DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090061

InvaGen Pharmaceuticals Inc.
U.S. Agent for Hetero Drugs Limited, Unit III
Attention: Sudhakar Rao Vidiyala, Ph.D.
President
7 Oser Avenue
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 3, 2007, 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 your amendments dated March 21, and December 23, 2008; April 9, and November 13, 2009; and April 23, and May 7, 2010.

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 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 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
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 '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 Hetero Drugs Limited Unit III (Hetero) for infringement of the listed '184 patent. This action must have been brought against Hetero 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 Hetero complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Hetero 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).[1]

With respect to the '519 and '183 patents, your ANDA contains statements 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 proposed indication for which you are seeking approval under your ANDA.

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.

We note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug will also be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA application 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.

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[1]Because information on the '184 patent was/were submitted to FDA before August 18, 2003, this is 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).

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. For administrative purposes, please designate this submission as "***LABELING/SPL FINAL for Approved ANDA 090061***".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90061	ORIG-1	HETERO DRUGS LTD UNIT III	FINASTERIDE

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
06/07/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.