



ANDA 76-802

Food and Drug Administration
Rockville MD 20857

001 6 2005

TEVA Pharmaceuticals USA
Attention: Philip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 21, 2003, 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 made to the tentative approval letter issued by this office on July 27, 2005, and to your amendments dated June 25, 2004; and August 17, 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 patent) expired on October 6, 2005 (with 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
Division of Drug Marketing, Advertising, and Communications,
5901-B Ammendale Road
Beltsville, MD 20705-1266

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