DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-260/S-013

King Pharmaceuticals, Inc.
Attention: Greg Carrier, Vice-President, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated August 14, 2008, received August 154, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avinza® (morphine sulfate) Capsules.

We acknowledge receipt of your submission dated December 12, 2008.

This supplemental new drug application provides for two additional intermediate strength capsules (45 mg and 75 mg) for Avinza.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format submitted on August 14, 2008.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the submitted immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Container Labels for approved NDA 21-260/S-013**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

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