Baxter

# Urgent Drug Recall

September 15, 2017

Dear Director of Materials Management:

**Problem Description**

Baxter Healthcare Corporation is issuing a voluntary product recall for one shipment of the product code and lot number listed below due to product being exposed to subfreezing temperatures during transit to a distribution facility. The subfreezing temperature is outside of the acceptable storage range listed on the product labeling. Your facility has been identified as one that had received a shipment of the affected product. **Other shipments of this lot are not affected by this issue.** The affected lot was distributed between 8/11/17 and 8/31/17 in the United States.

**Affected Product**

| Product Code | Product Description | Lot Number | Expiration Date | NDC |
|---|---|---|---|---|
| 2B6061 | INTRALIPID 20% IV Fat Emulsion, 100 mL | 10LE9597* | 4/1/2019 | 0338-0519-58 |

*Only customers affected by this particular shipment of this lot are receiving this notification.

**Hazard Involved**

If accidentally frozen, INTRALIPID 20% IV Fat Emulsion should not be used. When subjected to freezing, the emulsion droplets will increase in size, forming aggregates that can lead to serious adverse health consequences. There have been no reports of adverse events associated with this issue.

**Actions to be taken if product was purchased directly from Baxter**

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product or shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.
3. Complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to fca@baxter.com. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.
4. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers.

**Action to be taken if product was purchased from a distributor**

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product or shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.
3. Please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

**Further information and support**

For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form:
    MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
  - **Fax:** Submit to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

C Chamoun

Camil Chamoun
Vice President, Quality
Baxter Healthcare Corporation

cc: Director of Nursing
Director of Pharmacy

Enclosure: Baxter Customer Reply Form