

## **URGENT: SECOND CUSTOMER RECALL INSTRUCTIONS**

## Voluntary Recall of Abelcet<sup>®</sup> (Amphotericin B Lipid Complex Injection), Lot 1203A (Exp. 11 May 2024), NDC 57665-101-41 affected by the potential of non-sterile vials

## This is <u>updated</u> communication regarding the Abelcet Lot 1203A recall. You may have been notified of this recall previously in a letter dated 3 February 2023. Below you will find updated instructions.

14 March 2023

Dear Customer:

This is to inform you of a product recall involving:

## Abelcet<sup>®</sup> (Amphotericin B Lipid Complex Injection), Lot 1203A (Exp. 11 May 2024), NDC 57665-101-41

This recall has been initiated due to the potential of non-sterile vials. Use of this product may introduce a bacterial contaminant into the bloodstream of the recipient.

Leadiant Biosciences, Inc. began shipping this product on 15 February 2022.

Your assistance is appreciated and necessary to prevent patient harm due to exposure to a non-sterile product. Please notify your downstream customers.

This Class II recall is being made with the approval of the Food and Drug Administration.

For additional information and to obtain pertinent recall instructions, please call Sedgwick at (888) 679-5285, Monday-Friday 8:00 am to 5:00 pm EST/EDT or email leadiant7131@sedgwick.com.

Sincerely, Huston Howell, Ph. D. Assoc. Director and Head of Quality Assurance Leadiant Biosciences, Inc.