

Date: July 28, 2022
Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Citizen Petition

Fujian Shengdi Pharmaceutical Co., Ltd. submits this petition under 21 CFR §10.20 & §10.30 to request the Commissioner of Food and Drugs to designate an additional RS for Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container (2.5GM/100ML; 450MG/100ML).

A. Action Requested

Fujian Shengdi Pharmaceutical Co., Ltd. requests the Commissioner of Food and Drugs to designate Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container (2.5GM/100ML; 450MG/100ML) from FRESENIUS KABI USA LLC with the application No. A211190 as an additional RS for Dextrose 2.5% and Sodium Chloride 0.45% Injection (2.5GM/100ML; 450MG/100ML). As the currently designated RLD/RS - Dextrose 2.5% and Sodium Chloride 0.45% Injection in plastic container (2.5GM/100ML; 450MG/100ML, BAXTER HEALTHCARE CORP) is not available. This is in connection with the development of our generic drug for a potential ANDA Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container (2.5GM/100ML; 450MG/100ML).

B. Statement of Grounds

As listed in the current orange book, both the RLD and RS were assigned by FDA to the products with the application number N016697, which applicant holder is BAXTER HEALTHCARE CORP. The detailed information from FDA website is as below:

Product Details for NDA 016697

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (DEXTROSE; SODIUM CHLORIDE)
2.5GM/100ML; 450MG/100ML
Marketing Status: Prescription

Active Ingredient: DEXTROSE; SODIUM CHLORIDE
Proprietary Name: DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
Dosage Form; Route of Administration: INJECTABLE; INJECTION
Strength: 2.5GM/100ML; 450MG/100ML
Reference Listed Drug: Yes
Reference Standard: Yes
TE Code: AP
Application Number: N016697
Product Number: 001
Approval Date: Approved Prior to Jan 1, 1982
Applicant Holder Full Name: BAXTER HEALTHCARE CORP
Marketing Status: Prescription

The detailed NDC information about the product of BAXTER HEALTHCARE CORP from FDA National Drug Code Directory is shown in the figure below:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type	Start Marketing Date	End Marketing Date	Market Category
Dextrose and Sodium Chloride	0338-0073-04	2.5 g/100mL, 450 mg/100mL	INJECTION, SOLUTION	INTRAVENOUS	NDA016697	Baxter Healthcare Corporation	0338-0073	Dextrose and Sodium Chloride	DEXTROSE MONOHYDRATE, SODIUM CHLORIDE	HUMAN PRESCRIPTION DRUG	03/22/1971	N/A	NDA

Though DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (2.5GM/100ML; 450MG/100ML, NDA # N016697) held by BAXTER HEALTHCARE CORP is not listed as discontinued in Electronic Orange Book, we are unable to obtain the necessary samples of RLD through normal drug distribution channel for a long time. According to the latest email from the RLD/RS provider, the product of BAXTER HEALTHCARE CORP with NDC 0338-0073-04 is not available in the market (Attachment 1).

As shown in the table below, the Orange Book currently lists three approved applicants which are not discontinued for Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container. According to the information in the first email in Attachment 1, we have been known that the product of BAXTER HEALTHCARE CORP is not available, and we have been also informed by the RLD/RS supplier that Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container held by B BRAUN MEDICAL INC is none in the market from the second email in Attachment 1. As the latest information that we have, Only FRESENIUS KABI USA LLC are distributing the Dextrose 2.5% and Sodium Chloride 0.45% Injection in the US market. We request FDA to designate Dextrose 2.5% and Sodium Chloride 0.45% Injection in plastic container of FRESENIUS KABI USA LLC as an additional RS for this product.

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	DEXTROSE; SODIUM CHLORIDE	DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER	N019631	INJECTABLE	INJECTION	2.5GM/100ML; 450MG/100ML	AP			B BRAUN MEDICAL INC
RX	DEXTROSE; SODIUM CHLORIDE	DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER	N016697	INJECTABLE	INJECTION	2.5GM/100ML; 450MG/100ML	AP	RLD	RS	BAXTER HEALTHCARE CORP
RX	DEXTROSE; SODIUM CHLORIDE	DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER	A211190	INJECTABLE	INJECTION	2.5GM/100ML; 450MG/100ML	AP			FRESENIUS KABI USA LLC

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. Economic Impact

Information on the economic impact of this proposal will be submitted upon request of the Commissioner.

E. Certification

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

Respectfully submitted,

Sincerely,



福建盛迪医药有限公司
FUJIAN SHENGDI PHARMACEUTICAL CO., LTD.

Li Yan

A handwritten signature in black ink, appearing to be the name 'Li Yan' in a stylized, cursive script.

Manager of Regulatory Affairs

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