ANDA 75-400 March 25, 2002

L. Perrigo Company
Attention: Brian R. Schuster
515 Eastern Avenue
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 18, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg (OTC).

Reference is also made to your amendments dated April 29, 1999; September 26, and November 7, 2000; October 25, 2001; and January 9, January 14, January 29, March 11, and March 15, 2002.

The listed drug product referenced in your application, Pepcid AC Tablets of Merck Research Laboratories, is subject to periods of patent protection which expire on November 2, 2015 [U.S. Patent No. 5,667,794 (the '794 patent)], and June 29, 2016 [U.S. Patent No. 5,854,267 (the '267 patent)]. Your application contains Paragraph IV Certifications to both the '794 and '267 patents 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 patent, or that the patents are invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of one or more of the patents which are the subject of the certifications 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 L. Perrigo Company (Perrigo) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Perrigo within the statutory forty-five day period.

However, we are unable to grant final approval to your application at this time because Danbury Pharmacal Inc.'s (Danbury) ANDA for the same drug product (Famotidine Tablets USP, 10 mg) contained Paragraph IV Certifications to both patents, including the '267 patent for the "prevention" indication and was accepted for filing by this office prior to the filing of your application. Danbury's application was approved on November 28, 2001. Upon approval, Danbury became eligible for 180-days of generic drug market exclusivity for the "prevention" indication [21 CFR 314.107(c)]. Consequently, your application is **tentatively** approved and will be eligible for final approval beginning one hundred and eighty (180) days after the first commercial marketing of the product approved under Danbury's ANDA. We refer you to the Agency's guidance document entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments" (June 1998) for additional information.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

In order to reactivate your application prior to final approval, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED between 60 to 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. This 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 – FINAL APPROVAL REQUESTED. 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 Nicole Park, Pharm.D., Project Manager, at (301) 827-5849.

Sincerely yours,

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