Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2023
Compounding and Related Documents

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Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

Under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b), a drug compounded by an outsourcing facility[2] qualifies for exemptions from certain statutory requirements if, among other conditions, the drug "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."[3] However, this provision "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."[4] This guidance describes FDA's interpretation of, and policies concerning, the prohibition on wholesaling in section 503B of the FD&C Act. This guidance also describes examples of how FDA intends to apply section 503B's wholesaling provision.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research in cooperation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] *Outsourcing facility* is defined in in section 503B(d)(4)(A) of the FD&C Act as a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of section 503B of the FD&C Act. See the guidance for industry *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (May 2018). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[3] Section 503B(a)(8) of the FD&C Act.

[4] Id.

II. BACKGROUND

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications), section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and section 582 of the FD&C Act (21 U.S.C. 360eee-1) (concerning drug supply chain security requirements).[5]

In contrast to drug products compounded in compliance with section 503A of the FD&C Act, drugs compounded in compliance with section 503B of the FD&C Act are not exempt from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act. Furthermore, among other requirements under section 501, a drug is deemed to be adulterated under section 501(a)(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, regardless of whether the drugs qualify for exemptions set forth in section 503B of the FD&C Act.[6] Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drugs they compound.[7] In addition, outsourcing facilities may or may not obtain prescriptions for identified individual patients.[8]

One of the conditions that must be met for a drug compounded by an outsourcing facility to qualify for the exemptions in section 503B of the FD&C Act is that the drug "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."[9] However, this provision "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."[10]

The statutory prohibition on wholesaling in section 503B(a)(8) of the FD&C Act helps to ensure that compounding is based on individual patients' needs, which, in turn, reduces the overall risk of patient harm and helps to preserve the integrity of the U.S. drug approval process. It also helps to preserve the integrity of the U.S. drug supply chain. This prohibition, like other conditions in section 503B, preserves important distinctions between outsourcing facilities, which are intended to compound drugs for patients whose medical needs cannot be met by approved drugs, from conventional manufacturers, which generally engage in mass manufacturing of FDA-approved drug products.[11]

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[5] Section 503B(a) of the FD&C Act.

[6] Section 501(a)(2)(A) of the FD&C Act. For purposes of section 503B, a drug does not include any biological product that is subject to licensure under section 351 of the Public Health Service (PHS) Act. Accordingly, such biological products are not eligible for the exemptions for compounded drugs under section 503B of the FD&C Act.

[7] Section 503B(a), 503B(b)(4) and (5) of the FD&C Act.

[8] Section 503B(d)(4)(C) of the FD&C Act.

[9] Section 503B(a)(8) of the FD&C Act.

[10] Id.

[11] See, e.g., section 503B(a)(2) of the FD&C Act (bulk drug substances for which there is a clinical need can be used to compound drug products) and section 503B(a)(5) and 503B(d)(2)(B) of the FD&C Act (cannot compound drug

Compounded drugs present a higher risk to patients than approved drugs. Compounded drugs are not FDA-approved and have not been reviewed by the Agency for safety, effectiveness, or quality before they are marketed. Because compounded drugs are subject to a lower regulatory standard than approved drugs, patients should not receive them unless an approved drug does not meet their medical needs. Accordingly, although compounding under section 503B of the FD&C Act need not be based on the receipt of a prescription for an individually identified patient, Congress nevertheless contemplated a relationship between the outsourcing facility and prescriber to supply compounded drugs only to such patients.[12] The more attenuated the connection between the outsourcing facility and patient or prescriber, the more the outsourcing facility resembles a conventional drug manufacturer that distributes drug products to its customers without regard to individual patient need.

