DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-793

KV Pharmaceutical Company
Attention: Herbert Luther, Ph.D.
Vice President, Regulatory and Clinical Affairs
2503 South Hanley Road
St. Louis, Mo 63144-2555

Dear Dr. Luther:

Please refer to your new drug application (NDA) dated October 30, 2003, received October 31, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Clindesse™ (clindamycin phosphate) Vaginal Cream, 2%. We note that this application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated:

August 15, 2003
August 25, 2003
January 14, 2004
January 22, 2004
February 13, 2004 (2)
April 6, 2004
July 23, 2004 (2)
August 20, 2004
September 14, 2004
September 16, 2004
September 22, 2004
October 8, 2004
November 4, 2004
November 5, 2004
November 9, 2004 (2)
November 10, 2004
November 11, 2004 (2)
November 17, 2004
November 24, 2004

This new drug application provides for the use of Clindesse™ (clindamycin phosphate) Vaginal Cream, 2%, for the treatment of bacterial vaginosis.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. In addition, submit content of labeling in electronic format as required by 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html. For administrative purposes, designate this submission "FPL for approved NDA 50-793." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

We note that you have fulfilled the pediatric study requirement for the treatment of bacterial vaginosis in post-menarchal female patients. We are waiving the pediatric study requirement for the treatment of bacterial vaginosis in pre-menarchal female patients.

Please submit one market package of the drug product when it is available.

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, please call Christina H. Chi, Ph.D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.,
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: labeling

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

/s/

Renata Albrecht
11/30/04 02:26:16 PM