DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-132

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 April 22, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Risedronate Sodium Tablets, 5 mg, 30 mg, and 35 mg.

Reference is made to the tentative approval letter issued by this office on August 11, 2005, and to your amendments dated April 18, 2005; August 24, 2006; and February 2, February 26, August 2, August 27, and August 30, 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 Risedronate Sodium Tablets, 5 mg, 30 mg, and 35 mg, to be bioequivalent and therefore, therapeutically equivalent to the reference listed drug (RLD), Actonel Tablets, 5 mg, 30 mg, and 35 mg, respectively, of Procter & Gamble Pharmaceuticals, Inc. (P&G). 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, P&G's Actonel Tablets, is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number		Expiration Date
5,583,122	(the ‘122 patent)	December 10, 2013
5,994,329*	(the ‘329 patent)	July 17, 2018
6,015,801*	(the ‘801 patent)	July 17, 2018
6,096,342	(the ‘342 patent)	November 22, 2011
6,165,513	(the ‘513 patent)	June 10, 2018
6,432,932*	(the ‘932 patent)	July 17, 2018
6,465,443*	(the ‘443 patent)	August 14, 2018

*35 mg strength only

FDA has determined that information on the '932 and ‘443 patents was submitted to FDA by the NDA holder after the date of the submission of your ANDA. FDA has also determined that information on the '932 and ‘443 patents was submitted by the NDA holder more than 30 days after the patent was issued by the U.S. Patent and Trademark Office (PTO). Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission of the patents was required to submit an amended patent certification to address the '932 and ‘443 patents. You elected not to submit an amended patent certification with respect to these patents.

With respect to the remaining patents, your ANDA contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the ‘122, ‘329, ‘801, ‘342 and ‘513 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Risedronate Sodium Tablets, 5 mg, 30 mg, and 35 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 one or more of these patents that were the subjects of 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) 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 litigation for infringement was brought against TEVA in the United States District Court for the District of Delaware. This involved the ‘122 and ‘342 patents [Procter & Gamble Company v. TEVA Pharmaceuticals USA, Civil Action No. 04-CV-940] and the ‘329, ‘932 and ‘443 patents [Merck & Company, Inc. v. TEVA Pharmaceuticals USA, Civil Action No. 04-CV-939]. With respect to this litigation, the agency recognizes that the 30-month period identified in section

505(j)(5)(B)(iii) of the Act,[1] during which time FDA was precluded from approving your application, has expired.

With respect to portions of the '122 patent, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that its associated use (U-756) is not claimed in any of the indications for which you are seeking approval under this ANDA.

With regard to 180-day generic drug exclusivity and Risedronate Sodium Tablets, 5 mg, 30 mg, and 35 mg, the agency has determined that TEVA was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the ‘122, ‘329, ‘801, ‘342 and ‘513 patents. Therefore, with this approval, TEVA is eligible for 180 days of generic drug exclusivity for Risedronate Sodium Tablets, 5 mg, 30 mg, and 35 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 commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this application 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.

Post-marketing 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:

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[1] Because information on the patents was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

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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