DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 17, 2020

Irina Pashyan
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 the drug product under NDA 018897 held by Hospira, Inc. Sodium Chloride 14.6% 50mEq/20mL in Plastic Containers was withdrawn from the market place for reasons other than safety or efficacy was received by this office on 12/16/2020.

It was assigned docket number FDA-2020-P-2304. 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 Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.17 14:28:19 -05'00'

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