ANDA 75-294 Janaury 29, 1999

Reddy-Cheminor, Inc.
Attention: Paul V. Campanelli
U.S. Agent for: Cheminor Drugs Ltd.-Pharma Division
66 South Maple Avenue
Ridgewood, New Jersey 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.

Reference is also made to your amendments dated February 5, April 9, June 3, July 29 and November 13, 1998; and January 28, 1999.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture testing of the drug product), and is therefore subject to change on the basis of new information that may come to our attention.

The listed drug product referenced in your application is subject to periods of patent protection which expire on December 4, 2002, (patent 4,521,431 [the '431 patent]), and November 13, 2008 (patent 4,880,636 [the '636 patent]), respectively. Your application contains patent certifications 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 of these patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought 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 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.

In addition, the reference listed drug product upon which you have based your application is subject to a period of market exclusivity. As noted in the current edition of the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", this period was scheduled to expire on December 19, 1998. However, this period has been extended under Section 111 of the Food and Drug Administration Modernization Act (21 U.S.C. 355a (1997) for an additional six months until June 19, 1999.

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 under the previous application, or

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

An abbreviated application for Ranitidine Tablets USP, 75 mg, containing a Paragraph IV Certification was previously accepted for filing by this office prior to the receipt of your application. Accordingly, your application will be eligible for final approval beginning on the date that is one hundred and eighty (180) days after the first commercial marketing of the drug under the previous application, or the date of a court decision described under section 505(j)(5)(B)(iv), whichever is earlier. We refer you to the Agency’s recently issued guidance document entitled “180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments” (June 1998), for additional information.

Because the Agency is granting a tentative approval for this application, before your application may be considered for final approval you must amend your application at least 60, but not more than 90 days prior to the date you believe the Agency may

approve your application. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing and controls data as appropriate. Alternatively, an amendment should be submitted stating that no such changes have been made to the application since the date of tentative approval. This submission should be designated as a MINOR amendment in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may at any time prior to the final date of approval request that you submit an amendment containing the information described above.

Any changes in the conditions outlined in this abbreviated application or the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

Failure to submit amendments as requested above may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The introduction or delivery for introduction of this drug product into interstate commerce before the effective date of approval is prohibited under 21 U.S.C. 331(d).

Prior to submitting the amendment(s), please contact Kassandra Sherrod, Project Manager, at (301) 827–5849, for further instructions.

Sincerely yours,

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