



NDA 50-168/S-078

King Pharmaceuticals, Inc.
Attention: Tom W. Der, RAC
Director, Regulatory Affairs
501 Fifth Street
Bristol, Tennessee 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated October 1, 2003, received October 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cortisporin® Ointment (neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone ointment, 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.

This supplemental new drug application provides for a **Geriatric Use** subsection in the **PRECAUTIONS** section of the labeling.

We completed our review of this application, as amended. This application 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 submitted labeling (package insert submitted October 1, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-168/S-078." Approval of this submission by FDA is not required before the labeling is used.

Additionally, we request that the **PRECAUTIONS** section be updated to address the following:

1. In the Carcinogenesis, mutagenesis, impairment of fertility subsection, provide information on the potential for each of the active ingredients to cause cancer, genotoxicity and impairment of fertility as prescribed in the regulations (21 CFR 201.57). Please also address the same for the potential teratogenic effects of each active ingredient.
2. Concentrations and dosages (mg/kg) for each active ingredient should be declared in the label for each of the supportive studies.

3. If no data is available for the active ingredients, other than for hydrocortisone, this should be stated in the label.

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 Maureen Dillon-Parker, Regulatory 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

Enclosure (labeling -7 pages)

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/s/

Janice Soreth
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