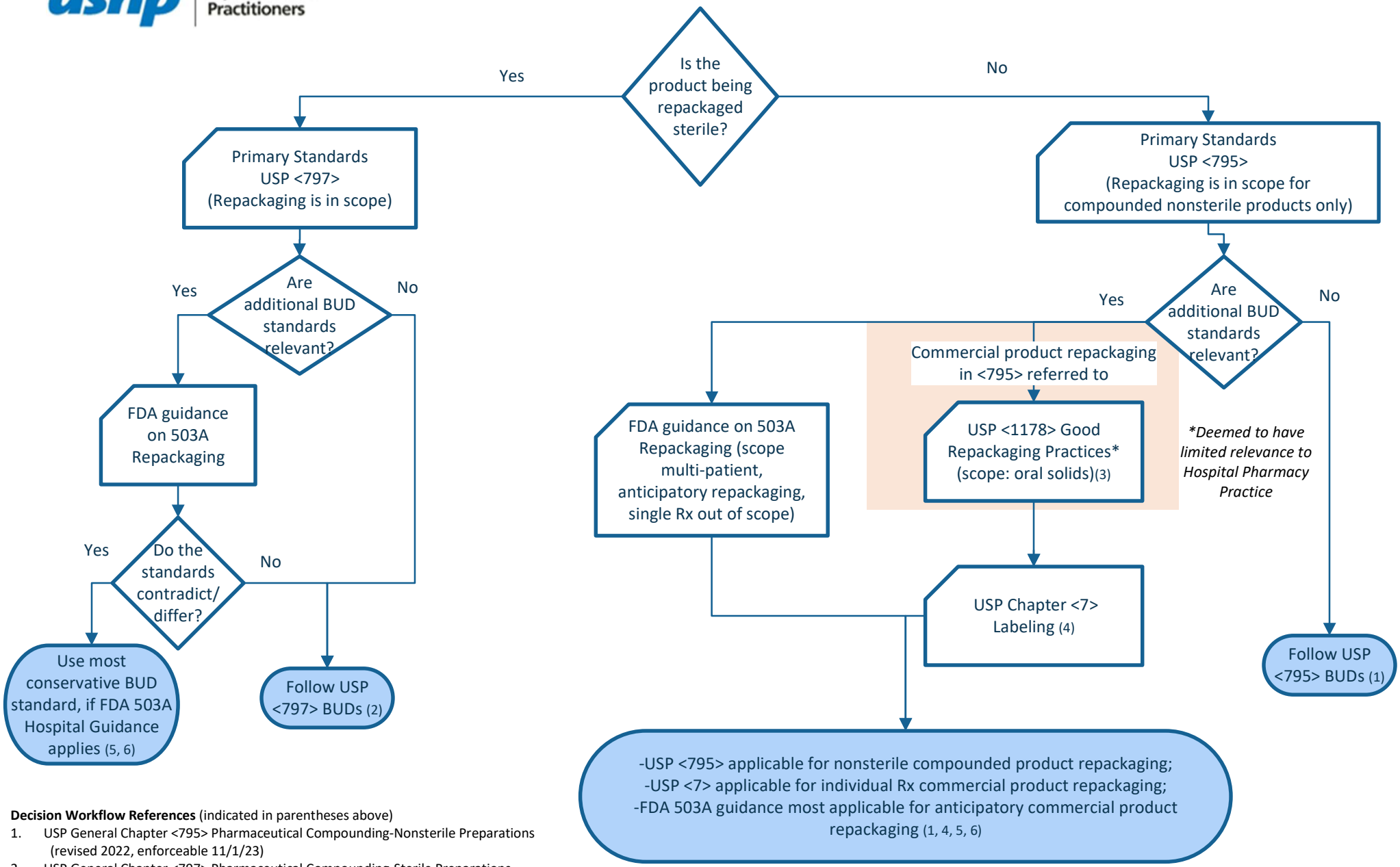
Product Repackaging Standards Assessment and Guideline



Decision Workflow References (indicated in parentheses above)

1. USP General Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations (revised 2022, enforceable 11/1/23)
2. USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations (revised 2022, enforceable 11/1/23)
3. USP General Chapter <1178> GOOD REPACKAGING PRACTICES (updated December 2020)
4. USP General Chapter <7> Labeling (Official May 2020)
5. FDA. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance. (Jan 2017, https://www.fda.gov/media/90978/download)
6. FDA. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance. (June 2016, https://www.fda.gov/media/94393/download).

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