Similarly, the prohibition on wholesaling helps to preserve the integrity of the drug approval process. Approval of a new drug means that FDA has determined that it is safe and effective and that it was manufactured by a facility with appropriate methods used in, and facilities and controls used for, preserving the drug's identity, strength, quality, and purity to produce a high-quality product.[13] Approval of new, innovative treatments can save lives, and approval of generic drug products can increase access to critical therapies. If an outsourcing facility could manufacture drug products for further sale or transfer by, for example, wholesale distributors, the outsourcing facility would more closely resemble a conventional manufacturer whose drug products are subject to new drug approval requirements. Section 503B of the FD&C Act therefore imposes conditions which reduce the risk that conventional manufacturers would forgo seeking FDA approval of their drug products to instead market unapproved, compounded drugs as an outsourcing facility. Because the typical supply chain for approved drug products involves wholesaling, consisting of multiple transfers between the manufacture of the drug and ultimately dispensing or administering it to a patient, section 503B's prohibition on wholesaling helps reduce the incentive to compound drugs as an outsourcing facility rather than seek premarket approval.

Finally, because drugs compounded by outsourcing facilities in accordance with the conditions of section 503B of the FD&C Act are exempt from drug supply chain security requirements in section 582 of the FD&C Act, the prohibition on wholesaling is an important control to protect the drug supply chain. Conditioning the exemption from section 582 on limitations on the sale or transfer of a compounded drug reduces supply chain concerns such as diversion. The short supply chain required under section 503B also makes it easier to associate the compounded drug with the relevant outsourcing facility in the case of an adverse event or product quality issue. We further note that outsourcing facilities are required to report adverse events to FDA.[14]

products that contain the same bulk drug substance as an approved drug unless there is a change that produces a clinical difference for an individual patient).

[12] See, e.g., section 503B(a)(8) of the FD&C Act.

[13] See section 505(d) of the FD&C Act.

[14] See section 503B(b)(5) of the FD&C Act.

III. POLICY

A. Key Terms

1. Sold or Transferred

As discussed above, one of the conditions for a drug compounded by an outsourcing facility to qualify for the exemptions in section 503B of the FD&C Act is that the drug "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."[15] This provision "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."[16] The phrase, "sold or transferred by an entity other than the outsourcing facility," as used in section 503B(a)(8) of the FD&C Act, encompasses instances when an entity other than the outsourcing facility that compounded a drug has sold or transferred the drug. Transfers, for purposes of this provision, encompass movements of the drug from one entity to another, regardless of whether the drug was sold as part of the transfer. We note that Congress included within the wholesaling prohibition the sale *or transfer* of compounded drugs, indicating that the provision is intended to capture movements where money does not change hands.

FDA generally does not intend to apply this provision in instances when a common carrier that has experience in safely and securely delivering drug products to health care providers, which does not take ownership of a product, takes physical possession of a drug compounded by an outsourcing facility but only provides transportation services by delivering the drug to the outsourcing facility's customers. Additionally, FDA generally does not intend to apply this provision when an outsourcing facility uses an authorized third-party logistics provider (3PL),[17] which also does not take ownership of products, to provide or coordinate warehousing or other logistics services for the compounded drug on behalf of the outsourcing facility. The compounded drugs would remain subject to CGMP and other requirements, including with regard to proper storage and handling. Outsourcing facilities should only use common carriers and 3PLs that will provide appropriate safeguards for their compounded drugs.

In addition, FDA generally does not intend to apply this provision to a compounded drug solely because it was moved: (1) to a regulatory entity;[18] (2) to a returns processor for credit or

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[15] Section 503B(a)(8) of the FD&C Act.

[16] Id.

[17] Section 581(2)(C) of the FD&C Act defines *authorized* in the case of a third-party logistics provider, as having a valid license under state law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b) of the FD&C Act. Section 581(22) of the FD&C Act defines a *third-party logistics provider* (3PL) as an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product. The Agency has provided additional interpretations regarding the term *3PL* in the revised draft guidance *Identifying Trading Partners Under the Drug Supply Chain Security Act* (July 2022). When final, this guidance will represent the FDA's current thinking on this topic.

[18] Such as a federal agency (e.g., FDA), state agency (e.g., a board of pharmacy), or local agency (e.g., a health department).

disposition for destruction;[19] (3) to a waste disposal company;[20] (4) under a recall; or (5) to or from a contract testing laboratory solely for testing purposes.[21] These types of transfers do not affect the integrity of the drug approval process or drug supply chain and are typically conducted for public health reasons.

Furthermore, 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.[22] Generally, intracompany transfers to facilitate the delivery of products to outsourcing facilities' customers do not have an effect on the integrity of the drug approval process or drug supply chain.

