KING & SPALDING LLP

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November 27, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

CITIZEN PETITION

King & Spalding LLP submits this petition in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (FDC Act) (21 U.S.C. § 355(j)(2)(C)) and 21 C.F.R. §§ 314.93, 10.25, and 10.30.

A. Action Requested

The petition requests that the Commissioner of Food and Drugs declare an abbreviated new drug application ("ANDA") may be submitted for potassium chloride *oral solution* drug products in strengths of 10% (15 mL equals 20 mEq of potassium chloride) and 5% (15 mL equals 10 mEq of potassium chloride).

The reference listed drug upon which this petition is based is K-DUR® (Potassium Chloride USP) Extended Release Tablets, available in strengths of 20 mEq and 10 mEq (approved under NDA 019439), indicated for the treatment of patients with hypokalemia, and for the prevention of hypokalemia. This petition requests a change in dosage form: from extended-release tablets to oral solution products containing equivalent amounts of the active ingredient potassium chloride.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage form from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change from the reference listed drug *in dosage form only*. The active ingredient, indications, dosage recommendations, strengths and route of administration are the same as those in approved labeling of the reference listed drug products. An oral solution provides an alternative for physicians to prescribe for certain patient groups, particularly the elderly, who have problems swallowing the tablet dosage form.

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In accordance with 21 C.F.R. § 314.93(d), the following labeling information and comparisons are attached to this petition:

1. An annotated copy of the current prescribing information for the reference listed drug products (K-DUR (Potassium Chloride USP) Extended Release Tablets) is Attachment 1. The annotations identify specific portions of the proposed products' labeling that would vary from the reference listed drugs' approved prescribing labeling.

2. Draft prescribing labeling for the proposed products, which corresponds to the reference listed drugs except for permitted deviations (including description of the dosage form and related administration information). The draft package insert for proposed Potassium Chloride Oral Solution USP 5% and 10% is Attachment 2.

The proposed change in dosage form from K-DUR Extended-Release Tablets to potassium chloride oral solution raises no questions regarding the safety and efficacy of the proposed products. The indication remains unchanged and the proposed labeling will be generally the same as that of the approved labeling for the reference listed drugs. *See* Attachment 2. Thus, the Food and Drug Administration should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of preparing an environmental assessment or environmental impact statement, pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this petition.

E. Certification

The undersigned representative of King & Spalding certifies that, to the best of her knowledge and belief, this petition includes all information and views upon which the petition relies, and includes representative data and information that are known to be unfavorable to the petition.

Sincerely,

Gillian Russell

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Admitted in Pennsylvania and New Jersey only