ANDA 75-945 November 8, 2002

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

Dear Sir:

This is in reference to Genpharm Inc.'s abbreviated new drug application (ANDA) dated August 21, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Amnesteem™ Capsules (Isotretinoin Capsules USP), 10 mg, 20 mg, and 40 mg.

Reference is also made to your amendments dated March 21, June 14, August 1, and December 14, 2001; and February 12, February 19, February 20, March 4, April 2, April 12, May 8, June 13, June 20, July 23, and November 8, 2002.

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 Amnesteem™ Capsules 10 mg, 20 mg, and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Accutane® Capsules, 10 mg, 20 mg, and 40 mg, respectively of HLR Technology). Your dissolution testing method is acceptable as an "interim" dissolution method until the USP dissolution method is published. Your dissolution testing should be incorporated into the stability and quality control program using the same "interim" 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.

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.

Sincerely yours,

/S/

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