes wholesale distribution, and especially where there	New § 205. __ *Examples of wholesale distribution*. **Unless otherwise exempt, any entity that engages in the activity defined in § 205.3(n) is engaged in wholesale distribution and must be licensed as a wholesale distributor and comply with all other wholesale distributor requirements of this part, § 503(e), and § 582 of the FD&C Act. Examples of wholesale distribution include, but are not limited to:** **(a) Sales of prescription drugs by a retail pharmacy to licensed practitioners for office use that exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription drug sales;** **(b) A borrow, loan, sale, or trade of a prescription drug from one pharmacy to another pharmacy unless to fulfill a specific need for an identified patient;** **(c) A pharmacy's sale, transfer, loan, or other distribution to a wholesale distributor unless the wholesale distributor is an affiliate or the product is a return as defined in § 581(17);** **(d) A health care entity's sale, transfer, loan, or other distribution of a prescription drug to another health care entity unless both entities are under common control; and,** **(e) A trading partner's sale, transfer, loan, or other distribution of a prescription drug to alleviate a drug**

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
	may be impact upon current pharmacy practice, we recommend additions to the final rule that are very clear, explicit, easy to find, and not solely in the preamble. To that end, we believe it would be useful for authorized trading partners if the proposed rule added a new section or modified an existing section such as the definition of "wholesale distribution" in proposed § 205.3(n), to include, clearly and in one place, examples of activities that are and are not wholesale distribution. Examples should include "borrow and loan arrangements," "minimal quantities rule," "sales for office use," "public health emergency," and "transfers to meet specific patient need." This section should also emphasize that, if an entity is engaging in wholesale distribution, it must meet all applicable requirements under this proposed rule ***and*** § 582, including receiving, providing, and maintaining electronic, interoperable transaction data. We provide suggested language for the agency's consideration. We also suggest that FDA explain prominently in the preamble and elsewhere that it will (and State authorities should) pay rigorous attention to whether an entity is appropriately licensed or registered for the role it has in a particular transaction and that, for example, a pharmacy that is engaged in wholesale distribution must both be licensed as a wholesale distributor and must comply with all applicable requirements under these rules and § 582 (including provision, receipt, and retention of transaction data in a secure, electronic, and interoperable manner).	**shortage unless the shortage is caused by a public health emergency.**
§ 205.3(j)(3)	We support the clarity regarding distributions to a clinical investigator. However, we believe that confusion has continued to persist around this issue. There has, for instance, been confusion regarding whether the purchase and sale of approved products for use in a clinical trial (*e.g.*, approved product being used as a control, approved product being investigated for new use) are "transactions" under the Act. We ask that FDA clarify that distributions of drugs to clinical investigators and clinical study sites for use in clinical investigations and research are not DSCSA-covered transactions. We have additional comments regarding exempting distributions to clinical study sites and investigators in our comments to the Revised Trading Partner Draft Guidance where clinical trial sites and investigators were 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	New § 205.3(j)(3) (3) The clinical investigator, as defined in 312.3(b) of this chapter **or clinical study site, regardless of whether the drug being received is the article under investigation**.

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
	wholesale distributor that sells drugs for clinical research to an investigator or clinical trial site is not a dispenser.	
§§ 205.3(n)(8), (n)(11)	The definition of "wholesale distribution" in proposed §§ 205.3(n)(8) and (n)(11) excludes from the definition of wholesale distribution manufacturers and repackagers, respectively, that distribute their own products. We believe, however, that some states have required manufacturers and/or repackagers, and their affiliates and co-licensed partners, to hold wholesale distributor licenses even though the manufacturer or repackager is only distributing its own products. We explain why we believe these different State requirements are preempted in our HDA Preemption Analysis, Attachment 1, included with our cover letter. As discussed in section 1 above, we urge a stronger statement on this issue in the rule itself.	New § 205. _ (g) *Scope of Preemption*. **(g) No licensing authority shall license or otherwise regulate a manufacturer or repackager, including the manufacturer's or repackager's affiliates and co-licensed partners, as a wholesale distributor where the manufacturer or repackager is only distributing its own product.**

6. Other Definitions, ***Proposed § 205.3***

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.3(c), *co-licensed partner*	What a "co-licensed partner" is continues to be a source of confusion among supply chain members. We support the proposed definition in proposed § 205.3(c). Wholesale distributors have relied upon the attestations of their supplier trading partners regarding their status as co-licensed partners of registered manufacturers and will continue to do so. We suggest adding "manufacturing" to the definition to clarify that those co-licensed partners include contract manufacturers.	New § 205.3(c) *Co-licensed partner* means one of two or more entities that have entered a written agreement for the right to engage in the **manufacturing or** marketing of a prescription drug.
§ 205.3(d), *designated representative*	We note that the facility manager and the role of the facility manager are not defined. However, we do not believe it is accurate to characterize the designated representative as always being the designee of the facility manager; at a facility, there may not be a facility manager, or the facility manager and the designated representative may be the same person. We believe that, generally, the facility manager, and not the designated representative as proposed, is the person "responsible for managing the daily operations" of the facility. We believe the most important issue regarding designated representatives/facility managers is that they are qualified for their responsibilities. This is the approach taken by many States. We discuss, in section 18 below, the critical issues regarding	New § 205.3(d) *Designated representative* means an individual who is **the facility manager or** is designated as the representative of the facility manager and**:** ~~Is responsible for managing the daily operations of the wholesale distributor or 3PL facility.~~ **(i) Is employed by the wholesale distributor or 3PL in a full-time capacity;** **(ii) Has the appropriate education and/or experience; and**

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	the responsibilities and qualifications of a designated representative. We offer editorial changes to the definition for the agency's consideration.	**(iii) Is knowledgeable about policies and procedures pertaining to the operations and license requirements of the wholesale distributor or 3PL.**
§ 205.3(f), *facility*	The proposed rule defines "facility" as an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location used for distribution, including storage and handling, of prescription drugs." We support this definition and believe that it permits a single operation, under a single corporate entity and management, such as a wholesale distributor with several buildings on a single campus, to operate its facility under a single license.	
§ 205.3(i), *other logistics services*	We support the addition of services for repackagers in the definition of "other logistics services" given their omission from the statutory definition of 3PLs in § 581(22). However, we believe the proposed definition in § 205.3(i) unduly limits repackager services to when the repackager is acting on behalf of another trading partner. Repackagers are trading partners in their own right and may use 3PLs just as manufacturers, dispensers, and wholesale distributors do. We suggest amending proposed § 205.3(i) to specifically include 3PL services performed on behalf of repackagers. The Revised Trading Partners Draft Guidance (available here) appears to recognize, as this proposed rule does not, that a repackager can be acting on behalf of itself, or on behalf of another trading partner, when using a 3PL's services. We support the Revised Draft Guidance's treatment of 3PL services performed on behalf of repackagers and suggest aligning § 205.3(i) with the Revised Draft Guidance.	New § 205.3(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, **repackager**, 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~~ **by a 3PL on behalf of a repackager.**
§ 205.3(m), *definition of unfit for distribution*	We appreciate that, in the proposed definition of "unfit for distribution," the proposed rule recognizes the distinction between suspect and illegitimate products under § 581 and § 582 and products that, though they are unfit for distribution, are not suspect or illegitimate. However, the definition in proposed § 205.3(m) is otherwise overbroad, particularly given the many instances where the proposed rule links requirements to products that are or may be "unfit for distribution." We are very concerned with a definition that bluntly declares that any product in violation of the FD&C Act is, necessarily, unfit for distribution. ***Very minor*** non-compliance, such as what may arise from packaging and labeling, under this definition would render all such products unfit for distribution even though they are still safe for their intended use, pure, and have been held under appropriate conditions to maintain their integrity and strength.	New § 205.3(m) (m) *Unfit for distribution* means a prescription drug that **the wholesale distributor or 3PL** has ~~been~~ identified**, whether on its own or via notification from another entity,** as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act. This includes prescription drugs identified as suspect or illegitimate pursuant to section 582(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee-1(c)); adulterated pursuant to section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), including drugs rendered nonsaleable because conditions such as return, recall, damage, or expiry cast doubt on the drug's safety, identity, strength,

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	Additionally, a wholesale distributor or 3PL would not know or even be able to detect many of the concerns that would render a product unfit for distribution under this definition. Only the most obvious of problems would be discernable to a 3PL or wholesale distributor, such as if a product has obvious, visible damage or is expired, or if the 3PL or wholesale distributor has received a notification that the product is being recalled or is illegitimate. The definition does attempt to limit its scope with the first sentence, clarifying that "unfit for distribution" "means a prescription drug ***that has been identified*** as a drug whose sale would violate the Federal Food, Drug, and Cosmetic Act" (emphasis added). We strongly recommend more clarity around "that has been identified." Without further qualification – ***and consistent use of this qualifier throughout the Licensure Rule*** – wholesale distributors and 3PLs could otherwise be responsible for products they had no way of knowing were unfit for distribution. An aggressive interpretation could also result in conservative actions, including the removal from distribution – and potential shortage -- of products that are otherwise completely fit for distribution and safe for patient use.	quality, or purity; or misbranded pursuant to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

7. Requirement that 3PLs be Licensed, *Proposed § 205.4*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.4	Proposed § 205.4 is, in our view, accurately presenting the requirements of § 584(a). We note that the status of 3PLs has been an ongoing issue in many States. We support this clear articulation of the law. Further, a critical addition, (which we have suggested be added to a new section on preemption as described in section 1 above) is to repeat that a licensing authority may not require a 3PL to be licensed (or otherwise regulated) as a wholesale distributor.	New § 205.4(e) **(e) No licensing authority shall license or otherwise regulate third-party logistics providers as wholesale distributors.**

8. Co-location of 3PLs and Wholesale Distributors, *for 3PLs, Proposed § 205.10(b),* and *for Wholesale Distributors, Proposed § 205.26(a)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
Proposed § 205.10(b), 3PL Proposed § 205.26(a), wholesale distributor	FDA requires that "an entity that operates a facility in which it engages in wholesale distribution and performs 3PL activities on behalf of other trading partners for products it does not own or direct the sale or disposition of is required to obtain both a wholesale distributor and 3PL license for that facility." 87 Fed. Reg. at 6716. We agree that an entity operating both a wholesale distributor and a 3PL at the same facility should assure that each it is appropriately licensed for those functions it is performing. However, we have some concerns with the requirement to maintain "separate systems and processes." We agree that a 3PL and wholesale distributor under common ownership must each operate as a distinct business unit and maintain separate inventory. However, for reasons of efficiency, quality control, oversight, and overall management, a corporation may use some of the same "systems" across its commonly owned businesses. A single corporate entity may institute, across its business, certain common systems, such as a common enterprise resource planning (ERP) system, and/or inventory management system. Separating all systems could be overly burdensome for businesses, without any added patient safety benefit, and could detrimentally introduce confusion and inconsistency. We believe requiring all systems to be separate is overbroad and that the concept can be narrowed while still assuring adequate (and separate) operations where needed and appropriate. We note that the co-location requirements for 3PLs (proposed § 205.10(b)) and wholesale distributors (proposed 205.26(a)) are not parallel. We recommend the two sections be aligned. We are also concerned with the requirement that the co-located enterprises must have licenses issued "in the same name." As we discuss in section 35 and proposed § 205.13(a)(4) and proposed § 205.27(b)(1), it is largely impossible for a wholesale distributor or 3PL to police how they are identified by other entities, including licensing authorities. Facility names are often abbreviated in State license applications because there are not enough characters and space in an electronically generated box. If the name is cut off due to space constraints, the license the authority issues might not match the facility's name. Moreover, in the experience of HDA's wholesale distributor members, (i) many companies prefer to assign distinct names to their various business units; and (ii)	New § 205.10(b) (b) A facility to which a 3PL license has been issued ~~in the same name~~ and **which is co-located at one general, permanent, physical location** ~~at the same address as~~ **with** another **authorized** trading partner, such as a wholesale distributor, **where both enterprises are under common ownership,** must maintain ~~separate~~ **appropriate** systems and processes for products that are specific to the 3PL. **The co-located 3PL and other authorized trading partner may share those systems that are typically shared across an organization, such as an enterprise resource planning system and inventory management system. The 3PL and other authorized trading partner shall maintain separate inventory.** --- New § 205.26(a) (a) A wholesale distributor **facility** to which a license has been issued ~~in the same name~~ and **which is co-located at one general, permanent, physical location** ~~at the same address as~~ **with** another authorized trading partner, such as a 3PL, **where both enterprises are under common ownership,** must maintain ~~separate~~ **appropriate** systems and processes for the distribution of drugs that are specific to the wholesale distributor. **The co-located wholesale distributor and other authorized trading partner may share those systems that are typically shared across an organization, such as an enterprise resource planning system and inventory management system. The wholesale distributor and other authorized trading partner shall maintain separate inventory.**

	manufacturer suppliers may have a strong preference, or even business requirement, that co-located 3PLs and wholesale distributors have different business names. Distinct names may also be useful for customers and other trading partners who wish to easily distinguish, on invoices or other documentation, whether they are dealing with a 3PL or a wholesale distributor, which cannot be accomplished easily if both have the same business name. We also note that it is possible for the same physical location or building where a 3PL and wholesale distributor are co-located to be assigned two different addresses by the U.S. Postal Service. This might occur, for example, if the same building is large enough to have entrances on two cross streets, and, therefore, may have two different street addresses. We believe that what the licensure rule is concerned with and seeks to ensure is not the same name and address, but that co-located enterprises operating under ***common ownership at the same facility*** are appropriately licensed for the activities they are performing The definition of "facility" in proposed § 205.3(f) is instructive and useful: "(f) *Facility* means an establishment, warehouse, structure, or structures under common ownership at one general, permanent, physical location…". We believe that concept should be extended to proposed § 205.10(b) and proposed § 205.26(a) and suggest changes to clarify that co-located enterprises must have the same common owner and be at one general, permanent, physical location – which may, or may not have the same street address as the other entity but is at the same physical location.	

9. Requirement that Prescription Drug Wholesale Distributors be Licensed, *Proposed § 205.20*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.20	The proposed rule provides that no wholesale distributor may engage in wholesale distribution unless the "person" is licensed. The 3PL provision, in contrast, in proposed § 205.4(a), requires that each "facility" be licensed. We suggest similar language for proposed § 205.20(a) to make clear that a wholesale distributor must secure licenses on a facility-by-facility basis. We recognize that there may be some ambiguity because the FD&C Act refers to the license of a "person" engaged in the wholesale distribution (*see, e.g.,* § 583 and § 503(e)), with a potential implication that a wholesale distribution facility does not have to hold a license but only be inspected. Requiring only a "person" engaged in wholesale distribution to be licensed could be read as requiring that only a single	New § 205.20(a) (a) No ~~wholesale distributor~~ **entity** may engage in wholesale distribution of a prescription drug **from a facility** unless ~~the person~~ **the facility** is licensed: (1)**(i)** By the State from which the drug is distributed; or ~~(2)~~**(ii)** If the State from which the drug is distributed has not established a licensure requirement in accordance with the standards set forth in this part, by the Food and Drug Administration; and

	corporate entity have a single license to cover all its facilities. We urge FDA to address this issue plainly because we believe supply chain security depends upon each, individual, wholesale distribution facility being licensed. This is the current regime in State licensure schemes, and we do not believe that the DSCSA was intended to lessen or eliminate that oversight, but only to assure that State and federal standards for that oversight be the same. Not requiring a wholesale distributor facility to be licensed, as 3PL facilities must be, in our view, represents a potentially significant gap in security and accountability. We also believe that the "or" and "and" presentation in proposed § 205.20(a)(1), (2), and (3) is confusing, and we suggest a different format.	~~(3)~~**(2)** If the drug is distributed interstate, by the State into which the drug is distributed if such licensure is required by that State.

