CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74726

APPROVAL LETTER

ANDA 74-726

NOV 20 1998

Upsher-Smith Laboratories, Inc.
Attention: Mark B. Halvorsen, Pharm.D.
14905 23rd Avenue North
Minneapolis, MN 55447-4709

Dear Sir:

This is in reference to your abbreviated new drug application dated August 8, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for KLOR-CON® M20 (Potassium Chloride Extended-release Tablets USP, 20 mEq).

Reference is also made to your amendments dated June 20 and 26, 1996; February 12, March 14, November 7, 1997; and February 13, August 20, September 2, and September 24, 1998.

The listed drug product referenced in your application is subject to a period of patent protection which expires on September 5, 2006, (patent 4,863,743). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Potassium Chloride Extended-release Tablets USP, 20 mEq, will not infringe on the patent or that the patent is otherwise invalid. You have informed the Agency that Key Pharmaceuticals, Inc. initiated a patent infringement suit against you in the United States District Court for the District of New Jersey (Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Civil Action No. 95-6281 [WHW]). You have also notified the Agency that on July 24, 1997, the New Jersey court issued a Stipulation and Order of Dismissal officially terminating the litigation with Key Pharmaceuticals, Inc.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your KLOR-CON® M20 (Potassium Chloride Extended-release Tablets USP, 20 mEq) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (K-DUR 20® Extended-release Tablets of Key Pharmaceuticals, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 11/20/98

Douglas L. Spohn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research