DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-270

Hi-Tech Pharmacal Co., Inc.
Attention: Joanne Curri
Director, Regulatory Affairs
369 Bayview Avenue
Amityville, NY 11701

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 18, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ciclopirox Topical Solution, 8% (Nail Lacquer).

Reference is also made to the tentative approval letter issued by this office on April 16, 2007, and to your amendments dated November 20, 2006; and June 27, August 30, and September 12, 2007.

We have completed the review of this ANDA and based upon the information you have presented to date, we have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Ciclopirox Topical Solution, 8% (Nail Lacquer) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Penlac Nail Lacquer, 8%, (Topical Solution), of Sanofi Aventis US, LLC.

The reference listed drug product (RLD) upon which you have based your ANDA, Penlac Nail Lacquer, 8%, (Topical Solution) of Sanofi Aventis US, LLC, was subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,957,730 (the '730 patent) expired on September 18, 2007.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
9/18/2007 05:18:37 PM
for Gary Buehler