10. Surety Bond Requirements, *for Wholesale Distributors, Proposed § 205.21*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.21, *wholesale distributors*	We support the surety bond requirements in proposed § 205.21. We are aware that the FDA was seeking comment regarding the waiver of an additional surety bond if the wholesale distributor can provide a bond from its resident State to satisfy the non-resident licensure requirements of the State into which the wholesale distributor plans to distribute. 87 Fed. Reg. at 6723-34. FDA noted that it was unclear if and how this waiver should apply when an equivalent means of security to the surety bond are used. We strongly support the ability to provide evidence of a bond from a resident State to satisfy non-resident licensure requirements of a non-resident State. We further recommend that FDA establish a single, recommended surety form. We believe this would provide enormous efficiencies and consistency. We specifically recommend that FDA permit a corporate bond that covers the entire corporation, rather than individual, facility-specific bonds. The corporate bond would identify each facility covered and would identify State licensing authorities as obligees.	New § 205.21 … (b) *Surety bond requirements*. … (3) If a wholesale distributor can provide evidence that it possesses the required bond in the State where the wholesale distributor is located, the requirement for a bond in another State for a non-resident wholesale distributor license **shall** ~~will~~ be waived **by the licensing authority**. … **(i) *Company bond*. A wholesale distributor may satisfy the requirement to furnish a surety bond if it obtains a bond covering the entire company entity. Such bond shall name the wholesale distributor as Principal, each facility covered by the bond, each applicable licensing authority as an obligee, and the surety company (and its heirs, executors, administrators, successors, and assignees, jointly and severally) as surety.**

11. Submission of Licensure Application General Requirements, *for Wholesale Distributors, Proposed § 205.22*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.22(c)(2), *wholesale distributors*	The general requirements for licensure, as proposed in § 205.22(c), do not require the wholesale distributor applicant to specifically identify the address and phone number of the facility to be licensed. Rather, the wholesale distributor applicant is only required to identify its name. Thus, the proposed rule could be interpreted as requiring only corporate-level information from a wholesale distributor and that there is no specific requirement for an individual wholesale distributor facility to be licensed or even that the applicant identifies the specific facility to be licensed. As discussed in section 9 above and in our cover letter, we believe this approach is arising from the agency's interpretation of the FD&C Act, which refers to the license of a "person" engaged in wholesale distribution. *See, e.g.,* § 583 and § 503(e). We do not believe the DSCSA was intended to establish a national wholesale distributor license nor to lessen or eliminate the licensure of individual facilities by State authorities and State oversight. The DSCSA's preemption requirements are to assure that State and federal standards for that oversight are the same. We believe that the identification of the physical location and phone number of the wholesale distributor facility that is to be licensed is critical to supply chain security, and we urge clarification to that effect.	New § 205.22(c)(2) (c) *General requirements for licensure application.* The State or Federal licensing authority will require the following information from each wholesale distributor as part of the initial application for the license described in this section and as part of any renewal of such license: … (2) The name of the wholesale distributor as it should appear on the license and the full business address and telephone number of the wholesale ~~distributor~~ **distribution facility to be licensed**; …

12. Federal Licensure Process, *for 3PLs, Proposed § 205.6,* and *for Wholesale Distributors, Proposed § 205.23*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.6(a), *3PLs* § 205.23(a), *wholesale distributors*	While proposed § 205.6 and proposed § 205.23 set out the federal licensure process, State licensing authorities should adopt the same procedures. We believe FDA should clarify the obligations of State licensing authorities to adopt and implement these national standards. Proposed § 205.6 and proposed § 205.23 should not imply, as they do currently, that these application requirements apply only to the federal licensure process and that States may implement some other regime that requires submission of additional or different information.	Example for § 205.6 205.6(a) ~~Federal Licensure~~ Process **for Submission of License Application** (a) *Procedures for filing an ~~FDA~~ application for a 3PL license.*

	We believe it will be significantly easier for States to adopt these licensure standards if proposed § 205.6 and proposed § 205.23 were recast as the "Process for Submission of License Application" so that it is clear that each section and the process it describes apply to ***both*** federal and state licensing authorities. The process and application should be the same, regardless of who the licensing authority is. We recommend, therefore, that proposed § 205.6 and proposed § 205.23 be amended so that the "Food and Drug Administration" is replaced with "licensing authority" and that language that is specific to FDA is broadened to include State licensing authorities. We provide a sample of this change for proposed § 205.6(a)(1) and proposed § 205.23(a)(1) and clarify that State licensing authority application processes must be the same as the standards of this part. To ease burdens on state licensing authorities and to ensure compliance with these national standards, we strongly urge FDA to develop a common application to be used by all licensing authorities. The 3PL provision, proposed § 205.6(a)(1), clarifies that the 3PL must submit an application for a federal "license to conduct 3PL activities ***in a State*** if the State does not have a 3PL licensure program…" (emphasis added). The wholesale distributor provision does not include the "in a State" language; its addition would clarify when a wholesale distributor must obtain a federal license. We are also concerned that the requirement in both provisions to provide "supporting documentation" is overly broad. We urge greater specificity and clarity around this requirement, or it could become extremely burdensome and could be inconsistently applied by different licensure authorities. "Supporting documentation" could be thousands of pages ***for each*** facility – which becomes even more burdensome when the same documentation (such as SOPs) is consistent across an entire company but still would have to be submitted for each facility seeking a license in each State. Moreover, the licensing authority will be inspecting a wholesale distributor or 3PL every two or three years, respectively. As such, there is no need to submit all supporting documentation when it can and will be readily available during the inspection. We also note that, as we discuss in section 44 below, regarding changes in license information for 3PLs and wholesale distributors, proposed § 205.7(a) and proposed § 205.24(a), not all States are able to process license applications electronically. Though we believe licensing authorities should migrate to and enable electronic submissions, we recommend that the proposed rule recognize that not all States yet have this capacity.	(1) Each 3PL facility must electronically submit an application to the Food and Drug Administration for a license to conduct 3PL activities in a State if the State does not have a 3PL licensure program **or submit an application to the State licensing authority if the State does have a 3PL licensure program. Such application shall be in accordance** ~~consistent~~ with the standards set forth in this section. The application must include the information specified in § 205.5~~, along with supporting documentation that demonstrates the applicant's storage practices are sufficient to ensure the continued safety, identity, strength, quality, and purity of the products in the facility~~. [Conforming changes would follow for the remainder of § 205.6] --- Example for § 205.23 § 205.23 ~~Federal Licensure~~ Process **for Submission of License Application** (a) *Procedures for filing an ~~FDA~~ application for a wholesale distributor license*. (1) All wholesale distributors must electronically submit an application to the Food and Drug Administration for a license to engage in wholesale distribution **in a State if the State does not have a wholesale distributor licensure program or submit an application to the State licensing authority if the State does have a wholesale distribution licensure program. Such application shall be in accordance** ~~if the State does not have a licensing program for wholesale distributors consistent~~ with the standards set forth in this section. The application must include the information in §§ 205.21 and 205.22, along with a surety bond ~~and supporting documentation that demonstrates the applicant's ability to comply with requirements intended to ensure the continued safety, identity, strength, quality, and purity of the prescription drugs~~. [Conforming changes would follow for the remainder of § 205.23]

6740; § 205.6(c), *notification of easily correctable deficiencies*, *3PLs* 6749; § 205.23(c), *notification of easily correctable deficiencies, wholesale distributors*	The proposed rule states that FDA will make "every reasonable effort to promptly communicate…easily correctable deficiencies…" for 3PL applications. We support this process for prompt communication by the licensing authority regarding easily correctable problems in an application so that issues may be swiftly remedied. We believe the contemplated process is achievable and efficient, while also respectful of time and resources for both the license applicant and the licensing authority. We recommend the 3PL provision, proposed § 205.6(c), be extended to the wholesale distributor provision, proposed § 205.23(c). Prompt communication regarding easily correctable deficiencies should be the same for both 3PLs and wholesale distributors.	New § 205.6(c) The **licensing authority** ~~Food and Drug Administration~~ will make every reasonable effort to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning storage, handling, distribution, or recordkeeping issues. The **licensing authority** ~~Food and Drug Administration~~ will also promptly inform applicants of its need for more data or information or for changes in the application needed to facilitate the Agency's review. --- New § 205.23(c) (c) The **licensing authority** ~~Food and Drug Administration~~ will make **every** reasonable ~~efforts~~ **effort** to promptly communicate to applicants easily correctable deficiencies found in an application when those deficiencies are discovered**, particularly deficiencies concerning storage, handling, distribution, or recordkeeping issues**. The **licensing authority** ~~Food and Drug Administration~~ will also promptly inform applicants **of its need for more data or information or for changes in the application needed to facilitate the licensing authority's review** ~~if more data or information is needed to facilitate the Agency's review~~.

13. General Requirements, *for 3PLs, Proposed § 205.10(c)(1),* and *for Wholesale Distributors, Proposed § 205.26(b)(1)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.10(c)(1), *general requirements*, *3PLs*	Proposed § 205.10(c)(1) (for 3PLs) and proposed § 205.26(b)(1) (for wholesale distributors) are similar and address the same substantive requirements yet are not parallel in language and structure. This is an area where we believe aligning the 3PL and wholesale distributor requirements as closely as possible would make for better regulation overall. Seemingly minor differences may distract both the regulated and regulator with whether the difference is meaningful and intended, mandated by differences in the DSCSA, or simply a drafting artifact.	New § 205.10(c)(1) [replace with the following, modeled on proposed § 205.26(b)(1)] **The facility the 3PL owns, leases, or rents for purposes of engaging in 3PL activities must be suitable for the storage and handling of prescription drugs, as demonstrated by the following:**

§ 205.26(b)(1), *general requirements, wholesale distributors*	We strongly urge that the two sections be aligned and, in this case, recommend that the wholesale distributor provision be modified to apply to 3PLs as proposed § 205.26(b)(1) appears more comprehensive. However, the 3PL provision contains more detailed requirements regarding pest management and we suggest that this 3PL requirement be added to the wholesale distributor provision.	**(1) *General requirements*. The facility is:** **(i) Not a personal residence;** **(ii) Of a suitable size, construction, and configuration designed to ensure proper distribution, including storage and handing, of all prescription drugs stored at or distributed from the facility;** **(iii) Of a suitable size, construction, and configuration to facilitate cleaning, maintenance, and proper 3PL operations;** **(iv) Maintained in a clean and orderly condition, free from infestation of any kind;** **(A) A cleaning program schedule must be maintained, documented, and followed;** **(B) A pest control program, which is designed to ensure that the facility is free from infestation, must be in place, and pest control records must be kept;** **(v) Equipped with sufficient lighting, ventilation, temperature, sanitation, humidity, space, equipment, and secure conditions for prescription drug storage; and** **(vi) Equipped with clearly defined designated areas that separate saleable prescription drugs from prescription drugs that are unfit for distribution.** --- New § 205.26(b)(1)(iv) … (iv) Maintained in a clean and orderly condition, free from infestation of any kind; **(A) A cleaning program schedule must be maintained, documented, and followed;** **(B) A pest control program, which is designed to ensure that the facility is free from infestation, must be in place, and pest control records must be kept;** …

14. Separation of Saleable & Unsaleable Products, *for 3PLs, Proposed § 205.10(c)(2),* and Separation of Prescription Drugs, *for Wholesale Distributors, Proposed § 205.26(b)(1)(vi)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.10(c)(2), *3PLs* § 205.26(b)(1)(vi), *wholesale distributors*	We believe that the 3PL provision in proposed § 205.10(c)(2) complicates and confuses the important separation of saleable from nonsaleable prescription drugs. It is unclear why the 3PL provision attempts to categorize different types of unsaleable prescription drugs when none of them should be sold. We believe the wholesale distributor provision in proposed § 205.26(b)(1)(vi) adequately describes what a facility must do to protect patients and the supply chain from nonsaleable prescription drugs and we recommend its adoption for 3PLs. Additionally, though proposed § 205.10(c)(2) and proposed § 205.26(b)(1)(vi) use the term "unfit for distribution," neither section includes the important qualifier described in section 6 above, that is, products that have been "identified as" unfit for distribution. To avoid an otherwise impossibly broad legal obligation based upon what is likely unknowable for a 3PL or wholesale distributor, only products that are "identified" as unfit for distribution should be covered by this regulation. We also are concerned with the proposed § 205.10(c)(2) inclusion of "returns" as unfit for distribution. A product returned to a 3PL may be in good, saleable condition and it is not automatically "unfit for distribution" simply because it is returned. Of course, a 3PL should have processes for determining whether a return is in good condition and saleable. Additionally, proposed § 205.26(c)(5)(ii)(A) and (B) allow wholesale distributors to electronically segregate products. Subsection (B) states: "Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in accordance with the standards in paragraph (c)(6) of this section." As we explain in section 21 below, Handling of Prescription Drugs for Wholesale Distributors, proposed § 205.26(c)(5)(ii), we strongly support the proposed rule's option of electronic segregation. We believe these provisions regarding segregated areas need to be aligned with the proposed rule's provisions on electronic segregation. These provisions should also be extended to 3PLs.	New § 205.10(c)(2), (2) *Areas to handle separation of products that are **identified as** unfit for distribution*. **The facility is equipped with clearly defined designated areas that physically or, if appropriate, electronically, separate saleable products from products that have been identified by the 3PL as unfit for distribution, either on its own or via notification from another entity.** ~~The facility has:~~ ~~(i) Clearly defined, designated areas separate from saleable products to quarantine suspect product, illegitimate product, and other products that are unfit for distribution until dispositioned.~~ ~~(ii) Clearly defined, designated areas to handle separation of products that are returned, recalled, or expired.~~ ~~(iii) For returned or recalled products, clearly defined, designated areas separate from saleable products to handle returned or recalled product.~~ ~~(iv) For expired products, clearly defined, designated areas separate from saleable products from which expired product may be returned to the manufacturer or repackager or destroyed.~~ --- New § 205.26(b)(1)(vi) (vi) Equipped with clearly defined designated areas that **physically or, if appropriate, electronically,** separate saleable prescription drugs from prescription drugs that **have been identified by the wholesale distributor as** ~~are~~ unfit for distribution, **either on its own or via notification from another entity.**

15. Security of Premises, *for 3PLs, Proposed § 205.10(c)(3),* and *for Wholesale Distributors, Proposed § 205.26(b)(2)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.10(c)(3), *security of premises*, *3PLs* § 205.26(b)(2), *security of premises, wholesale distributors*	The "security of premises" requirements in proposed § 205.10(c)(3) and proposed § 205.26(b)(2) appear similar and address the same substantive requirements. Yet, the sections are not parallel in language and structure. We believe aligning the 3PL and wholesale distributor requirements as closely as possible would make for better regulation overall. Seemingly minor differences may distract both the regulated and regulator with whether the difference is meaningful and intended, mandated by differences in the DSCSA, or simply a drafting artifact. We recommend that the proposed § 205.10(c)(3), security of premises for 3PLs, be deleted and replaced with requirements identical to proposed § 205.26(b)(2) for wholesale distributors.	

16. Equipment, *by 3PLs, Proposed § 205.10(c)(5),* and *by Wholesale Distributors, Proposed § 205.26(b)(3)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
6743; § 205.10(c)(5), *equipment*, *3PLs* 6751; § 205.26(b)(3), *equipment, wholesale distributors*	The 3PL provision (proposed § 205.10(c)(5)(iii)) specifies a "timely" alert of any deviations from intended storage conditions, whereas the wholesale distributor provision (proposed 205.26(b)(3)(iii)) requires an alert "immediately." We believe that the 3PL provision is a better and more accurate description of the systems, processes, and protections around monitoring and subsequent handling when deviations occur. Alerts, depending upon what they pertain to, may not require immediate attention – for instance, if a system is informing warehouse personnel that a piece of equipment will soon need to be replaced or serviced, or that a threshold is being approached but not yet crossed. Certainly, some alerts would require an immediate response, but not all. We believe that requiring a response in a timely manner, rather than immediately will assure proper and appropriate, but not unnecessary and needless, attention. We are concerned with the requirement in both proposed § 205.10(c)(5)(i) and proposed § 205.26(b)(3)(i) that the 3PL and wholesale distributor, respectively, must have "validated" equipment. HDA explained previously in our comments following FDA's November 16, 2021, public meeting that good manufacturing	New § 205.10(c)(5)(i) (i) The 3PL must be able to demonstrate that all **environmental monitoring** equipment has been calibrated, as applicable, and **confirmed as accurate** ~~validated~~ at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following approved procedures; … (iii) The monitoring equipment must alert appropriate personnel in a timely manner of any deviations from the intended storage conditions. --- New § 205.26(b)(3)(i)

	practice (GMP) requirements (and the validation requirements embedded in them) do not apply to wholesale distributors. *See* 86 Fed. Reg. 57435 (Oct. 15, 2021), Docket No. FDA–2021–N–1004, and HDA comments here. As we explained in that comment, there is a long history of the FDA specifically stating that GMP requirements in 21 C.F.R. Parts 210 and 211 apply ***only*** to manufacturers and not to wholesale distributors (and, by extension, 3PLs). Until FDA formally undertakes new rulemaking and applies Parts 210 and 211 to wholesale distributors and 3PLs, wholesale distributors and 3PLs are not legally required to comply with GMPs, including validation requirements. We ask that the word "validated" be removed from the Licensure Rule and replaced with another, more appropriate, term such as "confirmed." Additionally, given the discussion of monitoring and alerts, we believe this section is intended specifically to address environmental monitoring in facilities for conditions such as temperature, rather than ***all*** equipment in a facility, such as intercoms, scanners, or forklifts. We recommend that clarification be added to the final rule.	(i) All **environmental monitoring** equipment must be installed, maintained, and repaired by qualified individuals following written procedures established by the wholesale distributor. The wholesale distributor must be able to demonstrate that all equipment has been calibrated, as applicable, and **confirmed** ~~validated~~ at regular intervals to achieve the intended results accurately, consistently, and in a manner that can be reproduced by qualified individuals following the wholesale distributor's written procedures. Such actions must be documented; … (iii) **Environmental m**~~m~~onitoring equipment must **timely** ~~immediately~~ alert appropriate personnel of any deviations from the required storage conditions.

