DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078648

KVK-Tech, Inc.
U.S. Agent for: Avanthi, Inc.
Attention: Ashvin Panchal
Director, Quality
110 Terry Drive, Suite 200
Newtown, PA 18940

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 30, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexbrompheniramine Maleate and Pseudoephedrine Sulfate Extended-release Tablets, 6 mg/120 mg (OTC).

Reference is also made to your amendments dated December 24, 2007; June 19, and December 3, 2009; January 22, July 6, and August 9, 2010; July 21, August 8, August 15, August 30, September 21, September 23, October 5, and December 29, 2011; January 27, February 6, August 21, and August 28, 2012; and January 2, and January 10, 2013.

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 over-the-counter (OTC) 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 Dexbrompheniramine Maleate and Pseudoephedrine Sulfate Extended-release Tablets, 6 mg/120 mg, to be bioequivalent to the reference listed drug product (RLD), Drixoral® Extended-release Cold and Allergy Tablets, 6 mg/120 mg, of Schering Plough Healthcare Products, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing for both components should be conducted in:

Apparatus: 3 (Bio-Dis II)
Speed: 12 dpm
Medium: 0.02N HCl (2 hours) followed by 0.05M Phosphate buffer pH 7.5 (6 hours) (no surfactant)
Volume: 250 mL at 37°C ± 0.5°C
Sampling: 2, 3, 4, 5, 6, 7 and 8 hours

"Interim" Specifications:

Time (Hours)	Percent Dissolved
2	(b) (4)
3	(b) (4)
8	NLT (b) (4)

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. The data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package

insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
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

02/27/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.