ashp Inpatient Care Practitioners

# BUD Assignment for Repackaged Nonsterile Products in a Licensed Pharmacy or Federal Facility Under Pharmacist Supervision

Is the repackaged product nonsterile?

No → **Follow the BUD assignment for the repackaged sterile products algorithm** (See Page 2)

Yes

Is the product commercially manufactured or compounded? (1, 2)

Compounded → **Follow USP Compounded Monograph (if meets container specifications) or USP <795> BUDs, stability references** (2, 3 6,7,8)

CNSP BUD Limits per Ref 3
- Non-preserved aqueous (Fridge): up to 14 d
- Preserved aqueous (room temp or Fridge): up to 35 d
- Non-aqueous (room temp or Fridge): up to 90 d
- Solid (room temp or Fridge): up to 180 d

Commercially manufactured

Is this repackaging for multiple patients? (e.g. anticipatory repackaging)

No (e.g. single-patient repackaging per community pharmacy practice) → **Follow available stability references, USP <7> BUD limits of up to 12 months or product expiration date** (5, 6, 7)

Note: Review PI for allowance to repackage

Yes

Does the manufacturer provide repackaging dating in labeling information?

Yes → **May follow manufacturer in-use time / repackaging dating** (6, 7)

Comment: If the repackaged dating in the manufacturer's PI is shorter than the maximum allowable BUDs in Ref 3, you may consider additional published stability studies to extend the BUD upto the maximum dating allowed in Ref 3.

No

What is the dosage form of the repackaged product?

Tablets/Capsules → **Assign BUD ≤ 6 months**
**The ≤ 6 months expiration period does not exceed 25 % of the remaining expiration time** (1, 2)

Example: 12 months remaining on expiration date --> Allowable BUD is 3 months

Liquid

Is the product non-aqueous?

Yes → **BUD ≤ 6 months or product expiration date** (2, 3, 7)

No

Will this be repackaged in a USP Class A or Class B tested unit-dose container? (1, 9)

Yes → **Assign BUD ≤ 6 months**
**The ≤ 6 months expiration period does not exceed 25 % of the remaining expiration time** (1, 2)

Comment: Per Ref 9
Moisture ingress for tested containers does not exceed the following
Class A: 0.5 mg/day
Class B: 5 mg/day

No → **Apply BUD based on formulation type:** (2, 3, 6)
- **Non-preserved aqueous: up to 14 d**
- **Preserved aqueous: up to 35 d**
- **Non-aqueous: up to 90 d**

Comments: Ref 2 defers to Ref 3 in this situation; Apply opened-container storage conditions from the PI (e.g., Room Temp, Refrigerated, Protect From Light, etc)

**References:**


1. FDA Compliance Policy Guide (CPG) Sec. 430.100 – Unit Dose Labeling for Solid and Liquid Oral Dosage Forms (Feb 1984, Final). *(Unit-dose labeling content expectations / misbranding interpretation.)
2. FDA Guidance for Industry (Jan 2017) – Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Nonbinding Recommendations). *(Defines "repackaging," enforcement discretion conditions, BUD logic for repackaging, labeling/ storage expectations.)
3. USP <795> Pharmaceutical Compounding—Nonsterile Preparations (official 11/1/23) (process expectations for nonsterile prep; referenced by ASHP algorithm)
4. USP <797> Pharmaceutical Compounding—Sterile Preparations (official 11/1/23) (sterile repackaging/processing and BUD framework; referenced by ASHP algorithm)
5. USP <7> Labeling (Official May 2020) (labeling principles; referenced by ASHP algorithm)
6. Manufacturers prescribing information (PI) (product specific)
7. Published Stability Literature References (varied)
8. USP Compounded Preparation Monograph (preparation specific)
9. USP <671> Containers-Performance Testing (Official December 2020)


**Notes:**

-If there are any situations where stability data suggest the product is not stable in the planned final container or storage conditions, do not exceed available stability data for the assigned BUD.

