DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-758

Medicis Pharmaceutical Corporation
Attn: R. Todd Plott, M.D.
Vice President, Clinical Research and Regulatory Affairs
8125 North Hayden Road
Scottsdale, AZ 85258

Dear Dr. Plott:

Please refer to your new drug applications (NDA) dated April 7, 2004, received April 14, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VANOS (fluocinonide) Cream, 0.1%.

We acknowledge receipt of your submissions dated June 8, July 21, August 26, September 30, 5, 8, and 29, November 3, 8, 15, and 22, December 2, 13, 14, 17, 20, 27, and 28, 2004; January 14, 17, 20, and 23, and February 3 (2), 7, 8 (facsimile), and 10 (facsimile), 2005.

This new drug application provides for the use of VANOS (fluocinonide) Cream, 0.1%, for plaque-type psoriasis.

We completed our review of this application, as amended. It 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, immediate container and carton labels) Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-758**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application for the psoriasis indication.

We remind you of your postmarketing study commitments in your submission dated February 8, 2005. These commitments are listed below.

1. The applicant commits to conduct a dermal carcinogenicity study with VANOS (fluocinonide) Cream, 0.1%.

Development of dosing formulations:	By August 15, 2005
Development and validation of analytical methodology:	By February 15, 2006
90-day dose range-finding study:	By December 15, 2006
Study protocol submission:	By June 15, 2007
Study start date:	By February 15, 2008
Final report submission:	By August 15, 2011

2. The applicant commits to conduct a study to determine the photoco-carcinogenic potential of VANOS (fluocinonide) Cream, 0.1%.

90-day dose range-finding study:	By December 15, 2006
Study protocol submission:	By June 15, 2007
Study start date:	By February 15, 2008
Final report submission:	By August 15, 2010

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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 the Division of Dermatologic and Dental Drug Products and two copies of both the promotional materials and the package inserts directly to:

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

Please submit one market package of the drug product when it is available.

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 Melinda Harris-Bauerlien, M.S., Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Jonathan Wilkin
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