DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 09-402/S-040

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 24, 2004, received May 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delestrogen® (estradiol valerate injection, USP).

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 Delestrogen® 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 09-402/S-040." 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

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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