DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020528/S-017

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Sou-Jen Chang
Associate Director
Abbott Laboratories
Dept. PA71/AP30-1
200 Abbott Park Rd,
Abbott Park, IL, 60064-6157

Dear Ms. Chang:

Please refer to your Supplemental New Drug Application (sNDA) dated May 11, 2011 submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MAVIK (trandolapril) Tablets, 1 mg, 2 mg, and 4 mg.

We acknowledge receipt of your amendment(s) dated November 9, 2011.

This "Prior Approval" supplemental new drug application provides for revisions to your Carton/Container labels.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on Novmeber 9, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020528S-017**." Approval of this submission by FDA is not required before the labeling is used.

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 Michael Monteleone, Regulatory Project Manager, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm D
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

MARY R SOUTHWORTH
11/10/2011