



Clifton Health Department Food Recall Notification



Public Health
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Food/Drug/Pet Recall: ICU Medical, Inc.

ICU Medical, Inc. is voluntarily recalling one single lot of Lactated Ringer's Injection, USP. The products are being recalled to the hospital/user level due to the presence of particulate matter identified as iron oxide. ICU Medical became aware of this issue through a single customer complaint.

Administration of a drug product that contains metal particulate matter could result in adverse events ranging from inflammation at the site of injection to more serious events that could include the formation of a blood clot obstructing the flow of blood which could lead to end-organ damage or death. To date, ICU Medical, Inc. has not received reports of adverse events related to this recall.

Lactated Ringer's Injection, USP is indicated for parenteral replacement of extracellular losses of fluid and electrolytes, with or without minimal carbohydrate calories, as required by the clinical condition of the patient. Product was distributed nationwide both by ICU Medical direct to customers and through medical distributors. The product is for human and veterinary use.

The affected product lot, manufactured in the U.S. for ICU Medical by Hospira, a Pfizer company in July 2019 is listed below:

NDC Number	Product Description	Lot Number	Expiration Date	Configuration	Manufacture Date	Distribution Dates
0409-7953-09	Lactated Ringer's Injection, USP	07-514-FW	01-Jul-2021	1000 mL Flexible Container	July 2019	September 2019 - October 2019

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products. Hospitals/distributors that have product that is being recalled should stop use/further distribution and return to place of purchase.

Customers with questions regarding this recall can call ICU Medical at 1-844-654-7780 Monday through Friday between the hours of 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 these drug products.

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.



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- . Complete and submit the report Online
- . Regular Mail or Fax: Download form 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
- . The Center for Veterinary Medicine recommends calling the drug company to report the adverse drug experience or product defect. The drug company responsible for the approved product(s) is required to submit reports of adverse drug experiences and product defects to FDA.
- . If you prefer to report directly to the FDA, you can submit FORM FDA 1932a, "Veterinary Adverse Experience, Lack of Effectiveness or Product Defect Report". You can use this form to report adverse drug experiences for any animal drug (approved or not approved by FDA) or animal device. Unapproved animal drugs include compounded drug products.
- . Download the fillable 1932a electronic form and email the completed form to CVM1932a@fda.hhs.gov
- . If you have a question about ADE reporting or need a hard copy of the form, contact CVM by email at AskCVM@fda.hhs.gov, by phone at 1-888-FDA-VETS (1-888-332-8387)

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

No action is required of local health departments at this time for either of these recalls. If any requests for assistance are received from FDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

For all recalls - <http://www.recalls.gov/recent.html>