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October 22, 2019

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Suitability Petition

Dear Sir or Madam:

Andersen Pharma LLC submits this suitability petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, to request that the Food and Drug Administration ("FDA") determine that the proposed drug product, Magnesium Sulfate in 5% Dextrose Injection, USP, 1 gm/50 mL, is suitable for submission in an Abbreviated New Drug Application ("ANDA").

A. Actions Requested

The petitioner requests that the FDA declare the drug product, Magnesium Sulfate in Dextrose 5% Injection, USP, in the total drug content strength of 1 gm/50 mL is suitable for submission in an ANDA. The Reference Listed Drug ("RLD") upon which this petition is based is Hospira Inc NDA 020309 for Magenisum Sulfate in Dextrose 5% in plastic Container, in a 2 gm/100 mL strength.(refer to **Attachment 1).**

This petition seeks only a change in fill volume (but same concentration) from that of RLD; from 2 gm/100 mL to the proposed strength of 1 gm/50 mL. The drug, route of administration, and recommendations for use are the same as thse of the RLD.

B. Statement of Grounds

FD&C Act § 505G)(2)(C) permits the submission of an ANDA for a drug product that differs in strength from the listed drug provided the FDA has approved a petition that seeks permission to file such an application. This petition requests a change in fill volume for the proposed drug from that of the RLD, as described above.

Andersen's proposed formulation would be identical to the RLD NDA 020488 except either fill size (1 gm/50 mL). The active ingredient, route of administration and the dosage form of Andersen's proposed drug product Magnesium Sulfate in Dextrose 5% is same as that of the listed drug NDA 020488. Andersen's proposed product will be Ready-To-Use Magnesium Sulfate Solution for IV drip injection with additional fill -size, potentially offering safe and efficient medication administration because compounding is not necessary. The proposed package insert of Andersen's drug product Magnesium Sulfate in Dextrose 5% Injection USP, 1 gm/50 mL will be consistence with the RLD Labeling. A comparison of Andersen's proposed product and Listed Drug **Magnesium Sulfate in Dextrose 5% in Plastic Container**, 2 gm/100 mL, NDA 020488 is given in Table 1.

Table 1. Comparison of Proposed Magnesium Sulfate in 5% Dextrose Injection, USP and Listed Drug Magnesium Sulfate in Dextrose 5% in Plastic Container

Characteristics	**Listed Drug Product Magnesium Sulfate in Dextrose 5% in Plastic Container, 2 gm/100 mL, NDA 020488**	**Proposed New Drug Product, Magnesium Sulfate in 5% Dextrose Injection, USP, 1 gm/50 mL,**
Indications	For the prevention and control of seizures in preeclampsia and eclampsia, respectively	For the prevention and control of seizures in preeclampsia and eclampsia, respectively
Active Ingredient	Magnesium sulfate heptahydrate 20 mg/mL	Magnesium sulfate heptahydrate 20 mg/mL
Inactive Ingredients	Water for injection Sulfuric acid Sodium hydroxide Dextrose monohydrate	Water for injection – Vehicle Sulfuric acid – pH adjuster Sodium hydroxide – pH adjuster Dextrose monohydrate – Tonicity modifier
Dosage Form	Solution	Solution
Route of Administration	Intravenous	Intravenous
Strength	Magnesium Sulfate, 2 gm/100 mL	Magnesium Sulfate, 1 gm/50 mL,
Dosage Regimen	In severe pre-eclampsia or eclampsia, the total initial dose is 10 to 14 g of magnesium sulfate.	In severe pre-eclampsia or eclampsia, the total initial dose is 10 to 14 g of magnesium sulfate. To initiate therapy, 4 g