17. Personnel Lists, *for 3PLs, Proposed § 205.11(a),* and *for Wholesale Distributors, Proposed § 205.25(d)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.11(a), *personnel lists, 3PLs* § 205.25(d), *personnel lists, wholesale distributors*	The comparable provision for wholesale distributor personnel lists, proposed § 205.25(d), states that the facility must maintain a "list of officers, directors, ***facility*** managers, designated representatives, and other key personnel…" (emphasis added). We believe that the 3PL provision, proposed § 205.11(a), inadvertently omitted "facility" before the word "managers."	New, § 205.11(a) (a) The 3PL must maintain a list of officers, directors, **facility** managers, and designated representatives; a description of their duties; and a summary of their qualifications. This list must be available for review by the State or Federal licensing authority.

18. Facility Manager/Designated Representative, *for 3PLs, Proposed §§ 205.11(b), (c), (d), and for Wholesale Distributors, Proposed § 205.25(f)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.11(b), *facility manager or designated representative*, *3PLs* § 205.25(f), *facility manager or designated representative, wholesale distributors*	The provisions regarding the Facility Manager/Designated Representative are similar in proposed §§ 205.11 and 205.25(f) and address the same substantive requirements, yet the regulations are not parallel in structure. We suggest that the final rule harmonize these respective provisions and make them parallel in both format and content. The qualifications for the wholesale distributor designated representative and facility manager are not in their own, discrete section. Rather, proposed § 205.25(f) includes the awkward cross-reference, "In addition to the qualifications for key personnel in paragraphs (a) through (e) of this section." We strongly recommend that these important requirements for wholesale distributors be presented as they are for 3PLs, in their own independent section, entitled *Qualifications for the wholesale distributor's facility manager or designated representative,* and be aligned with the 3PL requirements in proposed § 205.11. Current State requirements regarding facility managers and designated representatives vary widely and have led to numerous, highly variable requirements. We ask that FDA be clear that the imposition of such additional requirements by State regulatory authorities is not permissible. Further, to demonstrate adequate education of the designated representative or facility manager, some licensing authorities have required licensees to submit high school diplomas and transcripts. We believe that, rather than a focus on minimum education (and the arbitrary location of a diploma that the employee might have obtained decades earlier), the qualifications for the facility manager or designated representative should focus upon demonstrable experience and active involvement at the facility. Our recommendations for this important provision combine and/or expand proposed §§ 205.11 and 205.25(f), include the above suggested changes, and present these requirements in its own, consolidated subsection.	New § 205.11(b) and § 205.25(f) **(1) The designated representative or facility manager identified in the license application shall meet the following qualifications:** **(i) Is at least 21 years of age;** **(ii) Has been employed full time for at least 2 years in a pharmacy, 3PL, wholesale distributor, manufacturer, or repackager in a capacity related to the distribution of, and recordkeeping associated with, prescription drugs, or possesses other comparable experience;** **(iii) Is employed by the license applicant full-time in a leadership level position;** **(iv) Serves as a facility manager or designated representative for only one facility at a time;** **(v) Has appropriate education and/or experience to assume responsibility for compliance with licensing requirements at the facility; and** **(vi) Is aware of, and knowledgeable about, the policies and procedures pertaining to the prescription drug operations of the license applicant.** **(2) The designated representative or facility manager shall be physically present at the license applicant's facility during normal business hours, except for authorized absences. Other full-time personnel with appropriate knowledge and experience may be appointed to assume the responsibilities in the event of such an authorized absence, but such personnel do not need to be identified on the license or in the license application.** **(3) The designated representative or facility manager that meets the requirements of this subpart shall not**

		be required to undergo testing or further qualifications or certifications by the licensing authority. **(4) The designated representative or facility manager remains responsible for duties that they delegate to other personnel at the facility.**

19. Criminal Background Checks for Facility Managers & Designated Representatives, *for 3PLs, Proposed § 205.11(g),* and *for Wholesale Distributors, Proposed § 205.25(g)*

Cite to Preamble or Proposed Rule	HDA Comments	HDA Recommended Changes
§ 205.11(g), *criminal background checks*, *3PLs* § 205.25(g), *criminal background checks, wholesale distributors*	We note that § 584 for 3PLs requires only a "background check" whereas § 583 for wholesale distributors specifically identifies both a background check and fingerprinting. We do not believe it is possible to conduct the "background check" that § 584 requires without fingerprinting. We suggest that the agency acknowledge this difference between § 583 and § 584 expressly and clearly explain its interpretation of what is required for compliance. We believe the better reading is that each license applicant, whether 3PL or wholesale distributor, must submit to a State and federal criminal history search for the proposed designated representative/ facility manager for a facility and that this is done by obtaining the individual's fingerprints and submitting the fingerprint card to (1) the Federal Bureau of Investigation (FBI) to search for federal criminal history and (2) to the local jurisdiction to search for a State criminal history. We recommend this be made clear in the Licensure Rule. There is enormous variety in current State licensing requirements around fingerprinting and criminal background checks. Some States have required fingerprinting of persons in addition to designated representatives and facility managers, such as corporate owners, officers, and directors. Some States require fingerprints only on special cards with the State's own assigned number on them; others permit the applicant to add this special number to an existing card. Some States will only provide the fingerprint card after an initial application is submitted. We urge FDA to explain in a discrete subsection the process of background checks and fingerprinting very clearly and specifically to bring greater consistency to the widely varying and sometimes idiosyncratic State requirements. Further, we ask that FDA make expressly clear that differing State requirements are preempted and	New § 205. __ *Fingerprints and criminal background checks* **(a) The facility manager or designated representative identified in the licensure application of a wholesale distributor or 3PL will be subject to state and federal criminal background checks conducted within six months prior to submission of the license application. The applicant should attest that there has been no change in the criminal background of the facility manager or designated representative during the period between the date of the background check and the date of submission of the license application.** **(b) In order to facilitate the background check of the facility manager or designated representative identified in the license application, the applicant shall submit a set of fingerprints of the designated representative or facility manager that has been collected pursuant to procedures determined by the Federal Bureau of Investigation (FBI). The fingerprints shall be collected on an FBI Form 258 or in a digital scan acceptable to the FBI.** **(c) Once the fingerprints of the designated representative or facility manager have been submitted to the licensing authority and accepted as part of the**

	that the only persons subject to the criminal background check and fingerprinting are designated representatives and facility managers. As fingerprints do not change, we ask that the Licensure Rule be clear that a facility manager or designated representative's fingerprints need to be submitted only once to the licensing authority. (Of course, if there is a new designated representative or facility manager at a facility, that person's fingerprints would need to be submitted to the licensing authority – changes in applications are discussed further in section 44 below.) A related point is that, where required by State law, current facility license applications and files with State licensing authorities already include the fingerprints of the facility managers and designated representatives for those already licensed facilities. We ask that, in transitioning from State licensing requirements to these national standards, the FDA not require the re-submission of new sets of fingerprints for existing designated representatives and facility managers if those fingerprints are already on file with the State licensing authority. For the collection of fingerprints, we strongly urge FDA to specify the format for collection and to instruct States to use that form. Acceptable forms should be a standardized form, such as the FBI 258, or a digital fingerprint scan. In the interests of economy, a 3PL or wholesale distributor may want to request criminal background checks (from federal and/or state authorities) for designated representatives and facilities managers across its network of facilities in a "batch" at the same time and to have those background checks deemed to be valid by the licensing authority for some period of time while the license application is under review. The background checks, as discussed in section 42 below regarding renewals, would of course be updated at each renewal (though not the fingerprinting). We ask that a background check conducted within 6 months of submission to the licensure authority be deemed acceptable, with an attestation that there has been no change.	**licensing authority's approval of a facility, the fingerprints of the designated representative or facility manager need not be resubmitted to the licensing authority again. In the case of a wholesale distributor or 3PL holding an existing license as of the effective date of this part, that 3PL or wholesale distributor is not required to submit the fingerprints of the designated representative or facility manager if the wholesale distributor or 3PL previously submitted the fingerprints of the designated representative or facility manager to the licensing authority.** **(d) Nothing in this section shall prohibit an applicant or licensing authority from utilizing a third-party service to collect fingerprints.** **(e) Pursuant to this part, no licensing authority may require the fingerprinting or criminal background checks of persons other than the facility manager or designated representative identified in an application for wholesale distribution or 3PL licensure.** **(f) The results of the background checks must demonstrate no history of criminal convictions pursuant to § 205.11 for the designated representative/ facility manager for a 3PL and § 205.25 for the designated representative/facility manager for a wholesale distributor**.

20. Written Policies & Procedures for Personnel, *for 3PLs, Proposed § 205.12(b),* and *for Wholesale Distributors, Proposed § 205.25(e)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(b), *personnel, 3PLs* § 205.25(e), *personnel, wholesale distributors*	We have no concerns or comments on proposed § 205.12(b) and proposed § 205.25(e). However, in implementing these provisions, the preamble, in several places refers to personnel-related "best practices." *See, e.g.*, 87 Fed. Reg. at 6719, 625-26 (3PL and wholesale distributor "best practices" around federal controlled substances and prescription drug convictions). We do not believe that the preamble is the appropriate place to describe FDA views on "best practices." If the agency has current thinking on and recommendations concerning personnel practices apart from what is provided for in the proposed rule, the appropriate place to provide those views is in properly promulgated guidance.	

21. Required Written Policies & Procedures, *for 3PLs, Proposed § 205.12(a),* and National Standards for the Storage & Handling of Prescription Drugs, *for Wholesale Distributors, Proposed § 205.26(c)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(a), *general requirements for written policies and procedures, 3PLs* § 205.26(c), *storage and handing, wholesale distributors*	We note that much of proposed § 205.12(a) and proposed § 205.26(c) are similar, yet the sections are not parallel. For example, records availability is included in the general requirements (proposed § 205.12(a)) for 3PLs but is in recordkeeping and document maintenance (proposed § 205.13(a)(1)) for wholesale distributors. We believe compliance will be more smoothly accomplished, with a better understanding of responsibilities and requirements for regulators and regulated industry, if the two sections are more closely aligned and do not convey the perception (through their differences) that they impose different requirements. We are concerned that proposed § 205.12(a) and proposed § 205.26(c) imply GMP compliance with the discussion of "written policies and procedures" that "describe a system" for monitoring "all processes" and "root cause" investigation of seemingly all "deviations." Additionally, the preamble states, at 87 Fed. Reg. at 6726, "FDA believes that wholesale distributors should establish and maintain quality systems that encompass the organizational structure, account for potential vulnerabilities or threats to the systems, and clearly articulate the procedures and processes for all wholesale distribution activity. A proper quality system should be fully documented,	Wherever the term "quality systems" appears in the preamble, it should be changed to "policies and procedures." --- New § 205. __ **§ 205.__ *General exclusion.* The requirements of 21 C.F.R. Parts 210 and 211 do not apply to wholesale distributors and 3PLs.** --- New § 205.12(a) (a) *General requirements for written policies and procedures.* Every 3PL must establish, maintain, and follow written policies and procedures ~~as described in this section and~~ **for each of the requirements described in this section that is** relevant to the scope of their 3PL activities

	and the effectiveness of the system should be continually monitored to ensure the quality is maintained." As we discussed in section 16 above, GMPs do not apply to wholesale distributors or 3PLs. We believe the above-quoted language suggests that they do. The language about monitoring "all" processes and conducting a root cause analysis for any resulting deviations in proposed §§ 205.12(a) and 205.26(c) also seems overbroad as it is imposed without limitation and regardless of whether the deviation has any impact on product strength, identify, quality and patient safety.	**involving prescription drugs at the facility**. The written policies and procedures must clearly delineate the responsibilities of the 3PL**,** and any contractors used to fulfill any of the 3PL's duties. The written policies and procedures must also describe **how** ~~a system by which~~ the 3PL will monitor all processes **that could impact product safety, strength, identity, and quality,** and, if deviations occur, document and investigate to determine the ~~root~~ cause of the deviation in a timely manner. … --- New § 205.26(c) (c) Every wholesale distributor must establish, maintain, and follow written policies and procedures for each of the requirements described in this section that are relevant to the scope of the wholesale distributor's activities involving prescription drugs at the facility. The written policies and procedures must describe **how** ~~a system by which~~ the wholesale distributor will monitor all processes **that could impact product safety, strength, identity, and quality**, and, if deviations occur, promptly document and investigate to determine the ~~root~~ cause of the deviation.

22. Inspection & Handling of Inbound & Outbound Shipments, *for 3PLs, Proposed § 205.12(c)(1),* and Examination of Shipping Containers, *for Wholesale Distributors, Proposed § 205.26(c)(4)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(c)(1), *inspection of inbound and outbound shipments, 3PLs* § 205.26(c)(4) *examination of shipping*	Throughout the proposed rule for 3PLs, there are numerous instances, such as proposed § 205.12, where the proposed rule, rather than setting forth the action the 3PL is expected to take, (*e.g.*, inspect all outbound containers), instead states that the 3PL must have written policies and procedures to take the particular act, (*e.g.*, policies and procedures for the inspection of all outbound containers). We believe the focus on policies and procedures is likely a construct of how the FDA interprets § 584(d)(2)(C)(iii). In contrast, the presentation of wholesale distributor requirements addressing the same topic (*e.g.*, outbound product) presents the licensee's obligations in terms of	

containers, wholesale distributors	an affirmative act that must be taken, rather than policies around that act. This construction of 3PL requirements can make for an awkward and unclear presentation of requirements and obligations. We recommend that FDA recast the 3PL requirements as affirmative acts for clarity and consistency with the wholesale distributor provisions wherever possible.	
6743; § 205.12(c)(1), *inbound, outgoing shipments, 3PLs* § 205.26(c)(4), *examination of shipping containers, wholesale distributors*	We recommend that in proposed § 205.12(c)(1), the title, *Receipt,* be modified as it suggests policies and procedures only around inbound products and not also including outgoing shipments, which the proposed rule does also address in proposed § 205.12(c)(1)(ii). The comparable wholesale distributor provision, proposed § 205.26(c)(4), is entitled "*Examination of shipping containers.*" Separately, as we discussed in section 6 above, the proposed rule's definition and application of "unfit for distribution" is so overbroad that it renders distribution of such prescription drugs illegal even when there are minor problems with no bearing upon product safety. The breadth and vagueness of the concept of "unfit for distribution" potentially make wholesale distributors and 3PLs responsible for even the most inconsequential of problems, and for product/ prescription drug problems for which they have no visibility, notice, knowledge, or understanding. The definition of "unfit for distribution" does assume that a prescription drug "***has been identified***" as violative of the FD&C Act. Proposed § 205.3(m). As discussed in section 6 above, we urged modification of the definition to further clarify that the wholesale distributor or 3PL ***must have identified*** that the prescription drug/product is violative and unfit for distribution, either through its own efforts or via notification from another entity. Proposed §§ 205.12(c) and 205.26(c), however, seem at odds with the limitation in proposed § 205.3(m) to products "***identified***" as "unfit for distribution." In these sections, inbound shipping containers must be visually examined to "prevent the acceptance" of prescription drugs/products that "***are***" unfit for distribution, even though a visual inspection of shipping containers would not identify if, for instance, the prescription drug/product was adulterated during manufacture, or that its package insert contains errors rendering the product misbranded. Similarly, for outbound shipments, containers must be inspected "***to ensure***" product is not unfit when it is highly unlikely that a mere visual inspection of shipping containers could determine much, if anything, about the actual product quality, strength, or purity of a product or prescription drug within its sealed packaging, carton and/or case. The requirement that the prescription drug is "identified" as unfit – which ensures that wholesale distributors and 3PLs are not held responsible for what is, in most instances, going to be unknowable to them – is not present in proposed § 205.12(c) or proposed § 205.26(c). Therefore, we believe this concept should be included in the proposed rule.	New § 205.12(c)(1) (1) ~~*Receipt.*~~ ***Examination of shipping containers.*** The 3PL must establish, maintain, and follow written policies and procedures providing for the inspection of all shipping containers in accordance with the following standards: … (i) *Incoming shipments.* **A 3PL must have systems and processes for the receiving of inspected shipping containers and their transfer to inventory. During the receiving process** ~~Upon receipt~~, each shipping container must be visually examined for identity and for conditions that would suggest the product may be unfit for distribution. (ii) *Outgoing shipments.* Each outgoing shipment must be properly inspected for identity ~~of the product~~ and to ensure that there is no shipment of product that **has been identified by the 3PL, either through its own efforts or via notification from another entity, as** ~~is~~ unfit for distribution. --- New § 205.26(c)(4) (i) *Incoming shipments*. **A wholesale distributor must have systems and processes for the receiving of inspected shipping containers and their transfer to inventory. During the receiving process** ~~Upon receipt~~, each shipping container must be visually examined for identity and **for conditions that would suggest the product may be** ~~to prevent the acceptance of prescription drugs that are~~ unfit for distribution. ~~This examination must be adequate to detect conditions that would suggest that the prescription drug may be unfit for distribution, such as alterations made or damage to the shipping container.~~ (ii) *Outgoing shipments*. Each outgoing shipment must be properly inspected for identity ~~of the prescription drug~~ **and** to ensure that there is no shipment of a prescription drug that **the wholesale distributor has identified, either**

	The statement in proposed § 205.26(c)(4)(i) that a prescription drug may be "unfit for distribution" due to "damage to the shipping container" also appears overbroad as it does not consider the customary wear and tear associated with the ordinary shipment. We are also concerned with the use of the term "acceptance" of inbound shipments in proposed § 205.26(c)(4)(i). Receiving is a complex process and damaged product might be refused at the loading dock if it is identified soon enough. If not, it could be "received" – that is, come into a wholesale distributor warehouse, but it would not be "accepted" and transferred to saleable inventory. We are concerned that the terms that are used may not align with how they are, in fact, operationalized, which could lead to confusion during inspections. We suggest edits to clarify these important processes. Additionally, though proposed §§ 205.12(c)(1) and 205.26(c)(4) are intended to be limited to processes around shipping containers, there are several instances where the proposed language suggests inspection of individual products and prescription drugs, rather than the shipping containers that hold them. FDA has supported the use of aggregation and inference as an essential business process while also expecting security procedures around transport containers. *See* Section III.B. of *Draft Guidance for Industry, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; See* Section III.A.3. of *Final Guidance for Industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*. If individual products are packaged in sealed cases, they are not, and cannot be, individually inspected. We ask that proposed §§ 205.12(c)(1) and 205.26(c)(4) be unambiguously limited to processes around shipping containers and without an expectation of examination of products in sealed containers. We suggest aligning proposed § 205.26(c)(4) with the 3PL provision, proposed § 205.12(c)(1). We believe the 3PL requirements are clearer, as protective, and appropriate, with some minor editorial changes. We note that wholesale distributors and 3PLs should have systems and processes for the examination of shipping containers and their delivery, receipt, acceptance, and transfer into inventory. In proposed § 205.26(c)(4)(ii), *outgoing shipments,* it is unclear why the final clause is included, "including through the process of returned or recalled drugs." Recalled products are unfit for distribution – there is no need to include them as an example. On the other hand, the DSCSA expressly permits returned drugs to be resold if they meet applicable statutory requirements, including that they are verified and associated with appropriate	**through its own efforts or via notification from another entity, as** ~~has been damaged in storage or held under improper conditions and to prevent the introduction or further shipment of any prescription drug that is~~ unfit for distribution.~~, including through the wholesale distributor's processing of returned or recalled drugs.~~

	transaction data. *See, e.g.*, § 582(c)(4)(D), § 582(g)(1)(F). They must also be intact, unused, not recalled, and within expiry.	

