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20 May 2021

Division of Dockets Management
Food and Drug Administration
(HFA-305) Room 1061
5630 Fishers Lane
Rockville, MD 20852

REQUEST FOR WITHDRAWAL - CITIZEN PETITION

DOCKET NUMBER FDA-2020-P-2130

Dear Sir/Madam:

Reference is made to the Fresenius Kabi USA, LLC's (FK USA) Citizen Petition for Bortezomib for Injection submitted to the Agency on 26 October 2020.

FK USA) respectfully requests a withdrawal of the Citizen Petition – Docket Number FDA-2020-P-2130.

In the aforementioned Citizen Petition, FK USA requested the FDA to make a determination whether the listed drug product under Hospira Inc's NDA 209191 for Bortezomib for Injection 2.5 mg/vial has been withdrawn from sale for reasons of safety or effectiveness. Since the petition was submitted, this drug product has been removed from the list of Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), including from the Discontinued Drug Product List. Therefore, FK USA is withdrawing this petition.

If there are any questions, please feel free to contact me at (847) 550-2298 or Andrea Redd, Vice President, Regulatory Affairs, at 847-550-5767.

Sincerely,

Aditi Dron

Digitally signed by Aditi Dron
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