DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-758/S-007

Medicis Pharmaceutical Corporation
Attention: 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 supplemental new drug application dated July 5, 2006, received July 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vanos (fluocinonide) Cream, 0.1%.

This supplemental new drug application provides for revisions to the carton and tubes in accordance with revisions to the package insert approved on March 2, 2006. This change is to amend all Vanos (fluocinonide) Cream, 0.1% cartons and tubes to note the approved package insert as follows:

The text “For Dermatologic Use Only” has been changed to “For Topical Use Only.”

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 (immediate container and carton labels).

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 supplement NDA 21-758/S-007**." 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 the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road

Beltsville, MD 20705-1266

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 Bauerlien, M.S., Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

Susan Walker
12/13/2006 12:34:14 PM