DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-489

TEVA Pharmaceuticals USA
Attention: Philip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 27, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Trandolapril Tablets, 1 mg, 2 mg, and 4 mg.

Reference is also made to your amendments dated August 12, 2005; and August 25, November 6, and November 13, 2006. We also acknowledge receipt of your correspondence contained in your August 25, 2006, amendment addressing the patent issues noted below.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Trandolapril Tablets, 1 mg, 2 mg, and 4 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Mavik® Tablets, 1 mg, 2 mg, and 4 mg, respectively, of Abbott Laboratories. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Mavik® Tablets, of Abbott Laboratories (Abbott), is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations(the “Orange Book”), U.S. Patent No. 4,933,361 (the '361 patent) is scheduled to expire on June 12,

2007, and U.S. Patent No. 5,744,496 (the '496 patent) is scheduled to expire on April 28, 2015.

Your ANDA contains a paragraph IV certification to the ‘361 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Trandolapril Tablets, 1 mg, 2 mg, and 4 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against TEVA Pharmaceuticals (TEVA) for infringement of the ‘361 patent that was the subject of the paragraph IV certification. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that Abbott waived their rights to bring suit for infringement against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii). You have also referenced a licensing agreement between TEVA and Abbott allowing TEVA to market this product immediately upon approval of this ANDA.

With respect to the ‘496 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that the ‘496 patent is a method of use patent that does not claim any indication for which you are seeking approval under your ANDA.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
12/12/2006 02:47:37 PM
for Gary Buehler