ANDA 75-122 June 19, 1998

Lek USA, Inc.
Attention: Andrej Gasperlin
U.S. Agent for: Lek, Pharmaceutical and Chemical Company d.d.
333 Sylvan Avenue
Englewood Cliffs, NJ 07632

Dear Sir:

This is in reference to your abbreviated new drug application dated April 10, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Cimetidine Tablets USP, 100 mg and 200 mg.

Reference is also made to your amendment dated June 3, 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 Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Cimetidine Tablets USP, 100 mg and 200 mg to be bioequivalent to the listed drug (Tagamet HB, 100 mg and 200 mg of Smith Kline Beecham Pharmaceuticals). 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