DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-279/S-027

Abbott Laboratories
Attention: Alexa L. Chun, R.Ph., Ph.D.
Global Pharmaceutical Regulatory Affairs
Dept. RA 76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Dr. Chun:

Please refer to your supplemental new drug application dated September 13, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for K-Tab (potassium chloride) 10 mEq (750 mg) Extended-Release Tablets.

We acknowledge receipt of your submission dated September 13, 2004 which constituted a complete response to our February 11, and August 7, 2003 supplement request letters.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised in response to our supplement request letters dated February 11 (OVERDOSAGE), and August 7, 2003 (PRECAUTIONS/Geriatric Use), as follows:

1. The following paragraph was 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.

2. The following subsection was added to the end of the PRECAUTIONS section:

   Geriatric Use
   Clinical studies of K-Tab 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.

We also note the following minor editorial changes:

1. "Rx only" was added following the name of the drug at the beginning of the package insert.

2. The revision date and manufacturer codes 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 final printed labeling submitted on September 13, 2004.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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