23. Shipment, *for 3PLs, Proposed § 205.12(c)(5),* and Transportation, *for Wholesale Distributors, Proposed § 205.26(c)(3)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(c)(5), *shipment, 3PLs* § 205.26(c)(3), *transportation, wholesale distributors*	Physical shipment or transportation is complex, with wholesale distributors and 3PLs having to work with, and rely on, suppliers, customers, common carriers, and third-party transportation vendors. We believe that, overall, proposed § 205.12(c)(5) and proposed § 205.26(c)(3) go too far in their prescriptive requirements and are not feasible given the pharmaceutical industry's approaches to addressing shipment challenges. 3PLs and wholesale distributors can only completely control what they do themselves. The provisions regarding "shipment" and "transportation" for 3PLs and wholesale distributors, respectively, are not fully aligned and parallel. Nor do we understand how the two are intended to be different. We believe "shipment" is the better term but regardless the term to describe physical distribution should be used consistently and the two sections aligned. We believe that the USP <1079>, *Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products*, provides a sound operating principle -- that storage and shipment of drug products should maintain the integrity of the drug product in its packaging during distribution. We suggest incorporating this principle of USP <1079> in proposed § 205.12(c)(5)(i)(B) and proposed § 205.26(c)(3)(i)(B) as an alternative to the current language. In the language regarding reporting, both proposed §§ 205.12(c)(5) and 205.26(c)(3) seem to presuppose transportation problems only between the supplier and the 3PL or wholesale distributor, when issues could also arise between the 3PL or wholesale distributor and the downstream customer. Additionally, for outbound shipments, in the case of a wholesale distributor, there may not be anyone to report to – the wholesale distributor owns the prescription drug – and if a problem occurs during its shipment to a customer, the resolution may only involve the wholesale distributor and possibly the customer and third-party transportation provider, if used. We believe that wholesale distributors, like 3PLs, should be permitted to investigate and, if necessary, report shipping problems and deviations "promptly," rather than	New § 205.12(c)(5) (5) *Shipment*. The 3PL must establish, maintain, and follow written policies and procedures providing for the **shipment** ~~transportation~~ of products in accordance with the following standards: (i) **The 3PL will pack products for shipment** ~~Products must be transported~~ in a manner that ~~will~~: (A) Protect**s** against breakage, contamination, adulteration, and theft **during shipment; and** (B) **Maintains the integrity of the product in its packaging during storage and shipment.** ~~Prevent exposure to conditions that may compromise their quality and integrity; and~~ ~~(C)~~ **(ii) In the event that the 3PL learns of** ~~Ensure that~~ deviations from ~~storage~~ **shipment** requirements during **a product's** transport, it will ~~are~~ promptly **identify, investigate, and document the deviation. The 3PL may need to promptly report the deviation** ~~identified, investigated, documented, and reported~~ to the **authorized** trading partner from whom the product was received and to the manufacturer to determine if further commercial distribution is appropriate. --- New § 205.26(c)(3) (3) ~~*Transportation*~~ ***Shipment***.

	within a fixed 24-hour window. Proposed § 205.26(c)(3)(iii). Given the complexities of shipment, we do not believe that a fixed 24-hour window for identification, investigation, documentation, correction and reporting will always be achievable or feasible. Nor do we see any reason to treat 3PLs and wholesale distributors differently. We believe that proposed § 205.12(c)(5)(i)(C) should require reporting to an "authorized" trading partner.	**(i)** The wholesale distributor must **pack** ~~ensure~~ prescription drugs **for shipment** ~~are transported~~ in a manner that: **(A)**~~(i)~~ Protects against breakage, contamination, adulteration, and theft **during shipment; and** **(B) Maintains the integrity of the product in its packaging during shipment.** ~~(ii) Prevents exposure to conditions that may compromise prescription drug identity, strength, quality, or purity; and~~ ~~(iii)~~ **(ii) In the event that the wholesale distributor learns of** ~~Ensures that~~ deviations from ~~storage~~ **shipment** requirements during **a prescription drug's shipment** ~~transport~~**, it will promptly identify, investigate, and document the deviation. The wholesale distributor may need to promptly report the deviation** ~~are identified, investigated, documented, corrected, and reported no later than 24 hours after discovery~~ to the authorized trading partner from which the prescription drug was received, and**/or** to the manufacturer to determine if further commercial distribution is appropriate.

24. Storage, *for 3PLs, Proposed § 205.12(c)(3),* and Storage & Handling, *for Wholesale Distributors, Proposed § 205.26(c)(5)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(c)(3), *storage, 3PLs* § 205.26(c)(5), *storage and handling, wholesale distributors*	Unlike the storage requirements for wholesale distributors (proposed § 205.26(c)(5)), the comparable 3PL provision does not address storage conditions where none are provided for in the product's labeling (proposed § 205.12(c)(3)). We recommend proposed § 205.12(c)(3) include the same instruction that is provided in proposed § 205.26(c)(5).	New § 205.12(c)(3) (3) *Storage*. The 3PL must establish, maintain, and follow written policies and procedures that ensure products are stored at appropriate temperatures and under appropriate conditions, in accordance with the requirements in the products' labeling, **except that if no storage requirements are established in the products' labeling, the products may be held at controlled room temperature** to preserve their identity, strength, quality, and purity.

25. Inventory, *for 3PLs, Proposed § 205.12(c)(4)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(c)(4), *inventory, 3PLs*	In the context of inventory management for 3PLs in proposed § 205.12(c)(4), we are concerned with whether the proposed rule permits modern methods of inventorying, such as cycle counts. We understand phrases, such as ensuring stock "is inventoried," to often mean shutting down an entire facility and counting every item in it – something that is not feasible for the 24/7 requirement of delivering prescription drugs to healthcare providers. This type of "shutting down the warehouse," physical inventory practice is no longer typically undertaken in the pharmaceutical industry. Rather, 3PLs and wholesale distributors rely more on modern practices, such as cycle counts, where inventory is continuously audited by rotating through subsets of products in inventory. We suggest modifying proposed § 205.12(c)(4)(i) to make clear that "inventoried" is not limited to physical count inventorying. We do not believe the word "trace" should be used in (iv) as it might imply that 3PLs are subject to DSCSA transaction data and tracing requirements in § 582. We suggest reframing (iv) as a recordkeeping requirement. All transaction data is maintained and provided by the product owner, not the 3PL.	New § 205.12(c)(4) (i) Ensure the facility's stock is inventoried **or that cycle counts, or other similar audit methods are used** regularly to protect against diversion and against distribution of product that may be unfit for distribution; … (iv) Ensure that the 3PL **maintains records of** ~~can trace~~ the receipt and outbound **shipment** ~~distribution~~ of a product, as well as ~~maintain~~ supply and inventory records.

26. Inventory Management, *for Wholesale Distributors, Proposed § 205.26(c)(5)(i)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
6751-52, § 205.26(c)(5)(i), inventory management, wholesale distributors	For the most part, proposed rule § 205.26(c)(5)(i) correctly cites the obligations for wholesale distributors set forth in § 582(c). Where the proposed rule seems to stray from DSCSA requirements, we recommend editorial changes to proposed § 205.26(c)(5)(i) to assure alignment with a wholesale distributor's applicable verification requirements in § 582(c)(4)(B)(ii). We addressed in *Definitions*, section 6, our concerns with the "unfit for distribution" definition in proposed rule § 205.3(m) and again recommend clarifying that products must be ***identified*** by the wholesale distributor as unfit for distribution (either by the wholesale distributor itself or by notification from another entity). The	New § 205.26(c)(5)(i) (i) *Inventory management*. The wholesale distributor must: … (B) Ensure that the facility's stock is inspected regularly to protect against drug diversion and distribution of prescription drugs that **the wholesale distributor has identified, whether on its own or via notification from another entity,** are unfit for distribution; (C) Investigate, document, and correct

	proposed rule does not and should not apply to all prescription drugs that actually are or may be unfit for distribution but which the wholesale distributor has no knowledge of.	any stock irregularities, including theft, loss, or diversion of prescription drugs, in accordance with section 582(c) of the Federal Food, Drug, and Cosmetic Act, as applicable; (D) Ensure that any prescription drug that appears to be unfit for distribution is removed from saleable stock and handled appropriately according to the requirements in paragraphs (c)(5)(ii) through (iv) of this section; (E) ~~Immediately~~ **Make required notifications** ~~report any confirmed losses or theft of prescription drugs~~ to ~~the manufacturer of the drug~~ **immediate trading partners** and the Food and Drug Administration **in accordance with § 582(c)(4)(B)(ii) upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product**; and …

27. Handling of Prescription Drugs, *for Wholesale Distributors, Proposed § 205.26(c)(5)(ii)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.26(c)(5)(ii), *handling of prescription drugs, wholesale distributors*	We addressed in *Other Definitions*, section 6 above, our concerns with the "unfit for distribution" definition in proposed § 205.3(m). We believe that a wholesale distributor cannot meet the requirement of proposed § 205.26(c)(5)(ii) that it "ensure[s]" that "only" prescription drugs that are fit for distribution are distributed or transferred. A wholesale distributor would not know or even be able to detect most of the problems that would render a product unfit for distribution – such as adulteration of the product or misbranding of its labeling that occurred before the product left the manufacturer. Only the most obvious of problems would be discernable to a wholesale distributor, such as if a product has visible damage, obvious mislabeling, or is expired, or if the wholesale distributor has received a notification that the product is being recalled or is illegitimate. The requirement that the prescription drug is "identified" as unfit – which ensures that wholesale distributors and 3PLs are not held responsible for what is, in most instances, going to be unknowable to them – is not present in proposed 205.26(c)(5)(ii) and we believe this concept should be included in the proposed rule. We also recommend deleting "or transferred" as this could prevent unfit prescription drugs from being transferred to a reverse logistics provider or returns processor for	New § 205.26(c)(5)(ii) (ii) *Handling of prescription drugs.* The wholesale distributor must ensure that **no** ~~only~~ prescription drugs **it has identified, whether on its own or via notification from another entity, as unfit** ~~fit~~ for distribution are further distributed ~~or transferred~~. (A) Any prescription drug that appears to be unfit for distribution must be stored in a secure area clearly defined for such use and physically segregated from saleable drugs, or electronically segregated, if appropriate, until the wholesale distributor determines by thorough examination that such drugs are fit for human use or nonsaleable. (B) Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in

	disposition. Additionally, depending on the circumstances, a wholesale distributor might be asked to transfer an unfit prescription drug to its manufacturer, to law enforcement, or to a testing laboratory. We believe that retaining the words "further distributed" will clarify that unfit products should not be intentionally distributed in the pharmaceutical supply chain for consumption, administration, or use. We specifically support the provision in proposed § 205.26(c)(5)(ii) for electronic segregation where appropriate. The treatment of segregation and quarantine was also addressed in the Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Draft Guidance (March 2022). However, we believe that the proposed rule's requirements provide clearer instruction on quarantine/segregation, and we have urged that the above Draft Guidance be aligned with the proposed rule.	accordance with the standards in paragraph (c)(6) of this section. …

28. Returned Prescription Drugs, *for Wholesale Distributors, Proposed § 205.26(c)(5)(iii)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.26(c)(5)(iii), *returned prescription drugs, wholesale distributors*	Given that approximately 4 to 5 percent of all prescription drugs wholesale distributors sell to their dispenser customers are returned, management of returns is a serious matter for the pharmaceutical supply chain. Millions of dollars are saved and potential shortages and other harms to patients are mitigated because wholesale distributors can resell a product (returned from a dispenser customer that product was sold to) that is whole, intact, within expiry, and not subject to a recall, investigation, or other adverse action. Robust systems and processes around returns are essential to protect patients while also reducing the excessive waste that would otherwise occur if all returns were automatically dispositioned for destruction. We find the requirement that returns be stored in a "secure" area odd as an entire prescription drug wholesale distributor facility must be "secure." We believe that there are adequate protections if returns processing occurs in a clearly defined area, designated for that purpose, and physically separate from saleable inventory. We believe that subsection (B) needlessly complicates what constitutes a nonsaleable return. Subsection (A) affirmatively states the conditions a return must meet to be saleable. Anything not meeting the definition of saleable is automatically nonsaleable. Moreover, subsection (B) erroneously assumes that a product is nonsaleable only because of its safety, identity, strength, quality, or purity. While these are certainly reasons for a product to be nonsaleable, in the experience of HDA members, manufacturers and wholesale distributors may elect for business	New § 205.26(c)(5)(iii) (iii) *Returned prescription drugs*. All returned prescription drugs must be stored in a **designated** ~~secure~~ area clearly defined for such use and physically segregated from saleable prescription drugs, until the wholesale distributor determines by thorough examination that such drugs are saleable or nonsaleable. … (B) *Nonsaleable returns*. ~~If the conditions under which the prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, drugs~~ **Prescription drugs that are not to be returned to inventory for resale** may be returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor **or reverse logistics provider**, or may be destroyed in a timely manner and in accordance with paragraph (c)(6) of this section and all applicable Federal and State laws. **If the conditions under which the prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, it is nonsaleable.**

	reasons to classify as nonsaleable a product that is otherwise wholly fit for distribution. For example, slow-selling products and products that are within a few months of expiration are technically saleable and fit for distribution but, for business reasons, might not be returned to saleable inventory. We want to be sure the final rule's requirements around nonsaleable returns allow these well-established business practices to continue. We offer minor suggestions to clarify (B). Some parts of proposed § 205.26(c)(6) refer to "returns processor" only, and other parts refer to "returns processor or reverse logistics provider." We suggest that the terms be defined and used consistently.	

