June 11, 2019

BY ELECTRONIC SUBMISSION

Division of Dockets Management,

Department of Health and Human Services,

Food and Drug Administration,

5630 Fishers Lane, Rm.1061,

Rockville, MD 20852

Citizen Petition
Designation of Referenced Listed Drug (RLD) & Reference Standard (RS) for Dextrose Peritoneal Dialysis Solution

Dear Sir/Madam,

Fresenius Medical Care North America (FMCNA) submits this Citizen Petition under 21 CFR 10.25 and 10.30 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of Food and Drug Administration to issue RLD & RS status for NDA's 018883 & 020171. There are no current RLD's and RS's status assigned to any products as per Orange book[1].

A. Action Requested

The undersigned requests that FDA designate NDA 018883 and NDA 020171 in the Orange book as RLD (Reference Listed Drug) and RS (Reference Standard).

B. Statement of Grounds

As per Orange book, Fresenius Medical Care North America's Delflex w/dextrose 1.5% in plastic container, Delflex w/dextrose 1.5% low magnesium in plastic container, Delflex w/dextrose 2.5% in plastic container, Delflex w/dextrose 2.5% Low magnesium in plastic container, Delflex w/dextrose 4.25% in plastic container, Delflex w/dextrose 4.25% Low magnesium in plastic container, with the respective strengths 25.7mg/100ml; 1.5gm/100ml; 15.2mg/100ml; 567mg/100ml; 392mg/100ml, 25.7mg/100ml; 1.5gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml, 25.7mg/100ml; 2.5gm/100ml; 15.2mg/100ml; 567ml/100ml; 392mg/100ml, 25.7mg/100ml; 2.5gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml, 25.7mg/100ml; 4.25gm/100ml; 15.2mg/100ml; 567mg/100ml; 392mg/100ml, 25.7mg/100ml; 4.25gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml strengths are approved under NDA 018883.

[1] Per Orange book database.

Delflex w/dextrose 1.5% Low magnesium low calcium in plastic container, Delflex w/dextrose 2.5% Low magnesium low calcium in plastic container, Delflex w/dextrose 4.25% low magnesium low calcium in plastic container with the respective strengths 18.4mg/100ml; 1.5gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml, 18.4mg/100ml; 2.5gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml, 18.4mg/10ml; 4.25gm/100ml; 5.08mg/100ml; 538mg/100ml; 448mg/100ml strengths are approved under NDA 020171.

The products were approved on November 30, 1984 & August 19, 1992 respectively. They have since been used widely in a medical setting in the U.S without any issues.

We have included the following data:

1. **Current Orange Book Search Results**

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

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.

Sincerely,

Seth.Shapiro
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Digitally signed by
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Date: 2019.06.11 13:37:08
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Seth Shapiro
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Attachment 1 – Current Orange Book Listing

Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 1.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 2.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 4.25GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER	N018883	SOLUTION	INTRAPERITONEAL	25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
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RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER	N020171	SOLUTION	INTRAPERITONEAL	18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER	N020171	SOLUTION	INTRAPERITONEAL	18.4MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
RX	CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER	N020171	SOLUTION	INTRAPERITONEAL	18.4MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	AT			FRESENIUS MEDICAL CARE NORTH AMERICA
Mkt. Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder