ANDA 75-758 December 13, 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 22, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg.

Reference is made to your amendments dated March 21, June 30, August 23, and September 8, 2000.

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 and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Pepcid-AC Tablets of Merck Research Laboratories (Merck), is subject to a periods of patent protection which are currently set to expire on April 15, 2001 (U.S. Patent No. 4,283,408), November 2, 2015 (U.S. Patent No. 5,667,794), and June 29, 2016 (U.S. Patent No. 5,854,267). Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, offer for sale within the United States, or importation into the United

States of this drug product will not infringe on either the ‘794 or ‘267 patents or that these patents are invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug 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 the agency that Cheminor Drugs Limited (Cheminor) 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, your application contains a Paragraph III Certification to the ‘408 patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiry of this patent. Please note that the ‘408 patent was scheduled to expire on October 15, 2000. However, as noted in the current edition of the Agency’s publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations”, the “Orange Book”, the expiration of this patent (as well as for the other two patents noted above) has effectively been extended until April 15, 2001. Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) created section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits the holder of the new drug application (NDA) for the RLD to obtain an additional six months of marketing exclusivity (pediatric exclusivity). To be awarded this exclusivity, the NDA holder must abide by the terms of the statute and submit data previously requested by the agency relating to the use of the drug product in the pediatric population. Merck has submitted data to the agency to support the use of famotidine in the pediatric population. The agency’s Pediatric Exclusivity Board has reviewed the data. As a result, the agency has awarded Merck 6-months of pediatric exclusivity. Therefore, final approval of your application may not be made effective until the expiration of the ‘408 patent which is currently set to expire on April 15, 2001.

Because the agency is granting a tentative approval to this application, please submit an amendment at least 60 days (but not more than 90 days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the

conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and/or controls data as appropriate. An amendment should be submitted even if none of these changes were made. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either, or if requested both amendments may result in rescission of the tentative approval status of your application, may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to agency review before final approval of the application will be made.

If you have questions concerning the status of this application, please contact Kassandra Sherrod, R.Ph., Project Manager, at (301) 827-5849.

Sincerely yours,

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