



Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact Gail Bormel, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC), at 301-796-3110.

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

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Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

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Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov*

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- 29 • Repackaging drug products for use in animals. FDA will consider addressing this issue
30 in a separate guidance document.
- 31 • Repackaging by entities that are not state-licensed pharmacies, Federal facilities, or
32 outsourcing facilities. See additional information in section III.A. of this draft guidance
33 document.
- 34 • Removing a drug product from the original container at the point of care for immediate
35 administration to a single patient after receipt of a patient-specific prescription or order
36 for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA
37 does not consider this to be “repackaging,” for purposes of this guidance document.
- 38 • Upon receipt of an individual patient-specific prescription, a licensed pharmacy removing
39 from one container the quantity of solid oral dosage form drug products necessary to fill
40 the prescription and placing it in a smaller container to dispense directly to its customer.

41

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

47

II. BACKGROUND

48

A. Repackaging, Generally

49

50 **A. Repackaging, Generally**

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

59

60 Repackaging is performed by a range of entities, including facilities that specialize in
61 repackaging drug products, and pharmacies, including pharmacies in hospitals and health
62 systems. FDA is aware that repackaging is done for a variety of reasons including: to meet the
63 needs of specific groups of patients (e.g., pediatric patients or ophthalmic patients who require
64 smaller doses of approved sterile drug products that may not be available commercially); to
65 reduce medication errors associated with drawing up a dose from a vial at the point of patient
66 care; to reduce the availability of drug products of abuse when controlled substances are left over
67 in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular
68 device to administer the drug (such as a particular pain medication pump); for convenience for
69 the practitioner administering an injection to a patient; and in some cases to reduce cost. Some
70 repackagers repackage both sterile and non-sterile drug products. For example, tablets and
71 capsules are repackaged from large containers into smaller containers or blister packs, and
72 creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or
73 containers.

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

86
87 When a drug product is repackaged, its characteristics may change in ways that have not been
88 evaluated during the FDA approval process and that could affect the safety and efficacy of the
89 drug product. Improper repackaging of drug products can cause serious adverse events. Of
90 particular concern is repackaging of sterile drug products, which are susceptible to contamination
91 and degradation. For example, failure to properly manipulate sterile drug products under
92 appropriate aseptic conditions could introduce contaminants that could cause serious patient
93 injury or death. Repackaging practices that conflict with approved product labeling could result
94 in drug product degradation and adverse events associated with impurities in the product or lack
95 of efficacy because the active ingredient has deteriorated.

B. Regulatory Framework for Repackaging

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97
98
99 Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act
100 related to the production of drugs. For example, repackaged drug products are generally subject
101 to the premarket approval, misbranding, and adulteration provisions of the FD&C Act, including
102 section 505 (concerning new drug applications),⁴ section 502(f)(1) (concerning labeling with
103 adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing
104 practice (CGMP)).

105
106 Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act.⁵
107 Therefore, drug products repackaged by state-licensed pharmacies, Federal facilities, or
108 outsourcing facilities are not eligible for the exemptions provided under those sections. In this

⁴ 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).

⁵ 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 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 compounding can register as an outsourcing facility with FDA. Drug products compounded under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act and the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act if the conditions in section 503B are met. Drug products compounded in outsourcing facilities are not exempt from the CGMP requirements of section 501(a)(2)(B).

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109 guidance, FDA describes the conditions under which it does not intend to take action regarding
110 violations of certain requirements of the FD&C Act, in the context of drug repackaging.

111

C. Hospital and Health System⁶ Repackaging of Drugs In Shortage For Use in the Health System (Section 506F of the FD&C Act)

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115 The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in
116 July, 2012, added section 506F to the FD&C Act. This section exempts certain hospitals within
117 a health system from registration requirements in section 510 of the Act provided certain
118 conditions are met, including that the drugs are, or have recently been, listed on FDA’s drug
119 shortage list⁷ and are repackaged for the health system. Section 506F of the FD&C Act defines
120 “repackaging,” for purposes of that section only, as “divid[ing] the volume of a drug into smaller
121 amounts in order to—(A) extend the supply of a drug in response to the placement of the drug on
122 a drug shortage list under section 506E; and (B) facilitate access to the drug by hospitals within
123 the same health system.”

