



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-217/S-046

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

Attention: Douglas Dewar, Ph.D.
Senior Director, Regulatory Affairs

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 submissions dated July 30, 2003, April 5 and October 5, 2004, April 22, 2005, and October 5, 2006.

Your submission of October 5, 2006, constituted a complete response to our August 14, 2006, action letter.

This supplemental new drug application provides for a revised **CLINICAL PHARMACOLOGY: Pharmacokinetics** section of the package insert.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Please submit an electronic version of the FPL. 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 supplement NDA 13-217/S-046.**" Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, R.Ph., Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

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

Rigoberto Roca
11/24/2006 01:57:09 PM
for Bob Rappaport, M.D.