DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 40-713

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, 50 mg.

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

We note that the reference listed drug product (RLD) upon which you have based this ANDA, Phenergan Tablets, 50 mg, of Wyeth Pharmaceuticals, Inc., is no longer being marketed in the United States. Thus, Wyeth's Phenergan Tablets 50 mg have been moved to the Discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". Reference is made to the Federal Register Notice dated July 14, 2006, in which the agency announced its determination that Wyeth's Phenergan Tablets, 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for this discontinued drug product.

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, 50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Phenergan Tablets, 50 mg Tablets, 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,

Robert Lee Est/for

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