



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

**NDA 17-741/S-021**

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 May 16, 2003, received May 19 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Florone<sup>®</sup> (diflorasone diacetate cream) Cream, 0.05%.

We acknowledge receipt of your submission dated May 23, 2003.

This special supplemental new drug application changes being effected provides the final printed package insert for Florone<sup>®</sup> (diflorasone diacetate cream) Cream, 0.05%. The combined package insert approved on March 29, 1984 for NDA 17-741 Florone Cream, 0.05% and NDA 17-994 Florone Ointment, 0.05% is now divided into separate package inserts for each product.

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 May 23, 2003. 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 17-741 Florone<sup>®</sup> (diflorasone diacetate cream) Cream, 0.05% containing draft labeling providing for a Geriatric Use subsection in the PRECAUTIONS section. This should be 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 Melinda Harris, 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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/s/

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John Kelsey  
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for Dr. Wilkin