LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
KURT R. KARST WASHINGTON, D.C. 20005-5929 Direct Dial (202) 737-7544
(202) 737-5600 KKarst@hpm.com
FACSIMILE
(202) 737-9329
www.hpm.com

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SUBMITTED VIA REGULATIONS.GOV

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned, on behalf of a client, submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. §§ 10.20 and 10.30, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug product Potassium Chloride Extended-release for Liquid Suspension, 8 mEq (600 mg) and 10 mEq (750 mg), are suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that FDA declare that Potassium Chloride Extended-release for Liquid Suspension, 8 mEq and 10 mEq, are suitable for submission as an ANDA. As designated in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is KV Pharmaceutical Company's Micro-K® LS Packets (potassium chloride) Extended-release for Liquid Suspension, which is approved for prescription use under New Drug Application ("NDA") 019561 in a 20 mEq (1,500 mg) strength. The petitioner seeks to introduce new 8 mEq and 10 mEq strengths for prescription use.

B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) provides for the submission of an ANDA for a drug product that differs in strength from that of the listed drug provided FDA has first approved a petition permitting the submission of such an application.

Micro-K® LS Packets approved under NDA 019561 contain 20 mEq of potassium chloride in an extended-release for liquid suspension dosage form. A copy of the current Orange Book entry for Micro-K® LS Packets (NDA 019561) is included in ***Attachment 1***. The proposed drug product also contains potassium chloride in an extended-release for liquid suspension dosage form, but in 8 mEq and 10 mEq strengths. The petition is thus seeking a change in extended-release for liquid suspension strengths to 8 mEq and 10 mEq from that of the Reference Listed Drug ("RLD") (20 mEq).

The proposed change in strength is consistent with the dosing recommendations of the RLD's approved labeling. For example, the prescribing information for Micro-K® LS Packets provides the following dosing information:

DOSAGE AND ADMINISTRATION

The usual dietary potassium intake by the average adult is 50 to 100 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store.

Dosage must be adjusted to the individual needs of each patient. The dose for the prevention of hypokalemia is typically in the range of 20 mEq per day. Doses of 40–100 mEq per day or more are used for the treatment of potassium depletion. Dosage should be divided if more than 20 mEq per day are given such that no more than 20 mEq is given in a single dose.

Usual Adult dose—One Micro-K LS 20 mEq packet 1 to 5 times daily, depending on the requirements of the patient. This product must be suspended in a liquid, preferably water, or sprinkled on food prior to ingestion

Prescribing Information, Micro-K® LS Packets (1998) (***Attachment 2***).

The availability of new 8 mEq and 10 mEq strengths is consistent with the dosing instructions for the RLD (NDA 019561). Moreover, the availability of 8 mEq and 10 mEq strengths will provide a prescribing physician with a greater degree of flexibility in achieving proper dosing for a specific patient's needs. The proposed changes in

strength from that of the RLD do not raise questions of safety or efficacy for the proposed drug products. Therefore, FDA should conclude that clinical investigations are not necessary to demonstrate safety or effectiveness of the proposed drug product.

There are no proposed changes in labeling with the exception of changes in strength sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Approved labeling for Micro-K® LS Packets (NDA 019561), updated in 1998, is included as ***Attachment 2***. Draft labeling for the proposed drug product is included as ***Attachment 3***. Therefore, the Petitioner requests that FDA find that a change in extended-release for liquid suspension strength from 20 mEq to 8 mEq and 10 mEq strengths of potassium chloride raises no questions of safety or effectiveness.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. *See* FDC Act § 505B(a)(1)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. *See id.* ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. *See* FDA, Draft Guidance for Industry, How to Comply with the Pediatric Research Equity Act, 4 (Sep. 2005). Petitioner asserts that PREA is not applicable to the proposed Potassium Chloride Extended-release for Liquid Suspension, 8 mEq and 10 mEq, drug products because the proposed change concerns only new strengths. As such, PREA should not serve as an impediment to the Agency granting this petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

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 are unfavorable to the Petition.

Sincerely,

Kurt R. Karst