Characteristics	**Listed Drug Product Magnesium Sulfate in Dextrose 5% in Plastic Container, 2 gm/100 mL, NDA 020488**	**Proposed New Drug Product, Magnesium Sulfate in 5% Dextrose Injection, USP, 1 gm/50 mL,**
	To initiate therapy, 4 g of Magnesium Sulfate in 5% Dextrose Injection, USP may be administered intravenously. The rate of I.V. infusion should generally not exceed 150 mg/minute or 7.5 mL of a 2% concentration (or its equivalent) per minute, except in severe eclampsia with seizures. Simultaneously, 4 to 5 g (32.5 to 40.6 mEq) of magnesium sulfate may be administered intramuscularly into each buttock using undiluted 50% Magnesium Sulfate Injection, USP. After the initial I.V. dose, some clinicians administer 1-2 g/hour by constant I.V. infusion.	of Magnesium Sulfate in 5% Dextrose Injection, USP may be administered intravenously. The rate of I.V. infusion should generally not exceed 150 mg/minute or 7.5 mL of a 2% concentration (or its equivalent) per minute, except in severe eclampsia with seizures. Simultaneously, 4 to 5 g (32.5 to 40.6 mEq) of magnesium sulfate may be administered intramuscularly into each buttock using undiluted 50% Magnesium Sulfate Injection, USP. After the initial I.V. dose, some clinicians administer 1-2 g/hour by constant I.V. infusion.
Conditions of Use	For the prevention and control of seizures in preeclampsia and eclampsia, respectively. When used judiciously it effectively prevents and controls the convulsions of eclampsia without producing deleterious depression of the central nervous system of the mother or infant. However, other effective drugs are available for this purpose.	For the prevention and control of seizures in preeclampsia and eclampsia, respectively. When used judiciously it effectively prevents and controls the convulsions of eclampsia without producing deleterious depression of the central nervous system of the mother or infant. However, other effective drugs are available for this purpose.
Container Closure System	**Magnesium Sulfate in Dextrose 5% in Plastic Container,** is supplied in a flexible plastic container, for single use	Proposed product **Magnesium Sulfate in 5% dextrose Injection, USP,** is supplied in a flexible polypropylene bag with aluminum over pouch and chlorobutyl rubber stopper; for single use.

A copy of the relevant excerpt from the current electronic edition of the Approved Drug Products with Therapeutic Equivalence Evaluations is provided as **Attachment 1.** A copy of the current

labeling for Magnesium Sulfate in Dextrose 5 % in Plastic Container, is provided as **Attachment 2.** The draft labeling for the proposed product is provided as **Attachment 3.**

There are no proposed changes in labeling, with the exceptions of the obvious changes in strength as described in this petition. The active ingredient, inactive ingredients, dosage form, and route of administration are the same as those of the current listed drug, as are the uses, indications, warnings, intended patient population and directions for use. The proposed product will have same pH of 4.5 (3.5 to 6.5) and same osmolarity of 415 mOsmol/Liter as that of RLD.
Therefore, there will be no differences from the RLD in terms of the safety and efficacy of the proposed strength of Magnesium Sulfate Injection, USP.
Accordingly, the petitioner requests for the Commissioner to find that a change in fill volume (same concentration) from 2 gm/100 mL to 1 gm/50 mL for Magnesium Sulfate in Dextrose 5% Injection, USP should raise no questions of safety or effectiveness, and the FDA should approve the petition.

Pediatric Research Equity Act (FD&C Act section 505(B)(b))

The Pediatric Research Equity Act requires that applications be evaluated for safety and efficacy in pediatric populations when the submission is for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition does not seek any such changes to the RLD; therefore, the petitioner believes that it is not necessary to seek a waiver or deferral for pediatric studies.

C. Environment Impact

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.31(a) from the requirement to submit an environment assessment.

D. Economic Impact Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

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 is unfavorable to the petition.

Suitability Petition- Magnesium Sulfate in 5% Dextrose Injection, USP, 1 gm/50 mL, **RLD Magnesium Sulfate in Dextrose 5% in Plastic Container, 2 gm/100 mL, NDA 020488-** Acceptability to file an ANDA

Sincerely,

mchilakuri@andersen-pharma.com Digitally signed by mchilakuri@andersen-pharma.com Date: 2019.10.22 14:02:25 -05'00'

Madan Chilakuri

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Attachments:

1. *Approved Drug Products with Therapeutic Equivalence Evaluations* (Electronic Orange Book) for RLD
2. Reference Listed Drug Prescribing Information
3. Draft labeling for proposed Magnesium Sulfate in Dextrose 5% Injection USP, 1 gm/50 mL