DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-259/S-009

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 July 31, 1998, received August 3, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Psorcon® E (diflorasone diacetate cream) Emollient Cream, 0.05%.

We acknowledge receipt of your submissions dated October 27, 2000 and January 16, 2002.

This special supplemental new drug application changes being effected with final printed labeling provides for the deletion of the third paragraph in the Pediatric Use subsection of the Precautions section as follows: "Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients."

Please note that the supplemental application 19-259/S-002 approved October 14, 1986 provided for the trade name change from Florone E (diflorasone diacetate cream) Emollient Cream, 0.05% to Psorcon® E (diflorasone diacetate cream) Emollient Cream, 0.05%.

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 16, 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 19-259 Psorcon®E (diflorasone diacetate cream) Emollient Cream, 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.

If you have any questions, call Kalyani Bhatt, 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
5/29/03 02:08:07 PM
for Dr. Wilkin