ANDA 75-294 March 28, 2000

Reddy-Cheminor, Inc.
Attention: Paul V. Campanelli
U.S. Agent for: Cheminor Drugs, Ltd.
66 South Maple Avenue
Ridgewood, NJ 07450

Dear Sir:

This is in reference to your abbreviated new drug application dated December 29, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Tablets USP, 75 mg (OTC).

Reference is also made to your amendments dated April 9, 1998; and January 14, and February 16, 2000.

The listed drug product (RLD) referenced in your application, Zantac-75 Tablets of Glaxo Wellcome Inc., 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 Cheminor Drugs Ltd. (Cheminor) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Cheminor within the statutory forty-five day period. It should be noted that the RLD upon which you based your application was also subject to a period of market exclusivity granted under Section 111 of Title I of the Food and Drug Modernization Act of 1997 (FDAMA) that expired on June 19, 1999. In

addition, Novopharm Ltd. was granted 180 days of generic drug exclusivity under Section 505(j)(5)(B)(iv) for this drug product which 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 use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ranitidine Tablets, 75 mg to be bioequivalent to the listed drug
(Zantac-75 Tablets of Warner Lambert Company). 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.

Sincerely yours,

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