



THE WEINBERG GROUP INC.

March 15, 2001

**Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23, 12420 Parklawn Drive
Rockville, MD 20857**

1220 Nineteenth St, NW, Suite 300
Washington, DC 20036-2400
Phone 202.833.8077
Fax 202.833.7057
e-mail science@weinberggroup.com

WASHINGTON
NEW YORK
SAN FRANCISCO
BRUSSELS
PARIS

CITIZEN PETITION

The undersigned submits this petition under 21 CFR §10.20 and §10.30 and in accordance with 21 CFR §314.161 to request the Commissioner of Food and Drugs to provide a determination whether a listed drug has been voluntarily withdrawn from sale for safety or effectiveness reasons.

A. Action Requested

The petition is submitted to request that the Commissioner of the Food and Drug Administration determine whether Dermatop Ointment (prednicarbate) 0.1% (NDA 19-568), manufactured by Aventis, has been voluntarily withdrawn for safety or effectiveness reasons.

B. Statement of Grounds

This petition refers to the publication, **Approved Drug Products with Therapeutic Equivalence Evaluations** (the List), which identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). According to the List, Dermatop Ointment (prednicarbate) 0.1% was approved for marketing on September 23, 1991, but the product is listed in the Discontinued Section. This indicates that, although the application for this product was approved, the product is not currently marketed or has been withdrawn for safety or efficacy reasons.

In accordance with 21 CFR §314.161, the Agency must make a determination whether a listed drug has been voluntarily withdrawn from sale for safety or effectiveness reasons prior to approval of an abbreviated new drug application that refers to the listed drug and upon the Agency's receipt of a petition for such a determination.

At the time of submission of this petition, there is no information available to the petitioner concerning the reason that the drug has been withdrawn from sale by Aventis.

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C. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

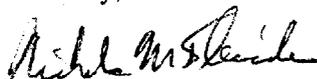
D. Economic Impact

Pursuant to 21 CFR §10.30(b), the petitioner agrees to provide economic impact information only upon request by the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,



Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.
1220 19th Street NW, Suite 300
Washington, DC 20036-2400
(202) 833-8077

cc: Gary Buehler
Director (Acting), Office of Generic Drugs

