DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077157

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
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 May 24, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg.

Reference is made to the tentative approval letters issued by this office on June 13, 2006, and October 17, 2007. Also, reference is made to your amendments dated June 10 and July 29, 2005; June 10, 2009; January 14, March 29, and March 31, 2010.

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 Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Hyzaar Tablets, 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg, respectively, of Merck and Co., Inc. (Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Merck’s Hyzaar Tablets, 50 mg/12.5 mg, 100 mg/12.5 mg and 100 mg/25 mg, is subject to a period of patent protection for the 50 mg/12.5 mg and 100 mg/25 mg strengths only. The following patents and

expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,138,069 (the '069 patent)	February 11, 2010
5,153,197 (the '197 patent)	April 6, 2010
5,608,075 (the '075 patent)*	September 4, 2009

*the '075 patent is not listed for the 100 mg/12.5 mg strength

With respect to the '069 and '197 patents, your ANDA contained paragraph III certifications under section 505(j)(2)(A)(vii)(III) of the Act. The agency notes that these patents have expired and are no longer a barrier to approval of your ANDA.

With respect to the '075 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg, under this ANDA. You have notified the agency that TEVA Pharmaceuticals USA (TEVA) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '075 patent was brought 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).

As explained in a separate letter issued today, TEVA is eligible for 180 days of generic drug exclusivity for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg strengths only. This exclusivity is provided for in section 505(j)(5)(B)(iv) of the Act, as amended on December 8, 2003, by the Medicare Prescription Drug, Improvement and Modernization Act. TEVA was the first applicant to submit a substantially complete ANDA with a paragraph IV certification for Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg, and TEVA has lawfully maintained this certification. As provided in section 505(j)(5)(B)(iv)(I), the exclusivity will begin to run from the date of the first commercial marketing of Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5

mg and 100 mg/25 mg (including the first commercial marketing of the listed drug) by any first applicant. Within 10 days of first commercial marketing, please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing of Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg and 100 mg/25 mg. Please also be aware that, under section 505(j)(5)(D), the 180-day exclusivity shall be forfeited by TEVA if a forfeiture event, as described in section 505(j)(5)(D), occurs with respect to TEVA.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. For administrative purposes, please designate this submission as "***Labeling/SPL Final for Approved ANDA 077157***".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77157	ORIG-1	TEVA PHARMACEUTICALS USA	LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

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

04/06/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.