124

125 Section 506F of the FD&C Act has a termination clause that states “This section [506F] shall not
126 apply on or after the date on which the Secretary issues final guidance that clarifies the policy of
127 the Food and Drug Administration regarding hospital pharmacies repackaging and safely
128 transferring repackaged drugs to other hospitals within the same health system during a drug
129 shortage.”⁸ These issues are addressed and clarified by this guidance and the guidance on
130 *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved*
131 *Biologics License Application*. Therefore, when these guidances become final, section 506F of
132 the FD&C Act will no longer apply.

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III. POLICY

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138 As discussed above, repackaged drug products are generally subject to the adulteration,
139 misbranding, and approval provisions of the FD&C Act.⁹ FDA does not intend to take action for
140 violations of sections 505 and 502(f)(1) if a state-licensed pharmacy, a Federal facility, or an

⁶ For purposes of this guidance, the term “*health system*” refers to a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

⁷ See section 506F(b) (providing that the exemption may be available if, among other factors, the drug is repackaged (1) during any period in which the drug is listed on the drug shortage list under section 506E; or (2) during the 60-day period following any period described in paragraph (1)).

⁸ See section 506F(d) of the FD&C Act.

⁹ As described in section II.B., repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. Therefore, drug products that do not meet the conditions in this guidance, including drug products repackaged by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities, generally must comply with requirements in the FD&C Act and FDA regulations applicable to drug products including, but not limited to, CGMP and new drug approval requirements.

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141 outsourcing facility repackages drug products in accordance with the conditions described below,
142 and any applicable requirements.¹⁰ In addition, FDA does not intend to take action for violations
143 of section 501(a)(2)(B) of the FD&C Act if the drug product is repackaged by a state-licensed
144 pharmacy or a Federal facility in accordance with the conditions described below, and any
145 applicable requirements.

146

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

148

- 149 1. The drug that is being repackaged is a prescription drug product approved under
150 section 505 of the FD&C Act, except as provided in section III.B of this guidance
151 regarding repackaging unapproved drug products that appear on FDA's drug shortage
152 list under section 506E.
- 153 2. The drug product is repackaged in a state-licensed pharmacy, a Federal facility, or an
154 outsourcing facility.
- 155 3. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility
156 (but not an outsourcing facility), it is repackaged and distributed¹¹ after (a) the receipt
157 of a valid prescription for an identified, individual patient directly from the
158 prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's
159 chart in a health care setting, unless it is repackaged (but not distributed) in advance
160 of receipt of such a prescription or a written order in a patient's chart in a quantity
161 that does not exceed the amount of drug product that the state-licensed pharmacy or
162 the Federal facility repackaged pursuant to patient-specific prescriptions or written
163 orders in a previous, consecutive 14-day period, and based on a history of receipt of
164 prescriptions or written orders over a consecutive 14-day period for such repackaged
165 drug products.
- 166 4. The drug product is repackaged by or under the direct supervision of a licensed
167 pharmacist.
- 168 5. Except as provided below for a single-dose vial, the drug product is repackaged in a
169 way that does not conflict with approved drug product labeling.¹²

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¹⁰ 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.

¹¹ Distribution means that the repackaged drug product has left the facility in which it was repackaged.

¹² For example, if the approved labeling contains instructions for handling or storage of the product, the repackaging is done in accordance with those instructions. Otherwise, it would be considered to be in conflict with the approved labeling.

