ANDA 75-564 October 27, 2000

King & Spalding
U.S. Agent for: Genpharm Inc.
Attention: Eugene Pfeifer
1730 Pennsylvania Ave., N.W.
Washington, DC 20006-4706

Dear Sir:

This is in reference to your abbreviated new drug application dated January 4, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Capsules, 150 mg and 300 mg.

Reference is also made to your amendments dated March 17, 1999; and February 15, August 15, September 25, and September 29, 2000.

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 Ranitidine Capsules, 150 mg and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zantac® GELdose Capsules, 150 mg and 300 mg, respectively, 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.

The listed drug referenced in your application, Zantac GELdose Capsules of Glaxo Wellcome, Inc., is subject to periods of patent protection which expire on December 4, 2002 (U.S. Patent No. 4,521,431 and August 22, 2010 (U.S. Patent No. 5,028,432). Your application contains certifications to these patents under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of a certification before the expiration of forty-five days from the date the

notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Genpharm Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Genpharm Inc. within the statutory forty-five day period.

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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies that may be identified.

Sincerely yours,

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