DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-040/S-010

King Pharmaceuticals
Attention: Greg Carrier
Senior Director
Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated June 27, 2002, received July 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho-Prefest® (estradiol/norgestimate) Tablets.

We acknowledge receipt of your submission dated September 13, 2002.

This supplemental new drug application provides for modifying the product's band name.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use of "Prefest" as the brand name. The alternate proposed brandname, (b)----------was not acceptable. References to (b)----------are misleading in that they broadly imply that estrogens are indicated for any woman who has achieved menopause.

The final printed labeling (FPL) must be identical to the draft labeling reflecting the brandname "Prefest" submitted on June 27, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format-NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-040/S-010." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug 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/

Daniel A. Shames

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