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

KURT R. KARST

Direct Dial (202) 737-7544
KKarst@hpm.com

September 23, 2020

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 Tablets, 15 mEq (1125 mg), is suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that FDA declare that Potassium Chloride Extended-release Tablets, 15 mEq, is suitable for submission as an ANDA.[1] 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 AbbVie Inc.'s K-TAB (potassium chloride extended-release tablets), which is approved for prescription use under New Drug Application ("NDA") 018279 in 8 mEq, 10 mEq, and

[1] FDA previously approved a similar request for a Potassium Chloride Extended-release Tablets, 15 mEq, drug product; however, in that case the RLD was K-DUR (potassium chloride extended-release tablets) approved under NDA 019439. *See* FDA, Suitability Petition Decision, Docket No. FDA-2001-P-0412 (July 9, 2001), *available at* https://beta.regulations.gov/document/FDA-2001-P-0412-0003.

20 mEq strengths. The petitioner seeks to introduce a new 15 mEq strength 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.

K-TAB approved under NDA 018279 contains either 8 mEq, 10 mEq, or 20 mEq of potassium chloride in an extended-release tablet dosage form. A copy of the current Orange Book entry for K-TAB (NDA 018279) is included in ***Attachment 1***. The proposed drug product also contains potassium chloride in an extended-release tablet dosage form, but in a 15 mEq strength. The petition is thus seeking a change in extended-release tablet strength to 15 mEq from that of the RLD (8 mEq, 10 mEq, and 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 K-TAB provides the following dosing information:

> **2.2 Dosing**
>
> Dosage must be adjusted to the individual needs of each patient. Dosages greater than 20 mEq per day should be divided such that no more than 20 mEq is given in a single dose.
>
> Treatment of hypokalemia: Typical dose range is 40-100 mEq per day.
>
> Prevention of hypokalemia: Typical dose is 20 mEq per day.

Prescribing Information, K-TAB (Apr. 2018), *available at* https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=6594df99-d8ce-49b9-3fbe-9ec7cdc9199b&type=pdf.

The availability of a new 15 mEq intermediate strength is consistent with the dosing instructions for the RLD (NDA 018279). Moreover, the availability of a 15 mEq strength will provide a prescribing physician with a greater degree of flexibility in achieving proper dosing for a specific patient's needs. The proposed change in strength from that of the RLD does 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 K-TAB (NDA 018279), updated in April 2018, 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 tablet strength from 8 mEq, 10 mEq, and 20 mEq to 15 mEq 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 Tablets, 15 mEq, drug product because the proposed change concerns only a new strength. 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.

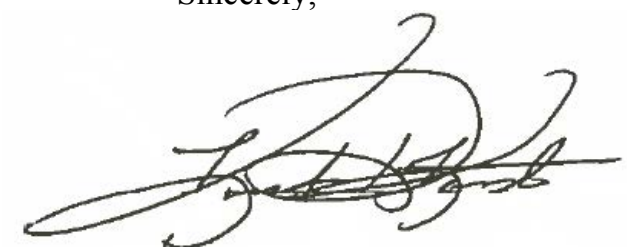
D. Economic Impact

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