ANDA 75-254

Ranbaxy Pharmaceuticals, Inc.
Attention: Shirley Terynik
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application dated November 14, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ranitidine Tablets USP, 75 mg (OTC).

Reference is also made to our Tentative Approval letter dated March 10, 1999, and to your amendment dated November 15, 1999.

The listed drug product (RLD) referenced in your application, Zantac-75 Tablets of Warner Lambert Company, is subject to periods of patent protection which expire on December 4, 2002 (U.S. patent 4,521,431 [the '431 patent] and November 13, 2008 (U.S. patent 4,880,636 [the '636 patent]), respectively. Your application contains patent certifications to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on either patent. 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 patents 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 Pharmaceuticals, Inc. (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. In addition, the RLD upon which you based your application was also subject to a period of market exclusivity that was extended until June

19, 1999 under Section 111 of the Food and Drug Administration Modernization Act [21 U.S.C. 355a (1997)].

Furthermore, the Act provides that approval of an abbreviated application that contains a certification described in Section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), and that is for a drug product for which a previous abbreviated application has been submitted which also contains a Paragraph IV Certification, shall be made effective not earlier than one hundred and eighty days after:

1. the date the Secretary receives notice of the first commercial marketing of the drug product under the previous application, or

2. the date of a final decision of a court holding the patent(s) which is the subject of the certification to be invalid or not infringed, whichever event occurs first {Section 505(j)(5)(B)(iv)}.

As noted in the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), an abbreviated new drug application for this drug product was approved for Novopharm, Inc. (Novopharm) on June 21, 1999. This application also contained a Paragraph IV Certification and was the first application received by the Agency for this drug product. Consequently, Novopharm became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", Novopharm's market exclusivity expired on January 14, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for Over-the-Counter (OTC) use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ranitidine Tablets USP, 75 mg, to be bioequivalent to the listed drug (Zantac**7** 75 Tablets of Warner Lambert Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, 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.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research