

OCT 6 2005

Ranbaxy Inc.
Attention: Abha Pant
U.S. Agent for: Ranbaxy Laboratories Limited
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 20, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Glimepiride Tablets, 1 mg, 2 mg, 4 mg, and 8 mg.

Reference is also made to the tentative approval letter issued by this office on July 20, 2005, and to your amendments dated August 11, September 13, and November 19, 2004; and August 25, 2005. Reference is also made the ANDA Suitability Petition filed on October 6, 2003. This petition requested the agency to make a determination that your application to include Glimepiride Tablets 8 mg was suitable for filing as an ANDA. This determination was necessary because the 8 mg strength of the drug product proposed in your ANDA differs from those of the reference listed drug product; e.g., 8 mg v. 1 mg, 2 mg, and 4 mg. The agency has determined that the additional tablet strength you have requested (8 mg) is the type of change that is authorized under the Act.

The listed drug product (RLD) referenced in your application 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, 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. The Division of Bioequivalence has also determined that your Glimepiride Tablets 8 mg can be expected to have the same therapeutic effect as that of the reference listed product which the agency relied upon for basis of safety and effectiveness. 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 Amundale 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