

ANDA 75-718
2000

November 29,

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 October 8, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 20 mg and 40 mg.

Reference is made to our tentative approval letter dated July 27, 2000, and to your amendment dated August 7, 2000.

Our July 27, 2000 tentative approval letter informed you that final approval of this application could not be made effective pursuant to 21 U.S.C. 355 (j)(5)(B)(ii) of the Act until U.S. Patent No. 4,283,408 had expired. This patent was issued to the holder of the reference listed drug product (RLD), Pepcid Tablets of Merck Research Laboratories. As noted in the current edition of the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", this period was scheduled to expire on October 15, 2000. However, 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 an additional 6-months of pediatric exclusivity. This additional 6-months will effectively extend

the expiration of the '408 patent until April 15, 2001. Therefore, final approval of this application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(D) of the Act until April 15, 2001.

We refer you to the three paragraphs on page 2 of our July 27, 2000, tentative approval letter regarding reactivation of this application in anticipation of final approval. The comments provided therein remain current. The actions requested of you in the first paragraph should be addressed when requesting final approval.

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

