ANDA 75-296 January 14, 2000

Zenith Goldline Pharmaceuticals, Inc.
Attention: Jason A. Gross, Pharm.D.
140 Legrand Ave.
Northvale, NJ 07647

Dear Sir:

This is in reference to your abbreviated new drug application dated December 29, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Tablets USP, 75 mg.

Reference is also made to your amendment dated November 1, 1999.

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 Ranitidine Tablets USP, 75 mg to be bioequivalent to the listed drug (Zantac Tablets, 75 mg of Glaxo Wellcome, Inc.). 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 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