



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-260/S-007

Pharmacia & Upjohn Company
Attention: Terry L. Reinstein
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, Michigan 49001

Dear Mr. Reinstein:

Please refer to your supplemental new drug application dated January 17, 2002, received January 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PSORCON[®] (diflorasone diacetate ointment) Ointment, 0.05%.

This special supplemental new drug application changes being effected provides for the revision of the Pediatric Use subsection in the PRECAUTIONS section.

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 17, 2002. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

In addition, we have the following request. Please submit a supplemental application to NDA 19-260 PSORCON[®] (diflorasone diacetate ointment 0.05%) Ointment, 0.05% containing draft labeling providing for a Geriatric Use subsection in the PRECAUTIONS section that is compliant with the requirements under 21 CFR 201.57(f)(10).

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 these drugs becomes available, revision of the labeling may be necessary.

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If you have any questions, call Margo Owens, 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
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/s/

John Kelsey
4/24/03 11:27:39 AM
for Dr. Wilkin