FRESENIUS KABI

Fresenius Kabi USA, LLC

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CITIZEN PETITION
VIA ELECTRONIC SUBMISSION

04 March 2022

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

Dear Sir/Madam:

The undersigned submits this petition pursuant to the Federal Food, Drug and Cosmetic Act and 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration to designate Fresenius Kabi USA, LLC's (FK USA) Calcium Gluconate in Sodium Chloride Injection 1g/50mL and 2g/100mL approved under 505(b)(2) NDA 208418 as therapeutically equivalent with an 'AP' rating to the Calcium Gluconate in Sodium Chloride Injection 1g/50mL and 2g/100mL NDA 210906, by HQ Specialty Pharma Corp.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration designate Calcium Gluconate in Sodium Chloride Injection 1g/50mL and 2g/100mL manufactured by FK USA (NDA 208418), as a therapeutic equivalent, with an 'AP' rating, to the Calcium Gluconate in Sodium Chloride Injection 1g/50mL and 2g/100mL NDA 210906, by HQ Specialty Pharma Corp.

B. Statement of Grounds

FK USA's Calcium Gluconate in Sodium Chloride Injection drug product (NDA 208418) is therapeutically and pharmaceutically equivalent to Calcium Gluconate in Sodium Chloride Injection 1g/50mL and 2g/100mL NDA 210906, by HQ Specialty Pharma Corp, and is expected to have the same clinical effect and safety profile. A side-by-side pharmaceutical comparison of FK USA's NDA 208418 and NDA 210906 is provided in Table 1 for the reviewer's convenience.

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Table 1 Side-By-Side Pharmaceutical Equivalence Comparison of FK USA NDA 208418 and HQ Specialty Pharma Corp. NDA 210906

Attributes	**FK USA NDA 208418**	**HQ Specialty NDA 210906**	**Comparison**
Strengths	1g/50mL and 2g/100mL	1g/50mL and 2g/100mL	same
Route of administration	Intravenous	Intravenous	same
Dosage Form	Sterile liquid	Sterile liquid	same
Active Ingredient	Calcium Gluconate	Calcium Gluconate	same
Excipients present per mL of solution	Each mL of Calcium Gluconate in Sodium Chloride Injection contains 20 mg of calcium gluconate (equivalent to 18.8 mg of calcium gluconate and 0.9 mg of calcium saccharate tetrahydrate), hydrochloric acid and/or sodium hydroxide for pH adjustment (6.0 to 8.2) and sodium chloride 6.75 mg/mL as tonicity adjustor. Each mL of Calcium Gluconate in Sodium Chloride Injection contains 1.86 mg (0.093 mEq) of elemental calcium.	Each mL of Calcium Gluconate in Sodium Chloride Injection contains 20 mg of calcium gluconate (equivalent to 18.8 mg of calcium gluconate anhydrous), hydrochloric acid and/or sodium hydroxide for pH adjustment (6.0 to 8.2) and sodium chloride 6.75 mg/mL as tonicity adjustor. Each mL of Calcium Gluconate in Sodium Chloride Injection contains 1.86 mg (0.093 mEq) of elemental calcium.	equivalent
Labeling Indications	Calcium Gluconate in Sodium Chloride Injection is indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia. Limitations of Use The safety of Calcium Gluconate Injection for long term use has not been established	Calcium Gluconate in Sodium Chloride Injection is indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia. Limitations of Use The safety of Calcium Gluconate Injection for long term use has not been established	same

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The "Approved Drug Products with Therapeutic Equivalence Evaluations", ("The Orange Book"), defines pharmaceutically equivalent drug products as follows:

1. Contain identical amounts of the same active drug ingredient in the same dosage form and route of administration
2. Meet compendial or other applicable standards of strength, quality, purity and identity

The "Approved Drug Products with Therapeutic Equivalence Evaluations", ("The Orange Book"), defines therapeutically equivalent drug products as follows:

1. Are approved as safe and effective.
2. Contain identical amounts of the same active drug ingredient in the same dosage form and route of administration
3. Meet compendial or other applicable standards of strength, quality, purity and identity
4. Are bioequivalent
5. Are adequately labeled
6. Were manufactured under cGMP

According to the Orange Book Preface to the 39th Edition, therapeutically equivalent drug products can differ in certain other characteristics, such as shape, scoring configuration, release mechanisms, packaging, excipients, expiration date/time, minor aspects of labeling and storage conditions.

Table 1 demonstrates that the HQ Specialty Pharma and FK drug products are identical. They are identical in active ingredient, formulation, dosage form, route of administration and indication. Because these products are injectable, bioequivalency is self evident under 21 CFR 314.94. Additionally, both products are approved by FDA, hence meeting the requirements for applicable standards, adequate labeling and manufacturing under GMP.

Based on all the above mentioned reasons, FK USA kindly requests the Agency to grant a therapeutic equivalence rating 'AP' for NDA 208418, Calcium Gluconate in Sodium Chloride Injection.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, FK USA 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.

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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 are unfavorable to the petition.

Respectfully submitted,

Molly Ventrelli

Digitally signed by Molly Ventrelli
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