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APPLICATION NUMBER:

208019Orig1s000

SUMMARY REVIEW

DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS

Divisional Memo

NDA: 208019 Potassium chloride powder for oral solution.

Sponsor: Pharma Research Software Solutions

Review date: 19 August 2015

Reviewer: N. Stockbridge, M.D., Ph.D., HFD-110

This memo conveys the Division's decision to approve this application.

This application has been the subject of reviews of CMC (Kambhampati; 25 June 2015), biopharmaceutics (Zolnik; 24 June2015), microbiology (Pfeiler; 5 March 2015), clinical pharmacology (Hinderling; 29 June and 3 August 2015), and pharmacology/toxicology (Yang; 27 April 2015). This memo also serves as the CDTL memo.

The applicant seeks to market a 20 mEq [redacted] (b) (4) orally to treat hypokalemia. The approval pathway is 505(b)(2), relying for safety and effectiveness upon literature and the Agency's findings for other oral dosage forms.

There are no manufacturing issues and manufacturing facilities have been deemed satisfactory.

There is no microbiology issue.

Potassium chloride is highly soluble and highly bioavailable (BCS Class 1). Because the body adjusts rapidly to potassium load, the pharmacokinetics is usually assessed by excretion; about 90% of which is renal. The solution has bioavailability similar to that of tablets. Kinetics is linear and unaffected by food.

The formulation contains the [redacted] (b) (4) sucralose [redacted] (b) (4) 20 mEq of potassium, which would result in daily intake of [redacted] (b) (4) at the highest recommended dose. This is about the same as the CFSAN-approved acceptable daily intake (ADI). Toxicological studies of sucralose demonstrate the first effect being weight loss because of displacement of calories in the diet. The review team and I agree that there is no safety concern here.

Labeling has been fully negotiated. There are no remaining approval issues.

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/s/

NORMAN L STOCKBRIDGE
08/19/2015