29. Disposition, *for Wholesale Distributors, Proposed § 205.26(c)(6)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.26(c)(6), *disposition, wholesale distributors*	We have no objections to most of proposed § 205.26(c)(6). We are concerned, however, with its use of the word "quarantine" as we do not believe its use here reflects current or appropriate practice. This section exclusively deals with products for which the determination has already been made that they should be dispositioned. We believe the better articulation, which is consistent with obligations under § 582, is not that a product should be dispositioned ***if*** it is quarantined but rather that ***it is released from quarantine for*** dispositioning. Some parts of proposed § 205.26(c) refer to "returns processor" only and other parts refer to "returns processor or reverse logistics provider." We suggest that the terms be defined and used consistently. We recommend using the term "disposition" rather than "destruction" or "destroy" as "disposition" is the broader term and includes, but is not limited to, destruction. *See* § 581(4) (definition of disposition). While we recognize and support the concerns proposed § 205.26(c)(6)(iii) seeks to address, we do not believe these licensure rules can or should address the complexity of waste disposal. The disposal of pharmaceuticals is comprehensively regulated by federal, state, and local laws, for example: • The Environmental Protection Agency (EPA) has implemented a complex regulatory scheme for the management of hazardous waste pharmaceuticals.	New § 205.26(c)(6)(iii) (iii) ***Disposition~~Destroy~~***. **(A)**When prescription drugs are authorized for **disposition** ~~destruction~~, the wholesale distributor must~~:~~ **either destroy the prescription drugs itself, or arrange for a returns processor, reverse logistics provider, or other appropriately licensed and permitted disposal or destruction entity to disposition the prescription drugs. Alternatively, the wholesale distributor may follow the instructions for disposition if provided by the product's manufacturer.** **(B) If the wholesale distributor arranges for another entity to undertake the disposition** ~~destruction~~**, it must establish and maintain records of the disposition.** **(C) If the wholesale distributor undertakes destruction itself, it must:** (**1**~~A~~) Destroy all containers, labels, and packaging to ensure that such items cannot be used in counterfeiting activities;

	• Most states manage their own solid waste disposal programs, which must be at least as stringent as federal EPA's. Disposal in the remaining states is regulated under EPA's rules. • Controlled Substances, where the greatest concern for potential theft, diversion, or counterfeiting likely exists, are subject to a final Drug Enforcement Administration (DEA) rule: Disposal of Controlled Substances. • Other requirements are likely applicable including local permitting and licensing and Department of Transportation regulations. Alternatively, the product's original manufacturer may wish to have the product returned to it (perhaps by way of a reverse logistics provider or returns processor) for evaluation and determination of final disposition. The forward wholesale distributors that HDA has conferred with report that they do not destroy their unsaleable pharmaceuticals themselves. Doing so would likely trigger the above environmental requirements and they could be handling pharmaceutical waste in the same facility where wholesale distribution occurs. These wholesale distributors rely upon entities that are appropriately permitted and licensed, such as returns processors and reverse logistics providers to arrange for product disposition. Returns processors and reverse logistics providers also manage the credit process for pharmaceutical manufacturers. A wholesale distributor that undertakes its own destruction also may jeopardize the ability to obtain a manufacturer's credit for the destruction. Last, we believe that handling and disposal of pharmaceutical waste likely strays into State regulatory requirements that we believe the DSCSA was ***not*** intended to preempt. We address this issue in the HDA Preemption Analysis accompanying our cover letter. We have included potential changes to the proposed rule if FDA disagrees and wishes to provide directions to wholesale distributors should they "destroy" the products themselves. However, given the above, we do not believe that the disposal specifications in proposed § 205.26(c)(6)(iii) are necessary. We do not believe that they advance security and environmentally safe – and highly regulated – destruction practices. We believe the proposed rule should reflect that wholesale distributors satisfy their legal obligations to disposition pharmaceuticals by contracting with entities that are licensed and permitted to do it. We also believe that only a subset of prescription drug destruction must be witnessed.	(2~~B~~) Ensure that the destruction of prescription drugs, containers, labels, and packaging are witnessed; and (3~~C~~) Establish and maintain records for destroyed drugs and the witnessing thereof.

30. Recalled Products, *for 3PLs, Proposed § 205.12(d),* and Recalled Drugs, *for Wholesale Distributors, Proposed § 205.26(c)(5)(iv)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(d), *recalled products, 3PLs* § 205.26(c)(5)(iv), *recalled drugs, wholesale distributors*	Both provisions regarding recalls, proposed § 205.12(d) and proposed § 205.26(c)(5)(iv), assume that the manufacturer is the recalling party. However, others can initiate a recall, including repackagers and wholesale distributors. We recommend amending proposed § 205.12(d) and proposed § 205.26(c)(5)(iv) to reflect other potential recalling parties. Some parts of proposed § 205.26(c) refer to "returns processor" only and other parts refer to "returns processor or reverse logistics provider." We suggest that the terms be defined and used consistently. We also recommend that the lengthy description of what should be done with products under recall in proposed § 205.26(c)(5)(iv) be more simply resolved by requiring that they be quarantined. "Quarantine" is well described and established in the proposed rule and guidance implementing § 582. We recommend its consistent use in the proposed rule.	New § 205.12(d) (d) *Recalled products.* The 3PL must establish, maintain, and follow written policies and procedures to support **the** ~~manufacturer~~ recalls **of the trading partner that initiated them**. --- New § 205.26(c)(5)(iv) (iv) *Recalled drugs.* Recalled prescription drugs must be handled as instructed **by the party that initiated the recall** ~~manufacturer~~ in the recall notice, which may require that the recalled drugs be **quarantined** ~~stored in a secure area clearly defined for such purpose and physically segregated from saleable drugs~~ until they are returned to the manufacturer or repackager, to the wholesale distributor from which such drug was purchased, or to an individual acting on behalf of such an entity, including a returns processor **or reverse logistics provider**, or destroyed in accordance with the standards in paragraph (c)(6) of this section.

31. Products that are Unfit for Distribution, *for 3PLs, Proposed § 205.12(f)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(f), *unfit for distribution, 3PLs*	We addressed in section 6 above, our concerns with the "unfit for distribution" definition in proposed § 205.3(m). As we discussed, the proposed rule's definition and application of "unfit for distribution" are so broad that it renders products illegal even when there are minor problems with no bearing upon product safety. The breadth and vagueness of the concept of "unfit for distribution" potentially makes 3PLs responsible for even the most inconsequential of problems, and for product problems for which they have no visibility, knowledge, notice, or understanding.	New § 205.12(f) (f) *Products that are unfit for distribution.* The 3PL must establish, maintain, and follow written policies and procedures for handling products that **it has identified, whether on its own or via notification from another entity,** are adulterated, misbranded, or otherwise unfit for distribution~~, as well as returned products,~~ that:

	The definition of "unfit for distribution" does assume that a prescription drug "***has been identified***" as violative of the FD&C Act. As with the sections above, we urge modification to proposed § 205.12(f) to align with our earlier suggestions that the 3PL must have ***identified*** that the product is unfit for distribution, either through its own efforts or via notification from another entity. Additionally, proposed § 205.26(c)(5)(ii)(B) allows wholesale distributors to electronically segregate products: "Any prescription drug found to be adulterated, misbranded, or otherwise unfit for distribution must be stored in a secure area clearly defined for such use and physically or electronically segregated from saleable drugs until they are returned to the supplier or destroyed in accordance with the standards in paragraph (c)(6) of this section." We believe these provisions permitting electronic segregation should be aligned throughout the proposed rule and should be extended to 3PLs. We raised this issue previously in section 6 above regarding proposed § 205.10(c)(2). As with our discussion of section 6 and proposed § 205.10(c)(2), we do not believe "returns" should automatically be categorized as unfit for distribution. A product returned to a 3PL may be in good, saleable condition and it is not "unfit for distribution" simply because it is returned. Of course, a 3PL should have processes for determining whether a return is in good condition and saleable.	(1) Require such products to be **physically or electronically** segregated from ~~other~~ **saleable** products and dispositioned as directed by the applicable manufacturer, wholesale distributor, dispenser, or an authorized government agency and in accordance with all applicable State and Federal laws; (2) Identify a contact person responsible for communicating with the manufacturer, wholesale distributor, dispenser, or an authorized government agency regarding nonsaleable and returned products; (3) Include procedures to prevent products **the 3PL has identified, whether on its own or via notification from another entity, as** unfit for distribution from entering the supply chain through the 3PL's disposition of nonsaleable products; and (4) Require the 3PL to document the disposition of all nonsaleable ~~and returned~~ products, and maintain such records for inventory accountability.

32. Products that are Suspect & Illegitimate, *for 3PLs, Proposed §§ 205.12(g) & (h)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§§ 205.12 (g), (h), *suspect and illegitimate products, 3PLs*	We support the provisions of proposed § 205.12(h). Proposed § 205.12(g) could be made simpler, and we recommend that the provision more closely parallel § 205.12(h). 3PLs will, in the event of a suspect or illegitimate product situation, follow the instructions of an authorized trading partner. The 3PL should have processes and procedures regarding how to implement these instructions.	New § 205.12(g) (g) *Suspect product.* The 3PL must establish, maintain, and follow written policies and procedures to quarantine**, or disposition** ~~or destroy~~ a suspect product **as** ~~if~~ directed ~~to do so~~ by the **respective** ~~product's~~ manufacturer, repackager, wholesale distributor, dispenser, or an authorized government agency.

33. Security/Data Integrity, *for 3PLs, Proposed § 205.12(c)(2),* and Integrity of Records, *for Wholesale Distributors, Proposed § 205.27(c)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(c)(2), *3PLs* § 205.27(c), *wholesale distributors*	Proposed § 205.12(c)(2) appears to confuse and mix both physical product security and data security. Product security is addressed in proposed §§ 205.10 and elsewhere in § 205.12. We suggest aligning proposed § 205.12(c)(2) with proposed § 205.27(c) and omitting the references to the storage of product, which is addressed elsewhere in the proposed rule. We otherwise support these provisions.	New § 205.12(c)(2) (2) *Security.* The 3PL must establish, maintain, and follow written policies and procedures that ~~provide for the secured storage of products and~~ preserve the integrity of the 3PL's data and records.

34. Recordkeeping, *for 3PLs, Proposed § 205.12(a),* and Required Records, *for Wholesale Distributors, Proposed § 205.27(a)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.12(a), *recordkeeping, 3PLs* § 205.27(a), *recordkeeping, wholesale distributors*	We have no comment on the 3PL recordkeeping requirements of proposed § 205.12(a)(1). We are concerned, however, with the specificity of the documents required for wholesale distributors in proposed § 205.27(a)(3). For instance, wholesale distributors may not even have or generate packing slips. Additionally, many (or most) of these documents may be electronic. We believe the intent is to assure records are maintained that are sufficient to document the distribution of prescription drugs, and so recommend that this section be modified accordingly and that it provide examples of documents that might be used to meet this documentation of distribution requirement. Also, we are uncertain what the agency means by including both "transport" and "shipping" in proposed § 205.27(a)(1). We suggest conforming proposed § 205.27(a)(1) to proposed § 205.12(a)(1)(i), or otherwise clarifying why the two provisions are different and what is meant by the difference between "transport" and "shipping." Alternatively, as discussed in section 23 above, we recommend the proposed rule use "shipment" and then make conforming changes. Repeated use of both terms suggests they could be different and impose different requirements.	New § 205.27(a) (1) Documentation pertaining to distribution, including **receipt,** storage, handling, security, inventory**, and shipment**~~transport, and shipping~~ of prescription drugs including written policies and procedures for identifying, recording, and reporting confirmed losses, thefts, and diversions, and prescription drugs **that** ~~are~~ **have been identified by the wholesale distributor as** unfit for distribution**, either on its own or via notification from another entity**; (2) All policies, procedures, instructions, contracts, data, inspection reports, and any documentation related to compliance with this subpart; and (3) ~~Invoices, purchase orders, packing slips, shipping records, and any other records~~ **Records sufficient to document** ~~of~~ the distribution of prescription drugs**, which might include invoices, shipping records, and packing slips**.

35. Maintenance, Availability, & Accuracy of Records, *for 3PLs, Proposed § 205.13(a),* and *for Wholesale Distributors, Proposed § 205.27(b)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.13(a), *maintenance, availability, accuracy of records, 3PLs* § 205.27(b), *standards for recordkeeping, required records*	Proposed § 205.13(a)(4) and proposed § 205.27(b)(1) require that all records accurately reflect the name of the 3PL or wholesale distributor as it appears on the facility's license, and this must match the information annually reported to FDA. While we recognize the reasons behind this proposed requirement, it is impossible to comply with in practice. Wholesale distributors and 3PLs have no control over how their trading partners, contractors, sub-contractors, and other entities might choose to identify them in shipping and distribution-related records, contracts, and other business documents. A wholesale distributor or 3PL can ask its trading partners, business associates, and regulators to identify them by a particular name, but there is absolutely no guarantee that this will occur, and it is unreasonable to assume it will. Additionally, facility names are often abbreviated in State license applications because there are not enough characters and space in an electronically generated box. If the name is cut off due to space constraints, the license itself might not match the facility's name. Proposed § 205.13(a)(4) and proposed § 205.27(b)(1) are not requirements where compliance is even possible, and we urge their deletion and replacement with a more general requirement of sufficient information to identify the 3PL or wholesale distributor. We are also concerned with the requirement of proposed § 205.13(a)(3) and proposed § 205.27(b)(4) that any alteration must be signed and dated by the individual who made the alteration, and the alteration must preserve the original document and the reason for the alteration. As we discussed in section 16 above, GMPs do not apply to wholesale distributors or 3PLs, and we believe proposed § 205.13(a)(3) and proposed § 205.27(b)(4) suggest that they do. Imposing GMP requirements upon wholesale distributors and 3PLs would need to be accomplished through rulemaking. A very broad range of records are required under the proposed rule that do not involve product quality and integrity or DSCSA compliance, including packing slips, invoices, contracts, and purchase orders. *See, e.g.,* proposed § 205.12(c), proposed § 205.27(c). Therefore, if FDA means to apply the standards that apply to pharmaceutical manufacturer batch records to all 3PL and wholesale distributor licensure-related records without qualification, there needs to be more discussion around this issue and precise identification of the records covered.	New § 205.13(a) (1) Be readily retrievable and made available to licensing authorities upon request; (2) Be securely stored from unauthorized access or modifications; ~~(3)Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration~~; and (**3**~~4~~) **Include information sufficient to identify the 3PL** ~~Accurately reflect the name of the 3PL as it appears on the 3PL facility's license, which must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.15~~. --- New § 205.27(b) (1) **Include information sufficient to identify** ~~Accurately reflect the name of~~ the wholesale distributor ~~as it appears on the wholesale distributor license and must match the information that is reported to the Food and Drug Administration pursuant to the Food and Drug Administration reporting requirements at § 205.29~~; (2) Be readily retrievable and made available to regulatory authorities upon request; **and** (3) Be securely stored and protected from unauthorized access or modifications**.**~~; and~~ ~~(4) Contain only alterations signed and dated by the individual who made the alteration. Such alteration must preserve the original information and document the reason for the alteration.~~ --- New § 205. __ *Document Control*.

	We recommend in the alternative that the rule include here or elsewhere a requirement that wholesale distributors and 3PLs have policies and procedures to ensure appropriate document control.	**The 3PL shall have adequate policies and procedures to ensure appropriate document control.** New § 205. __ *Document Control*. **The wholesale distributor shall have adequate policies and procedures to ensure appropriate document control.**

36. Record Retention, *for 3PLs, Proposed § 205.13(b),* and *for Wholesale Distributors, Proposed § 205.27(d)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.13(b), *document retention, 3PLs* § 205.27(d), *document retention, wholesale distributors*	We support the proposed record and document retention requirements. We appreciate that proposed § 205.12(b)(1) and (2) and § 205.27(d)(1) and (2) recognize that the DSCSA requires some categories of records to be retained for 6 years but that other records, outside those statutory requirements in § 582, need not be maintained for as long a period. Record retention is another area where there are widespread differences in State requirements and providing for a single, national record and retention requirement will, we believe, aid in supply chain security and ease of implementation.	

