



ANDA 77-846

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 Ophthalmic Solution, 2% (base).

Reference is also made to your amendments dated April 24, 2006; November 9, December 10, December 14, and December 18, 2007; and March 4, April 22, (two amendments), May 21, July 25, September 5, September 26, and October 14, 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 Ophthalmic Solution, 2% (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Trusopt Ophthalmic Solution, 2% (base) of Merck Research Laboratories.

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 505-1(i).

Postmarketing reporting requirements for this ANDA 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.

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.

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. 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 77-846*”.

Sincerely yours,

*{See appended electronic signature page}*

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

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

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Robert L. West  
10/28/2008 08:07:49 AM  
Deputy Director, for Gary Buehler