



NDA 19-123/S-022

Upsher-Smith Laboratories, Inc.
Attention: Ms. Tanya Carone
6701 Evenstad Drive
Maple Grove, MN 55369

Dear Ms. Carone:

Please refer to your supplemental new drug application dated November 17, 2003, received December 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Klor-Con® (potassium chloride) Extended-release 8 & 10 mEq Tablets, USP.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling (FPL) revised by adding a *Geriatric Use* subsection at the end of PRECAUTIONS as requested in our supplement request letter dated August 7, 2003, as follows:

PRECAUTIONS

Geriatric Use: Clinical studies of Klor-Con® Extended-release tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

In addition, we note the manufacturer code and revised date were updated.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the FPL submitted on November 17, 2003.

In addition, we noted in our supplement request letter dated August 7, 2003, that the drug product is also marketed under the names KAON-CL and Potassium Chloride Extended-release Tablets. We request that you revise the respective package inserts for these drugs and submit the revised labeling to the Agency in your next annual report.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office for Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Norman Stockbridge
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