

FOR IMMEDIATE RELEASE

**Media Contact:**

Jorge Valencia  
(224) 948-5353  
[media@baxter.com](mailto:media@baxter.com)

**Investor Contact:**

Clare Trachtman  
(224) 948-3085

**BAXTER INITIATES VOLUNTARY NATIONWIDE RECALL OF ONE SHIPMENT OF  
INTRALIPID 20% IV FAT EMULSION DUE TO PRODUCT BEING EXPOSED TO  
SUBFREEZING TEMPERATURES**

**DEERFIELD, Ill., October 4, 2017** – Baxter International Inc. announced today it is voluntarily recalling one shipment from a single lot of INTRALIPID 20% IV Fat Emulsion, 100 mL, distributed between 8/11/17 and 8/31/17 to hospitals and healthcare providers in the United States, to the user level. The product has been 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. Other shipments of this lot are not affected by this issue.

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 block pulmonary circulation and lead to serious adverse health consequences that can be life-threatening. To date, Baxter has not received any reports of associated adverse events or product complaints. INTRALIPID 20% IV Fat Emulsion is a prescription product indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition for extended periods of times. The product is packaged in 100 mL bags.

This recall affects one shipment of the following lot:

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

Baxter has informed customers affected by this particular shipment to locate and remove all affected product. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 888-229-0001, Monday through Friday, between 7 a.m. and 6 p.m. Central Time.

Customers with questions regarding this recall can contact Baxter Corporate Product Surveillance at 800-437-5176, Monday through Friday, between 8 a.m. and 5 p.m. Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product.

**BAXTER INITIATES VOLUNTARY NATIONWIDE RECALL OF ONE SHIPMENT OF INTRALIPID 20% IV FAT EMULSION DUE TO PRODUCT BEING EXPOSED TO SUBFREEZING TEMPERATURES – PAGE 2**



Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Baxter is voluntarily conducting this recall with the knowledge of the U.S. Food and Drug Administration.

**About Baxter**

Baxter provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; surgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

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