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- 177 statements designating the product as a single dose or single use product, and related
178 language (e.g., discard remaining contents).¹³
179
- 180 6. The repackaged drug product is assigned a beyond-use-date (BUD)¹⁴ as described below:
181
- 182 a. **FDA-approved drug product with a specified in-use time:** If the drug product
183 being repackaged is an FDA-approved drug product that specifies in the labeling a
184 time within which the opened product is to be used (an “in-use” time), the repackaged
185 drug product is assigned a BUD (1) that is established in accordance with the in-use
186 time on the drug product being repackaged; or (2) that is the expiration date on the
187 drug product being repackaged, whichever is shorter.¹⁵
188
- 189 b. **FDA-approved drug product without an in-use time or unapproved drug**
190 **product:** If the drug product being repackaged is an FDA-approved drug product
191 whose labeling does not specify an in-use time, or if it is an unapproved drug product
192 on the FDA drug shortage list (which does not have an in-use time reviewed by FDA
193 as part of the drug approval process), the repackaged drug product is assigned a BUD
194 (1) that is established in accordance with the time described in (i) or (ii) below, as
195 applicable, or (2) that is the expiration date on the drug product being repackaged,
196 whichever is shorter.¹⁶
197
- 198 i. **Sterile Drug Products:** The repackaged drug product is assigned a BUD no
199 longer than the following, even if the time until the expiration date on the drug
200 product being repackaged is longer:
201
- 202 1. **If repackaged in a state-licensed pharmacy or Federal facility, the**
203 **repackaged drug product is assigned a BUD that is¹⁷:**

¹³ 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).

¹⁴ Unless otherwise indicated, 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.

¹⁵ For example, if an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2015 on the label is repackaged on January 1, 2015, the applicable BUD for the repackaged drug product would be January 4, 2015, 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, 2015, the applicable BUD for the repackaged drug product would be January 15, 2015, 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.

¹⁶ In other words, if the FDA-approved drug product does not have an in-use time, or the drug product being repackaged is an unapproved drug product, the times in (i) and (ii) are the default BUDs, unless the expiration date on the drug product being repackaged is shorter, in which case the BUD would be the same as the expiration date.

¹⁷ These BUDs are consistent with the BUDs established by USP Chapter <797> for “medium-risk” compounded sterile preparations. Although USP <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 put appropriate BUDs on the product, also apply to repackaged sterile drug products to help ensure their quality is not compromised during

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- ≤ 30 hours if stored at USP controlled room temperature;
 - ≤ 9 days if stored in a refrigerator; or
 - ≤ 45 days if stored in a solid frozen state between -25°C and -10°C
2. **If repackaged in an outsourcing facility**, the outsourcing facility conducts a sterility test in accordance with CGMP requirements¹⁸ (e.g., using the sterility test described in USP Chapter <71>) and receives passing results before release, and the repackaged drug product is assigned a BUD that is¹⁹:
- Not more than 14 days beyond completion of the sterility test or 28 days from the time of repackaging, whichever is shorter, if stored at USP controlled room temperature or in a refrigerator; or
 - Not more than 45 days beyond completion of the sterility test or 59 days from the time of repackaging, whichever is shorter, if stored in a solid frozen state between -25°C and -10°C²⁰
- ii. **Non-sterile Drug Products:** The BUD for the repackaged drug product is no longer than the expiration date on the original drug product being repackaged.
7. Except with regard to BUDs, which are addressed in condition 6, above:
- 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>; or

and after the repackaging operation. The BUDs for medium-risk compounded preparations in USP <797> are appropriate for sterile drug products that do not include an “in-use” time and are repackaged by a state-licensed pharmacy or Federal facility because the two activities present comparable risks.

¹⁸ See 21 CFR part 211.

¹⁹ These longer BUDs reflect that outsourcing facilities must comply with CGMP requirements and are subject to FDA inspections on a risk-based schedule. 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. FDA has issued a draft guidance entitled, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (“Interim CGMP Guidance”). (See <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>) The Interim CGMP Guidance, when finalized, will describe FDA’s expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated. The BUDs set forth for sterile drug products repackaged by outsourcing facilities in this condition are consistent with the BUDs listed in the Interim CGMP Guidance that are applicable to sterile drug products compounded at outsourcing facilities.

