

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

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

**January 2017
Compounding and Related Documents**

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Guidance for Industry¹

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities²

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance.

I. INTRODUCTION AND SCOPE

This guidance sets forth the FDA's policy regarding repackaging by State-licensed pharmacies, Federal facilities, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), 582, and where specified, section 501(a)(2)(B) of the Act, when a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages human prescription drug products.

This guidance **does not address** the following:

- Biological products that are subject to licensure under section 351 of the Public Health Service (PHS) Act. The repackaging of biological products subject to licensure under section 351 is addressed in a separate guidance document.³
- Repackaging drug products for use in animals.
- Repackaging non-prescription drug products.
- Radiopharmaceuticals.⁴

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

² *Outsourcing facility* refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the Federal Food, Drug, and Cosmetic Act.

³ FDA has issued a draft guidance entitled, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. Once finalized, that guidance will represent FDA's thinking on this topic.

All FDA guidances are available on the Agency's guidance website at <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm>. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

⁴ FDA has issued draft guidances entitled, *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Pharmacies and Federal Facilities* and *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities*. Once finalized, those guidances will represent FDA's thinking on that topic.

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- Repackaging by entities that are not State-licensed pharmacies, Federal facilities, or outsourcing facilities (e.g., repackers registered with FDA under section 510 of the FD&C Act).
- Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA does not consider this to be "repackaging," for purposes of this guidance document.
- Upon receipt of a valid patient-specific prescription, a licensed pharmacy removing from one container the quantity of non-sterile drug products⁵ (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient.
- Investigational new drugs being studied under an investigational new drug application. This guidance does not alter FDA's existing approach to regulating investigational new drugs.

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.

II. BACKGROUND

A. Repackaging, Generally

FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.⁶ Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.⁷

Repackaging is performed by a range of entities, including pharmacies and other facilities that specialize in repackaging drug products. FDA is aware that repackaging is done for a variety of

⁵ For purposes of this guidance, a sterile drug is a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

⁶ For example, if tablets are removed from a blister pack and placed into a different container, that would be repackaging. However, if the blister packs containing tablets are placed into a different container for later use (without opening the individual blister packs), that would not be repackaging.

⁷ This guidance does not apply to the compounding of drug products. Compounding is addressed in other guidance documents. See, for example, the guidances *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* and *For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

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reasons including: to meet the needs of specific groups of patients (e.g., pediatric patients or patients receiving drugs for ophthalmic use) who require smaller doses of approved sterile drug products that may not be available commercially; to reduce medication errors associated with drawing up a dose from a vial at the point of patient care; to reduce the availability of drug products that could be abused when controlled substances are left over in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular device to administer the drug (such as a particular pain medication pump); for convenience for the practitioner administering an injection to a patient; to reduce waste and conserve drug supplies; and in some cases to reduce cost. Some repackagers repackage both sterile and non-sterile drug products. Examples of repackaging include tablets and capsules that are repackaged from large containers into smaller containers or blister packs, and creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or containers.

As part of the drug application review and approval process, FDA evaluates the container closure system and the packaging into which the drug will be placed, as well as the conditions under which the drug will be packaged. The container closure system and packaging can affect the quality of the drug product when it is on the market. In particular, during the approval process, FDA reviews whether the container closure system and the packaging are appropriate for maintaining the stability of the drug product through its expiration date, as long as the container-closure and package are not breached, and the drug is stored according to the conditions specified in the application. For drug products required to be sterile, FDA also considers whether the container closure system and packaging are adequate to ensure that the drug product will remain sterile until its expiration date, as long as the container closure is not breached and the drug product is stored appropriately.

When a drug product is repackaged, its characteristics may change in ways that have not been evaluated during the FDA approval process and that could affect the safety and efficacy of the drug product. Improper repackaging of drug products can cause serious adverse events. Of particular concern is repackaging of sterile drug products, which are susceptible to contamination and degradation. For example, failure to properly manipulate sterile drug products under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling could result in drug product degradation and adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated.

B. Regulatory Framework for Repackaging

Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. For example, repackaged drug products are generally subject to the premarket approval, misbranding, adulteration, and drug supply chain security provisions of the FD&C Act, including section 505 (concerning new drug applications),⁸ section 502(f)(1)

⁸ *But see U.S. v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970) (holding that repackaging of approved Enovid (estrogen) tablets from large bottles into small bottles did not require pre-approval under section 505 of the FD&C Act).

