



NDA 20-985/S-004

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 November 19, 2002, received November 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Carac (fluorouracil) Cream, 0.05%.

Your submission of June 26, 2003, constituted a complete response to our March 24, 2003, action letter.

This supplemental new drug application provides for proposed labeling revisions to the Package Insert and Patient Information Leaflet, intended to clarify the risk benefit assessment with respect to the use of Carac (fluorouracil) Cream, 0.05%, and the potential of systemic fluorouracil toxicity.

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 enclosed labeling (text for the package insert and text for the patient information leaflet).

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 20-985/S-004." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410  
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).

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

*{See appended electronic signature page}*

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic & Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Stanka Kukich  
12/16/03 03:10:07 PM  
Signing for Jonathan Wilkin, Division Director