



NDA 20-591/S-011

Abbott Laboratories
Attention: Ms. Nancy P. Aiello
Regulatory Affairs Manager
200 Abbott Park Road
Department PA71/ Bldg. AP30-1E
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your supplemental new drug application dated February 21, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Tarka (trandolapril/verapamil hydrochloride) 2/180 mg, 1/240 mg, 2/240 mg, and 4/240 mg Extended Release Tablets.

This supplemental new drug application provides for standardized drug product labels for Tarka (trandolapril/verapamil hydrochloride) Extended Release Tablets.

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

The final printed labeling (FPL) must be identical to the submitted immediate container and carton labels submitted electronically on February 21, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-591/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

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 Denise Hinton, Regulatory Project Manager, at (301) 796-1090.

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

**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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