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# **Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency**

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## **Guidance for Industry**

**April 2020**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Quality and Office of Compliance**

# Preface

## Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to [CDER-OPQ-Inquiries@fda.hhs.gov](mailto:CDER-OPQ-Inquiries@fda.hhs.gov) to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1136 and complete title of the guidance in the request.

## Questions

For questions about this document, contact FDA's Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at [CDER-OPQ-Inquiries@fda.hhs.gov](mailto:CDER-OPQ-Inquiries@fda.hhs.gov).

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# Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency

## Guidance for Industry

This guidance represents 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 or Office responsible for this guidance as listed on the title page.

### I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

During the COVID-19 public health emergency, FDA has received several inquiries from health care professionals concerning the unavailability of propofol drug products used in the treatment and management of patients with complications related to COVID-19. FDA is issuing this guidance to communicate its temporary policy regarding the repackaging or combining of propofol drug products by a licensed pharmacist in a State licensed pharmacy, a Federal facility, or an outsourcing facility registered pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) as outlined in this guidance for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, or for such shorter time as FDA may announce through updated guidance.

This policy is intended to remain in effect for no longer than the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). FDA is continually assessing the needs and circumstances that make issuance of this guidance appropriate. As relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw policies in this guidance as appropriate.

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Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020 (85 FR 16949), titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, 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 guidance means that something is suggested or recommended, but not required.

## **II. Background**

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>1</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>2</sup>

During the public health emergency posed by COVID-19, FDA has received reports from some hospitals that they are having difficulty obtaining adequate supplies of FDA-approved propofol injectable emulsion (propofol) products, 10 milligram (mg) per milliliter (mL), in the presentations<sup>3</sup> used to support COVID-19 patients who have been sedated and intubated, or for other procedures involved in the care of such patients. Propofol is currently on FDA’s drug shortage list, with several presentations on backorder or on allocation. FDA understands that pharmacies and outsourcing facilities that have access to certain presentations would like to repackage<sup>4</sup> or combine units of a finished, FDA-approved drug product to provide hospitals with

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<sup>1</sup> Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

<sup>2</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

<sup>3</sup> For purposes of this guidance, presentations refer to how propofol is supplied (e.g., package size, volume).

<sup>4</sup> 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. Repackaging 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. See FDA’s guidance for industry: *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities* (January 2017), available at <https://www.fda.gov/media/90978/download>. FDA updates 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>.

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presentations needed for patients with COVID-19. Hospitals are seeking larger presentations of propofol drug products to minimize exposure between patients and hospital staff, as well as to conserve personal protective equipment (PPE) for hospital staff.

When an FDA-approved 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.

FDA has issued guidance for pharmacies or outsourcing facilities that repackage certain drug products, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities* (January 2017) (the Repackaging Guidance),<sup>5</sup> which sets forth FDA's current thinking on this subject. The guidance describes a number of practices to mitigate risks associated with repackaging, and explains that FDA does not intend to take action for violations of section 505 (concerning new drug applications), section 502(f)(1) (concerning labeling with adequate directions for use), and section 582 (concerning drug supply chain security) of the FD&C Act if a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages drug products as described in the guidance.<sup>6</sup> Additionally, the guidance states that 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 as described in the guidance.

FDA is issuing this guidance to address certain product changes that fall outside the Repackaging Guidance. First, a drug repackaged as described in the Repackaging Guidance, among other things, is repackaged, stored, and shipped in a way that does not conflict with its approved labeling. 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." Therefore, exposing propofol to oxygen during the repackaging process would be in conflict with the approved labeling and would fall outside the policy in the Repackaging Guidance. FDA understands that outsourcing facilities or pharmacies may not be able to repackage under nitrogen.

Second, some pharmacies have inquired about the risks of removing the contents of different manufacturers' propofol products and placing them in the same container. FDA generally does not consider this practice to be repackaging, and it is referred to in this guidance as "combining." In addition to the risks described above for repackaging, placing drug products with different formulations in the same container can adversely affect product quality and performance. With

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<sup>5</sup> See footnote 4 for the citation to the Repackaging Guidance. The Repackaging Guidance contains policies regarding the repackaging of certain drugs approved under section 505 of the FD&C Act. The Repackaging Guidance does not address, among other things, the repackaging of biological products.