-Traditional state practice of pharmacy is out of scope for USP <1178> Good Repackaging Practices

-Stability literature must meet requirements to extend BUDs for CNSPs per USP <795>


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Ensorsed by ASHP Section of Inpatient Practitioners - Compounding Practice Section Advisory Group
Published March 2024; Revised April 2026

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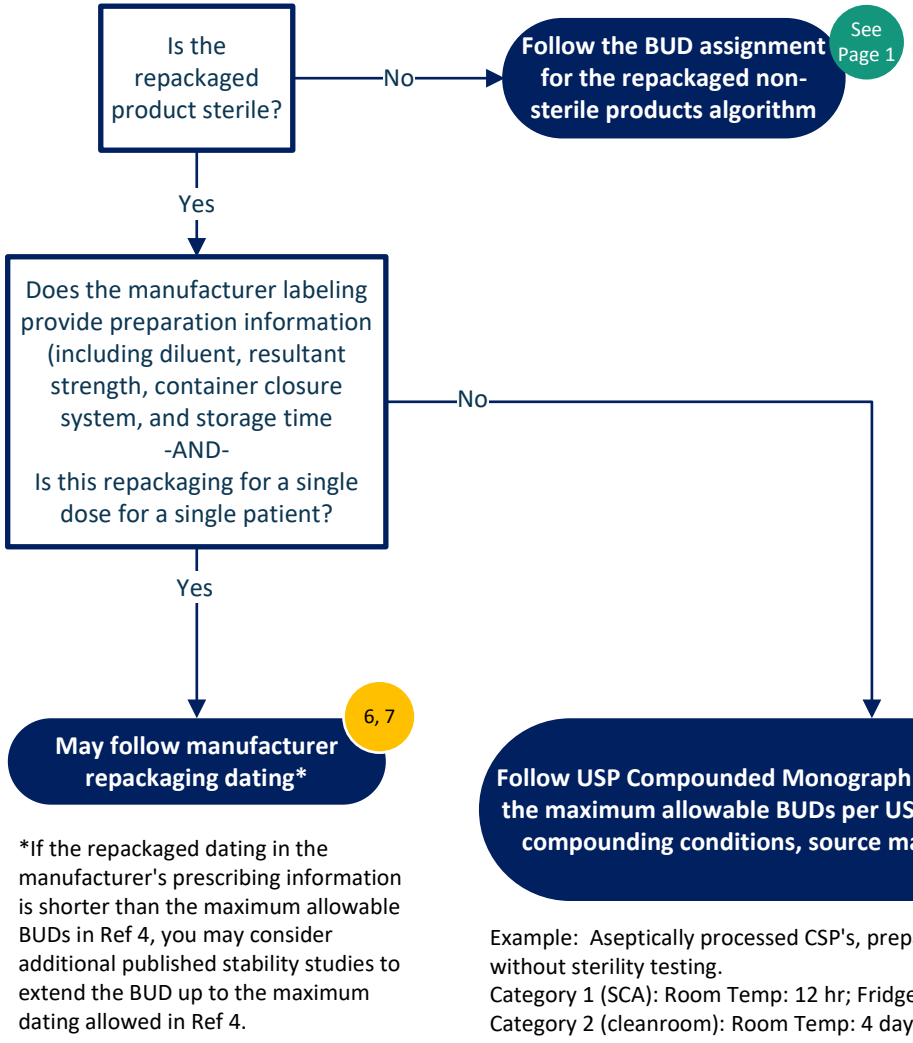
# BUD Assignment for Repackaged Sterile Products in a Licensed Pharmacy or Federal Facility Under Pharmacist Supervision




*If the repackaged dating in the manufacturer's prescribing information is shorter than the maximum allowable BUDs in Ref 4, you may consider additional published stability studies to extend the BUD up to the maximum dating allowed in Ref 4.

Example: Aseptically processed CSP's, prepared from sterile components without sterility testing.
Category 1 (SCA): Room Temp: 12 hr; Fridge: 24 hr
Category 2 (cleanroom): Room Temp: 4 days; Fridge: 10 days; Frozen: 45 days


**References:**
1. FDA Compliance Policy Guide (CPG) Sec. 430.100 – Unit Dose Labeling for Solid and Liquid Oral Dosage Forms (Feb 1984, Final). *(Unit-dose labeling content expectations / misbranding interpretation.)
2. FDA Guidance for Industry (Jan 2017) – Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Nonbinding Recommendations). *(Defines "repackaging," enforcement discretion conditions, BUD logic for repackaging, labeling/ storage expectations.)
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5. USP <7> Labeling (Official May 2020) (labeling principles; referenced by ASHP algorithm)
6. Manufacturers prescribing information (product specific)
7. Published Stability Literature References (varied)
8. USP Compounded Preparation Monograph (preparation specific)


**Notes:**
-If there are any situations where stability data suggest the product is not stable in the planned final container, do not exceed available stability data for the assigned BUD.
-Traditional state practice of pharmacy is out of scope for USP <1178> Good Repackaging Practices


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