37. Inspections Generally, *for 3PLs, Proposed § 205.16(a),* and *for Wholesale Distributors, Proposed § 205.28(a)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.16(a), *inspections, 3PLs* § 205.28(a), *inspections,*	We interpret the preamble and proposed rule as proposing that every 3PL must obtain a new license and that both 3PLs and wholesale distributors be inspected before the new license compliant with and issued pursuant to this rule (once final) can be issued. If this is correct, we are concerned with the burdens these inspection requirements will impose upon State licensing authorities, particularly in the initial stages of	New § 205. __ *Applicability to existing facility licenses* **(a) A 3PL holding a 3PL license for a facility issued by a State licensing authority as of the effective date of this part shall not be required to submit an initial application under this part for that facility. The holder of an existing 3PL license shall submit to the State**

wholesale distributors	implementation. Indeed, at present, in at least one State, the licensing authority has no inspectors and has told wholesale distributors that all inspections must be conducted by the National Association of Boards of Pharmacy ("NABP"), though the State bears the costs. To be able to implement the proposed rule's inspectional requirements and frequency of inspections, some States will likely need to increase staffing, training, and infrastructure. The DSCSA and the proposed rule contemplate the approval of third-party organizations ("AOs") who can be deployed to conduct inspections. However, these AOs will also have to be stood up and approved before they will be able to help ease a State's inspectional load (assuming a State elects to use them). The inability to review applications, conduct inspections, and approve applications in a timely manner is a potential, if not likely, outcome of the initial implementation of these licensure and inspection requirements. Further, product shortages and product waste could occur if products must be held in inventory (rather than being distributed) while awaiting completion of State license review(s) and/or inspections. To enable an orderly transition, we strongly recommend that each existing license be allowed to continue to its natural expiration, regardless of the effective date of the licensure rule, with inspections to coincide with that renewal. At the license holder's next renewal, it and the licensing authority would then bring the licensee into compliance with the State-implemented national standards, including the conduct of the inspection. We suggest a new provision to make this "grandfathering" and transitioning of existing licenses explicit.	**licensing authority the information required by this part upon renewal of its existing license.** **(b) A wholesale distributor holding a wholesale distributor license for a facility issued by a State licensing authority as of the effective date of this part shall not be required to submit an initial application under this part for that facility. The holder of an existing wholesale distributor license shall submit to the State licensing authority the information required by this part upon renewal of its existing license.** **(c) As of the effective date of this part, the licensing authority shall inspect an already licensed wholesale distributor or 3PL at or before the renewal of its existing license. The wholesale distributor's or 3PL's existing license shall remain in force and effective even if the licensing authority cannot initiate inspection before the expiration of the existing license. Such existing licenses will remain in effect until the licensing authority can complete the inspection.** **(d) The licensing authority may inspect a wholesale distributor or 3PL facility itself, or the licensing authority may accept the inspection of the wholesale distributor or 3PL facility conducted by an approved organization acceptable to the licensing authority or by another licensing authority.**

38. Who Conducts Inspections, *for 3PLs, Proposed §§ 205.16(a)(1)-(2),* and *for Wholesale Distributors, Proposed §§ 205.28(a)(1)-(2)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.16(a)(1), (2), *inspections, 3PLs*	Proposed §§ 205.16(a)(1)-(2) and proposed §§ 205.28(a)(1)-(2) both use the term "third-party accreditation or inspection service." The proposed rule refers to these organizations specifically (and we believe appropriately) as "approved organizations" or "AOs." We believe this term should be used consistently in the	New § 205. __ *Separate Accreditation Not Permitted*. **A licensing authority may not require a wholesale distributor or 3PL to obtain a certification or accreditation by a third party as a condition of**

§ 205.28(a)(1), *inspections, wholesale distributors*	proposed rule and that other terms, including "third-party accreditation or inspection service," be conformed to this change. The DSCSA makes no provision for any separate accreditation or accrediting requirement by a third-party as a condition of licensure, and these rules preempt contrary State requirements. FDA has, consistent with the DSCSA, proposed AOs (which may offer accrediting or inspection services) to inspect wholesale distributors and 3PLs and to review 3PL licensure applications. There is no place or provision for an additional "accreditation" imposed by State licensing authorities upon licensees. We urge that this point be made explicitly and that language regarding "accreditation" be deleted from the proposed rule. Moreover, the proposed rule provides for no "inspection service" other than AOs so "inspection service" should also be deleted. We discuss the scope of DSCSA preemption of State requirements in Attachment 1, HDA Preemption Analysis. We suggest that proposed § 205.16(a)(1) and proposed § 205.28(a)(1) be aligned to give a licensing State authority maximum flexibility to accept an inspection of a 3PL or wholesale distributor facility. That is, we believe the State licensing authority should be able to accept an inspection it conducts or may elect, if it chooses, to accept an inspection conducted by another licensing authority (another State or FDA), or by a third-party AO that is acceptable to the State licensing authority. As proposed § 205.16(a)(1) appears straightforward in its organization, we suggest adoption of its format for proposed § 205.28(a)(1) as well. We suggest parallel language in proposed § 205.16(a)(1) and proposed § 205.28(a)(1)-(2). We believe aligning the 3PL and wholesale distributor provisions as closely as possible would make for better regulation overall. Seemingly minor differences may distract both the regulated and regulator with whether the difference is meaningful and intended, mandated by differences in the DSCSA, or simply a drafting artifact.	**licensure. A licensing authority may, as set forth in this part, use an approved third-party organization to conduct inspections of wholesale distributors and 3PLs, to review the license applications of 3PLs, and to make recommendations for licensure of 3PLs.** --- New § 205.16(a)(1) (1) Where the State is the licensing authority, the State may conduct the inspection or may accept an inspection by a **third-party organization** ~~accreditation or inspection service~~ approved by the State licensing authority. If the facility is out of state, the State **licensing authority** may conduct the inspection or **the State licensing authority may accept the inspection of the 3PL facility conducted by an approved organization acceptable to the State licensing authority or by another licensing authority.** ~~may accept an inspection by the State in which the facility is located.~~ --- New § 205.28(a)(1) (1) Where the State is the licensing authority, **the State may conduct the inspection of** ~~such inspection may be conducted by: (i) The State in which~~ the facility to be licensed~~is located;~~ or **may accept an inspection by a** ~~(ii)~~ A third-party **approved organization** ~~accreditation or inspection service~~ approved by the State licensing the wholesale distributor.~~or(iii)~~ If the facility is located out of State, the State issuing the license may conduct the inspection or **the State licensing authority may accept the inspection of the wholesale distributor facility conducted by an approved organization acceptable to the State licensing authority or by another licensing authority.** ~~may accept an inspection by the State in which the facility is located or by a third-party, as described in paragraph (a)(1)(ii) of this section.~~

39. Records Access for Inspections, *for 3PLs, Proposed § 205.16(c),* and *for Wholesale Distributors, Proposed § 205.28(b)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.16(c), *records access, 3PLs* § 205.28(b), *records access, wholesale distributors*	Proposed § 205.16(c) and proposed § 205.28(b) both provide that off-site records must be available within two business days or sooner if necessitated by the duration of the inspection. We are concerned with the lack of flexibility in this provision, and that it may impose the onerous duty of production of off-site records earlier than the two-business day limit solely for the convenience of the inspection authority. We recommend deleting this language and replacing it with a requirement that a wholesale distributor or 3PL may need to produce off-site records as soon as possible where there is a serious risk to public health or patient safety.	New § 205.16(c) (c) Records described in § 205.12(a)(1) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or **as soon as possible** ~~sooner~~ if necessitated by ~~the duration of the inspection~~ **a serious risk to public health or patient safety.** --- New § 205.28(b) (b) Records described in § 205.27 that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 2 business days of a request by a State or Federal official, or **as soon as possible** ~~sooner~~ if necessitated by ~~the duration of the inspection~~ **a serious risk to public health or patient safety**.

40. Conduct of Inspections, *for 3PLs, Proposed § 205.16(d),* and *for Wholesale Distributors, Proposed § 205.28(c)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.16(d), *conduct of inspections, 3PLs* § 205.28(c), *conduct of inspections, wholesale distributors*	As discussed previously, we recommend the proposed rule consistently identify third-party organizations, accreditation services, and inspection services as "AOs" or "Approved Organizations" to avoid confusion. We are concerned that the proposed rule never sets out the conduct of the inspector (whether State, FDA, or AO). FDA inspections are governed by a robust set of requirements, including the Investigations Operations Manual (IOM). We recommend that all inspections be conducted pursuant to a clear set of requirements and expectations. We suggest a new section in Part 205, *Duties of the Inspector*, which establishes the basic parameters for a lawful DSCSA-related inspection. This suggested language is provided **below.**	New § 205.16(d) (d) The 3PLs must permit the Federal or State licensing authority and third-party **approved** organizations ~~or inspection services~~ approved by the Food and Drug Administration or the State to enter and inspect their facilities and to audit their records and written operating procedures. --- New § 205.28(c) (c) Wholesale distributors must permit the appropriate Federal, or State licensing authority and State- or FDA-approved third-party **approved organizations** ~~inspection services~~ to enter and inspect their premises and to audit their records and written operating procedures.

41. Inspections Interval, *for 3PLs, Proposed § 205.16(b),* and *for Wholesale Distributors, Proposed § 205.28(d)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.16(b), *inspections interval, 3PLs* § 205.28(d), *inspections interval, wholesale distributors*	As discussed previously, we recommend consistently identifying third-party organizations, accreditation services, and inspection services as "AOs" or "Approved Organizations." Additionally, we recommend aligning proposed § 205.16(b) and proposed § 205.28(d) and making them more parallel. The phrasing appears awkward, particularly in proposed § 205.16, and proposed § 205.28(d) seems clearer. Because a State licensing authority may accept an inspection conducted by an out-of-state licensing authority, we believe proposed § 205.16(b) and proposed § 205.28(d) need to reflect that inspections may be conducted by "a" licensing authority rather than "the" licensing authority.	New § 205.16(b) (b) **To ensure compliance with this subpart,** ~~R~~routine inspections **will** ~~must~~ be conducted ~~thereafter~~ once every 3 years by **a** ~~the~~ licensing authority, **or by** a third-party **organization that is** approved ~~organization or inspection service approved~~ by the Food and Drug Administration ~~under § 205.18,~~ or **by** the State **authority** licensing the 3PL. --- New § 205.28(d)

	We are uncertain why proposed § 205.16(b) includes the "under § 205.18" phrase when proposed § 205.28(d) does not contain a comparable cross-reference. We believe the phrase "under § 205.18" could be deleted.	(d) To ensure compliance with this subpart, routine inspections will be conducted once every 3 years by ~~the~~ **a** licensing authority, or **by** a third-party **organization that is** ~~accreditation or inspection service~~ approved by the Food and Drug Administration or **by** the State **authority** licensing the wholesale distributor.

42. License Expiry & Renewal, *for 3PLs, Proposed § 205.8,* and *for Wholesale Distributors, Proposed §§ 205.20(b) & 205.22(d)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.8, *expiry and renewal, 3PLs* § 205.20(b), *general requirements for licensure, wholesale distributors*	We strongly recommend that the wholesale distributor provisions regarding licensure renewal more closely follow the form and format of the 3PL provision, Expiry and Renewal, proposed § 205.8. The wholesale distributor renewal provisions, like those for 3PLs, should be in their own, separately titled section. The language in both regulations regarding having licenses expire within two or three years of issuance should be modified to track current practice more closely. The proposed rule's language is not the current practice in many, and perhaps even most, States. Rather, many States have set a uniform license renewal date for all facilities licensed in the State – typically assigning a different, uniform date, for each category of license (*e.g.*, pharmacy, wholesale distributor, 3PL, manufacturer, etc.). When the State licenses a new facility during the year, it typically prorates the term so that that license, like every other license for that category, renews on the same date. For example, South Carolina wholesale distributor licenses all expire on June 30, the Nebraska renewal date is July 1 and Indiana is on September 30. Other States renew from the date of issuance as proposed in the rule. This approach, with all licenses in a State being renewed on the same date (in much the same way that the FDA requires updating the submission of licensure information between January 1st and March 31st), can be enormously helpful for States and the regulated industry. We emphasize, though, that States should have the flexibility to set and maintain their own renewal date so that not all licenses in all 50 States expire on the same calendar day. This would be very burdensome for license holders and a company would easily be overwhelmed if ***all*** its licenses in ***all*** the States it was operating in came due on a single day. Additionally, AOs that licensing authorities have approved to inspect, and those state authorities conducting their own licensing and	New § 205.8 *Expiry and renewal.* Any license issued or renewed pursuant to § 205.5 or § 205.6 will expire 3 years after the date issued**, or such other date within 3 years from the date of first issuance that the licensing authority determines, and then every 3 years thereafter.** A 3PL renewal application will not be accepted more than 90 calendar days before the date of expiration. A 3PL will not be penalized for administrative delay on the part of the licensing authority in issuing a new license. A license will be considered valid during **any** ~~the~~ period of ~~the~~ administrative delay if the 3PL timely submitted the renewal application. **A license renewal application is timely submitted if it is submitted electronically to the licensing authority on or by the date of expiration of the existing license, or, if submitted by mail, is postmarked on or by the date of expiration of the existing license.** --- Replace proposed § 205.20(b) with new § 205. __, *Expiry and renewal*. Type in regular, black font is language original to proposed § 205.20(b) and now inserted into the new section specifically for wholesale distributor expiry and renewal. **205.__ *Expiry and renewal*.**

	inspection functions, would also be overwhelmed if all licenses in the U.S. expired on the same day. We believe permitting States to set their own renewal dates, whether on different, fixed dates as is done in some States currently, or from the date of the first issuance, will significantly reduce burdens, both for licensing authorities and regulated industry. We strongly urge FDA to permit States to set a renewal date that is most convenient for the management of their own resources and burdens. We also ask that the rule specify when an application for renewal is timely filed and suggest the application must be postmarked or electronically submitted on or by the day it is due.	Any license issued or renewed pursuant to this section will expire 2 years after the date on which the license was issued**, or such other date within 2 years from the date of first issuance that the licensing authority determines, and then every 2 years thereafter.** A wholesale distributor may submit a renewal application up to 90 calendar days before the date of expiration. A license will be considered valid during any period of ~~the~~ administrative delay on the part of the licensing authority~~,~~ if the wholesale distributor timely submitted the renewal application. **A license renewal application is timely submitted if it is submitted electronically to the licensing authority on or by the date of expiration of the existing license, or, if submitted by mail, is postmarked on or by the date of expiration of the existing license.**

43. Initial & Annual Reporting to FDA, *for 3PLs, Proposed § 205.15,* and *for Wholesale Distributors, Proposed § 205.29*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.15, *reporting, 3PLs* § 205.29, *reporting, wholesale distributors*	3PLs and wholesale distributors have been submitting licensure information to FDA for many years. Proposed § 205.15 and proposed § 205.29 appear consistent with current practice and the DSCSA. We continue to have security concerns with making any personal information of employees available on the FDA website. To protect the privacy of employees and reduce security risks, we urge FDA to consider removing the names of facility contacts from the FDA website.	

44. Changes in License Information, *for 3PLs, Proposed § 205.7(a), and for Wholesale Distributors, Proposed § 205.24(a)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
6741, proposed rule § 205.7(a), license changes, 3PLs 6750, proposed rule § 205.24(a), license changes, wholesale distributors	We have numerous concerns with proposed § 205.7(a) and proposed § 205.24(a) regarding reporting of changes to a licensing authority. We believe this subsection may require significant revision to accomplish the reporting of important information to the relevant licensing authority or authorities without also hopelessly burying license holders and licensing authorities in notifications for every mundane and routine change that has no bearing on compliance, patient health, or supply chain security. Proposed § 205.7(a) and proposed § 205.24(a) require the reporting to the licensure authority of a change to "any information required in this subpart." This provision is so broad, we believe it would enormously burden licensing authorities and license holders. The information required in proposed Part 205, subpart A (3PLs) and subpart C (wholesale distributor) is immense and could involve documents that frequently change. For example, this information might include lists of authorized trading partners, and a huge body of additional documents, policies and procedures, such as cleaning, maintenance, and pest control schedules, equipment servicing, new equipment installation, new employee training, environmental monitoring, and inventory cycle count procedures. Virtually ***any*** change to any licensure-related process, policy, or procedure in a facility could potentially trigger a submission to ***each*** licensing authority in ***every*** State the wholesale distributor or 3PL is licensed. This cycle of updates and changes would be never-ending and very burdensome for both the licensed entity to process/submit and for the State licensing authority to manage. Additionally, what reportable information is covered in proposed § 205.7(a) and proposed § 205.24(a) is so broad, it requires a licensee to guess what might be a change that must be submitted to every licensing authority. Therefore, we believe the changes that trigger notification to the licensing authority should be identified and not left open to interpretation. Reportable changes should be important and substantial matters that bear upon compliance, security, and safety. We believe that changes to the designated representative or facility manager and changes to the surety bond (for wholesale distributors) are all substantial changes that should trigger notification to the licensing authority. We also believe the 3PL or wholesale distributor should report to the licensing authority	New § 205.7(a) (a) **Any change to a 3PL's designated representative or facility manager and any change to any information required pursuant to §§ 205.5(b)(7), 205.11(e) and 205.15(d), must be submitted to the licensing authority within 45 calendar days after such change is effective, except where otherwise provided in this subpart.** Any **other** change to any information required in this subpart, including changes to any information required pursuant to §§ 205.5, 205.6, 205.11, and 205.15, must be submitted ~~electronically~~ to the licensing authority **at the time of renewal of the license,** ~~within 30 calendar days after such change is effective,~~ except where otherwise provided in this subpart. --- New § 205.24(a) (a) **Any change to a wholesale distributor's designated representative or facility manager and any change to any information required pursuant to §§ 205.21, 205.22(c)(7)-(8), 205.25(a), and 205.29(d) must be submitted to the licensing authority within 45 calendar days after such change is effective, except where otherwise provided in this subpart.** Any **other** change to any information required in this subpart, including changes to any information required pursuant to §§, 205.22, and 205.25, must be submitted ~~electronically~~ to the licensing **at the time of renewal of the license,** ~~within 30 calendar days after such change is effective,~~ except where otherwise provided in this subpart.

	any disciplinary action so significant it must be reported to FDA pursuant to proposed § 205.15(d) (3PLs) and § 205.29(d) (wholesale distributors). Additionally, the 3PL or wholesale distributor should report to the licensing authority information related to felony convictions or citations described in proposed § 205.5(b)(7), § 205.11(e), 205.22(c)(7)-(8), and § 205.25(a). All other reportable changes would be submitted at renewal. We caution that we do not believe making a new designated representative or facility manager submission within 30 days is feasible, particularly if fingerprint cards must come from the State licensing authority and a State and federal criminal background check must be conducted. We, therefore, recommend that proposed § 205.7(a) and proposed § 205.24(a) be altered so that reporting of major changes must be made within 45 days of the change. We suggest that the "submitted electronically" directive be amended as not all States currently have the capacity to process license applications electronically.	