<sup>6</sup> FDA is considering the applicability of the policies described in its Repackaging Guidance to hospitals and health systems and intends to address these issues in separate guidance. As explained further below, the temporary policy set forth in this guidance applies to hospital and health system pharmacies.

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respect to propofol, for example, differences in the preservatives used may result in a final product with a less effective antimicrobial preservative system.

### **III. Discussion**

As noted above, FDA's Repackaging Guidance describes FDA's policies regarding the repackaging of certain human drug products by pharmacies and outsourcing facilities. The guidance describes a policy of enforcement discretion when FDA-approved drug products are repackaged, provided certain steps are taken to mitigate the risks of repackaging, including that drug products are repackaged and stored in a way that does not conflict with their approved labeling.

However, propofol is currently on FDA's drug shortage list, and FDA has received reports that hospitals are, in particular, having difficulty obtaining certain presentations that are needed in the care of critically ill COVID-19 patients. Other presentations may be available for repackaging or combining for this use. Having evaluated information regarding product availability, the physicochemical stability of approved propofol products, the inclusion of preservative systems in those products, and in a situation in which propofol is repackaged or combined under aseptic conditions, as a temporary measure, FDA has determined additional regulatory flexibility is appropriate.

Therefore, as a temporary measure during the public health emergency related to COVID-19, or for such shorter time as FDA may announce by updating or withdrawing this guidance based on evolving needs and circumstances, FDA intends to extend the enforcement discretion policy described in its Repackaging Guidance<sup>7</sup> when a State-licensed pharmacy, Federal facility, or outsourcing facility<sup>8</sup> repackages an FDA-approved propofol injectable emulsion, 10 mg/ mL product, or combines different FDA-approved propofol injectable emulsion, 10 mg/mL products in the same container, under the following circumstances:<sup>9</sup>

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<sup>7</sup> Specifically, FDA does not intend to take action for violations of sections 505, 502(f)(1), and 582 of the FD&C Act if a State-licensed pharmacy, a Federal facility, or an outsourcing facility prepares drug products as described in this guidance and meets other applicable requirements. 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. 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 in this guidance, and any applicable requirements. Finally, with respect to entities that do not qualify for the exemptions from registration under section 510 of the FD&C Act, FDA does not intend to take action for violations of section 502(o) of the FD&C Act. See Repackaging Guidance III.A., B. FDA does not consider repackaging to be compounding. This guidance provides FDA's temporary policy regarding repackaging and combining propofol during the COVID-19 pandemic under the conditions described, and does not address the potential applicability of sections 503A or 503B of the FD&C Act to the combining of approved propofol drugs.

<sup>8</sup> This also includes a State-licensed pharmacy, Federal facility, or outsourcing facility in a hospital or health system.

<sup>9</sup> Propofol is not one of the drugs identified in Appendix A of FDA's guidance for industry *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency*, available at <https://www.fda.gov/media/137031/download>, and in Appendix A of FDA's guidance for industry *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency*, available at <https://www.fda.gov/media/137125/download>. Therefore, propofol may not be compounded under the policies described in those guidances. Propofol was not included in these appendices because it is a complex injectable oil in water

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- 1) The repackaged or combined drug product is provided directly to a hospital that informs the pharmacy (including a hospital or health system pharmacy) or outsourcing facility that it (a) is treating patients with COVID-19, and (b) has made reasonable attempts to obtain adequate supplies of an FDA-approved drug product in clinically appropriate presentations and has been unable to do so.
- 2) The repackaged or combined product is discarded if there is any change in appearance such as color, visible separation of the water and oil occurs such as the formation of any visible oil droplets, or particulate matter.
- 3) The product is repackaged or combined consistent with the practices described in the Repackaging Guidance except that, with respect to (1) combining products, (2) the application of a beyond-use-date (BUD),<sup>10</sup> (3) product labeling, and (4) container closures, the State-licensed pharmacy, Federal facility, or outsourcing facility proceeds as follows:
  - a) FDA-approved propofol products may be repackaged or combined without doing so under nitrogen.<sup>11</sup>
  - b) When a drug product is prepared by placing FDA-approved propofol products into a new container, and the preservatives and antioxidants listed in the DESCRIPTION sections of the approved products' labeling match, a BUD of **not more than 12 hours** is used and the resulting product is NOT frozen.<sup>12</sup> The tubing and any unused portions of the propofol injectable emulsion should be discarded after 12 hours.
  - c) If there is a difference in the preservative or antioxidant components listed in the DESCRIPTION section of the FDA-approved drug products' labeling, the products are not combined except as follows:

Only products that are under abbreviated new drug application (ANDA) 077908, ANDA 205067, and ANDA 205307 are combined, and the BUD is not more than **4 hours**. See Appendix A.

