DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-179

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 June 8, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Amlodipine Besylate and Benazepril Hydrochloride Capsules, 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg, and 10 mg (base)/20 mg.

Reference is also made to the tentative approval letter issued by this office on July 11, 2006, and to your amendments dated June 20, 2005, September 28, 2006 and March 22, 2007.

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 Amlodipine Besylate and Benazepril Hydrochloride Capsules, 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg and 10 mg (base)/20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lotrel Capsules 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg, and 10 mg (base)/20 mg of Novartis Pharmaceuticals Corporation (Novartis). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD for your ANDA, Novartis' Lotrel Capsules, 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. 6,162,802 (the '802 patent) expires on December 19, 2017 (the two other patents listed for the RLD have expired).

Your ANDA contains a certification to the '802 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 Amlodipine Besylate and Benazepril Hydrochloride Capsules, 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg and 10 mg (base)/20 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 USA (TEVA) for infringement of the '802 patent prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder(s). You notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '802 patent was initiated against TEVA within the statutory 45-day period in the United States District Court for the District of New Jersey [Novartis Corporation, Novartis Pharmaceuticals Corporation and Novartis International AG v. TEVA Pharmaceuticals USA, Inc., Civil Action No. 04-4473]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that TEVA was the first applicant to submit a substantially complete ANDA for Amlodipine Besylate and Benazepril Hydrochloride Capsules, 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg and 10 mg (base)/20 mg, with a paragraph IV certification to the '802 patent. Therefore, with this approval, the agency has concluded that TEVA is eligible for 180 days of generic drug exclusivity for Amlodipine Besylate and Benazepril Hydrochloride Capsules, 2.5 mg (base)/10 mg, 5 mg (base)/10 mg, 5 mg (base)/20 mg and 10 mg (base)/20 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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 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/

Gary Buehler

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