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APPLICATION NUMBER:

210906Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

CLINICAL PHARMACOLOGY REVIEW

NDA	210906
Submission Dates	09/29/2017
Brand Name	N.A.
Generic Names	Calcium gluconate injection
Reviewer	Jing Niu, M.D.
Team Leader	Jayabharathi Vaidyanathan, Ph.D.
OCP Division	Clinical Pharmacology 2
OND Division	Metabolism and Endocrinology Products
Sponsor	HQ Specialty Pharma Corporation
Formulation; Strength	Calcium gluconate injection for intravenous use; 1000 mg/50 mL, and 2000 mg/100 mL
Relevant IND	N.A.
Indication	Treatment of symptomatic hypocalcemia

1 Executive Summary

The applicant submitted a 505(b)(2) NDA relying on the Agency's previous finding of safety and effectiveness of Fresenius Kabi's NDA 208418. There is no clinical study conducted by the sponsor in this NDA. A request for a waiver from bioequivalence study was submitted, thus we defer the biowaiver decision to OPQ-Biopharm. Notable changes between the proposed product and the reference product were highlighted herein: (1) the proposed product is pre-diluted therefore no dilution needed prior to use; (2) the proposed product contains sodium chloride whereas the reference dose not; therefore, pertinent labeling changes were proposed by the sponsor. The proposed labeling language in section 7 (DRUG INTERACTIONS) and section 12 (CLINICAL PHARMACOLOGY) is identical to that in Fresenius Kabi's NDA 208418.

1.1 Recommendations/Comments

The Office of Clinical Pharmacology/Division of Clinical Pharmacology 2 (OCP/DCP2) has reviewed NDA 210906, and finds the application acceptable from a clinical pharmacology perspective. The proposed labeling is also acceptable.

1.2 Post-Marketing Requirements and Commitments

None

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/s/

JING NIU
05/04/2018

JAYABHARATHI VAIDYANATHAN
05/04/2018