As discussed in more detail below, prohibited sales and transfers under section 503B(a)(8) of the FD&C Act may include, for example, the distribution of a drug even if the entity does not take ownership and possession of the drug.

2. Entities Other Than the Outsourcing Facility

Generally, a drug compounded by an outsourcing facility is not eligible for the statutory exemptions under section 503B of the FD&C Act if the drug is sold or transferred by an "entity other than the outsourcing facility that compounded such drug."[23] FDA interprets this phrase to refer to any entity that sells or transfers a drug compounded by an outsourcing facility, other than the outsourcing facility that compounded the drug, regardless of whether that entity has a physical address.

As discussed in more detail below, examples may include:

- Outsourcing facilities that did not compound the drug being sold or transferred (but see section III.A.3.)
- Wholesale distributors
- Repackers and relabelers
- Marketing firms
- Website owners and operators
- Pharmacies (including mail order pharmacies) (but see section III.A.3.)
- Clinics (including virtual clinics) (but see section III.A.3.)

[19] Including a reverse logistics provider solely for return of nonsalable products.
[20] Solely for destruction in accordance with all applicable laws and regulations.
[21] Undertaken in accordance with all applicable laws and regulations.
[22] Including when an outsourcing facility sends drugs it compounded to a warehouse it owns or leases that is not located in the outsourcing facility that compounded the drugs for shipment to the outsourcing facility's customers.
[23] Section 503B(a)(8) of the FD&C Act.

3. Administration or Dispensing

Section 503B(a)(8) of the FD&C Act provides that the prohibition on wholesaling "does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1)."

FDA interprets this provision to mean that a drug compounded by an outsourcing facility may be eligible for the exemptions in section 503B of the FD&C Act where the drug is distributed directly from an outsourcing facility to a health care facility, such as a hospital or clinic, where the drug is administered to a patient, or to a State-licensed pharmacy or Federal facility where the drug is dispensed pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act. As discussed further below, certain activities by a health care facility or pharmacy would not be considered to constitute administration in a health care setting or dispensing to a patient in accordance with section 503(b)(1). In addition, the fact that a compounded drug is ultimately dispensed by a pharmacy or administered in a health care setting is not determinative of whether wholesaling (i.e., sales or transfers prohibited by section 503B(a)(8)) has occurred before that point, because ordinarily all prescription drugs are ultimately dispensed by a pharmacy or administered in a health care setting.

B. Application of the Wholesaling Prohibition to Examples of Sales and Transfers

1. Activities Prohibited by the Wholesaling Provision

Drugs compounded by outsourcing facilities must meet the conditions in section 503B of the FD&C Act, including the prohibition on wholesaling under section 503B(a)(8), to be eligible for the statutory exemptions available under that section. This guidance provides FDA's policies concerning the prohibition on wholesaling, as explained in section III.A. In general, as described in section III.A.1 and 2, the wholesaling provision applies to the sale or transfer of a compounded drug by an entity other than the outsourcing facility that compounded the drug. As described in section III.A.3, the prohibition on wholesaling does not apply to the administration of a compounded drug in a health care setting or dispensing a compounded drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act. None of the scenarios in section III.B.1 involve, among other things, administration of a drug in a health care setting or dispensing pursuant to a prescription in accordance with section 503(b)(1), so the exception to the prohibition on wholesaling would not apply to any of them.

The following are examples of situations that generally would be subject to the wholesaling prohibition of section 503B(a)(8) of the FD&C Act (i.e., in these situations the drug would be considered sold or transferred by an entity other than the outsourcing facility that compounded such drug):

(a) An outsourcing facility distributes a drug it compounded to a wholesale distributor that sells or otherwise transfers the compounded drug.

The drug has been sold or transferred by an entity (the wholesale distributor) other than the outsourcing facility that compounded it. Because the wholesale distributor does not administer the compounded drug or dispense it pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer by the wholesale distributor would not be included within the exception to the wholesaling prohibition.

