



NDA 20-743/S-006

Dermik Laboratories
Attn.: Jennifer W. Phillips, Pharm. D.
Director, Regulatory Affairs
1050 Westlakes Drive
Berwyn, PA 19312

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated December 30, 2003, received December 31, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noritate® (metronidazole cream) Cream, 1%

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 60g drug product container-closure system, where the proposed package size comprises the same packaging materials, construction and supplier as is used for the 30g package.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels submitted December 30, 2003). These revisions are terms of the approval of this application.

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 20-743/S-006." 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 Mildred A. Wright, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Norman R. Schmuff, Ph.D.
Chemistry Team Leader (Acting) for the
Division of Dermatologic & Dental Drug
Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Norman Schmuff
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