P.O. Box 25
450 Town Street
Circleville, OH 43113-0025
Phone Free: 1.800.848.1686
Fax Free: 1.800.447.3859
Website: www.gohcl.com

Health Care Logistics
2999 Lewis Centre Way
Grove City, OH 43123

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In July 2020, the Food & Drug Administration (FDA) released a guidance document, "Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products," addressing the repackaging of prescription and over-the-counter solid oral dosage form drugs into unit-dose containers. While this FDA guidance is intended for commercial pharmaceutical repackaging firms that are required to register with FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it also provides some direction for pharmacies by referring to USP <1178>, "Good Repackaging Practices."

USP <1178> states, "This chapter does not apply to pharmacists engaged in dispensing prescription drugs in accordance with state practice of pharmacy. The pharmacist needs to apply:

- the principal information provided in the USP general information chapters Plastic Packaging Systems and Their Materials of Construction <661>, Plastic Materials of Construction <661.1>, and Plastic Packaging Systems for Pharmaceutical Use <661.2> and
- other beyond-use date references in Labeling <7>, Expiration Date and Beyond Use Date."

USP <7> (official September 2023) defines proper labeling in the "Beyond-Use Date" (BUD) section and states that after considering several factors:

> "…the BUD must be no later than (a) the expiration date on the manufacturer's container; or (b) 1 year from the date the drug is packaged and/or labeled by the dispenser, whichever is earlier, unless stability data or the manufacturer's labeling indicates otherwise."

Health Care Logistics recommends pharmacists refer to their appropriate governing body for updated changes. As for now, we recommend pharmacists follow USP <1178>, "Good Repackaging Practices" and USP <7>, "Labeling" for beyond use- date expiration. In the event USP changes its guidance on this topic, HCL will comply accordingly.

Kind regards,
Tomeka Harris
Vice President, Quality & Regulatory Affairs