



NDA 19-561/S-004

KV Pharmaceutical Company
Attention: Ms. Scarlett Tumulty
2503 South Hanley Road
St. Louis, MO 63144

Dear Ms. Tumulty:

Please refer to your electronic supplemental new drug application dated June 21, 2005, received June 23, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Micro-K® LS Packets (potassium chloride) 20 mEq Extended-release Liquid Suspension.

We acknowledge receipt of your submission dated June 21, 2005. This "Changes Being Effected" supplemental new drug application provides a complete response to our supplemental NDA request letters of February 11, 2003 (OVERDOSAGE) and August 7, 2003 (Geriatric Use), requesting final printed labeling revised as follows:

1. The following paragraph was added at 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.

2. Under **PRECAUTIONS**, the following subsection was added:

Geriatric Use

Clinical studies of Micro-K LS 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 package insert revision date was updated.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on June 21, 2005.

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
301-594-5332

Sincerely,

{See appended electronic signature page}

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

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/s/

Norman Stockbridge
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