DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 26, 2020

Aditi Dron, Senior Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: aditi.dron@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether the NDA holder (Hospira Inc) for Bortezomib for Injection, 2.5 mg/vial, (NDA 209191) has withdrawn the product from sale for reasons of safety or effectiveness was received by this office on 10/26/2020.

It was assigned docket number FDA-2020-P-2130. 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: 2020.10.27 08:24:07 -04'00'

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