DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 75-710

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 September 29, 1999, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Alendronate Sodium Tablets USP, 5 mg (base), 10 mg (base), and 40 mg (base) for once-daily dosing and 35 mg (base) and 70 mg (base) for once-weekly dosing.

Reference is also made to the tentative approval letter issued by this office on December 27, 2002, and to your amendments dated December 28, 1999; April 29, 2005; December 12, 2006; October 19, November 20, and December 28, 2007; and January 2, and January 10, 2008.

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 Alendronate Sodium Tablets USP, 5 mg (base), 10 mg (base), 35 mg (base), 40 mg (base) and 70 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Fosamax Tablets, 5 mg (base), 10 mg (base), 35 mg (base), 40 mg (base) and 70 mg (base), 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 ANDA.

The RLD upon which you have based your ANDA, Merck's Fosamax Tablets, is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
4,621,077 (the '077 patent)	February 6, 2008*
5,358,941 (the '941 patent)	June 2, 2013*
5,681,590 (the '590 patent)	June 2, 2013*
5,849,726 (the '726 patent)	December 6, 2015*
5,994,329 (the '329 patent)	January 17, 2019*
6,008,207 (the '207 patent)	December 6, 2015*
6,015,801 (the '801 patent)	January 17, 2019*
6,090,410 (the '410 patent)	June 2, 2013*
6,225,294 (the '294 patent)	January 17, 2019*
6,194,004 (the '004 patent)	June 2, 2013*

* with pediatric exclusivity

To each of these 10 patents your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Alendronate Sodium Tablets USP, 5 mg (base), 10 mg (base), 35 mg (base), 40 mg (base) and 70 mg (base), 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 one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against TEVA 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 have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '004 patent was brought against TEVA within the statutory 45-day period, but litigation was initiated against TEVA for infringement of the other nine patents[1] in the United States District Court for the District of Delaware [Merck & Co., Inc. v. TEVA Pharmaceuticals USA, Inc., Civil Action Nos. 00-035, 01-675 and 01-728]. You have also notified the agency that the district court upheld the '077 and '329 patents and dismissed the cases with respect to the other seven patents. TEVA

[1] The actions for infringement of the '329, '801, and '294 patents pertained only to the 35 mg and 70 mg strengths.

appealed the ruling on the '329 patent to the United States Court of Appeals for the Federal Circuit [Merck & Co., Inc. v. TEVA Pharmaceuticals USA, Inc., No. 04-1005]. You have notified the agency that the Court of Appeals held the '329 patent to be invalid, unenforceable, or not infringed. Because the pediatric exclusivity period attaching to the'077 patent expired on February 6, 2008, under section 505(j)(5)(B)(iii) of the Act your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that TEVA was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the '077, '941, '590, '726, '329, '207, '801, and '410 patents. Therefore, with this approval, TEVA is eligible for 180 days of generic drug exclusivity for Alendronate Sodium Tablets USP, 5 mg (base), 10 mg (base), 35 mg (base), and 40 mg (base). With respect to Alendronate Sodium Tablets USP, 70 mg (base), TEVA will share 180-day generic exclusivity with Barr Laboratories Inc. (Barr) because Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '294 patent. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] 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

[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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 2070

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
2/6/2008 07:24:15 AM
for Gary Buehler