Fresenius Kabi USA, LLC

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September 26, 2019

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

CITIZEN PETITION

Dear Sir/Madam:

Fresenius Kabi USA, LLC (FK USA) submits this citizen petition pursuant to Code of Federal Regulations sections 21 CFR 10.20, 21 CFR 10.30 and 21 CFR 314.161 requesting the Commissioner of the Food and Drug Administration (FDA) to provide a determination whether a listed drug product has been withdrawn from the market place for reasons other than safety or efficacy.

A. Action Requested

FK USA requests that the FDA Commissioner makes a determination whether drug product under NDA 018365 held by ICU Medical Inc. Potassium Chloride (5mEq, 10mEq, 15mEq, 20mEq, 30mEq, and 40mEq) in Dextrose 5% and Sodium Chloride 0.225% in Plastic Containers was withdrawn from the market place for reasons other than safety or efficacy.

B. Statement of Grounds

The FDA 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. Potassium Chloride in Dextrose 5% and Sodium Chloride 0.225% drug product is currently listed as a reference listed drug under NDA 018365 (ICU Medical Inc.) and was approved prior to January 1, 1982. With an exception of one presentation - 20 mEq Potassium Chloride in Dextrose 5% and Sodium Chloride 0.225% Potassium Chloride in 1000 mL plastic container - all other drug product presentations under NDA 018365 now appear in the "Discontinued Section" of the Orange Book (see Attachment A- Orange Book).

Under FDA regulations, drugs are moved to the "Discontinued section" of the Orange Book and withdrawn from the market place if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or efficacy, or if the Agency determines that the listed drug was withdrawn or withheld from sale for reasons of safety or efficacy (21 CFR 314.162).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 The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or efficacy before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).

Hence, it is requested that the FDA determines wether Potassium Chloride (5mEq, 10mEq, 15mEq, 20mEq, 30mEq, and 40mEq) in Dextrose 5% and Sodium Chloride 0.225% in Plastic Containers (NDA 018365) drug product presentations listed as discontinued in the Orange Book were withdrawn from the market place for reasons other than safety and efficacy. This will allow for approval of a new ANDA referencing these discontinued drug products if such approval is requested.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, the petitioner 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 is unfavorable to the petition.

If you have any questions please feel free to contact the undersigned or Aparna Dagar, Director Regulatory Affairs, via phone 847-550-2649 or email Aparna.dagar@fresenius-kabi.com.

Sincerely,

Irina Pashyan

Digitally signed by Irina Pashyan
DN: c=US, st=Illinois, l=Lake Zurich, o=Fresenius Netcare, ou=IT, cn=Irina Pashyan, email=Irina.Pashyan@fresenius-kabi.com
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Attachment A: Orange Book Listing of Potassium Chloride in Dextrose 5% and Sodium Chloride 0.225% - NDA 018365 (September 26, 2019)