



NDA 50-108/S-024

Parkedale Pharmaceuticals
(a wholly owned subsidiary of King Pharmaceuticals, Inc.)
Attention: Michael Barrett
Supervisor, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Barrett:

Please refer to your supplemental new drug application dated July 22, 2005, received July 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coly-Mycin[®] M Parenteral (colistimethate for injection, USP).

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your additional correspondence of July 22, 2005.

This "Changes Being Effected" supplemental new drug application provides for labeling changes requested per the Systemic Antibacterial Final Rule (68 FR 6062, February 6, 2003).

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 22, 2005 (copy attached).

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Maureen Dillon-Parker, Regulatory Project Manager, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure – Labeling

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Janice Soreth
1/12/2006 05:05:52 PM