CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 74-726/S-013 and S-014

Name: Klor-Con® M (Potassium Chloride Extended-release Tablets USP, 10 mEq and 20 mEq)

Sponsor: Upsher-Smith Laboratories, Inc.

Approval Date: March 29, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 74-726/S-013 and S-014

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APPROVAL LETTER

ANDA 74-726/S-013, S-014

MAR 29 2002

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 November 30, 2001, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Klor-Con® M (Potassium Chloride Extended-release Tablets USP, 10 mEq and 20 mEq).

The supplemental applications, submitted as "Supplement-Changes Being Effected in 30 Days", provide for manufacturing scale-up and equipment and process parameter changes for the (b) (4) (b) (4) for the unit dose packaging configuration.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

DS Gill

for Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 74-726
Division File
FIELD COPY

Endorsements:

HFD-625/BCai/03/26/02
HFD-625/MSmela/3/26/02
HFD-617/MDillahunt/3/26/02

3/28/02
M Smela 3/28/02
MDillahunt 3/28/02

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F/T by cll/3/28/02

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 74-726/S-013 and S-014

CHEMISTRY REVIEWS

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Chemistry, Manufacturing and Controls Review

ANDA:74-726/S-013, S-014

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

Telephone: (763) 473-4412

PURPOSE OF AMENDMENT/SUPPLEMENT:
To provide for manufacturing scale-up for the [redacted] (b) (4) batch size and incorporated equipment and process parameter changes for the Unit Dose Packaging configuration.

DATE(S) OF SUBMISSION(S) and OTHERS(AMENDMENTS,TELECON OR OTHERS):

November 30, 2001: Original Submission

"Special Supplements, CBE 30"/SUPAC MR;

NONPROPRIETARY NAME:
Potassium Chloride Extended-Release Tablets USP

PHARMACOLOGICAL CATEGORY	TRADE NAME
Potassium Supplementation	N/A

DOSAGE FORM	POTENCY	RX OR OTC
Tablets	10 & 20 mEq	R_x

REMARKS AND CONCLUSION:
Approved

Reviewer: Bing Cai, Ph.D. **Date Completed:** March 25, 2002

SAMPLES:	N/A
RELATED IND/NDA/DMF(S):	N/A
LABELING:	N/A
ESTABLISHMENT INSPECTION:	N/A
PACKAGING:	N/A
STERILIZATION:	N/A
BIOEQUIVALENCY:	Not required/The same process changes are as those included in S-012.

COMPONENTS, COMPOSITION, MANUFACTURING PROCESSING & STABILITY:

Background: The supplement (CBE-30) provides for manufacturing scale-up for the [redacted] (b) (4) batch size and incorporated equipment and process parameter changes for the unit dose packaging configuration. Please note a similar supplement, S-012, was submitted on 10/05/2001, for the same process changes, except it was submitted only for bottle packaging configurations (The S-012 was approved in February 2002). Most of information submitted in the current submission are identical to those provided in S-012, except some minor editorial changes made to the Master Batch Records.

Potassium Chloride Extended-Release Tablets (Klor-Con® M, 10 & 20 mEq) are manufactured [redacted] (b) (4)

No changes are made to the formulation of the drug product. [redacted] (b) (4)

[redacted] (b) (4)

[redacted] (b) (4)

Following this page, 2 Pages Withheld in Full as (b)(4)

that it will provide the long-term stability results on two executed batches in a subsequent annual report.

REMARKS AND CONCLUSION:
Approved

ORDER OF REVIEW:
The application submission(s) covered by this review was taken in the date order of receipt Yes____X_____ No _____
Spot? Yes_____, No____X___

cc: ANDA 74-726
Division File
Field Copy

Endorsements:

HFD-625/B. Cai/03/26/02
HFD-625/M. Smela/03/26/02

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F/t by cll/3/28/02

CENTER FOR DRUG EVALUATION AND RESEARCH

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ANDA 74-726/S-013 and S-014

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

To. M. D'Illehunt

CBE- THIRTY (30) DAY SUPPLEMENT ROUTING FORM

This form is to accompany all CBE-30 Day supplements. Upon completion, return to the OGD Document Room

I. To be completed by the OGD Document Room using information from the applicant Cover letter:

DATE PROCESSED: 12-4-01
APPLICATION # : 74-726 SUPPLEMENT # : SCR-013-AT SCS-014-AT

II: To be determined by Chemistry Division Staff.

Date and initial appropriate category.

Thirty (30) Day CBEs:

Chemistry Div. Staff	Qualifies as CBE-30 (GR)	Does Not Qualify. This is a CBE-0. (DC)	Does not Qualify. This is an Annual Report (DA)	Does not Qualify. This is a Prior Approval Supp. (DN)
Chemistry/Micro Project Manager(s)	MDellehunt 12/13/01			
Micro and/or Labeling Team Leader (as needed)	N/A			
Chemistry Team Leader	M Spnela 12/13/01			
Chemistry Div. Dir. Or Deputy* Dir.				

*Div/Deputy Director signature needed only when 1) CBE elevated to PAS or 2) PM/TM recommend different actions.

COMMENTS: No bio assignment is needed. This same process change is included in S-012 which has been referred for DBE review.

III. To Project Manager Chemistry Team 4 :

Prepare letter and notify applicant by telephone when CBE is denied because it is a prior approval supplement. DATE: _____

Notify applicant by telephone that inappropriate CBE category used. DATE _____

Request that applicant withdraw supplement when CBE qualifies for submssion as an Annual Report DATE _____

IV. To Document Room

Record appropriate CBE Code GR
File in archival submission