45. Changes in Location, *for 3PLs, Proposed § 205.7(b),* and *for Wholesale Distributors, Proposed § 205.24(b)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.7(b), *change in facility location, 3PLs* 6750; § 205.24(b), *change in facility location, wholesale distributors*	Proposed § 205.7(b) and proposed § 205.24(b) are not aligned though both purport to address the same circumstance – a 3PL or wholesale distributor that changes locations. The 3PL must obtain a new license, the application for which must be submitted no later than 90 days before beginning operations, and the new facility must be inspected; the wholesale distributor must obtain only a new inspection and apparently does not need a new license for the location. We do not believe this is sound, and it is inconsistent with current requirements in most (and perhaps all) States. States licenses are facility-specific, for both 3PLs (if they have them) and wholesale distributors. As we raise in section 46 below (and as discussed in section 9) we believe the position taken in the proposed rule arises from the agency's interpretation of the FD&C Act, which refers to the license of a "person" engaged in wholesale distribution. *See, e.g.,* § 583 and § 503(e). Therefore, the implication appears to be that a wholesale distribution facility does not have to be the subject of a license. However, we believe individual wholesale distribution facility licensure is a critical component of supply chain security. This is the current regime in State licensure schemes, and we do not believe the DSCSA was intended to lessen or eliminate	New § 205.7(b) (b) Any change in the location of a facility at which 3PL activities are conducted will require a new license and inspection of the new facility prior to its beginning operations. (1) The application for a new license required by § 205.5 must be submitted no later than 90 calendar days prior to beginning operations at the new location. **(2) The new facility location must be inspected before the licensing authority issues a license. If the licensing authority cannot complete an inspection of the new facility location within 90 days of submission of a license application, the licensing authority shall grant a temporary license to the 3PL facility location until**

	that oversight but only to assure that State rules be the same as federal ones. We see the DSCSA as establishing national standards for wholesale distributors, not a single national license regardless of the number of facilities operated by the entity. Not requiring a wholesale distributor facility to be licensed, as 3PL facilities must be, represents a potentially significant gap in security and accountability. Both wholesale distributors and 3PLs should be required to obtain a new license for any new facility and the proposed rule should be amended to make this requirement clear. Proposed § 205.7(b)(2) and proposed § 205.24(b)(2) state that on the date of the changeover to the new facility, the 3PL or wholesale distributor must cease activity at the old location and surrender the license. To assure continuity of operations and delivery of care and needed medicines with minimal disruptions to patients, 3PLs and wholesalers typically maintain a license of the old facility to gradually phase out the operations and close the facility in an orderly manner. When operation ceases completely at the old facility, the wholesale distributor or 3PL surrenders the license. We recommend this approach here. Additionally, during this interim period where the old facility is being phased out and the new facility is opening and becoming operational, we ask that these national standards allow, temporarily, for a single individual to serve as the designated representative and/or facility manager for both the closing and the opening facility. Allowing one person to serve for both facilities, with the delegation of responsibility to other qualified persons when the designated representative/facility manager is not physically present, will help ensure the continuity of operations, appropriate personnel and operational oversight, and consistency in compliance. We suggest language to allow for this possibility. A time limit may also be appropriate, such as no longer than 90 days, with an extension granted by the licensing authority if a good cause is shown. We believe the greatest challenge with opening new facilities is obtaining the required inspection in a timely manner. Conflicting requirements also exist under current state licensure schemes, with at least one licensing authority refusing to inspect until the facility has been operational for several months. This same concern is present in section 46 below, regarding changes to owners of 3PLs and wholesale distributors in proposed § 205.7(c) and proposed § 205.24(c). The result is that a facility cannot be licensed until it has an inspection, but cannot be inspected until it has been operating, which it cannot do if it is not licensed. We appreciate the concerns with a facility operating without a license and the competing issue of resource constraints for regulators trying to conduct inspections in a timely and efficient manner. For license renewals, FDA provides that the 3PL or wholesale distributor will not be penalized for administrative delay. *See* proposed	**the inspection is complete as long as the license application is otherwise complete.** (~~2~~3) **During the period of time the 3PL is transitioning from the original to the new facility location, the 3PL will be temporarily permitted to conduct operations at both the originally licensed facility location and the new facility location to ensure an orderly and secure shutdown of the originally licensed facility.** On the date the **3PL ceases all operations at the originally licensed facility location, it must surrender its license to that location and may not engage in 3PL activities at that facility location without first securing a new license.** ~~change of location takes place, the license for the original facility is void.~~ **(4) During the period of time the 3PL is transitioning from the original to the new facility location, the 3PL may temporarily designate for up to 90 days one person as the designated representative and/or facility manager for both facility locations. The designated representative or facility manager shall delegate in writing their responsibilities to a qualified person when they are not physically present at one of the facility locations. The licensing authority may, at its discretion, extend this transition period for longer than 90 days if the 3PL can demonstrate good cause for such an extension.** **(5) A 3PL will not be penalized for administrative delay on the part of the licensing authority in approving the change in location. The license will be considered valid during the period of the administrative delay if the 3PL submitted a complete application for the change in location and is in good standing with the licensing authority.** --- New § 205.24(b) (b) Any change in the location of **a facility** ~~a wholesale distributor~~ at which wholesale distribution occurs will require **a new license and** an inspection of the new facility

	§ 205.20(b) and proposed § 205.8. We suggest a more limited exception here to assure that 3PLs and wholesale distributors can continue to distribute needed medicines as they move locations, but with continued oversight by the licensing authority. Assuming that a 3PL or wholesale distributor has submitted a complete application for a new location that is acceptable in all respects save for completion of the inspection, we recommend that the licensing authority issue a conditional license indicating the 3PL or wholesale distributor has met the requirements for a license, and is deemed to be temporarily licensed pending completion of a successful inspection. Proposed § 205.17(c)(1) and proposed § 205.31(b)(1) both require that an approved organization complete an inspection within 90 days when asked by FDA. We believe this is a reasonable timeframe for the conduct of an inspection by the licensing authority for a new facility location, particularly where the licensing authority may conduct the inspection itself or accept the inspection conducted by another licensing authority or by an acceptable approved organization (as in proposed § 205.16(a)(1)-(2) and § 205.28(a)(1)-(2)).	prior to the wholesale distributor beginning operations at the new facility. **(1) The application for a new license required by § 205.22 must be submitted no later than 90 calendar days prior to beginning operations at the new facility location.** **(2) The new facility location must be inspected before the licensing authority issues a license. If the licensing authority cannot complete an inspection of the new facility location within 90 days of submission of a license application, the licensing authority shall grant a temporary license to the wholesale distributor facility until the inspection is complete as long as the license application is otherwise complete.** (~~1~~3) **During the period of time the wholesale distributor is transitioning from the original to the new facility location, the wholesale distributor will be temporarily permitted to conduct operations at both the originally licensed facility location and the new location to ensure an orderly and secure shutdown of the originally licensed facility location.** On the date the **wholesale distributor ceases operations at the original facility location, it must surrender its license to that location, and** ~~change of location takes place, the wholesale distributor~~ may not engage in wholesale distribution at that original facility **location without first securing a new license**. ~~*(2) [Reserved]*~~ **(4) During the period of time the wholesale distributor is transitioning from the original to the new facility location, the wholesale distributor may temporarily designate for up to 90 days one person as the designated representative and/or facility manager for both facility locations. The designated representative or facility manager shall delegate in writing their responsibilities to a qualified person when they are not physically present at one of the facility locations. The licensing authority may, at its discretion, extend this transition period for longer than 90 days if the**

		wholesale distributor can demonstrate good cause for such an extension. **(5) A wholesale distributor will not be penalized for administrative delay on the part of the licensing authority in approving the change in location. The license will be considered valid during the period of the administrative delay if the wholesale distributor submitted a complete application for the change in location and is in good standing with the licensing authority.**

46. Changes in Entity, *for 3PLs, Proposed § 205.7(c),* and Change in Person, *for Wholesale Distributors, Proposed § 205.24(c)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.7(c), *change in entity, 3PLs* § 205.24(c), *change in persons engaged in wholesale distribution*	Many of the concerns we raise in the section above regarding proposed § 205.7(b) and proposed § 205.24(b) in section 45 above apply to proposed § 205.7(c) and proposed § 205.24(c) as well. We support the concept of requiring that a "change of entity ownership" as defined in proposed § 205.3(b) will trigger a requirement to obtain a new license for each facility. This is a current requirement under State laws and regulations. There are, however, several concerns with both current practice and the proposed rule that we believe can be addressed to make for a better, more efficient process that is still protective of the supply chain. We believe that some States have expressed concerns regarding what constitutes a reportable "change in entity ownership" in proposed § 205.3(b). We recommend that the term be used consistently in both proposed § 205.7(c) and § 205.24(c) for 3PLs and wholesale distributors respectively. As we raised in section 46 above and elsewhere, we disagree with the "change in the person" language in proposed § 205.24(c). As stated previously, we believe this "person" language arises from the agency's interpretation of the FD&C Act, which refers to the license of a "person" engaged in wholesale distribution. *See, e.g.,* § 583 and § 503(e). Therefore, the implication appears to be that a wholesale distribution facility does not have to hold a license. However, we believe individual wholesale distribution facility licensure is a critical component of supply chain security. This is the current regime in State licensure schemes, and we do not	New § 205.7(c) (c) Any change **of entity ownership of** ~~in~~ the entity engaged in 3PL activities in a facility will require a new license ~~prior to beginning operations~~. (1) The application for a new license required by § 205.5 must be submitted no later than **90** ~~30~~ calendar days ~~prior to~~ **after** the change in ownership. (2) A new inspection of the facility may also be required at the licensing authority's discretion**, and if one is required before issuance of a new license, it must be conducted within a reasonable time not to exceed 90 days from submission of the license application.** (3) A 3PL can continue to operate under the original license for **90** ~~30~~ calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner. **A 3PL will not be penalized for administrative delay on the part of the licensing authority in approving the change in entity ownership. The original license will be considered valid during the period of the administrative delay if the 3PL submitted a complete application for the**

	believe the DSCSA was intended to lessen or eliminate that oversight but only to assure that State rules be the same as federal ones. We, therefore, suggest aligning proposed § 205.24(c) with the similar 3PL language in proposed § 205.7(c) and aligning both with the "change in entity ownership" definition in proposed § 205.3(b). We further are concerned with the requirement to submit the ownership change 30 days ***prior*** to the change. Wholesale distributors and 3PLs would endeavor to make timely notifications in advance of ownership changes. However, the speed of mergers and acquisitions might not permit it and the final agreement to effectuate the merger/acquisition might not be made public (and sometimes might not even be announced internally) until shortly before the effective date, making 30-day prior notification impossible. Some State licensing authorities, recognizing this business reality, permit the submission of the new ownership license application within a reasonable timeframe after the transaction. For example, we understand that the State of Louisiana asks for submission of the new ownership change within 60 days of the effective date of the change and the original license remains valid if the physical distribution or business locations do not change. While timelines and processes vary widely, we believe the States of Arkansas, Connecticut, Kansas, New Hampshire, Alabama, and Alaska all permit change in entity ownership applications after the change is effective. However, we know of several States that will assess a fine for a notification not made prior to the corporate sale even if timely submission of the ownership change was not possible. States will assess fines even when the corporate change was confidential and had not been publicly released. We strongly support the concept behind proposed § 205.7(c)(3) and proposed § 205.24(c)(3) which permit the acquiring 3PL or wholesale distributor to operate under the seller's license for 30 days after the change in ownership occurs or until the licensing authority approves the change. However, as we interpret the "whichever is sooner" limitation severely constrains the utility of this provision as we believe it is very unlikely that new licenses can be obtained from all licensing authorities and any inspections conducted within this timeframe. We believe there is no need for an arbitrary deadline if the application is complete and the facility is operating under a valid license and is in good standing with the licensing authority. If an otherwise compliant 3PL or wholesale distributor must cease operation until the licensing authority reviews the change in ownership and conducts an inspection, the delivery of needed medicines could be severely disrupted.	**change in license entity ownership and is in good standing with the licensing authority.** --- New § 205.24(c) (c) Any change **of entity ownership of** ~~in~~ the **entity** ~~person~~ engaged in wholesale distribution **activities in a facility** will require a new license ~~prior to beginning operations~~. (1) The application for a new license required by § 205.23 must be submitted no later than ~~30~~ **90** calendar days ~~prior to~~ **after** the change in ownership. (2) A new inspection of the wholesale distributor **facility** ~~will be performed~~ may also be required at the licensing authority's discretion**, and if one is required before issuance of a new license, it must be conducted** within a reasonable time **not to exceed 90 days from submission of the license application**. (3) A wholesale distributor can continue to operate under the original license for **90** ~~30~~ calendar days after the change of ownership occurs or until the license application of the new owner is approved, whichever is sooner. **A wholesale distributor will not be penalized for administrative delay on the part of the licensing authority in approving the change in entity ownership. The original license will be considered valid during the period of the administrative delay if the wholesale distributor submitted a complete application for the change in license entity ownership and is in good standing with the licensing authority.**

	Where a merger or acquisition involves large corporations, the new license applications could involve dozens of facilities or more. It can be very onerous for both the licensed entities and the State licensing authorities. We ask for a uniform standard that does not penalize a wholesale distributor or 3PL in this manner and that, as many State licensing authorities do, recognizes the realities of corporate transactions to permit the submission of the application within a reasonable period after the ownership change occurs. To align these widely different requirements and processes, we urge an amendment of the proposed rule to permit the submission of a change of entity ownership within 90 days ***after*** the change of ownership has occurred. We are unclear why inspection is required for wholesale distributors and at the discretion of the licensing authority for 3PLs. We believe giving the licensing authority the flexibility to conduct an inspection in accordance with its own resource management and licensure priorities is sensible. We recommend aligning the wholesale distributor provisions with those for 3PLs. However, we believe there should be a time limit on the conduct of the inspection if it is required. As discussed in section 40, proposed § 205.17(c)(1) and § 205.31(b)(1) both require that an approved organization complete an inspection within 90 days when asked by FDA. We believe this is a reasonable timeframe for the conduct of an inspection by the licensing authority should it elect to do so, for an acquired facility location, particularly where the licensing authority may conduct the inspection itself or accept the inspection conducted by another licensing authority or the inspection of an acceptable approved organization (as in proposed § 205.16(a)(1)-(2) and § 205.28(a)(1)-(2)).	

47. Suspensions of License After Hearing, *for 3PLs, Proposed § 205.9(b),* and *for Wholesale Distributors, Proposed § 205.30(b)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.9(b)(1), *suspension after hearing, 3PLs* § 205.30(b)(1), *suspension after hearing,*	We support the provisions of proposed §§ 205.9(b)(2)-(8) and proposed §§ 205.30(b)(2)-(7) regarding the procedures the licensing authority must follow in a hearing to suspend a license. However, the two provisions are closely parallel but not identical. We believe aligning the 3PL and wholesale distributor requirements as closely as possible would make for better regulation overall. Seemingly minor differences may distract both the regulated and regulator with whether the difference is meaningful and intended, mandated by differences in the DSCSA, or simply a drafting artifact. In this case, the minor differences are likely a drafting	New § 205.9(b)(1) (1) The licensing authority may move to suspend a license if the licensing authority has ~~a reasonable belief~~ **credible evidence** that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart **and that the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety**.

wholesale distributors	artifact, and we believe it would be beneficial for both the regulated and the regulator that the provisions for 3PLs and wholesale distributors be identical. Regarding proposed § 205.9(b)(1), it does not include the qualifier present in proposed § 205.30(b)(1), that the licensing authority will issue a notice of intent to convene a hearing for purposes of suspending a license where the "noncompliance at issue would likely compromise the quality of product or threaten public safety." We recommend this important addition to proposed § 205.9(b)(1). Last, both proposed § 205.9(b)(1) and proposed § 205.30(b)(1) provide that the licensing authority may move to suspend a license if it has "a reasonable belief" that the licensee has failed to comply with any of the applicable standards. We recommend that the licensing authority be required to come forward with something more than a "belief" for so significant an action as suspension of a license. We suggest borrowing from the "illegitimate product" process and definition in § 581(8) and requiring that the licensing authority be required to go beyond belief to "credible evidence" that the licensee is out of compliance. Suspension of a license is a serious matter that should be reserved for serious noncompliance that endangers health and safety. We believe it is very reasonable to require the licensing authority to possess credible evidence of wrongdoing or noncompliance before it may begin the license suspension process.	--- New § 205.30(b)(1) (1) The licensing authority may move to suspend a license if the licensing authority has ~~a reasonable belief~~ **credible evidence** that the licensee has failed to comply with any of the standards for receiving and maintaining licensure described in this subpart and that the nature of the noncompliance at issue would likely compromise the quality of product or threaten public safety.

