**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

**NDA 19-824/S-008**

Medicis Pharmaceutical Corporation
Attention: Mitchell S. Wortzman, Ph.D.
Executive Vice President, Research & Development
8125 N. Hayden Road
Scottsdale, AZ 85258-2463

Dear Dr. Wortzman:

Please refer to your supplemental new drug application dated January 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Loprox® (ciclopirox) Lotion 0.77%.

This special supplemental new drug application changes being effected provides for the following revisions to the labeling:

- The declared strength is revised from "1.0%" to "0.77%"
- The established name is revised from "ciclopirox olamine" to "ciclopirox"
- The active ingredient is identified as "ciclopirox (as ciclopirox olamine)"

We completed our review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on January 20, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Please revise the statement "Caution: Federal Law prohibits dispensing without prescription" to "RX Only" at the next printing of the package insert and report the change in the Annual Report.

If a letter communicating important information about this drug product (i.e. a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be necessary.

If you have any questions, call Frank Cross, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}
Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

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/s/

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John Kelsey
3/26/03 12:46:05 PM
for Dr. Wilkin