



NDA 21-040/S-012

King Pharmaceuticals, Inc.  
Attention: Karen C. Baker  
Manager, Regulatory Affairs  
501 Fifth Street  
Bristol, TN 37620

Dear Ms. Baker:

Please refer to your supplemental new drug application dated May 18, 2004, received May 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREFEST™ (estradiol/norgestimate) Tablets.

We acknowledge receipt of your submission dated June 14, 2004.

This supplemental new drug application provides for labeling revisions to update the labeling regarding the Women's Health Initiative Memory Study (WHIMS), a substudy of the Women's Health Initiative (WHI) trial.

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

The final printed labeling (FPL) must be identical to the attached package insert and patient package insert.

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-012." 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

Enclosure

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/s/

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Daniel A. Shames  
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