DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 30, 2019

Jennifer Boysen
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: jennifer.boysen@fresenius-kabi.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner determine whether the NDA holder for Dextrose, 20gm/100mL, and Dextrose, 50gm/100mL (Dextrose 20%, and Dextrose 50%) in Plastic Containers (NDA 017521) has withdrawn the product for reasons of safety or efficacy was received by this office on 01/29/2019.

It was assigned docket number FDA-2019-P-0466. 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: 2019.01.30 18:18:54 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)