



NDA 50-557

Dermik Laboratories, Inc.  
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 July 26, 2002, received July 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzamycin (erythromycin, 3% and benzoyl peroxide, 5%) Topical Gel.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the replacement of the excipient Carbomer 940 NF with the chemically equivalent Carbomer 980.

We have completed our review of this application. This application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

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 50-557/S-025." Approval of this submission by FDA is not required before the labeling is used.

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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.,  
Chemistry Team Leader for the  
Division of Dermatologic and Dental Drug Products  
(HFD-540)  
DNDCIII, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

Enclosure

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/s/

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Jim Vidra  
1/27/03 04:56:03 PM

Wilson H. DeCamp  
1/27/03 05:17:16 PM  
approved