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OUTSOURCING FACILITIES ASSOCIATION

August 28, 2023

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2023-D-0939 for Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry; DRAFT GUIDANCE

I. About the Outsourcing Facilities Association ("OFA")

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered outsourcing facilities ("503Bs") operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). OFA's members provide compounding and repackaging services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications. OFA has been actively following U.S. Food and Drug Administration's (the "FDA") implementation of the Compounding Quality Act[1] ("CQA") and has brought together members of industry to advocate for a safe, reasonable and practical rollout of the CQA.

OFA respectfully submits this comment in response to FDA's draft guidance on the Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act ("Draft Guidance").

II. FDA's Draft Guidance will increase access to quality compounded drugs

OFA applauds FDA for clarifying that an entity which dispenses drugs obtained from an outsourcing facility is not subject to the wholesaling prohibition of Section 503B(a)(8). This clarification will increase access to drugs compounded and/or repackaged under the most robust quality standards in addition to enhancing 503B's ability to mitigate drug shortages, particularly in the ambulatory and community pharmacy settings. 503B outsourcing facilities voluntarily register with the Food and Drug Administration, undergo both regular and periodic risk-based inspections, and meet the same robust manufacturing safety and quality standards as conventional prescription drug manufacturers, FDA's Current Good Manufacturing Practices (cGMP). When a compounded drug is necessary as determined by a healthcare practitioner, compounded drugs should be sourced from outsourcing facilities. FDA's Draft Guidance allows for state-licensed pharmacies and healthcare practitioners to dispense drugs compounded by

[1] Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (codified at 21 U.S.C. § 353b)

outsourcing facilities, thus improving access to quality compounded drugs. While this is important in general, it is particularly important when the compounded medication is sterile.

III. FDA should clarify the labeling requirements.

Section 503B of the FD&C Act requires that all compounded products be labeled with certain information prohibiting ***resale***, specifically the phrase "Not for resale."[2] However, as FDA recognized in this Draft Guidance, the term "dispense" is distinct and different from the term "resale." Accordingly, utilizing this specific phrase on a 503B compounded product will lead to confusion in the market. This is because the "resale" of a compounded drug that is labeled "not for resale" in accordance with section 503B is a prohibited act.[3] Dispensing, however, is permitted by the plain text of Section 503B and such text is clarified in the Draft Guidance.

While we appreciate FDA's distinction in this Draft Guidance, the concern remains that other regulatory bodies that look to FDA for guidance will misinterpret the labeling requirement "Not for resale" and the act of dispensing. For example, when money changes hands during the dispensing process from patient to pharmacy, there is the potential that a regulator independent from FDA may view this exchange as a resale, especially in light of the "Not for resale" language that is required to be placed on the product's label. With this view, there is the potential conflict in some regulators' interpretation between the "Not for resale" label statement and the act of a monetary exchange as part of the dispensing process. Therefore, we encourage the FDA to further clarify and distinguish "dispensing" from the "sale or transfer." Explicitly carving out "dispensing" from the term "sold or transferred" will eliminate the potential for confusion. OFA requests that FDA exercise enforcement discretion and allow a 503B to use the term "not for wholesale" as an alternative statement to "not for resale" on a compounded product's label and further clarify that resale, and not dispensing, would be wholesaling. Specifically, resale is not dispensing when done via a patient-specific prescription or order. FDA should clarify that a state-licensed pharmacy that dispenses 503B product should follow state laws for labeling and dispensing via a patient-prescription.

IV. FDA should define "intracompany transfer"

The Draft Guidance provides:

> FDA generally does not intend to apply this provision to a compounded drug solely because it was moved as part of an intracompany transfer during shipment to an outsourcing facility's customer.[4]

Left undefined, outsourcing facilities are left in the dark as to what act constitutes an "intracompany transfer." OFA encourages the FDA to adopt a definition similar to NABP's model definition of "Intracompany Transaction."[5]

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[2] FD&C Act 503B(b)(10)(A)(iii)(IX).
[3] FD&C Act 301(ccc)(1).
[4] Draft Guidance at 5.
[5] *See* Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (August 2022), *hereinafter* NABP Model Rules.