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emulsion formulation drug product with a fine droplet size distribution so that it may flow through tiny blood vessels without occluding them. Propofol requires careful formulation design and manufacturing to be safe and effective. However, even when formulated and manufactured correctly, propofol promotes microbial growth. Owing to its milky appearance, microbial contamination or unsafe changes in droplet size are not discernable to the naked eye.

<sup>10</sup> A beyond-use date (BUD) is the date beyond which a repackaged or combined drug product should not be used. The BUD starts at the time when the propofol is repackaged or combined.

<sup>11</sup> Based on an assessment of the specific formulations of propofol included in this policy and with a limited time period preceding use of the repackaged or combined product, and considering the risks and benefits of product availability under these conditions, FDA believes that this flexibility is appropriate during this public health emergency. State-licensed pharmacies, Federal facilities, and outsourcing facilities are reminded that propofol is repackaged or combined under ISO 5 conditions.

<sup>12</sup> FDA-approved labeling for propofol products state that the drug should not be frozen. Freezing propofol could disrupt the physicochemical stability of the drug product.



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Although FDA believes that the formulations of these products are sufficiently similar to include in this policy, their preservatives or antioxidant components do not match exactly and combining them may result in a final mixture with a less effective antimicrobial preservative system. Such products should be used as close to preparation time as possible, and the shorter BUD of not more than **4 hours** mitigates the risk of microbial growth in the presence of reduced preservative content. Do NOT freeze. The tubing and any unused portions of the propofol injectable emulsion should be discarded after 4 hours.

Propofol products under new drug application (NDA) 019627 and ANDA 075102 are not combined with any other propofol product containing a different formulation because these two products have more significant differences in formulation, which may result in unknown physicochemical compatibility and reduced preservative effectiveness if combined with any other product. See Appendix A.

- d) The container into which the drug product is repackaged or combined is suitable for storage of the drug product through its BUD.<sup>13</sup> The active ingredient in propofol drug products may adsorb into certain plastic and rubber packaging components. While this is not a safety issue, it may impact efficacy.<sup>14</sup>
  - e) The labeling for the repackaged or combined drug product specifies: “Store between 4° to 25°C (40° to 77°F). Do not freeze. The tubing and any unused portions of the propofol injectable emulsion should be discarded after [insert time and date that corresponds to the BUD].”
- 4) The drug product is otherwise repackaged or combined consistent with the conditions described in the Repackaging Guidance. Relevant conditions, as applied to propofol products, are as follows:<sup>15</sup>
- a) The drug product is prepared by or under the direct supervision of a licensed pharmacist.
  - b) If the drug product is prepared in a State-licensed pharmacy or a Federal facility, it is distributed<sup>16</sup> only after the receipt of a valid prescription for an identified, individual patient (including a written order or notation in a

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<sup>13</sup> An outsourcing facility may repackage or combine propofol consistent with this condition without completing stability studies or validating container closure integrity, provided the container is suitable for storage of the drug product through its BUD.

<sup>14</sup> Barann M, P Friederich, K Retzmann, A Dybek, and BW Urban, 2000, Loss of Propofol during In Vitro Experiments, *Anesthesiology*, 93(1):310-311.

<sup>15</sup> Conditions of the Repackaging Guidance that are not applicable here are not reproduced in this guidance.

<sup>16</sup> For purposes of this guidance, “distributed” means that the repackaged drug product has left the facility in which it was repackaged.

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patient's chart in a health care setting) directly from the prescribing practitioner or patient. This condition does not apply to drug products repackaged in an outsourcing facility.

