DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-559/S-033

King Pharmaceuticals, Inc.
501 Fifth Street
Bristol, TN 37620

Attention: Greg Carrier
Senior Director, Regulatory Affairs

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated August 28, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brevital® (methohexital sodium for injection, USP), 500 mg/vial and 2.5 g/vial.

We acknowledge receipt of your submissions dated November 26, December 27, 2002, and January 23, and March 6, 2003. Your submission of January 23, 2003, constituted a complete response to our December 24, 2002, action letter.

This supplemental new drug application provides for a change in the manufacturing process and controls, a new manufacturing site for the drug product, and a change in the supplier of the drug substance.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the draft labeling submitted August 28, 2002 (package insert) and January 23, 2003 (immediate carton and container labels).

As agreed in your March 14, 2003 telephone conversation with Lisa Basham-Cruz, the Agency will issue a separate request to submit a labeling supplement for additional updates of the labeling.

In addition, we remind you of the following agreements, as discussed in our February 19, and March 10, 2003, teleconferences, respectively.

1. Although the drug substance batch MHT0212003 does not meet the updated specifications of this supplement, your proposal to manufacture the drug product using this batch is acceptable.

2. Submit a Methods Validation Package for the following analytical (b)(methods:

   a. Method **(b)()** (drug substance assay and chromatographic purity by (b)4----).
   b. Method **---------** (drug product assay and chromatographic purity by (b)4-----).

   We have not completed validation of the analytical regulatory methods. We expect your continued cooperation to resolve any problems that may be identified.

We recommend you propose **(b)4 ----------** to the USP for the analytical method for assay and chromatographic purity of methohexital, including the acceptance criteria for the (b)4---------- .

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

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