DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-217/S-053

King Pharmaceuticals Research and Development, Inc.
501 Fifth Street
Bristol, Tennessee 37620

Attention: Thomas K. Rogers, III
Executive Vice President, Regulatory Affairs

Dear Mr. Rogers:

Please refer to your supplemental new drug application September 17, 2007, received September 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin® (metaxalone) 800-mg tablets.

We acknowledge receipt of your submission dated April 30, 2008, which constituted a complete response to our April 9, 2008, action letter.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** and **PRECAUTIONS** sections of the package insert for Skelaxin.

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 final printed labeling (FPL) submitted on April 30, 2008.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology 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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