DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 74-726

[redacted]ministration
[redacted]67

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 [redacted] 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 [redacted]

[redacted]

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.

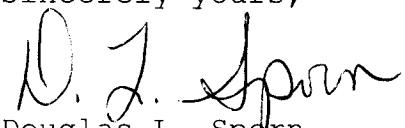
Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

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,



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

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 74-726/ [redacted] ation

Upsher-Smith Laboratories, Inc.
Attn: Mark S. Robbins
14905 23rd Avenue North
Minneapolis, MN 55447

Dear Sir:

This is in reference to your supplemental new drug applications dated August 5, 1999, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Klor-Con® M20 (Potassium Chloride Extended-Release Tablets USP, 20 mEq).

Reference is also made to [redacted]

The supplemental applications provide for:

[redacted] Addition of a new strength, 10 mEq,

[redacted]

We have completed the review of these supplemental abbreviated applications and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The

Division of Bioequivalence has determined your KLOR-CON® M10 (Potassium Chloride Extended-release Tablets USP, 10 mEq) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (K-DUR 10® 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.

We remind you that you must comply with the requirement for an approved abbreviated application described 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,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA: 74-726/[redacted]

[redacted]

Upsher-Smith Laboratories, Inc.
Attn: Mark S. Robbins, Ph.D., J.D.
14905 23rd Avenue North
Minneapolis, MN 55447

Dear Sir:

This is in reference to your supplemental new drug applications [redacted] submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), regarding your abbreviated new drug application for Klor-Con® M, (Potassium Chloride Extended-Release Tablets), USP 10 mEq and 20 mEq.

Reference is also made to your [redacted].

The supplemental applications, submitted as "Prior Approval Supplements" provide for the following changes:

[redacted]

New Strength (15 mEq extended-release tablet).

[redacted]

We have completed the review of these supplemental applications and have concluded that all three strengths of the drug product are safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The additional strength of the drug product, Klor-Con M15 Extended-release Tablets can be expected to have the same therapeutic effect as that of an equivalent dose of the listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your supplemental application.

[redacted]

We remind you that you must comply with the requirements for an approved abbreviated new drug application described 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 that you intend to use in your initial advertising or promotional campaigns for the additional strength. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the 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 the Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research