DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-743/S002

Dermik Laboratories
Attention: 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 May 13, 2002, received May 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noritate (metronidazole cream) Cream, 1%.

This "Changes Being Effected" supplemental new drug application provides for a safety update and revision to the ADVERSE REACTIONS section of the label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) as submitted on May 13, 2002.

We note your agreement as stated in the May 13, 2002 cover letter that you will revise the last paragraph of the ADVERSE REACTIONS section by adding "dry mouth" and removing "constipation" in your next printing. This change can be reported in your next annual report.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

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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 Mildred Wright, Regulatory Project Manager, at (301)827-2020.

Sincerely,

{See appended electronic signature page}
Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
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/

John Kelsey
4/4/03 04:00:40 PM
for Dr. Kelsey