ANDA 75-213 (0.1%)
75-264 (0.025%)
75-265 (0.05%)

December 24, 1998

Spear Pharmaceuticals
Attention: Kim L. Spear, M.D.
13100 Ponderosa Way
Fort Myers, FL 33907

Dear Dr. Spear:

This is in reference to your abbreviated new drug applications dated September 21, 1997 (ANDA 75-213) and December 2, 1997 (ANDAs 75-264 and 75-265), submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Tretinoin Cream USP 0.025%, 0.05%, and 0.1%.

Reference is also made to your amendments submitted individually to each application dated April 29, September 14, September 28, October 14, and November 13, 1998.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Tretinoin Cream USP 0.025%, 0.05%, and 0.1%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drugs (Retin-A Cream® 0.025%, 0.05% and 0.1%, respectively, of Johnson and Johnson Consumer Products Inc.).

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

Post-marketing reporting requirements for these abbreviated applications 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 these drugs.

We request that you submit, in duplicate, any proposed advertising or promotional copy which 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,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research