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BUD Recommendations for PN Formulation While Following FDA's Temporary Guidance for Parenteral Drug Products

The American Society for Parenteral and Enteral Nutrition (ASPEN) is grateful for the FDA's temporary [guidance](#) for compounding parenteral drug products during this time of shortage.

Importantly, Appendix A of this document, which provides a table for beyond-used dates (BUDs), only considers sterility and does not consider stability. Stability is another critical limit to consider when determining BUDs, and parenteral nutrition (PN) has a shorter BUD based on stability.

ASPEN urges anyone involved in the preparation and administration of PN to follow previous USP <797> BUD recommendations of **30 hours at room temperature and 9 days refrigerated for all PN formulations**. Specific manufacturer data may extend the BUD for particular products, and this should be discussed with the manufacturer. Please share this information with your clinician colleagues to avoid patient safety errors.

About ASPEN:

ASPEN is a medical professional organization whose members are involved in the provision of clinical nutrition therapies. With members worldwide, ASPEN is a community of dietitians, nurses, nurse practitioners, pharmacists, physicians, PAs, researchers, scientists, and students from every facet of nutrition support clinical practice, research, and education. ASPEN's mission is to improve patient care by advancing the science and practice of clinical nutrition and metabolism. For more information, visit www.nutritioncare.org.