

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 November 5, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Glimepiride Tablets, 3 mg and 6 mg.

Reference is also made to the tentative approval letter issued by this office on July 27, 2005, and to your amendments dated February 11, March 1, and August 25, 2005. Reference is also made to the ANDA Suitability Petition (04P-0123/CP1) filed on March 10, 2004, and approved on July 7, 2004. This petition requested the agency to make a determination that your application for Glimepiride Tablets 3 mg and 6 mg is suitable for filing as an ANDA. This determination is necessary because the strengths of the drug product proposed in your ANDA differ from those of the reference listed drug product; e.g., 3 mg and 6 mg v. 1 mg, 2 mg, and 4 mg. The agency has determined that the change in tablet strengths you have requested 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, 3 mg and 6 mg, to be bioequivalent and therapeutically

equivalent to the listed drug product that the agency have relied upon for basis of safety and efficacy. 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 10/6/05
Director
Office of Generic Drugs
Center for Drug Evaluation and Research