ANDA 75-742 November 29, 2000

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

Dear Sir:

This is in reference to your abbreviated new drug application dated December 1, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Hydrochloride Capsules, 150 mg (base) and 300 mg (base).

Reference is also made to your amendments dated May 23, June 6, July 13, July 24 and August 16, 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 labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ranitidine Hydrochloride Capsules, 150 mg and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zantac-150 GELdose Capsules and Zantac-300 GELdose Capsules, respectively, 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.

The reference listed drug product (RLD) upon which you have based your application, Zantac GELdose Capsules 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 August 22, 2010 (U.S. Patent No. 5,028,432). Your application contains patent certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act. 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 which is the subject of the certification before the expiration of forty-five days from the

date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Cheminor Drugs Limited (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.

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