Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

26 October 2020

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

CITIZEN PETITION

Dear Sir/Madam:

Fresenius Kabi USA, LLC (FK USA) submits this petition pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161 requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or effectiveness.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether the NDA holder (Hospira Inc) for Bortezomib for Injection, 2.5 mg/vial, (NDA 209191) has withdrawn the product from sale for reasons of safety or effectiveness.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The list, *Approved Drug Products with Therapeutic Equivalence Evaluations* referred to as the "Orange Book", lists all FDA approved drug products. Bortezomib for Injection, 2.5 mg/vial, NDA 209191, held by Hospira Inc, was approved on 12 July 2018. It is listed as the reference listed drug (RLD) for 2.5 mg/vial strength.

Bortezomib for Injection, 2.5 mg/vial, NDA 209191, now appears in the 'Discontinued Section' of the Orange Book (see attachment A).

Under FDA regulations, drugs are removed from the Orange Book list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness or if the Agency determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). Applicants may also voluntarily withdraw safe and effective drug products from sale for business or other reasons. The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons

of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1).

It is requested that the FDA determine whether the NDA holder for Bortezomib for Injection, 2.5 mg/vial, NDA 209191, has withdrawn the drug product for reasons of safety or effectiveness.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, FK USA hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

E. Certification

FK USA certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Aditi Dron

Digitally signed by Aditi Dron
DN: c=US, st=Illinois, l=Lake Zurich, o=Fresenius Netcare, ou=IT, cn=Aditi Dron, email=aditi.dron@fresenius-kabi.com
Reason: I attest to the accuracy and integrity of this document
Date: 2020.10.26 09:39:47 -05'00'

Aditi Dron
Senior Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Phone: 847-550-2298 ‖ Fax: 847-550-7121
E-mail: aditi.dron@fresenius-kabi.com

Attachment A: Product listing from the current (26 October 2020) Orange Book for Bortezomib for Injection.