



NDA 19-123/S-021

Upsher-Smith Laboratories, Inc.
Attention: Ms. Tanya L. Carone
14905 23rd Avenue North
Minneapolis, MN 55447

Dear Ms. Carone:

Please refer to your supplemental new drug application dated July 22, 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.

We acknowledge receipt of your submission dated August 7, 2003.

This "Changes Being Effected" supplemental new drug application provides for FPL revised as requested in our supplement request letter dated February 11, 2003.

The following paragraph has been added to the end of the OVERDOSAGE section:

The extended release feature means that absorption and toxic effects may be delayed for hours. Consider standard measures to remove any unabsorbed drug.

In addition, we note the following revisions and editorial changes:

1. Under DESCRIPTION, Inactive Ingredients, the text was changed from:

Caster oil, hydroxypropyl methylcellulose 2910, magnesium stearate, polyethylene glycol 3350, propylene glycol, synthetic iron oxide, titanium dioxide, and other ingredients. Yellow tablets also contain FD&C Yellow No. 10 aluminum lake and FD&C Yellow No. 6 aluminum lake. Blue tablets also contain FD&C Blue No. 1 aluminum lake.

To:

Castor oil, hydrogenated vegetable oil, hydroxypropyl cellulose, hypromellose 2910, magnesium stearate, polyethylene glycol 3350, propylene glycol, silicon dioxide and titanium dioxide. Yellow tablets also contain D&C Yellow No. 10 aluminum lake and FD&C Yellow No. 6 aluminum lake. Blue tablets also contain FD&C Blue No. 1 aluminum lake.

2. The terms 'controlled release' and 'sustained release' were changed to 'extended-release' throughout the labeling.

3. Under WARNINGS, Gastrointestinal Lesions, last sentence, the phrase ‘a controlled rate’ was changed to ‘an extended rate.’
4. Under PRECAUTIONS, General, second sentence, the phrase ‘bear in mind’ was changed to ‘be aware.’
5. Under PRECAUTIONS, the subsection ‘Pregnancy Category C:’ was changed to ‘Pregnancy: Pregnancy Category C.’
6. Under PRECAUTIONS, Pediatric Use, first sentence, the word ‘children’ was changed to ‘the pediatric population.’
7. Under DOSAGE AND ADMINISTRATION, first paragraph, the phrase ‘200 or more mEq’ was changed to ‘200 mEq or more.’
8. Under HOW SUPPLIED, the following additional packaging configurations were added:
 - ‘and bulk packs of 5,000 for repack only (NDC 0245-0040-55);’ [600mg (8 mEq tablet)]
 - ‘and bulk packs of 5,000 for repack only (NDC 0245-0041-55).’ [750mg (10 mEq tablet)]
9. Under HOW SUPPLIED, the storage instructions were changed from:

Protect from light and moisture. Store at controlled room temperature 50-86°F (15-30°C). Dispense in container with child-resistant closure.

To:

Store at controlled room temperature, 15-30°C (50-86°F). Protect from light and moisture. Dispense in a tight container with child-resistant closure.

10. The manufacturer codes and revised date were updated.
11. The statement ‘Caution: Federal law prohibits dispensing without prescription.’ was deleted.
12. The references to other sections in the label are ‘bolded’ and/or ‘italicized’ consistent with the format of section headings in the label.

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 final printed labeling (FPL) submitted on July 22, 2003.

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}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office for Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Doug Throckmorton
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