DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-351

SEP 25 2006

Perrigo R&D Company
Attention: Vallerie Gallagher
Manager, 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 Tablets USP, 20 mg (OTC).

Reference is also made to the tentative approval letter issued by this office on September 9, 2005, and your amendments dated February 7, 2005; and July 7, and August 17, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate 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 Tablets USP, 20 mg, (OTC), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Pepcid AC Tablets, 20 mg (OTC), of Merck Research Laboratories. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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,

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