DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-511

TEVA Pharmaceuticals, USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatoy 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 October 7, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Finasteride Tablets USP, 5 mg.

Reference is also made to the tentative approval letter issued by this office on October 26, 2004, and to your amendments dated June 20, September 15, December 6, December 12 and December 13, 2006.

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 Finasteride Tablets USP, 5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Proscar Tablets, 5 mg, of Merck & 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 Proscar Tablets, 5 mg, is subject to periods of patent protection. The following unexpired 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
5,886,184 (the '184 patent)	November 19, 2012
5,942,519 (the '519 patent)	October 23, 2018
6,046,183 (the '183 patent)	March 20, 2011

With respect to the '183 and '519 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these represent a method of use patents that do not claim any of the indications for which you are seeking approval.

With respect to the '184 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 Finasteride Tablets USP, 5 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 '184 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 no action for infringement of the '184 patent was brought against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii). Furthermore, you have provided documentation that IVAX Pharmaceuticals, Inc. has provided a selective waiver of the remainder of its 180-day generic drug exclusivity for this drug product 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.

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/

Robert L. West
12/15/2006 03:06:01 PM
for Gary Buehler