ANDA 75-709 February 28, 2001

American Pharmaceutical Partners, Inc.
Attention: Lincy Michael
2045 North Cornell Avenue
Melrose Park, IL 60160-1002

Dear Madam:

This is in reference to your abbreviated new drug application dated September 27, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Injection, 10 mg/mL, supplied in 4 mL and 20 mL Multiple-dose vials.

Reference is made to your amendments dated January 12, and January 30, 2001.

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 (CGMP) of the facilities used in the manufacture and testing of the drug product). Please note that this decision 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, 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. Therefore, final approval of this application may not be made effective pursuant to 21 U.S.C. 355 (j)(5)(B)(ii) of the Act until this patent has expires, i.e., currently April 15, 2001.

Because the agency is granting a tentative approval to this application, please submit an amendment at least 60 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. In order to reactivate your application prior to final approval, 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 amendment may result in rescission of the tentative approval status of your application, or 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.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 311(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there is a basis for issuing the final approval letter prior to April 15, 2001, you should amend your application accordingly.

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