DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-356/S-045

PARKEDALE PHARMACEUTICALS, INC.
(A wholly-owned subsidiary of King Pharmaceuticals, Inc.)
Attention: Suzanne E. Smith, M.S.
Manager, Regulatory Affairs
501 Fifth Street
Bristol, Tennessee 37620

Dear Ms. Smith:

Please refer to your supplemental new drug application dated December 3, 1996, received December 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coly-Mycin® S Otic Suspension (colistin sulfate; neomycin sulfate; thonzonium bromide; hydrocortisone acetate otic suspension). We note that 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 submissions dated February 10, 1997, April 22, 1999, and April 27, 2000. Your submission of April 27, 2000 constituted a complete response to our February 18, 2000 action letter.

This supplemental new drug application provides for revisions to the **DESCRIPTION**, **CLINICAL PHARMACOLOGY**, **Microbiology** and **Susceptibility** subsections, **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION,** and **REFERENCES** sections of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted April 27, 2000, dated March 2000, #3141G241). Accordingly, the supplemental application is approved effective on the date of this letter. Additionally, it is requested the periods which appear in the **Microbiology** subsection after the organisms "*Staphylococcus aureus*" and "*Pseudomonas aeruginosa*" be deleted at the next printing.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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