²⁰ The 28-day and 59-day timeframes provide for the 14 days it takes to receive results from the sterility test conducted under USP Chapter <71>.

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- ii. If it is sterile drug product, it is repackaged in accordance with USP Chapter <797>, e.g., a sterile drug product is repackaged in an area with air quality that meets or exceeds ISO Class 5 standards (see USP Chapter <797>, Table 1).
 - b. If the drug product is repackaged in an outsourcing facility, repackaging is conducted in accordance with CGMP requirements.
8. 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.
9. 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.
10. The repackaged drug product is distributed only in states in which the facility repackaging the drug product meets all applicable state requirements.
11. 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, approved 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 of 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 available²¹
 - xi. The statement “Not for resale,” and, if the drug product is distributed by an outsourcing facility other than pursuant to a

²¹ The NDC number of the original approved drug product should not be placed on the repackaged drug product.

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- 271 prescription for an individual identified patient, the statement
272 “Office Use Only”
- 273 xii. If included on the label of the FDA-approved drug product from
274 which the drug product is being repackaged, a list of the active
275 and inactive ingredients, unless such information is included on
276 the label for the container from which the individual units are
277 removed, as described below in 11.b.i.
- 278
- 279 b. The label on the container from which the individual units are removed for
280 administration (secondary packaging, e.g., the bag, box, or other package in
281 which the repackaged products are distributed) includes:
- 282 i. The active and inactive ingredients, if the immediate drug
283 product label is too small to include this information
- 284 ii. Directions for use, including, as appropriate, dosage and
285 administration, and the following information to facilitate
286 adverse event reporting: www.fda.gov/medwatch and 1-800-
287 FDA-1088.
- 288
- 289 c. Each repackaged drug product is also accompanied by a copy of the
290 prescribing information that accompanied the original drug product that was
291 repackaged.
- 292
- 293 d. The drug product is included on a report submitted to FDA each June and
294 December identifying the drug products made by the outsourcing facility
295 during the previous 6-month period, and providing the active ingredient(s);
296 source of the active ingredient(s); NDC number of the source ingredient(s), if
297 available; strength of the active ingredient(s) per unit; the dosage form and
298 route of administration; the package description; the number of individual
299 units produced; and the NDC number of the final product, if assigned.²²
- 300
- 301 e. The outsourcing facility reports serious adverse events to FDA that may be
302 associated with its repackaged drug products.
- 303

B. Repackaging Drugs on FDA’s Drug Shortage List

304 This guidance addresses repackaging of prescription drug products, including drug products on
305 FDA’s drug shortage list, by a state-licensed pharmacy, Federal facility, or outsourcing facility,
306 including within a hospital or health system. This guidance also specifically addresses the
307 repackaging of single-dose vials, a practice that is sometimes used to extend the supply of a drug
308
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²² FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the Agency’s current thinking on that topic. Although that guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the drug products they repackaged.

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310 product that is on the FDA drug shortage list. In addition, the first condition described in section
311 III.A.1 of this guidance provides that the drug product being repackaged is a prescription drug
312 product approved by FDA under section 505 of the FD&C Act. However, with respect to an
313 unapproved drug product that appears on FDA’s drug shortage list, FDA also does not intend to
314 take action for violations of sections 505, 502(f)(1), and, as specified above, section
315 501(a)(2)(B), provided that the state-licensed pharmacy, the Federal facility, or the outsourcing
316 facility (including within a hospital or health system) meets all of the conditions of this guidance,
317 and the repackaged drug product is distributed during any period in which the drug product is
318 listed on the drug shortage list under section 506E of the FD&C Act or during the 30 days
319 following such period. As stated above, this guidance and the guidance on *Mixing, Diluting, or*
320 *Repackaging Biological Products Outside the Scope of an Approved Biologics License*
321 *Application* clarify the Agency’s policy regarding hospital pharmacies repackaging and safely
322 transferring repackaged drug products to other hospitals within the same health system during a
323 drug shortage. Therefore, when these guidances become final, section 506F of the FD&C Act
324 will no longer apply.