



NDA 19-931/S-008

Jennifer W. Phillips, Pharm. D.
Director, Regulatory Affairs
Dermik Laboratories, Inc.
A Division of Aventis Pharmaceuticals, Inc.
1050 Westlake Drive
Berwyn, PA 19312

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated October 22, 2002, received October 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KLARON® (sulfacetamide sodium) Lotion, 10%.

We acknowledge receipt of your submission dated October 22, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 4 oz. package size for Klaron® Lotion, 10%.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted October 22, 2002). We note that the "How Supplied" section of the package insert has been revised to show the new 4 oz. package size.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-831/S-008". Approval of this submission by FDA is not required before the labeling is used.

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 Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for Division of Dermatological and
Dental Drug Products

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

/s/

Wilson H. DeCamp
2/21/03 02:41:07 PM
approved