DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-856/S-024
NDA 18-309/S-013

MEDICIS Pharmaceutical Corporation
Attention: R. Todd Plott, M.D.
8125 North Hayden Road
Scottsdale, AZ 85258

Dear Dr. Plott:

Please refer to your supplemental new drug applications dated September 6, 1991, received September 9, 1991, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Topicort® (desoximetasone) Emollient Cream, 0.25% and Topicort® (desoximetasone) LP Emollient Cream, 0.05%.

We acknowledge receipt of your submissions dated October 24 and 29, 2003 and April 16, 2004.

Your submissions of October 24, 2003, constituted a complete response to our May 29, 2003, action letter.

These supplemental new drug applications provides for the addition of a statement in the PRECAUTIONS, Carcinogenesis, Mutagenesis, and Impairment of Fertility section.

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).

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, these submissions should be designated "FPL for approved supplement NDA 17-856/S-024 and NDA 18-309/S-013." Approval of these submissions 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 these products. 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, HF-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 Melinda Harris, 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

4/27/04 12:49:00 PM