DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-123

[redacted]

Upsher-Smith Laboratories, Inc.
Attention: Mr. Fred I. Wehling
14905 23rd Avenue North
Minneapolis, MN 55441

Dear Mr. Wehling:

Please refer to your new drug application dated [redacted] under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act for Klor-Con (potassium chloride) 8 and 10 mEq Slow Release Tablets.

We also acknowledge receipt of [redacted]

We have completed the review of this application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the application is approved. Prior to marketing, however, please submit twelve copies of the final printed labeling that are identical to the draft. Please individually mount seven of the copies on heavy weight paper or similar material.

In the near future, we plan to request revision of current potassium chloride labeling that incorporates endoscopy study findings as well as content and format specifcations. We do expect your cooperation in making changes when our internal deliberations have been completed.

Marketing of the drug before the final printed labeling is submitted to FDA renders the product misbranded under 21 U.S.C. 352.

Should additional information relating to the safety and effectiveness of the drug become available prior to our receipt of the final printed labeling, revision of that labeling may be required.

In addition, please submit, in duplicate, the advertising copy that you intend to use in your proposed introductory promotional and advertising campaign. Please submit one copy to this division and the second, along with a copy of the package insert directly to:

Division of Drug Advertising and Labeling, HFN-240
Room 10B-04
5600 Fishers Lane
Rockville, Maryland 20857

Please submit all proposed materials in draft or mock-up form, not final print. Also, please do not use form FD-2253 for this submission; this form is for routine use, not proposed materials.

Please submit one market package of the drug when it is available.

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 contact:

Mr. Peter Manilla
Consumer Safety Officer
(301) 443-4730

Sincerely yours,

Ray Lipicky

Raymond J. Lipicky, M.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of drug Research and Review
Center for Drugs and Biologics

cc: Ellis Pharmaceutical Consulting, Inc.
Attention: Ms. Hanni Levi Ellis
913 State Road
Princeton, NJ 08540-1484