DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-847

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 August 12, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, 2%/0.5%.

Reference is also made to the tentative approval letter issued by this office on April 10, 2008, and to your amendments dated June 9, July 21, July 25, September 5, September 26, and October 23, 2008.

We have completed the review of this ANDA and 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 Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, 2%/0.5% to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Cosopt Ophthalmic Solution, of Merck & Co., Inc. (Merck).

The RLD upon which you have based your ANDA, Merck's Cosopt Ophthalmic Solution, was subject to unexpired periods of patent protection. The agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists U.S. Patent Nos. 6,248,735 (the '735 patent) and 6,316,443 (the '443 patent), with April 17, 2011 expiration dates, for Cosopt Ophthalmic Solution.[1]

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, 2%/0.5%, under this ANDA. You notified the agency that Hi-Tech Pharmacal Co., Inc (Hi-Tech) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of either the '735 patent or the '443 patent was brought

[1] Merck has requested that these patents be withdrawn from the Orange Book. In light of FDA's decision today on approval of ANDAs referencing Cosopt, information on the '735 and '443 patents is being removed from the Orange Book.

against Hi-Tech within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).[2]

FDA has determined that Hi-Tech was the first applicant to submit a substantially complete ANDA that contained paragraph IV certifications to the '735, and '443 patents (as well as the now-expired '413 patent) for Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, 2%/0.5%, and therefore, was eligible for 180-day generic-drug exclusivity under section 505(j)(5)(B)(iv) of the Act. However, as fully explained in our letter dated October 28, 2008, the 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(I) of the Act.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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(s) 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling.

[2] The agency also recognizes that U.S. Patent No. 4,797,413 (the '413 patent) and associated pediatric exclusivity have both expired, and that this patent and exclusivity are no longer barriers to the full approval of your ANDA.

Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence – SPL for Approved ANDA 77-847".***

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
10/28/2008 08:00:24 AM
Deputy Director, for Gary Buehler