(b) An outsourcing facility (A) compounds a drug and transfers the drug to a second outsourcing facility (B) for subsequent distribution (without obtaining a prescription in accordance with section 503(b)(1) of the FD&C Act) to customers. Outsourcing facilities (A) and (B) are owned by different entities and registered with FDA as separate outsourcing facilities.

The drug has been sold or transferred by an entity—outsourcing facility (B)—other than the outsourcing facility (A) that compounded the drug. Because the outsourcing facility (B) that distributed the drug, which it did not compound, does not administer the compounded drug or dispense the drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer by the outsourcing facility (B) of the drug to its customers would not be included within the exception to the wholesaling prohibition.

(c) An outsourcing facility distributes a drug it compounded to a manufacturer (e.g., a repacker or relabeler) that sells or transfers the compounded drug.

The drug has been sold or transferred by an entity other than the outsourcing facility that compounded it. Because the manufacturer (e.g., a repacker or relabeler) does not administer the compounded drug or dispense it pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer by the manufacturer would not be included within the exception to the wholesaling prohibition.

(d) An outsourcing facility distributes a drug it compounded to a repacker or relabeler (regardless of whether the repacker or relabeler actually repacks or relabels the drug) that sells or transfers the drug to another entity (e.g., a pharmacy, health clinic, or physician's office), which then dispenses the drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act.

The drug has been sold or transferred by an entity (the repacker or relabeler) other than the outsourcing facility that compounded it. Because the entity (the repacker or relabeler) to which the outsourcing facility distributed the compounded drug does not administer the compounded drug or dispense it pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer by the repacker or relabeler would not be included within the exception to the wholesaling prohibition.

(e) A third party (e.g., a marketing firm or operator of a website that is not a pharmacy) sells a drug compounded by an outsourcing facility, even though the third party does not take physical possession of the drug, by providing services (e.g., training, billing, advertising)

to physicians that prescribe the drug and bundling the cost of those services with the cost for obtaining the drug.

If the outsourcing facility does not recoup the cost of the compounded drug directly from the prescribing physicians, and the outsourcing facility is compensated by the third party from the proceeds of its bundled services that it charged the prescribing physicians, the third party is selling the compounded drug, regardless of whether the bundled services itemize the cost of the drugs. Because the third party (e.g., a marketing firm or operator of a website that is not a pharmacy) does not administer the compounded drug or dispense it pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale by the third party would not be included within the exception to the wholesaling prohibition.

2. Activities Not Prohibited by the Wholesaling Provision

The following are examples of situations that generally would not be subject to the wholesaling prohibition of section 503B(a)(8) (i.e., in these situations the drug would not be considered sold or transferred by an entity other than the outsourcing facility that compounded such drug, or the sale or transfer would fall within the exception to the wholesaling prohibition):

(a) An outsourcing facility moves a drug it compounded to another location (e.g., a warehouse) that is part of the same outsourcing facility (i.e., at the same address or geographic location) for subsequent distribution.[24]

The drug has not been sold or transferred by an entity other than the outsourcing facility that compounded it. Therefore, because the transfer was solely within the outsourcing facility that compounded the drug, the prohibition on wholesaling would not be applicable.

(b) An outsourcing facility distributes a drug it compounded (without obtaining a patient-specific prescription) to a health care professional who administers it in a health care setting (e.g., in a hospital or the physician's office).

The drug has been sold or transferred by an entity (a health care professional) other than the outsourcing facility that compounded it. However, because the sale or transfer by the health care professional took place as part of administering the drug in a health care setting, the sale or transfer involved would be included within the exception to the prohibition on wholesaling.

(c) An outsourcing facility distributes a drug it compounded (without obtaining a patient-specific prescription) to a hospital or health system,[25] health clinic, or physician's office,

[24] See the guidance for industry *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (May 2018).

[25] For purposes of this guidance, the term *health system* means an organization that includes at least one hospital and at least one group of physicians that provides comprehensive care (including primary and specialty care) who are

and it is administered within that hospital or health system, health clinic, or physician's office.

The drug has been sold or transferred by an entity (a hospital or health system, health clinic, or physician's office) other than the outsourcing facility that compounded it. However, because the sale or transfer in that health care setting took place as part of administering the drug, the sale or transfer involved would be included within the exception to the prohibition on wholesaling.

