DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

KV Pharmaceutical Company
Attention: Alison Parks
Manager, Regulatory Labeling
2503 South Hanley Road
St. Louis, MO 63144-2255

Dear Ms. Parks:

Please refer to your supplemental new drug application dated April 28, 2008, received April 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Evamist ™ (estradiol transdermal spray).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the updating of the carton and applicator labeling for Evamist™ (estradiol transdermal spray) to indicate a new distributor.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call George Lyght, R.Ph., Sr. Regulatory Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
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/

Scott Monroe

10/30/2008 04:29:26 PM