

Fresenius Kabi USA, LLC

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January 29, 2019

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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.

A. Action Requested

FK USA requests that the Commissioner of the Food and Drug Administration determine whether the NDA holder for Dextrose, 20gm/100mL, and Dextrose, 50gm/100mL (Dextrose 20%, and Dextrose 50%) in Plastic Containers (NDA 017521) has withdrawn the products for reasons of safety or efficacy.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. Dextrose, 20gm/100mL and Dextrose, 50gm/100mL (Dextrose 20% and Dextrose 50%) in Plastic Containers (NDA 017521) held by Baxter Healthcare Corp. was approved prior to January 01, 1982. The product was then considered to be a "listed drug product" in the Orange Book. Dextrose, 20gm/100mL and Dextrose, 50gm/100mL, (Dextrose 20% and Dextrose 50%) in Plastic Containers (NDA 017521) 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drug product's application for reasons of safety or effectiveness, or if the Agency determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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 The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).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 Dextrose, 20gm/100mL and Dextrose, 50gm/100mL, (Dextrose 20% and Dextrose 50%) in Plastic Containers (NDA 017521) has withdrawn the products for reason of safety of 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,

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Attachment A: Product listing from the current (29 January 2019) Orange Book listing

Attachment A – Current Orange Book Listing of Dextrose 20% and Dextrose 50%

Mkt.Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	RLD	RS	Applicant Holder	Approval Date
RX	DEXTROSE	DEXTROSE 70% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	70GM/100ML	RLD	RS	BAXTER HEALTHCARE CORP	Mar 26, 1982
DISCN	DEXTROSE	DEXTROSE 20% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	20GM/100ML	RLD		BAXTER HEALTHCARE CORP	Approved Prior to Jan 1, 1982
DISCN	DEXTROSE	DEXTROSE 30% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	30GM/100ML	RLD		BAXTER HEALTHCARE CORP	Approved Prior to Jan 1, 1982
DISCN	DEXTROSE	DEXTROSE 40% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	40GM/100ML	RLD		BAXTER HEALTHCARE CORP	Approved Prior to Jan 1, 1982
DISCN	DEXTROSE	DEXTROSE 50% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	50GM/100ML	RLD		BAXTER HEALTHCARE CORP	Approved Prior to Jan 1, 1982
DISCN	DEXTROSE	DEXTROSE 60% IN PLASTIC CONTAINER	N017521	INJECTABLE	INJECTION	60GM/100ML	RLD		BAXTER HEALTHCARE CORP	Mar 26, 1982