

JUN 19 2006

IVAX Pharmaceuticals, Inc.  
Attention: Patricia Jaworski  
Director, Regulatory Affairs  
125 Wells Avenue  
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 2, 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 our tentative approval letter dated January 7, 2005, and to your amendments dated September 20, 2002, and March 17, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Finasteride Tablets USP, 5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, 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 application.

The reference listed drug (RLD) upon which you have based your ANDA, Merck's Proscar Tablets, 5 mg, is subject to periods of patent protection. 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") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,942,519 (the '519 patent)	October 23, 2018
6,046,183 (the '183 patent)	March 20, 2011
5,886,184 (the '184 patent)	November 19, 2012
4,760,071 (the '071 patent)	June 19, 2006

With respect to the '519 and '183 patents, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, and that they do not claim any indication 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 the '184 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 action was brought against IVAX Pharmaceuticals, Inc. (IVAX) for infringement of the '184 patents that was the subject of paragraph IV certification. You have notified the agency that IVAX 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 IVAX 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).

With respect to the '071 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of this patent. This ANDA may be approved upon the expiration of the '071 patent on June 19, 2006.

With respect to 180-day generic drug exclusivity, the agency has determined that IVAX was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '184 patent. Therefore, with this approval IVAX is eligible for 180 days of generic drug exclusivity for Finasteride Tablets USP, 5 mg. 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). 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.

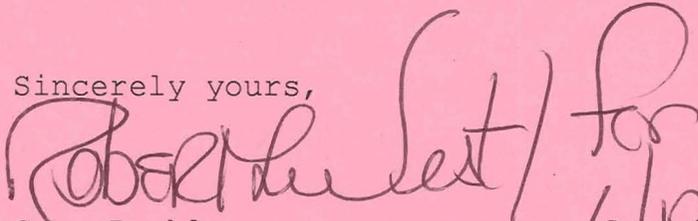
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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(s) 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,

 for  
6/19/2006

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

cc: ANDA 76-340  
Division File  
Field Copy  
HFD-610/R. West  
HFD-013

Endorsements:

HFD-630/N.Takiar *N. Takiar 5/30/06*  
HFD-630/H.Khorshidi *H. Khorshidi 5/31/06*  
HFD-617/J.Skanchy *JS Skanchy 5/31/06*  
HFD-613/P.Birch via email  
HFD-613/J.Grace via email

Approved Electronic Labeling Located at:

\\Cdsesub1\n76340\N\_000\2006-03-17\labeling\contain.pdf

\\Cdsesub1\n76340\N\_000\2006-03-17\labeling\pi.pdf

\\Cdsesub1\n76340\N\_000\2006-03-17\labeling\ppi.pdf

V:\FIRMSAM\IVAXPharm\LTRS&REV\76340ap.doc

F/T by: JS/5/30/06

APPROVAL

*come Sabre factory  
Alayp Kayu  
6/5/06.*

*Robert West  
6/6/2006*