

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

23 October 2023

Division of Dockets Management
Food and Drug Administration
(HFA-305) Room 1061
5360 Fishers Lane
Rockville, MD 20852

**REQUEST FOR WITHDRAWAL – CITIZEN PETITION
DOCKET NUMBER FDA-2022-P-0290**

Dear Sir/Madam:

Reference is made to Fresenius Kabi USA, LLC.'s (FK USA), Citizen Petition for Calcium Gluconate in Sodium Chloride Injection NDA 208418 submitted to the Agency on 04 March 2022.

FK USA respectfully requests a withdrawal of the Citizen Petition – Docket Number FDA-2022-P-0290.

In the aforementioned Citizen Petition, FK USA requested that the Agency 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.

On June 21, 2022, FDA issued a refund grant letter for prescription drug program fee for FK USA's Calcium Gluconate in Sodium Chloride, 1g/50mL (NDA 208418), reflecting FDA's decision that this product qualified for a refund because FDA has determined that this product is pharmaceutically equivalent to HQ Specialty Pharms Corp's Calcium Gluconate in Sodium Chloride, 1g/50mL approved under NDA 210906.

Further, on 20 October, 2023, FDA notified FK USA via email correspondence that Calcium Gluconate in Sodium Chloride (NDA 208418), 1g/50mL and 2g/100mL, approved under NDA 208418, have been designated with "AP" therapeutic equivalence codes in the FDA Orange Book with respect to Calcium Gluconate in Sodium Chloride, 1 g/50mL and 2g/100mL, approved under ANDA 217174.

Therefore, FK USA is withdrawing this petition.

Should you have any questions or require additional information, please do not hesitate to contact the undersigned.

Sincerely,

Molly Ventrelli
Sr. VP Regulatory Affairs
Phone: 847-550-2014 || Fax: 847-550-7121
E-mail: Molly.Ventrelli@fresenius-kabi.com