



NDA 17-381/S-041

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

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated October 23, 2002 received October 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Silvadene® Cream 1% (silver sulfadiazine cream).

We acknowledge receipt of your submissions dated January 9, August 8, and November 14, 2003.

Your submission of August 8, 2003 constituted a complete response to our January 6, 2003 action letter.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section of the package insert.

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 labeling submitted August 8, 2003 and further revised as agreed in your submission of November 14, 2003. These revisions are terms of the approval of this application.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 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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