DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-528/S-008

Abbott Laboratories
Attention: Ms. Marilou Reed
D-491/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 30064-6157

Dear Ms. Reed:

Please refer to your supplemental new drug application dated August 27, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mavik (trandolapril) 1, 2 and 4 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the package insert:

1. **WARNINGS/Angioedema** subsection:

   from: **Angioedema** (subsection heading)

   to: **Head and Neck Angioedema** (revised subsection heading)

2. Following the **Head and Neck Angioedema** subsection and before the paragraph entitled "In large U.S. postmarketing study…" the following subsection has been added:

Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. The angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor. Intestinal angioedema should be included in the differential diagnosis of patients on ACE inhibitors presenting with abdominal pain.

We also note the following changes under the **HOW SUPPLIED** section:

from: 1 mg tablet- salmon colored, round shaped, scored, compressed tablets, with code KNOLL 1 on one side.
NDC (0048-5805-01 - bottles of 100)

to: 1 mg tablet- salmon colored, round shaped, scored, compressed tablets, with XXX (Abbott's logo) on one side and Abbo-Code identification letters FT on the other side.
NDC 0074-2278-13 - bottles of 100
NDC 0074-2278-11 - unit dose packs of 100

from: 2 mg tablet- yellow colored, round shaped, compressed tablets with code KNOLL 2 on one side.
NDC (0048-5806-01 – bottles of 100)

to: 2 mg tablet- yellow colored, round shaped, compressed tablets with XXX (Abbott's logo) on one side and Abbo-Code identification letters FX on the other side.
NDC 0074-2279-13 – bottles of 100
NDC 0074-2279-11 – unit dose packs of 100

from: 4 mg tablet- rose colored, round shaped, compressed tablets, with code KNOLL 4 on one side.
NDC (0048-5807-01 – bottles of 100)

to: 4 mg tablets- rose colored, round shaped, compressed tablets, with XXX (Abbott's logo) on one side and the Abbo-Code identification letters FZ on the other side.
NDC 0074-2280-13 – bottles of 100
NDC 0074-2280-11 – unit dose packs of 100

- "Rx only" has been moved to the first page next to the heading.
- The manufacturer name and address has been changed:

from: Knoll Pharmaceutical Company
3000 Continental Drive – North
Mount Olive, New Jersey 07828-1234

to: Abbott Laboratories
North Chicago, IL 60064, U.S.A.

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 August 28, 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 contact:

Alisea Sermon, Pharm.D.
Regulatory Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
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/

Doug Throckmorton

2/6/04 01:06:18 PM