

ANDA 75-439

April 19, 2000

Ranbaxy Pharmaceuticals, Inc.
U.S. Agent for: Ranbaxy Laboratories, Ltd.
Attention: Shirley Ternyik
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application dated August 14, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ranitidine Tablets USP, 150 mg and 300 mg.

Reference is also made to your amendments dated September 21, and November 10, 1998; January 7, July 12 and October 6, 1999; and March 3, 2000.

The listed drug referenced in your application, Zantac Tablets of Glaxo Wellcome Inc., is subject to periods of patent protection which expire on December 4, 2002 (U.S. Patent No. 4,521,431) and November 13, 2008 (U.S. Patent No. 4,880,636). Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, sale, or offer to sell this drug product will not infringe on either of these patents. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent(s) which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the agency that Ranbaxy Laboratories Ltd. (Ranbaxy) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Ranbaxy within the statutory forty-five day period.

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 Ranitidine Tablets USP, 150 mg and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zantac Tablets, 150 mg and 300 mg, of Glaxo Wellcome 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.

Post-marketing 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research