DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 16-908/S-058; 16-909/S-049; 17-373/S-038; 18-849/S-018

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

Dear Dr. Plott:

Please refer to your supplemental new drug application dated August 28, 2003, received September 2, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the following finished drug products:

NDA 16-908/S-058 Lidex and Lidex E (fluocinonide) Creams, 0.05%.
NDA 16-909/S-049 Lidex (fluocinonide) Ointment, 0.05%
NDA 17-373/S-038 Lidex (fluocinonide) Gel, 0.05%
NDA 18-849/S-018 Lidex (fluocinonide) Topical Solution, 0.05%

These "prior approval" supplemental new drug applications provide modifications to the approved specifications, establish new regulatory procedures, and delete test parameters for Fluocinonide.

We have completed our review of these supplemental new drug applications and they are approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Maria Anderson, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chief, Branch III
Division of Premarketing Assessment II
Office of New Drug Quality Assessment
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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

/s/

Moo-Jhong Rhee
12/16/2005 10:50:44 AM
Chief, Branch III