



U.S. Pharmacopeia
The Standard of Quality™

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Dear Dr Gressitt:

Thank you for inviting a representative of the United States Pharmacopeia (USP) to attend the Third Annual Unused Drug Return International Conference. Although we are not able to attend the conference, we would like to share with you some information about USP's activities in the areas of pharmaceutical packaging, repackaging, and storage.

As an official public standards-setting authority for prescription and over-the-counter medicines, dietary supplements, and other healthcare products in the United States, USP establishes procedures to ensure that pharmaceutical products maintain a consistently high quality until they reach the patient. These procedures supplement the specifications set by USP in individual drug product and drug substance monographs, to which products must comply throughout their shelf lives.

USP has an important role in the topic of the redispensing ("reuse") of medicines and associated repackaging. Any redispensing or repackaging activity must ensure that the quality and integrity of the product is not affected. USP has provided guidance on these topics, as detailed below, but additional information, data, and procedures may be required to ensure that the drug retains its quality.

The *United States Pharmacopeia* and *National Formulary (USP-NF)* contains several General Chapters that discuss pharmaceutical packaging, repackaging, and storage, to help preserve drug quality. USP intends General Chapters numbered below <1000> to be enforceable by FDA, while General Chapters numbered above <1000> are intended to provide information or descriptions of "best practices." Regulatory authorities, including state practice authorities such as Boards of Pharmacy, may choose to require compliance with the General Chapters above <1000>. General Chapters in the current edition of the *USP-NF* that should be considered when discussing redispensing of pharmaceuticals include:

Containers <661>: Includes a section on Repackaging Into Single-Unit Containers and Unit-Dose Containers for Nonsterile Solid and Liquid Dosage Forms, as well as general standards for the materials of which pharmaceutical containers principally are made.

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Containers—Permeation <671>: Provides procedures to determine the moisture permeability of containers used when dispensing medicines, including a section on Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets.

Good Storage and Shipping Practices <1079>: Provides guidance concerning the storage of pharmaceuticals, including the procedures to maintain proper storage environments to ensure a preparation's integrity. Includes a section on Returns of Pharmaceutical Articles from Patients or Customers.

Packaging—Unit-of-Use <1136>: Provides guidance in the use and application of unit-of-use packaging for manufacturers, repackagers, and pharmacists.

Packaging Practice—Repackaging a Single Solid Oral Drug Product Into a Unit Dose Container <1146>: Describes minimum standards to be used in unit-dose repackaging by pharmacists and repackagers and states specifically that "Reprocessing of repackaged unit-dose containers, (i.e., removing medication from one unit-dose container and placing it into another unit-dose container) shall not be done. However, reprocessing of the secondary package (e.g., removing the blister card from the cardboard carrier and placing the blister card into another cardboard carrier) is allowed provided the original beyond-use date is maintained, and provided the integrity of the blister is ensured."

Pharmaceutical Stability <1150>: Provides information on the ways drug dosage forms can be influenced by environmental conditions of storage (e.g., temperature, light, air, and humidity) as well as the package components.

Good Packaging Practices <1177>: Describes packaging considerations that should be considered to help ensure that proper packaging practices are maintained. Includes a section on Environmental Issues.

Good Repackaging Practices <1178>: Provides guidance for repackagers that remove drugs from the original (manufacturer's) container and repacks them into a different container-closure system for resale or distribution.

In addition, the Preservation, Packaging, Storage, and Labeling section of the General Notices for the *USP* provides information and definitions necessary for maintaining drug quality that applies to all products that purport to meet *USP* standards.

USP also is actively monitoring the ongoing dialogue relating to pharmaceutical waste. *USP* is continuing to work with appropriate constituencies to develop programs to promote safe medication use and disposal, as directed by the membership of the *USP* Convention in a resolution for the 2005-2010 Cycle, adopted in March 2005.

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We look forward to continued dialogue on topics related to good pharmaceutical care for all. In addition, any interested party may comment on any *USP* provision at any time, and we welcome suggestions for improvement to *USP's* General Chapters, or expansion of General Chapters to include additional relevant topics.

If you have questions about USP's standards or suggestions for expansion or revisions of USP standards, please contact Desmond Hunt, Senior Scientific Associate, at (301) 816-8341 or dgh@usp.org. If you have questions about USP's standards-setting role, legal recognition, or processes, please feel free to contact me directly at (301) 816-8254 or rkm@usp.org.

Very truly yours,

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