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APPLICATION NUMBER:

ANDA 090095

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090095

Barr Laboratories, Inc.
Attention: Robert S. Vincent
Director, Regulatory Affairs
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 26, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dutasteride Capsules, 0.5 mg.

Reference is also made to your amendments dated June 2, and September 22, 2008; January 15, and February 1, 2009; and March 12, April 20, April 21, August 6, and August 27, 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 Dutasteride Capsules, 0.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Avodart Capsules, 0.5 mg, of GlaxoSmithKline (GSK). 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, GSK's Avodart Capsules, 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
5,565,467 (the '467 patent)	November 20, 2015
5,846,976 (the '976 patent)	September 17, 2013
5,998,427 (the '427 patent)	September 17, 2013

With respect to each of these patents, your ANDA contains paragraph IV certifications 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 Dutasteride Capsules, 0.5 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 Barr Laboratories, Inc. (Barr) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the three patents was brought against Barr within the statutory 45-day period in the United States District Court for the District of Delaware [SmithKline Beecham Corporation d/b/a GlaxoSmithKline v. Barr Laboratories, Inc., Civil Action No. 08-112]. This case was dismissed on May 10, 2010, by agreement of the parties.

With respect to 180-day generic drug exclusivity, we note that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Dutasteride Capsules, 0.5 mg. Therefore, with this approval, Barr may be eligible for 180 days of generic drug exclusivity for Dutasteride Capsules, 0.5 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Barr failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV)(forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Barr’s eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Barr begins commercial marketing of Dutasteride Capsules, 0.5 mg, or (b) at any time prior to the expiration of the last listed patent if Barr has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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.

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

Postmarketing reporting requirements 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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U CM072392.pdf The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

12/21/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.