DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-402/S-037 and S-039

King Pharmaceuticals, Inc.
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug applications dated April 23, 2001 (S-037) and October 1, 2003 (S-039), received May 9, 2001 and October 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delestrogen® (estradiol valerate injection, USP).

We acknowledge receipt of your submission dated February 27, 2003 to supplement 037. This submission constituted a complete response to our December 19, 2002 action letter.

These supplemental new drug applications provide for multiple revisions to the package insert and patient package insert to include safety information from the Women's Health Initiative trial (S-037) and the inclusion of a "Geriatric use" subsection in the package insert labeling (S-039).

We completed our review of these applications, as amended. These applications are 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 package insert and patient package insert submitted on October 1, 2003 to supplement 039.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 09-402/S-037 and 039." 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, HFD-410
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: agreed-upon labeling text

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

12/12/03 11:36:52 AM