- c) The drug product is repackaged or combined in accordance with the following:
  - i. If the drug product is prepared in a State-licensed pharmacy or a Federal facility, it is prepared in accordance with USP Chapter 797.
  - ii. If the drug product is prepared in an outsourcing facility, it is prepared in accordance with CGMP requirements, except for practices consistent with the circumstances described in items 3.b., c., or d. of this guidance with respect to establishing BUD and product containers.
- d) If the drug product is prepared by a State licensed pharmacy or outsourcing facility, the drug product is distributed only in States in which the facility repackaging or combining the drug product meets all applicable State requirements.
- e) If the drug product is prepared by an outsourcing facility, the outsourcing facility labels the combined or repackaged drug product and reports as set forth in Appendix B, which describes practices that are consistent with practices listed in the Repackaging Guidance.

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## Appendix A: Propofol Drug Products

To repackage or combine propofol drug products as described in the circumstances described in item 3 of this guidance, FDA provides the following table. Products that are included in the same column of this table may be prepared and given a BUD of not more than 12 hours consistent with the circumstances described in item 3.b. of this guidance because the preservatives/antioxidants in the DESCRIPTION section of the approved labeling match. To fall under the circumstances described in this guidance, propofol drug products in column A or column B are not to be combined with a propofol drug product in any column other than its own.<sup>17</sup> Propofol drug products in columns C, D, or E may be combined with a BUD of not more than 4 hours consistent with the circumstances described in item 3.c. of this guidance.

	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>Manufacturer/ application number</b>	Fresenius Kabi (NDA 019627)	Sagent Pharmaceuticals (ANDA 075102)	Hospira, Inc. (ANDA 077908)	Dr. Reddy's Laboratories (ANDA 205067)	Watson Laboratories, Inc. (ANDA 205307)
NDCs <sup>18</sup> of applicant	63323-269- XX; 65219- 800-XX	25021-608-XX	0409-4699-XX	43598-265- XX; 43598- 548-XX; 43598-549- XX	0591-2136-XX
Labeler/NDC	RX Pharma- Pack, Inc.: 49836-025-09; 49836-024-10		General Injectables and Vaccines, Inc: 52584-699-33		A-S Medication Solutions: 50090-4569-1
Labeler/NDC			HF Acquisition Co LLC, DBA HealthFirst: 51662-1471-1		General Injectables & Vaccines, Inc: 52584-098-55
Labeler/NDC			HF Acquisition Co LLC, DBA HealthFirst: 51662-1293-1 (20 mL)		
Labeler/NDC			HF Acquisition Co LLC, DBA HealthFirst: (100 mL) 51662-1470- 1		

<sup>17</sup> For instance, a drug in column A is not to be mixed with a drug in columns B-E; a drug in column B is not to be combined with a drug in column A or columns C-E.

<sup>18</sup> National Drug Code. The first 8 digits in the NDC code of the product used should match that NDC code in the table. XX refers to the package code. This number can vary.

## **Appendix B: Labeling and Reporting for Propofol Products Repackaged or Combined by Outsourcing Facilities**

To repackage or combine propofol drug products consistent with the circumstances described in item 4.e. of this guidance, the outsourcing facility would label the repackaged or combined drug products and report as described below. The practices described here are consistent with practices described in the Repackaging Guidance.

- a. The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged or combined product includes the following:
  - i. The statement “This drug product was repackaged or combined by [name of outsourcing facility]”.
  - ii. The address and phone number of the outsourcing facility that repackaged or combined the drug product.
  - iii. The established name of the original drug product that was repackaged or combined, i.e., Propofol Injectable Emulsion, USP.
  - iv. A newly assigned lot or batch number for the repackaged or combined drug product.
  - v. The dosage form and strength of the repackaged or combined drug product.
  - vi. A statement of the volume of the repackaged or combined drug product, whichever is appropriate.
  - vii. The date the drug product was repackaged or combined.
  - viii. The BUD as the expiry date for the repackaged or combined drug product.
  - ix. Storage and handling instructions for the repackaged or combined drug product.
  - x. The National Drug Code (NDC) number of the repackaged or combined drug product, if available.<sup>19</sup>
  - 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 “Hospital Use Only”.
  - xii. If included on the label of the drug product(s) from which the drug product is being repackaged or combined, 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 b.i.

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<sup>19</sup> The NDC number of the original approved drug product may not be placed on the repackaged or combined drug product. 21 CFR 207.37.

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- 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 or combined 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](http://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 or combined 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 of individual units produced; and the NDC number of the repackaged drug product, if assigned.
- d. The outsourcing facility reports serious adverse events to FDA that are associated with its repackaged or combined drug products.