DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-881/S-002

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

Dear Dr. Luther:

Please refer to your supplemental new drug application listed below, which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

NDA #	Drug Product	Supplement number	Letter Date	Receipt Date
19-881	Femstat One (butoconazole nitrate) Vaginal Cream, 2%	S-002	February 5, 1999	February 8, 1999

This supplemental new drug application provides for a change in the trademark name of the product Femstat One (butoconazole nitrate) Vaginal Cream, 2% to GYNAZOLE™•1 (butoconazole nitrate) Vaginal Cream, 2%. In addition, the following editorial and regulatory changes have been made to the labeling.

Package Insert, Patient Instructions, Carton, and Foil Pouch

1. The trademark name has been changed from Femstat One (butoconazole nitrate) Vaginal Cream, 2% to GYNAZOLE™• 1 (butoconazole nitrate) Vaginal Cream, 2%, throughout the labeling.

Package Insert

2. Description

   In the third paragraph, the typographical error(b)(4)---------- was corrected to "polyglyceryl-3".

3. HOW SUPPLIED:

   "CAUTION: Federal law prohibits dispensing without prescription" was changed to "**Rx Only**".

4. At the end of the package insert, "Manufactured for Syntex Laboratories Inc., Palo Alto, CA 94304 By KV Pharmaceuticals Co., St. Louis MO 63144 March 1992" was replaced with "Manufactured for Ther-Rx Corporation by KV Pharmaceutical Co., St. Louis, MO 63144 June 1998".

Carton

5. On the front, back, Side 1, and Side 2 of the carton, "CAUTION: Federal law prohibits dispensing without prescription" was changed to "**Rx Only**".

6. On the front, back, Side 1, and Side 2 of the carton, "Manufactured for Syntex Laboratories Inc., Palo Alto, CA 94304 By KV Pharmaceuticals Co., St. Louis MO 63144" was replaced with "Manufactured for THER-Rx Corporation by KV Pharmaceutical Co., St. Louis, MO 63144 USA".

7. On side 1, under the FORMULA section, the typographical error "pol(b)(4)---------- corrected to "polyglyceryl-3".

Foil Pouch

8. "CAUTION: Federal law prohibits dispensing without prescription" was changed to "**Rx Only**".

9. "Manufactured for Syntex Laboratories Inc., Palo Alto, CA 94304 By KV Pharmaceuticals Co., St. Louis MO 63144" was replaced with "Manufactured for THER-Rx Corporation by KV Pharmaceutical Co., St. Louis, MO 63144 USA".

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 5, 1999.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Christine Lincoln, RN, MS, MBA, Labeling Reviewer, 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

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

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