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(concerning labeling with adequate directions for use), section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)), and section 582 (concerning drug supply chain security).

Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act.⁹ Therefore, drug products repackaged by State-licensed pharmacies, Federal facilities, or outsourcing facilities are not eligible for the exemptions provided under those sections. In this guidance, FDA describes the conditions under which it does not intend to take action regarding violations of certain requirements of the FD&C Act, in the context of drug repackaging.

III. POLICY

A. General Policy¹⁰

As discussed above, repackaged drug products are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act.¹¹ FDA does not intend to take action for violations of sections 505, 502(f)(1), and 582 if a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages drug products in accordance with the conditions described below, and any applicable requirements.^{12, 13} In addition, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act if the drug product is repackaged by a State-licensed pharmacy or a Federal facility in accordance with the conditions described below, and any applicable requirements.¹⁴

The conditions referred to in the preceding paragraph are as follows:

⁹ Section 503A of the FD&C Act exempts compounded drug products from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act provided certain conditions are met, including that the drug product is compounded pursuant to a valid prescription for an individually identified patient from a licensed practitioner. The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act, the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act, and the Drug Supply Chain Security Act requirements in section 582 of the FD&C Act, if the conditions in section 503B are met. Drug products compounded in outsourcing facilities are not exempt from CGMP requirements under section 501(a)(2)(B).

¹⁰ Portions of this guidance are shaded in gray to indicate that they constitute collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

¹¹ See footnote 8.

¹² Applicable requirements include, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

¹³ FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance.

¹⁴ For purposes of the applicability of the conditions in this guidance document, references to a State-licensed pharmacy or Federal facility do not include a facility that is registered as an outsourcing facility under section 503B of the FD&C Act.

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1. The drug product that is being repackaged is a prescription drug product that:
 - a. is approved under section 505 of the FD&C Act, or
 - b. is an unapproved drug product that appears on the drug shortage list in effect under section 506E of the FD&C Act, and the repackaged drug product is distributed during any period in which it is listed on that drug shortage list or during the 30 days following such period.
2. The drug product is repackaged in a State-licensed pharmacy, a Federal facility, or an outsourcing facility.
3. The drug product is repackaged by or under the direct supervision of a licensed pharmacist.
4. If the drug product is repackaged in a State-licensed pharmacy or a Federal facility, it is distributed¹⁵ only after the receipt of a valid prescription for an identified, individual patient (including a written order or notation in a patient's chart in a health care setting) directly from the prescribing practitioner or patient.¹⁶ This condition does not apply to drug products repackaged in an outsourcing facility.¹⁷
5. Except as provided below for a single-dose vial, the drug product is repackaged, stored, and shipped in a way that does not conflict with approved drug product labeling.¹⁸

For a drug product that is packaged in a single-dose vial that is repackaged into multiple units, the drug product is repackaged in a way that does not conflict with the

¹⁵ "Distributed" means that the repackaged drug product has left the facility in which it was repackaged.

¹⁶ FDA is considering the applicability of this condition to certain non-sterile drug products repackaged by State-licensed pharmacies for distribution to long-term care facilities, and intends to revise this guidance or issue separate guidance to address this issue. During this interim period, FDA does not intend to apply this condition to non-sterile drug products repackaged by State-licensed pharmacies for use in long-term care facilities.

¹⁷ Note, however, that drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, a prescription drug cannot be dispensed to a patient without a prescription.

¹⁸ If the approved labeling contains instructions for handling or storage of the product, the drug product is repackaged in accordance with those instructions. Otherwise, the repackaging would be considered to be in conflict with the approved labeling. For example, the approved labeling for propofol states that "propofol undergoes oxidative degradation in the presence of oxygen and is therefore packaged under nitrogen to eliminate this degradation path", and it states, "Do not freeze." Therefore, exposing propofol to oxygen during the repackaging process or freezing it would be in conflict with the approved labeling. In contrast, the labeling of propofol is silent on the type of container into which it can be packaged. Therefore, packaging it into an appropriate container would not conflict with the approved labeling. Also note that section 502(g) of the FD&C Act states that a drug is misbranded if it is a drug that is recognized in an official compendium and among other things it is not packaged as prescribed therein.

