DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-355

Perrigo R&D Company
Attention: Valerie Gallagher
Associate Director, Regulatory Affairs
515 Eastern Avenue
Allegan, MI 49010

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 29, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC).

Reference is also made to your amendments dated February 3, March 10, April 14, and December 9, 2005, February 14, May 30, June 27, September 22, and December 5, 2006, February 19, March 22, June 8, and October 19, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly, the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pepcid Complete of Merck & Co., Inc. Merck). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Merck's Pepcid Complete, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,229,137 (the '137 patent)	November 16, 2012
5,817,340 (the '340 patent)	June 1, 2013
5,989,588 (the '588 patent)	March 30, 2016

With respect to all three patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets, under this ANDA. 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 against Perrigo R&D Company (Perrigo) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against Perrigo prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Perrigo complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Perrigo for infringement of the '340 patent within the statutory 45-day period in the United States District Court for the Southern District Court of New York [McNeil-PPC, Inc v. Perrigo Company, Civil Action No. 05-1321]. The 30-month period described in section 505(j)(2)(B), during which the agency could not approve your ANDA, expired in June 2007. You also have notified the agency that the court decided that the '340 patent is invalid. The order of the court was issued on July 3, 2007. You have informed us that this decision has been appealed.

With respect to 180-day generic drug exclusivity for Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC), Perrigo was the first ANDA applicant to submit a substantially complete ANDA for Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC), with paragraph IV certifications to the '137, '340, and '588 patents. Therefore, with this approval, Perrigo may be eligible for 180 days of generic drug exclusivity for Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC). Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the Agency of the date commercial marketing begins. The agency notes that

Perrigo failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Perrigo's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Perrigo begins commercial marketing of Famotidine 10 mg, Calcium Carbonate 800 mg, and Magnesium Hydroxide 165 mg, Chewable Tablets (OTC).

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
2/6/2008 02:22:53 PM
for Gary Buehler