ANDA 75-488 December 20, 2000

ESI Lederle
Attention: J. Barton Kalis
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Sir:

This is in reference to your abbreviated new drug application dated October 30, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Injection, 10 mg/mL, (Preserved), packaged in 4 mL and 20 mL multiple-dose vials.

Reference is made to your amendments dated November 10, November 28, and December 6, 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 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). The 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 Injection of Merck Research Laboratories (Merck), is subject to a period of patent protection (U.S. Patent No. 4,283,408). Your application contains a Paragraph III Certification to this patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to patent expiry. This 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 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 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