48. Immediate Suspensions of License, *for 3PLs, Proposed § 205.9(c),* and *for Wholesale Distributors, Proposed § 205.30(c)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§ 205.9(c), *immediate suspension, 3PLs* § 205.30(c), *immediate suspension order, wholesale distributors*	We support much of proposed § 205.9(c) and proposed § 205.30(c). The sections appear functionally identical, which we believe is helpful to both regulated industry and licensing authorities. We believe that the legal standard for imposition of an immediate suspension order in proposed § 205.9(c) and proposed § 205.30(c) should more closely parallel the recent, similar authority granted to the Drug Enforcement Administration (DEA). Under 21 U.S.C. § 824, the DEA may "suspend any registration simultaneously with the institution of proceedings" "in cases where DEA finds that there is an imminent danger to the public health or safety." A failure to comply with applicable standards may be treated as grounds for suspension. The phrase "imminent danger to the public health or safety" means "that, due to the failure of the registrant to maintain effective controls against diversion" or otherwise comply with legal obligations, "there is a substantial likelihood of an immediate threat that death,	New § 205.9(c) (1) The licensing authority may suspend a license effective immediately if the licensing authority **makes a finding** ~~reasonably believes~~ that the licensee has failed to comply with any of the standards for ~~receiving and maintaining~~ licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent **danger** ~~threat~~ to public health **or safety**. **The phrase "imminent danger to public health or safety" means that due to the 3PL's failure to comply with any of the standards for receiving and maintaining licensure described in this subpart, there is a substantial likelihood of an immediate threat that**

	serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *See* 21 U.S.C. §§ 824(d)(1)-(2). Given the even higher degree of risk associated with controlled substances, we believe that § 824(d) is a good model for establishing grounds for immediate suspension under these rules. We recommend that proposed § 205.9(c) and proposed § 205.30(c) be aligned with 21 U.S.C. § 824(d) and that an immediate suspension order may be called for upon finding that violations at a wholesale distributor or 3PL pose a substantial likelihood of an immediate threat that death or serious bodily harm will occur in the absence of the suspension. An immediate suspension order has severe consequences, potentially including the immediate cessation of the delivery of products to dispensers intending to use them in urgent, life-saving situations, and involving products that are unrelated to the underlying reasons for the suspension order. Thus, we also believe that the standards for "receiving and maintaining" licensure in proposed § 205.9(c)(1) and proposed § 205.30(c)(1) unnecessarily complicate these important provisions. We suggest their deletion. Additionally, the language in proposed § 205.9(c)(2) and proposed § 205.30(c)(2) regarding requests for hearings seems confusing. We suggest rewording slightly to make clear that the wholesale distributor or 3PL that receives a notice of immediate suspension of its license should have 10 calendar days from receipt of the notice to request a hearing, which then must occur within 10 calendar days.	**death or serious bodily harm will occur in the absence of an immediate suspension of the license.** (2) The licensing authority will provide the 3PL with written notice of immediate suspension of its license setting forth the **detailed** grounds for the immediate suspension pursuant to this part, including**:** **(i) What conduct the 3PL is engaged in that the licensing authority finds is not compliant;** **(ii) The provisions of this part and the FD&C Act or State law that the licensing authority has found the 3PL is violating;** **(iii) W**~~**w**~~hat information would be required to demonstrate compliance**;**~~**,**~~ and **(iv) T**~~**t**~~he opportunity to request a hearing within 10 calendar days of the 3PL's **receipt of the immediate suspension notice. The licensing authority shall conduct the hearing within 10 calendar days of receiving the** request for such hearing. --- New § 205.30(c) (1) The licensing authority may suspend a license effective immediately if the licensing authority **makes a finding** ~~reasonably believes~~ ~~t~~hat the licensee has failed to comply with any of the standards for~~ receiving and maintaining~~ licensure described in this subpart and that the nature of the noncompliance at issue would reasonably be expected to cause an imminent **danger** ~~threat~~ to public health **or safety**. **The phrase "imminent danger to public health or safety" means that due to the wholesale distributor's failure to comply with any of the standards for receiving and maintaining licensure described in this subpart, there is a substantial likelihood of an immediate threat that death or serious bodily harm will occur in the absence of an immediate suspension of the license.** (2) The licensing authority will provide the wholesale distributor with written notice of immediate suspension of its license setting forth the **detailed** grounds for the immediate suspension pursuant to this part, including**:**

		(i) What conduct the wholesale distributor is engaged in that the licensing authority finds is not compliant; **(ii) The provisions of this part and the FD&C Act or State law that the licensing authority has found the wholesale distributor is violating;** **(iii) W**~~w~~hat information would be required to demonstrate compliance**; and,** ~~,and~~ **(iv) T**~~t~~he opportunity to request a hearing within 10 calendar days of the wholesale distributor's **receipt of the immediate suspension notice. The licensing authority shall conduct the hearing within 10 calendar days of receiving the** request for such hearing.

49. Reinstatement, Revocation, Nonrenewal, Voluntary Termination of License, *for 3PLs, Proposed §§ 205.9(d), (e), (f), (g),* and *for Wholesale Distributors, Proposed §§ 205.30(d), (e), (f), (g)*

Cites to Preamble or Proposed Rule	HDA's Comments	HDA's Recommended Changes
§§ 205.9(d)-(g), *reinstatement, revocation, nonrenewal, voluntary termination, 3PLs* §§ 205.30(d)-(g), *reinstatement, revocation, nonrenewal, voluntary termination, wholesale distributors*	We raised in sections 5 above, 46 above, and elsewhere that the agency's interpretation of "person" engaged in wholesale distribution (*See, e.g.*, § 583 and § 503(e)) appears to not be aligned with existing State regulation of, and authority over, wholesale distributor facilities. Parts of proposed §§ 205.30(d)-(g) appear to be wholly separated from the fact that the wholesale distributor license that is reinstated, revoked, not renewed, or voluntarily terminated is linked to and for a specific facility where wholesale distribution occurs. We ask that the agency make clear in the final rule that a wholesale distributor license is not and cannot be separated from the specific facility that is subject to that license. As discussed, we do not see the DSCSA as intending to disrupt or alter traditional State authorities over facilities in favor of a more general, corporate-based "wholesale distributor license." We believe that proposed § 205.9(f), regarding license nonrenewal for 3PLs, requires revision. The provision, unlike the comparable proposed § 205.30(f) for wholesale distributors, seems to assume a license is suspended and then renewal is sought. We support the wholesale distributor provision of proposed § 205.30(f) and urge a comparable provision for 3PLs in proposed § 205.9(f).	New § 205.9(f) (f) *Nonrenewal.* If a license **renewal application is not submitted** ~~is suspended and the 3PL does not submit a renewal application~~ by the date of expiration of the suspended license, the license will be considered expired. A 3PL may not conduct 3PL activities with an expired license and must submit a new application for licensure if it wishes to conduct 3PL activities. --- New § 205.9(g) (g) *Voluntary termination of licensure upon request by the 3PL*. The licensing authority will terminate a 3PL facility's license upon the 3PL's request, which includes a notice of intent to discontinue its 3PL activities**. The notice of intent should include the name and address of the facility and license number assigned by the licensing authority. Where the 3PL has the right to a request a hearing, the notice of intent should also include a waiver of the** ~~and waive~~ opportunity for a hearing. A 3PL

	We believe some slight clarification would be useful to proposed § 205.9(g) and proposed § 205.30(g) regarding voluntary termination of a license and the "waive opportunity for a hearing" language in both sections. There will be instances, including with a change of location as addressed in proposed § 205.7(b) and proposed § 205.24(b), where the licensee wishes to voluntarily surrender its license and there would not, we believe, be any hearing available to a 3PL or wholesale distributor. Nor would there be any desire to obtain a hearing, even if the opportunity were available. We suggest minor changes to make this distinction clear. We also believe that the creation of a standardized form for the termination of a license would be useful.	facility that voluntarily terminates licensure must obtain a new license before resuming 3PL activities. --- New § 205.30(g) (g) *Voluntary termination of licensure upon request by the wholesale distributor*. The licensing authority will terminate a wholesale distributor's license upon the wholesale distributor's request, which will include a notice of intent to discontinue prescription drug wholesale distribution. **The notice of intent should include the name and address of the facility and license number assigned by the licensing authority. Where the wholesale distributor has the right to a request a hearing, the notice of intent should also include a waiver of the** ~~and waive~~ opportunity for a hearing. A wholesale distributor that voluntarily terminates licensure must obtain a new license before resuming wholesale distribution.

50. Duties of the Inspector

The following is HDA's suggested insert to Part 205 setting for the duties of a State, FDA, or third-party AO inspector.

205.__ *Duties of inspector of a wholesale distributor.*

(a) The inspector shall:

(1) Initiate an inspection of the wholesale distributor facility identified in the application during normal business hours by showing appropriate identification for the inspector(s) and their authority to conduct the inspection to the designated representative or facility manager identified in the application or their designee and stating that the purpose of the inspection is to conduct a physical inspection under the DSCSA;

(2) Examine the wholesale distributor's facility;

(3) Examine the methods for receiving, holding, and distributing prescription drugs;

(4) Inspect any records required to be kept pursuant to section 582(c) and section 503(e) of the FD&C Act or this part;

(5) Determine if the wholesale distributor applicant is in substantial compliance with the requirements of:

(i) Section 582(c) and section 503(e) of the FD&C Act;
(ii) This part; and
(iii) The wholesale distribution licensure requirements, standards, and regulations of the State licensing authority that are the same as this part;

(6) Conduct the inspection in accordance with FDA procedures applicable to the conduct of establishment inspections, including, but not limited to, the Investigations Operations Manual (IOM);

(7) Provide the wholesale distributor with the opportunity to respond to any shortcomings observed and to correct them before the conclusion of the inspection;

(8) Conduct a closing interview with the wholesale distributor to review any shortcomings or deficiencies observed;

(9) Provide a written copy of the inspectional findings to the wholesale distributor within 5 business days of the conclusion of the inspection, to which the wholesale distributor may provide a written response within 15 business days of receipt; and

(10) Submit an inspection report and any wholesale distributor response to the licensing authority following the FDA-prescribed format defined in FDA's IOM and in accordance with the timeframes and requirements of this part.

(11) The inspector must apply only these national standards during the inspection. No State inspector, whether on its own or through a third-party AO, may enhance, enlarge, or impose greater burdens than those of the national standards.

205.__*Duties of inspector of a 3PL.*

(a) The inspector shall:

(1) Initiate an inspection of the 3PL facility identified in the application during normal business hours by showing appropriate identification for the inspector(s) and their authority to conduct the inspection to the designated representative or facility manager identified in the application or their designee and stating that the purpose of the inspection is to conduct a physical inspection under the DSCSA;

(2) Examine the 3PL's facility;

(3) Examine the methods for receiving, holding, and distributing prescription drugs;

(4) Inspect any records required to be kept pursuant to this part;

(5) Determine if the 3PL applicant is in substantial compliance with the requirements of:

(i) The FD&C Act to the extent applicable;
(ii) This part; and
(iii) The 3PL licensure requirements, standards, and regulations of the State licensing authority that are the same as this part;

(6) Conduct the inspection in accordance with FDA procedures applicable to the conduct of establishment inspections, including, but not limited to, the Investigations Operations Manual (IOM);

(7) Provide the 3PL with the opportunity to respond to any shortcomings observed and correct them before the conclusion of the inspection;

(8) Conduct a closing interview with the 3PL to review any shortcomings or deficiencies observed;

(9) Provide a written copy of the inspectional findings to the 3PL within 5 business days of the conclusion of the inspection, to which the 3PL may provide a written response within 15 business days of receipt; and

(10) Submit an inspection report and any 3PL response to the licensing authority following the FDA-prescribed format defined in FDA's IOM and in accordance with the timeframes and requirements of this part.

(11) The inspector must apply only these national standards during the inspection. No State inspector, whether on its own or through a third-party AO, may enhance, enlarge, or impose greater burdens than those of the national standards.

Return to section **40**, Conduct of the Inspection

51. Use of Third-Party Organizations, *for 3PLs, Proposed Part 205, Subpart B, and for Wholesale Distributors, Proposed Part 205, Subpart D*

We support the provisions regarding approval and oversight of AOs in significant part. We offer the following additional comments regarding these provisions.

- Sections 583 and 584 both refer to a "third-party accreditation" program or service as potentially authorized to inspect wholesale distributor and 3PL facilities and, for 3PLs, to review the federal or State license application. ***However, this does not mean that the AO performs or issues accreditation to wholesale distributors or 3PLs.*** The DSCSA's reference to a "third-party accreditation" program or service is that only these types of entities may be approved to conduct inspections or 3PL license reviews. This reference to a "third-party accreditation" program or service should not be interpreted as permitting these entities to "accredit" the wholesale distributor or 3PL. The DSCSA has ***no*** requirement for accreditation by ***any*** third party; the ***only*** relevant criteria are the issuance of a license by a licensing authority if the 3PL or wholesale distributor meets the requirements of these national standards. In section 38 of our chart, we propose the inclusion of a regulation making clear that there is no separate accreditation process for licensure and that none is required (nor may such accreditation be required) under the DSCSA and these implementing rules. We discussion the preemption of such requirements, including separate accreditation, in Attachment 1, HDA's Preemption Analysis.

- Proposed § 205.17(a) and § 205.31(a) address the scope of authority of an AO. An AO may inspect both 3PLs and wholesale distributors and may review a 3PL's qualifications for licensure. The process appears clear for use of an FDA-approved AO within the context of an FDA-issued license for a 3PL (proposed § 205.6) and an FDA-issued license for a wholesale distributor (proposed § 205.23). However, we found the proposed rule less clear in its directions to State licensing authorities regarding the approval and use of AOs. We are unclear about the process by which a State licensing authority would approve and use an AO.

- Regarding wholesale distributor inspection, § 583(d) provides that the AO is "approved by [FDA] or the State licensing such wholesale distributor." Thus, each State licensing authority would have to separately approve and monitor each AO under the standards and procedures set out in proposed § 205.33. FDA "suggests" that States use the same or similar processes and qualifications (87 Fed. Reg. at 6730) – of course, State and national standards must be the same and we recommend this be made explicit in the proposed rule.

- We also recommend that FDA give State licensing authorities the option of approving an AO based upon the submission the AO has made to the FDA and the FDA's approval of it. In this way, the State licensing authority does not have to expend (if it chooses not to) scarce resources for a review that would duplicate what FDA had already undertaken.

- As to 3PLs, FDA interprets the AO provision from § 584 as permitting an approved AO to conduct a review of the 3PL's qualification for licensure, which may include an inspection and issuance of a report to the FDA. 87 Fed. Reg. at 6722. FDA "suggests that States that choose to rely on AOs for licensure reviews have in place the same or similar processes for approval of the AO." 87 Fed. Reg. at 6722. Again, we ask that FDA clarify that the processes States use should be the same as those in the national standards and that States be given the option of approving an AO that cross-references the AO's submission to the FDA and the FDA approval of it.

- We are concerned that if State licensing authorities have AOs conduct inspections that the AOs will charge the wholesale distributor or 3PL with a fee. Pursuant to § 585(b)(3), the State licensing authority may administer fee collections to effectuate wholesale distributor and 3PL licensure requirements. However, we believe this is different from requiring a wholesale distributor or 3PL to directly pay the AO. We strongly believe that AO compensation should be handled through the licensing authority, not the inspected entity. We ask that FDA clarify this point. State licensing authorities should manage all fee matters with AOs so that there will be no cause to question or allege "profit motives" that could cloud the legitimacy and rigor of AO inspections of a regulated entity. We believe wholesale distributors and 3PLs should have no role, whatsoever, in the compensation to AOs for their services and we urge FDA to make this clear in the proposed rule. Among other things, a State will be able to negotiate a much more reasonable inspection fee from an AO than a single inspected facility could on its own.

- Proposed § 205.17 addresses records to be maintained by the AO reviewing and inspecting a 3PL and includes the records and supporting documentation the AO reviewed as part of its inspection and in the licensure process for the 3PL. Proposed §§ 205.17(d)(2)(i)-(ii). The AO inspecting a wholesale distributor must similarly maintain copies of records and documentation reviewed as part of an inspection. Proposed § 205.31(c)(i). However, it appears that only 3PL AOs are expressly instructed to preserve the confidentiality of confidential commercial information. Under proposed § 205.17(e)(2), documentation regarding 3PL inspections and licensure review must be "maintained and protected in accordance with all applicable laws, including those regarding the protection of personal identifying information and confidential commercial information…" This protection for confidential commercial information and personal identifying information does not appear in the comparable wholesale distributor provision, proposed § 205.31. We ask that, when finalized, what is currently proposed § 205.31 be amended to include these same protections of personal identifying information and confidential commercial information.

- We support the conflicts of interest policies and restrictions in proposed § 205.18(a) for 3PL AOs and in proposed § 205.32(a) for wholesale distributors. We suggest adding a provision that no AO, or contractor hired by an AO, should be permitted to financially benefit from its position by offering consultancy and other services to remedy any shortcomings, deficiencies, and non-compliance it identifies.

- Last, we strongly urge the development of a mechanism for wholesale distributors and 3PLs to appeal to FDA disputes with State licensing authorities and/or AOs regarding inspections and interpretations of regulatory and statutory requirements. Since 2013, trading partners have struggled, repeatedly, with licensing authorities taking positions that we believe are contrary to DSCSA requirements. We are similarly concerned with inspectional demands that exceed what is required or even reasonable under the DSCSA and these national standards. A method for a formal and swift process for adjudication of these disputes before would be extremely helpful. FDA is the arbiter of the national standards the DSCSA imposes and there needs to be a process for obtaining agency views in intractable disputes with AOs and State licensing authorities. We point out that there are many provisions of this proposed rule that have been disputed by State licensing authorities for years – for instance, that manufacturers distributing their own product must be licensed as wholesale distributors – and the inability to resolve these issues of DSCSA interpretation has resulted in inconsistent application of the law (and potential security gaps) and needless burden to trading partners who seek to comply with the law.