

ANDA 77-091



OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

APPLICANT: Dr. Reddy's Laboratories Inc.,
U.S. Agent for Dr. Reddy's Laboratories Limited
ATTN: Kumara Sekar

TEL: 908-203-4937

FAX: 908-203-4980

FROM: Peter Chen

PROJECT MANAGER: (301) 827-5773

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated March 17, 2005⁴, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Glimepiride Tablets, 1 mg, 2 mg, and 4 mg.

We are pleased to inform you that this application is APPROVED!

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ANDA 77-091

Food and Drug Administration
Rockville MD 20857

OCT 6 2005

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 17, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Glimepiride Tablets, 1 mg, 2 mg, and 4 mg.

Reference is also made to the tentative approval letter issued by this office on August 18, 2005; and to your amendments dated March 31, June 8, June 10, September 6, and September 23, 2005.

The listed drug product (RLD) referenced in your application, Amaryl Tablets of Aventis Pharmaceuticals Inc., has been subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,379,785 (the '785) expired on October 6, 2005 (pediatric extension).

With the expiration of the '785 patent, we have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Glimepiride Tablets, 1 mg, 2 mg, and 4 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Amaryl Tablets, 1 mg, 2 mg, and 4 mg, respectively, of Aventis Pharmaceuticals Inc.). 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 abbreviated application require an approved supplemental application before the change may be made.


Postmarketing reporting requirements for this abbreviated 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 (HFD-42) 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