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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Re: Determination that Psorcon® E (Diflorasone Diacetate Ointment) Emollient Ointment, 0.05% (Emollient) Reference Listed Drug has been voluntarily withdrawn from sale in the United States

Dear Sir or Madam:

The undersigned submits this petition, on behalf of an unnamed client, pursuant to § 505(7) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR §§ 10.30 and 314.61, requesting that the Commissioner of the Food and Drug Administration (FDA) make a determination that the withdrawal of the Reference Listed Drug (RLD), Psorcon® E (diflorasone diacetate ointment) Emollient Ointment, 0.05%, was not for safety or effectiveness reasons. With this determination, the undersigned asks that FDA declare that it is appropriate to submit an Abbreviated New Drug Application (ANDA) for Diflorasone Diacetate Ointment USP, 0.05% (Emollient) that relies on an RLD that is no longer marketed.

A. Actions Requested

The RLD upon which this Petition is based is Psorcon® E (diflorasone diacetate ointment) Emollient Ointment, 0.05% marketed by Dermik Laboratories and formerly sold under the proprietary name, Florone®. Pharmacia and Upjohn is the NDA holder of this product, NDA 17-994, which was approved by FDA prior to January 1, 1982. A copy of the *"Prescription Drug Product List"* from FDA's list of *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), 26th edition, is provided as **Attachment 1**. Also included as **Attachment 2** is a copy of FDA correspondence approving the proprietary name change from Florone® (diflorasone diacetate ointment) Ointment, 0.05% to Psorcon® E (diflorasone diacetate ointment) Emollient Ointment, 0.05%.

The RLD had three marketed packaging presentations: 15, 30, and 60 gram tubes. All three marketed presentations have been voluntarily discontinued from the market by Dermik Laboratories, a business of Sanofi-Aventis U.S., effective from the dates described below:

NDC Number	Tube Size	Discontinuation Date
0066-0275-31	30 gram	December 14, 2005
0066-0275-60	60 gram	May 4, 2006
0066-0275-17	15 gram	June 5, 2006

An electronic query of the Orange Book made on November 30, 2006 (**Attachment 3**) confirms that the RLD has been discontinued.

The Petitioner requests that FDA make a determination that the withdrawal of the above-referenced RLD was for reasons other than safety or efficacy and, thus, permit the filing of ANDAs referencing Psorcon® E (diflorasone diacetate ointment) Emollient Ointment, 0.05%.

B. Statement of Grounds

In the Petitioner's opinion and to the best of Petitioner's knowledge, the withdrawal of the RLD was voluntary, was solely for marketing reasons, and was not for safety or effectiveness reasons. The Petitioner notes that there are at least two grounds that support the conclusion that the RLD was withdrawn for reasons other than safety or effectiveness. First, Sanofi-Aventis phased out the withdrawal of this RLD product over time, from December 14, 2005 to June 5, 2006. Copies of "Sanofi-Aventis Product Information, Discontinuation of Psorcon® E™ Emollient Ointment (diflorasone diacetate) Ointment, 5%" for the three packaging presentations (15 g, 30, and 60 g) are provided as **Attachment 4**. Second, an electronic query of the Orange Book made on November 30, 2006 (**Attachment 5**) establishes that there are other FDA-approved drugs containing the active ingredient, diflorasone diacetate, presently being marketed in the U.S.

C. Environmental Impact

A categorical exclusion is claimed as the granting of this Petition will result in an ANDA for a drug product that is consistent with the parameters for exclusion established under 21 CFR §25.31(a).

D. Economic Impact

Information under this section will be submitted if requested by the Commissioner following review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views upon which the Petition relies, and that it includes representative date and information known to the Petitioner which are unfavorable to the Petition.

All regulatory correspondence related to this Petition should be addressed to the following.

Sincerely,

Gary L. Yingling