DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-436

JUL 28 2006

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Director, Global Regulatory Affairs and Compliance
200 Somerset Corporate Blvd, 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 18, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Finasteride Tablets USP, 1 mg.

Reference is also made to our tentative approval letter dated October 14, 2004, and to your amendments dated April 25, 2003, and May 18, June 28, and July 13, 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, 1 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Propecia® Tablets, 1 mg, of Merck Research Laboratories (Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The referenced listed drug (RLD) upon which you have based your ANDA, Merck's Propecia® Tablets, 1 mg, is subject to multiple 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.S. Patent Number	Expiration Date
4,760,071 (the '071 patent)	June 19, 2006
5,547,957 (the '957 patent)	October 15, 2013
5,571,817 (the '817 patent)	November 5, 2013
5,886,184 (the '184 patent)	November 19, 2012

Your ANDA contains paragraph IV certifications to the '957, '817, and '184 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Finasteride Tablets USP, 1 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 Dr Reddy's Laboratories Limited (Dr Reddy's) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against Dr Reddy's 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 Dr Reddy's complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Dr Reddy's within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

Your application also contains a paragraph III certification to the '071 patent under Section 505(j)(2) (A)(vii)(III) of the Act. This patent, which previously blocked approval of your ANDA, expired on June 19, 2006.

With respect to 180-day generic drug exclusivity, the agency has determined that Dr Reddy's was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '957, '817, and '184 patents. Therefore, with this approval, Dr Reddy's is eligible for 180-days of generic drug exclusivity for Finasteride Tablets USP, 1 mg with respect to each of these patents. 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).

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[1]Because information on the '957, '817, and '184 patents 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).

Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.[2]

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 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.

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,

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

[2] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).