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- approved labeling, except for the statements designating the product as a single-dose or single-use product and related language (e.g., discard remaining contents).¹⁹
6. The container into which the drug product is repackaged is suitable for storage of the drug product through its beyond-use-date (BUD).²⁰
 7. If the labeling for the approved drug product being repackaged includes storage and/or handling instructions (e.g., protect from light, do not freeze, keep at specified storage temperature), the labeling for the repackaged drug product specifies the same storage conditions.
 8. The repackaged drug product is assigned a BUD^{21,22} as described below, unless literature or other scientific information suggests that a shorter BUD would be appropriate, in which case a shorter BUD is assigned consistent with such scientific information. The BUD timeframes in this condition begin from the time in which the container of the original drug product to be repackaged is punctured or otherwise opened.
 - a. **Sterile drug products repackaged by State-licensed pharmacies or Federal facilities:**
 - i. **FDA-approved drug product with a specified in-use time:** If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling a time within which the opened product is to be used (an “in-use” time), the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.²³

¹⁹ This condition would not be satisfied if a drug product repackaged from a single-dose vial is repackaged in a way that conflicts with other language in the approved labeling (e.g., regarding storage conditions).

²⁰ For example, for State-licensed pharmacies and Federal facilities, information provided by the container’s manufacturer could indicate that the container is suitable for drug products repackaged in accordance with this condition. For outsourcing facilities, CGMP requirements address container suitability and drug stability.

²¹ The BUD is the date beyond which a drug product should not be used.

²² FDA does not intend to take action against an outsourcing facility for assigning a BUD to be used as an expiration date in lieu of conducting stability studies required under 21 CFR part 211 for its repackaged drug products if the outsourcing facility assigns a BUD consistent with this condition.

²³ For example, if an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2017, on the label is repackaged on January 1, 2017, the applicable BUD for the repackaged drug product would be January 4, 2017, because the labeled in-use time of 3 days is shorter than the time until the labeled expiration date of the drug product (14 days). If the drug product is repackaged on January 14, 2017, the applicable BUD for the repackaged drug product would be January 15, 2017, because the time until the labeled expiration date of the approved drug product is 1 day, which is shorter than the labeled 3-day in-use time.

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- ii. **FDA-approved drug product without an in-use time or unapproved drug product:** If the drug product being repackaged is an FDA-approved drug product whose labeling does not specify an in-use time, or if it is an unapproved drug product on the FDA drug shortage list (which does not have an in-use time reviewed by FDA as part of the drug approval process), the repackaged drug product is assigned a BUD (1) that is established in accordance with the proposed revision to USP Chapter <797> published in the Pharmacopeial Forum (PF) 41(6) [Nov.–Dec. 2015] on November 2, 2015,²⁴ or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.

- b. **Sterile drug products repackaged by outsourcing facilities:**

The outsourcing facility assigns a BUD as described in the guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*.²⁵

- c. **Non-sterile drug products repackaged by State-licensed pharmacies, Federal facilities, or outsourcing facilities:**²⁶

- i. **FDA-approved drug product with a specified in-use time:** If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling an “in-use” time, the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.
- ii. **FDA-approved drug product without an in-use time or unapproved drug product:**²⁷

²⁴ Once USP has considered the public comments that it received and finalizes the revised Chapter <797>, FDA intends to evaluate whether condition 8 should refer to the updated chapter or BUDs that are different than those included in final Chapter <797>. Although USP Chapter <797> addresses *compounded* sterile preparations, many of the same principles for conditions and practices to assure sterility and stability of compounded drug products, such as the requirement to maintain a sterile environment, engage in appropriate sterile processing techniques, and assign the appropriate BUD to the product, also apply to repackaged sterile drug products to help assure their quality is not compromised during and after the repackaging operation.

²⁵ The longer BUDs set forth for outsourcing facilities reflect that conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility, and that outsourcing facilities are subject to FDA inspections on a risk-based schedule.

²⁶ In lieu of the BUDs set forth in this condition, outsourcing facilities may establish BUDs for non-sterile drug products that they repackage based on stability studies conducted in accordance with 21 CFR Part 211.

²⁷ The BUDs in this condition are based on the BUDs applicable to non-sterile compounded preparations in USP Chapter <795>.

