

June 19, 1998

L. Perrigo Company
Attention: Brian R. Schuster
117 Water Street
Allegan, MI 49010



Dear Sir:

This is in reference to your abbreviated new drug application dated October 3, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Cimetidine Tablets USP, 100 mg.

Reference is also made to your amendments dated November 13 and December 10, 1997 and May 11 and 26, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Cimetidine Tablets USP, 100 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Tagamet® HB, 100 mg of SmithKline Beecham Consumer Healthcare). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application 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,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research