

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you that B. Braun Medical Inc. (BBMI) is issuing a pharmaceutical recall for products LAC RNG INJ 1L E3, E7500, and NACL INJ 0.9% 1000ML E3, E8000, due to the potential for particulate matter in solution.

The depth of this recall is to the hospital/healthcare facility level. This recall is being conducted with the knowledge of the United States Food and Drug Administration.

BBMI has identified through complaints the potential for the product to contain particulate matter in solution. In the complaint investigations the particles were identified as cellulose and stearates with extremely low levels of inorganic materials such as copper. Stearates originate in the walls of the IV container and are typically embedded presenting themselves as green or blue in color and may, in some instances, be mistaken for mold.

To date, there have been no reports of serious injury or death associated with this issue. If the particulate matter is observed before use, a minor delay could occur while obtaining a replacement product. If the particulate matter is loose and the container is used on a patient, there is a potential for the particulate to be infused into the circulatory system. This could lead to patient harm that may require additional medical intervention and/or lead to permanent impairment or death.

The solubility and extractability risks associated with embedded stearates and metals (e.g. copper) in the container wall were assessed and no safety concerns were identified for patients using products with the identified sizes (length range of 2.33mm-4.56mm).

Product Catalog Number	NDC Number	Product Description	Lot Number	Distribution Range	Expiration Date
E7500	0264-7750-07	LAC RNG INJ 1L E3	J4S807	12/26/24 - 4/10/25	5/31/27
E8000	0264-7800-09	NACL INJ 0.9% 1000ML E3	V3k770	11/15/23 - 9/25/24	1/31/26