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- For nonaqueous formulations, the BUD does not exceed six months or the expiration date of the drug product being repackaged, whichever is shorter.
 - For water-containing oral formulations, the BUD does not exceed 14 days or the expiration date of the drug product being repackaged, whichever is shorter.
 - For water-containing topical/dermal and mucosal liquid and semisolid formulations, the BUD does not exceed 30 days or the expiration date of the drug product being repackaged, whichever is shorter.
9. The drug product is repackaged in accordance with the following²⁸:
- a. If the drug product is repackaged in a State-licensed pharmacy or a Federal facility:
 - i. If it is a non-sterile drug product, it is repackaged in accordance with USP Chapter <795>, except the BUD is as specified in condition 8; or
 - ii. If it is sterile drug product, it is repackaged in accordance with USP Chapter <797>, except the BUD is as specified in condition 8.
 - b. If the drug product is repackaged in an outsourcing facility, repackaging is conducted in accordance with CGMP requirements.²⁹
10. The drug product that is being repackaged does not appear on a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or ineffective. For purposes of this provision, repackagers should refer to the list of drug products in 21 CFR 216.24, developed for use with sections 503A and 503B of the FD&C Act.
11. The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.
12. The repackaged drug product is distributed only in States in which the facility repackaging the drug product meets all applicable State requirements.

²⁸ The intention is that the BUDs are set in accordance with condition 8.

²⁹ See the guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*.

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13. If the drug product is repackaged by an outsourcing facility:
- a. The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes the following:
 - i. The statement “This drug product was repackaged by [name of outsourcing facility]”
 - ii. The address and phone number of the outsourcing facility that repackaged the drug product
 - iii. The established name of the original drug product that was repackaged
 - iv. The lot or batch number of the repackaged drug product
 - v. The dosage form and strength of the repackaged drug product
 - vi. A statement of either the quantity or volume of the repackaged drug product, whichever is appropriate
 - vii. The date the drug product was repackaged
 - viii. The BUD as the expiry date for the repackaged drug product
 - ix. Storage and handling instructions for the repackaged drug product
 - x. The National Drug Code (NDC) number of the repackaged drug product, if available³⁰
 - xi. The statement “Not for resale,” and, if the drug product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement “Office Use Only”, and
 - xii. If included on the label of the drug product from which the drug product is being repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below in 11.b.i.
 - b. The label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the repackaged products are distributed) includes:
 - i. The active and inactive ingredients, if the immediate drug product label is too small to include this information
 - ii. Directions for use, including, as appropriate, dosage and administration
 - iii. The following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.
 - c. The drug product is included on a report submitted to FDA each June and December identifying the drug products repackaged by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number

³⁰ The NDC number of the original approved drug product should not be placed on the repackaged drug product.

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of individual units produced; and the NDC number of the repackaged drug product, if assigned.³¹

- d. The outsourcing facility reports serious adverse events to FDA that are associated with its repackaged drug products.³²

B. Establishment Registration and Drug Listing

Under section 510(b)(1) of the FD&C Act, between October 1 and December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs is required to register with FDA, and under section 510(j) of the FD&C Act, every person who registers with FDA under section 510(b) must list its drugs with the Agency. A drug is misbranded under section 502(o) of the FD&C Act if it was manufactured, prepared, propagated, compounded, or processed in an establishment that is not registered under section 510, or if it was not included on a list required by section 510(j). Pharmacies that repackaged drug products may qualify for an exemption from registration and thus also not be required to list their drugs with FDA. Specifically, under section 510(g)(1), the registration and listing requirements of section 510 do not apply to:

pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

With respect to entities that do not qualify for the exemptions from registration under section 510 of the FD&C Act,³³ FDA does not intend to take action for violations of section 502(o) of the

³¹ FDA has issued a guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. This guidance describes how outsourcing facilities submit drug product reports to FDA. Although that guidance addresses reporting of compounded drug products, outsourcing facilities should follow the same procedure to electronically report the drug products they repackaged.

³² FDA has issued a guidance for industry, *Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which describes how outsourcing facilities submit adverse event reports to FDA and the content and format of the reports that they are required to submit. Although that guidance addresses reporting of adverse events associated with compounded drug products, outsourcing facilities should follow the procedure described in that guidance to electronically report adverse events associated with the drug products they repackaged.

³³ See also, 21 CFR 207.10.

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FD&C Act for failure to register and list drugs under section 510 for drugs that are repackaged in accordance with this guidance.³⁴

³⁴ FDA has developed this policy because outsourcing facilities that repackage drug products in accordance with this guidance are registered with FDA under section 503B of the FD&C Act and report repackaged drug products to FDA in accordance with condition 13.c.