



NDA 20-519/S-005

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 September 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LOPROX[®] Gel (ciclopirox) 0.77%.

This supplemental new drug application provides for new LOPROX logo and art layout, and numerous editorial revisions to the package insert, tube, and carton labeling.

We completed our review of this supplemental new drug application. The supplemental new drug application is approved effective on the date of this letter for use as recommended in the attached agreed-upon labeling text.

Please present the drug products trade name LOPROX[®] consistently throughout the package insert, i.e. in all capital letters and with the [®] symbol, when final printed labeling is submitted. In addition, all references in the package insert to LOPROX[®] Cream as “(ciclopirox)” should be “(ciclopirox olamine)” until the USP monograph is changed to the designation “Ciclopirox”.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, tube and carton labels). Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternately, 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 20-519/S-005.” Approval of this submission by FDA is not required before the labeling is used.

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

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

/s/

John Kelsey
3/26/03 12:58:36 PM
for Dr. Wilkin