



# State of New Hampshire

## Department of Safety



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# CLINICAL BULLETIN

Bulletin #	Title			Date Issued
45	Normal saline shortage and warming recommendations			February 6, 2018
Superseded	Released By	Approved By	Source	
	Vicki Blanchard, NRP	Joey Scollan, DO	FDA & Baxter	

### Extension of Shelf Life Provided by Baxter Healthcare Corporation to Assist with IV Solution Shortages

Due to the ongoing critical shortage of IV solutions used in critical care, FDA is alerting health care professionals of extension of shelf life through which some of these products, manufactured by Baxter Healthcare Corporation, may be used beyond the manufacturer's labeled expiration date. To help ensure patient safety, these products should have been — and should continue to be — stored as labeled.

FDA is not requiring or recommending that the identified product codes in the following **TABLE 1** be relabeled with their new use dates. However, if replacement product becomes available during the extension period, then it is expected that the product codes in these tables will be replaced and properly disposed of as soon as possible.

Health care professionals are instructed to squeeze the bags prior to use for verification of no leaks. If leaks are found the bags are not to be used.

Based on data provided by Baxter Healthcare Corporation and reviewed by FDA, the following extended shelf life is supported for only the **product codes** indicated in **TABLE 1** on side 2 for the following products.

Please contact CDER Drug Shortage Staff at [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov) with questions regarding this table.

**TABLE 1**

Code	Product Description	Current Shelf Life (month/year)	Extended Shelf Life (month/year)	End-User May Extend Dating on Product by Adding
2D5613Q	10% Osmitol (Mannitol) in Water in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	18 months	3 months
2D5623Q	15% Osmitol (Mannitol) in Water in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	20 months	5 months
2D5633Q	20% Osmitol (Mannitol) in Water in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	18 months	3 months
2B2322Q	Lactated Ringers Injection USP in 250 mL Viaflex Container with 6.5 mil HDPE Overpouch	18 months	18 months + 21 days	21 days
2B2323Q	Lactated Ringers Injection USP in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	19 months	4 months
2B1323N	0.9% NaCl Injection USP in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	19 months	4 months
2B1323NF	0.9% NaCl Injection USP in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	19 months	4 months
2B1323Q	0.9% NaCl Injection USP in 500 mL Viaflex Container with 4.5 mil HDPE Overpouch	15 months	19 months	4 months

HDPE – High Density Polyethylene

**Additionally, the Medical Control Board makes the following recommendations:**

- When starting intravenous lines, if fluid resuscitation is not necessary, consider using a saline lock.
- D5W may be used in place of normal saline for mixing your medications requiring drip infusions.
- Normal saline which has been warmed and then cooled may continue to be used until its expiration date as long as it is **NOT** rewarmed.

**See the following recommendations from Baxter, in regards to warming recommendations:**

*“IV solutions of volumes 150mL or greater can be warmed in their plastic overpouches to temperatures not exceeding 40°C (104°F), and for a period no longer than 14 days. Once the VIAFLEX plastic containers have been in the warming cabinet for their maximum time period, the containers should be removed from the warming cabinet and identified as having been warmed. They should **not** be subsequently returned to the warmer. The VIAFLEX plastic containers may continue to be used until the labeled expiration date provided they have not been warmed more than once.”*