DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-591/S-016

Abbott Laboratories, Inc.
Attention: Ms. 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 October 13, 2008 submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Tarka® (trandolopril/verapamil hydrochloride) 2/180, 1/240, 2/240, 4/240 mg ER Tablets.

This "Changes-Being-Effected" supplemental application provides for additional information in the **PRECAUTIONS/Drug Interactions** section of the package insert as requested in our letters dated March 3 and July 22, 2008.

This supplemental new drug application provides for electronic labeling with the following revisions:

1. Under the **PRECAUTIONS/*Drug Interactions*** subsection, the following interactions have been added:

   Clarithromycin

   Hypotension, bradyarrhythmias, and lactic acidosis have been observed in patients receiving concurrent clarithromycin.

   Erythromycin

   Hypotension, bradyarrhythmias, and lactic acidosis have been observed in patients receiving concurrent erythromycin ethylsuccinate.

   Gold: Nitritoid 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 TARKA.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the electronic (SPL) labeling text submitted on October 13, 2008. 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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:

Alisea Crowley, Pharm.D., RAC
Senior Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and 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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