(d) An outsourcing facility distributes a drug it compounded (without obtaining a patient-specific prescription) to a hospital or health system, health clinic, or physician's office where it is used as office stock to dispense to patients pursuant to prescriptions in accordance with section 503(b)(1) of the FD&C Act.

The drug has been sold or transferred by an entity (a hospital or health system, health clinic, or physician's office) other than the outsourcing facility that compounded it. However, because the sale or transfer took place as part of dispensing the drug to a patient in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer involved would be included within the exception to the prohibition on wholesaling.

(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.

The drug has been sold or transferred by an entity (a state-licensed pharmacy, a federal facility, or licensed physician) other than the outsourcing facility that compounded it. However, because the sale or transfer by the state-licensed pharmacy, federal facility, or licensed physician took place as part of dispensing the drug pursuant to a prescription in accordance with section 503(b)(1) of the FD&C Act, the sale or transfer involved would be included within the exception to the prohibition on wholesaling.

(f) An outsourcing facility distributes a drug it compounded to an entity that provides healthcare services (e.g., a hospital or health system, health clinic, or physician's office) for administration in that health care setting based on pricing agreements the outsourcing facility negotiated with a third party (e.g., group purchasing organization (GPO)) acting on behalf of the healthcare services entity. In this example, the GPO only works on behalf of hospital and health systems, health clinics, and physicians' offices seeking multiple products produced by outsourcing facilities to facilitate business transactions by finding products based on availability and competitive pricing. The GPO does not own drugs, ship drugs, warehouse drugs, handle drugs, or hold drugs. The GPO does not sell or dispose of drugs. The GPO does not purchase, or decide to purchase, drugs. GPO

connected with each other and with the hospital through common ownership or joint management. See the Agency for Healthcare Research and Quality's *Compendium of U.S. Health Systems, 2016*, available at https://www.ahrq.gov/chsp/data-resources/compendium-2016.html.

members independently decide when and how much (if any) drugs to purchase from the outsourcing facility with which the GPO has an agreement.

The GPO has not sold or transferred the drug compounded by the outsourcing facility. The drug has been sold or transferred by an entity (the hospital or health system, health clinic, or physician's office) other than the outsourcing facility that compounded it. However, the sale and transfer of the drug by a hospital or health system, health clinic, or physician's office to administer in its health care setting would be included within the exception to the wholesaling prohibition, despite the involvement of the third-party GPO.

(g) An outsourcing facility dispenses its compounded drugs in accordance with section 503(b)(1) of the FD&C Act to patients of a third party (e.g., a health clinic) after receiving patient-specific prescriptions[26] for the patients from the third party and its affiliated medical providers. The third party does not receive any type of compensation and does not sell or transfer the drugs compounded by the outsourcing facility.

The drugs have not been sold or transferred by an entity other than the outsourcing facility that compounded them. Because the outsourcing facility that compounded the drugs sold or transferred the drugs directly to the patients, the prohibition on wholesaling would not be applicable.

C. Inspections and Regulatory or Enforcement Action

Pursuant to section 704(a) of the FD&C Act, during inspections of outsourcing facilities, FDA reviews records, such as contractual agreements, distribution data, shipment data, and customer lists to evaluate compliance with section 503B(a)(8) of the FD&C Act.[27] If the Agency identifies agreements or procedures concerning a third party's sale or transfer of the outsourcing facility's compounded drugs that are not limited to administration in a health care setting or dispensing pursuant to a prescription in accordance with section 503(b)(1), FDA may consider pursuing regulatory or enforcement action against the outsourcing facility because drugs that are not compounded in accordance with the conditions of section 503B of the FD&C Act are subject to the requirements of sections 505, 502(f)(1), and 582 of the FD&C Act. The third party that sold or transferred the outsourcing facility's drugs may also be subject to regulatory or enforcement action for distributing or causing the distribution of drugs in violation of section 301 of the FD&C Act.

[26] The patient-specific prescriptions may include situations where they are generated as a result of a telehealth visit.
[27] See section 503B(b)(4) of the FD&C Act.