



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 13-217/S-046

RECEIVED

MAR 15 2004

REGULATORY AFFAIRS
KING PHARMACEUTICAL, INC.

King Pharmaceuticals Inc.
Attention: Douglas Dewar, PhD
Senior Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Dr. Dewar:

Please refer to your supplemental new drug application dated April 21, 2003, received April 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin® (metaxalone) Tablets.

We acknowledge receipt of your two submissions dated July 30, 2003.

This supplemental new drug application provides for a revision to the labeling in the pharmacokinetics section.

We completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit draft printed labeling revised as follows:

The labeling as submitted is not acceptable. The information contained in the revised PK section does not follow the general ADME (absorption, distribution, metabolism, elimination) layout used in most PK labels. While a more narrative PK section was allowed in the past for this product, this was due to the lack of PK data with Skelaxin® (metaxalone) Tablets. As a whole series of new PK trials has been undertaken over the last few years, continued use of the narrative format is no longer acceptable. As submitted, the proposed PK section contained in this supplement is formatted such that it relies too much on study descriptions and bulleted conclusions rather than presenting the information in an accessible manner. The sponsor needs to re-submit the labeling in a more data driven and less editorial format.

In addition, all previous revisions as, reflected in the most recently approved package insert, must be included. To facilitate review of your submission, provide a highlighted or marked-up copy that shows the changes.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We

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will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes before approval of this supplemental application.

If you have any questions, please call Ms. Jane A. Dean, RN, MSN, Regulatory Project Manager, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, MD, PhD
Acting Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Brian Harvey
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