Specifically, OFA's proposed definition of "intracompany transfer" is:

> "Intracompany transfer" meaning any transfer between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity.

V. FDA should expand entities that may dispense 503B compounded drug product

Under the Draft Guidance:

> *2. Activities Not Prohibited by the Wholesaling Provision*
>
> (e) An outsourcing facility distributes a drug it compounded to a state-licensed pharmacy, federal facility, or licensed physician, which subsequently dispenses the drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act.

OFA urges the FDA to not limit dispensing from individuals solely to licensed physicians. Dispensing is a state-regulated activity, and many states permit dispensing by appropriately credentialed healthcare practitioners. Limiting dispensing only by licensed physicians limits patient access to quality compounded drugs. For example, dentists, veterinarians, physician assistants, nurse practitioners, nurse midwives and registered nurses may dispense medication if appropriately licensed in many states. In order to increase patient access to quality compounded medication, OFA encourages the FDA to revise this provision as follows:

> (e) An outsourcing facility distributes a drug it has compounded to a state-licensed pharmacy, health care practitioner authorized under state law to dispense drugs, federal facility, or health care practitioner practicing in a federal facility who subsequently dispenses the drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act.

VI. FDA should exempt Federal Facilities from the Prohibition on Wholesaling

Based on government contracts, many Federal healthcare facilities must obtain drug products from government contracted vendors. Most often, the contracted vendor is a traditional large wholesaler. For example, the Veterans Administration contracts with a particular wholesaler for all drugs. Therefore, the FDA should exempt outsourcing facilities from the prohibition on wholesaling where the ultimate customer is a Federal Facility or government agency.

VII. FDA should clarify marketing firm prohibition example

OFA agrees that third parties selling a drug compounded by an outsourcing facility clearly involves wholesaling and is prohibited under Section 503B. However, OFA encourages the FDA to acknowledge that 503Bs, like compounding pharmacies, may market and/or advertise, which includes on websites or other forms of media, the 503Bs services and products as recognized by

the US Supreme Court in *Thompson v. Western States Medical Center*.[6] Accordingly, OFA would encourage FDA to recognize that if a 503B pays a website a fee to advertise or market its services on said website, and orders can be placed to the 503B directly through the website from which the 503B fills such orders, this practice is not a violation of the prohibition on wholesaling. Instead, that would be speech that is considered advertising or marketing that is protected speech under the First Amendment.[7]

For example, traditional wholesalers have established relationships with hospitals and customers in the drug supply chain. A third party (*e.g.* marketing firm or operator of a website that is not a pharmacy) lists an advertisement that markets a drug compounded by an outsourcing facility and does not take physical possession of the drug, by providing services (*e.g.* microsite to advertise outsourcing facility products, capturing purchase orders, processing payments) to outsourcing facilities and healthcare practitioners that prescribe and administer or dispense the drug. The cost of the services are not bundled with the cost of the drugs. The cost the healthcare practitioner paid for the drug is the amount recouped by the outsourcing facility. The third-party charges healthcare practitioners a fee to advertise or market the product and services on website or the third-party charges the outsourcing facility a technology fee for maintenance of the microsite on the marketer's platform. And, the sale and transfer is occurring between the outsourcing facility and healthcare practitioner, not the website. Also, the third-party marketer does not own the drugs, ship drugs, warehouse drugs, handle drugs, or hold the drugs. Nor, does the third-party marketer sell or dispose of drugs., purchase, or decide to purchase drugs. For clarity, the health care practitioners independently decide when and how much (if any) drug to purchase from the outsourcing facility through the outsourcing facilities' microsites on the third-party's platform. Accordingly, the relationship would be truly advertising or marketing by the third party, which is protected First Amendment speech.

