DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021758/S-012 **SUPPLEMENT APPROVAL**

Medicis Pharmaceutical Corporation
ATTENTION: Diane Stroehmann, Associate Director
Regulatory Affairs
7720 North Dobson Road
Scottsdale, AZ 85256

Dear Ms. Stroehmann:

Please refer to your supplemental new drug application dated March 12, 2009, received March 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vanos® (fluocinonide) Cream, 0.1% indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years or older.

We acknowledge receipt of your submissions dated April 23, and May 13, 2009 and February 4, 2010.

This supplement provides for changes to the PRECAUTIONS- General, and Carcinogenesis, Mutagenesis, and Impairment of Fertility sections of the label.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling for the package insert. For administrative purposed, please designate this submission, "SPL for approved NDA 021758/S-012.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment in the February 11, 2005 approval letter. This commitment is listed below.

Study #2	The applicant commits to conducting a study to determine the photo-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 061701 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/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Dawn Williams, Regulatory Project Manager at (301) 796-5376.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21758	SUPPL-12	MEDICIS PHARMACEUTICAL CORP	VANOS (FLUOCINONIDE)

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

/s/

STANKA KUKICH
03/08/2010