DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-390

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories Ltd.
Attention: Kumar Sekar, Ph.D.
Director – Global Regulatory Affairs and Compliance
200 Somerset Corporate Blvd.
Bridgerwater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 28, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Terbinafine Hydrochloride Tablets, 250 mg (base).

Reference is also made to the tentative approval letter issued by this office on December 19, 2003, and to your amendments dated July 2, and September 9, 2002; and September 15, October 4, December 5, 2006; and April 3, May 15, and June 20, 2007.

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 the date of this letter. The Division of Bioequivalence has determined your Terbinafine Hydrochloride Tablets, 250 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Lamisil Tablets, 250 mg (base) of Novartis Pharmaceutical Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

We remind you of your commitment specified in your amendment dated June 25, 2007. To alert the Office of Generic Drugs staff that you are submitting information to address the post-approval commitment, please state “Post- Approval Commitment Response” at the top of your cover letter.

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/

Gary Buehler

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