DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-528/S-016

SUPPLEMENT APPROVAL

Abbott Laboratories (GPRA)
Attention: Jennifer Doney
Dept. PA76/Bldg. Ap30-1E
200 Abbott Park Road
Abbott Park, Il 60064-6157

Dear Ms. Doney:

Please refer to your supplemental new drug application dated September 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mavik (trandolopril) 1, 2, and 4 mg Tablets.

We acknowledge receipt of your submission dated March 20, 2009.

This "Changes Being Effected" supplemental new drug application provides for the following revision to the **PRECAUTIONS,** *Drug Interactions* section of the labeling:

> Gold
>
> Nitroid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including Mavik.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on March 20, 2009.

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-528/S-016**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane; Suite 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Edward Fromm, R.Ph., RAC
Chief, Project Management Staff
(301) 796-1072

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved labeling text

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

4/8/2009 11:18:12 AM