DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

September 27, 2019

Irina Pashyan
Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: irina.pashyan@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether drug product under NDA 018365 held by ICU Medical Inc. Potassium Chloride (5mEq, 10mEq, 15mEq, 20mEq, 30mEq, and 40mEq) in Dextrose 5% and Sodium Chloride 0.225% in plastic containers was withdrawn from the market place for reasons other than safety or efficacy was received by this office on 09/26/2019.

It was assigned docket number FDA-2019-P-4523. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.09.27 12:39:39 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)