DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-559/S-037

King Pharmaceuticals
501 Fifth Street
Bristol, TN 37620

Attention: Tom W. Der
Director, Regulatory Affairs

Dear Mr. Der:

Please refer to your supplemental new drug application dated December 3, 2003, received December 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brevital (methohexital sodium) Injection.

We also refer to your submission dated April 28, 2004.

This supplemental application provides for a revised **PRECAUTIONS** section. A **"Geriatric use"** subsection is added in accordance with the requirements of 21 CFR 201.57(f)(10).

We have completed our review of this application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling text for the package insert submitted on April 28, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 11-559/S-037**." Approval of this submission by FDA is not required before the labeling is used.

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 Allison Meyer, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

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