



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 40-712

Food and Drug Administration  
Rockville MD 20857

JUL 31 2006

KVK-Tech, Inc.  
Attention: Ashvin Panchal,  
                  Manager, Quality Assurance  
110 Terry Drive, Suite 200  
Newtown, PA 18940

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 16, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Promethazine Hydrochloride Tablets USP, 25 mg.

Reference is also made to your amendments dated April 25, May 4, May 8, May 12, and May 17, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Promethazine Hydrochloride Tablets USP, 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Phenergan Tablets, 25 mg, of Wyeth Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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(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.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Gary Buehler".

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