The FDA should clarify that this activity is not brokering as it recognized by the NABP model rule and the FDA as proposed in rules under the Drug Supply Chain Security Act ("DSCSA").[8] Many states look to the NABP Model Rules for what is considered "wholesaling." And, it should be noted that NABP includes "brokering" in its definition of "Distribute" or "Distribution," relating to wholesaling, which "means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both."[9] Further, as FDA aptly recognizes in its Proposed Rule on National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, "an entity that directs the sale or disposition of the product but does not take possession (such as a broker) would not be conducting 'other logistics services' and does not meet the definition of a 3PL, but may be engaged in activities that meet the

[6] Thompson v. Western States Medical Center, 535 U.S. 357 (2002).
[7] Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002) citing Edenfield v. Fane, 507 U.S. 761, 767 (1993) ("The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.").
[8] Proposed Rule on National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 Fed. Reg. 6708 (Feb. 4, 2022)
[9] NABP Model Rules at Section 105(n2)

definition of a manufacturer or wholesale distributor."[10] However, we note that "Broker" is "one who acts as an intermediary: such as an agent who negotiates contracts of purchase and sale (as of real estate, commodities, or securities)…or one who sells or distributes something."[11]

VIII. The FDA should encourage other compounders to use outsourcing facility drugs as components when possible.

As FDA has recognized, quality is built into products compounded by outsourcing facilities as compared to compounding pharmacies that utilize the USP standards. 503B outsourcing facilities voluntarily register with the FDA, undergo both regular and periodic risk-based inspections, and meet the same robust manufacturing safety and quality standards as conventional prescription drug manufacturers, FDA's Current Good Manufacturing Practices (cGMP). If compounding with multiple components is necessary, the least amount of components should be used. If a compounder (state-licensed pharmacy, federal facility, or health care practitioner authorized under state law to dispense drugs or a health care practitioner practicing in a federal facility) can source several components pre-mixed by an outsourcing facility, this increases the quality of the final product and decreases manipulations outside of a cGMP environment. For example, a banana bag is an isotonic crystalloid fluid mixed with thiamine, folic acid, and multiple vitamins. An outsourcing facility could compound isotonic crystalloid fluid mixed with thiamine, folic acid and common vitamins. Certain prescribers may wish to customize treatment with the addition of ascorbic acid. A state-licensed pharmacy, federal facility or health care practitioner practicing in a federal facility, or health care practitioner authorized under state law to dispense drugs could add ascorbic acid to the pre-made outsourcing facility banana bag where only two components are involved rather than compounding more than five components together. The FDA will increase the quality of compounded products by permitting a state-licensed pharmacy, federal facility, or health care practitioner (or health care practitioner practicing in a federal facility) authorized under state law to dispense drugs to use outsourcing facility compounded drugs as components in drug compounds that will then be dispensed or administered.

IX. Other Matters

The draft guidance clarifies that a 503B may sell to a state-licensed pharmacy (503A) who dispenses. In order to supply the products needed to a 503A, who has the ability to dispense the medication via a patient prescription, a 503B must have access to the same APIs and bulk substances for starting materials that a 503A has access to. Without access to these bulk substances, it is impossible for a 503B to provide these products to a 503A for dispensing.

OFA acknowledges that this Draft Guidance does not address compounding from bulk drug substances. However, OFA urges the FDA to reconsider its policy on 503B bulk drug substances, especially in light of this Draft Guidance. As a reminder, 503Bs cannot compound an essential copy of an FDA-approved product, unless that product is on the FDA drug shortage list. However, without recognizing a 503Bs ability to compound substances that 503As have access to, FDA ***would encourage*** more compounding at a lower standard in the 503A facility because a 503B will

[10] Proposed Rule at 6714-15.

[11] Merriam Webster Dictionary, https://www.merriam-webster.com/dictionary/broker (last accessed August 25, 2023).

not be able to supply that product. Accordingly, FDA ***should encourage compounding at the higher 503B cGMP standard*** and recognize that 503Bs should be able to compound with the same bulk substances as a 503A (*e.g*. component of an FDA-approved product, USP monograph, or 503A Category 1 list) and supply those products to a 503A to ensure that they are compounded at the higher standard.

X. Conclusion

OFA appreciates the steps FDA has taken to clarify the Prohibition on Wholesaling Under Section 503B. Industry, healthcare practitioners, and patients will benefit from further clarifications requested herein.

Respectfully submitted,

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Lee H. Rosebush, Chairman OFA

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