Fresenius Kabi USA, LLC

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05 March 2024

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.

A. Action Requested

FK USA requests that the Commissioner of the Food and Drug Administration determine whether the NDA holder (Exela Pharma Sciences LLC) for Diltiazem Hydrochloride in Dextrose Injection 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL) (NDA 215252) has withdrawn the product for reasons of safety or efficacy.

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. Diltiazem Hydrochloride in Dextrose Injection 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), (NDA 215252) held by Exela Pharma Sciences LLC was approved on October 28, 2021. Diltiazem Hydrochloride in Dextrose Injection 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), (NDA 215252) 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drug product's application for reasons of safety or effectiveness or if the Agency determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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 The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).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for Diltiazem Hydrochloride in Dextrose Injection 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), (NDA 215252) has withdrawn the products for reason of safety or effectiveness.

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.

Sincerely,

Peter Baer

Digitally signed by Peter Baer
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Attachment A: Product listing from the current (February 20, 2024) Orange Book