

April 28, 2005

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Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: CITIZEN PETITION:

Dear Sir or Madam:

The undersigned submits this petition pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, to request the Commissioner of Food and Drugs to provide a determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or efficacy reasons.

A. Action Requested

The petitioner requests that the Commissioner determine whether Aeroseb-Dex (Dexamethasone) Topical Aerosol, 0.01%, (NDA 083-296), by Allergan Herbert, has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications. That list, commonly referred to as the "Orange Book", contains all *FDA Approved Drug Products with Therapeutic Equivalence Evaluations*. The list is composed of four parts, one of which is the Discontinued Drug Product List. By definition:

The Discontinued Drug Product List contains approved products that have never been marketed, have been discontinued from marketing, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing.

NDA 083-296 for the reference listed drug (Aeroseb-Dex) was approved in a 0.01% strength for topical aerosol. According to the product labeling information, each second of spray dispenses approximately 0.02 mg of dexamethasone. After an extensive search of the literature and other public data sources we were unable to locate any direct information regarding reason for withdrawal.

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C. Environmental Impact

A claim for categorical exclusion of the requirements for environmental impact assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be provided if requested.

E. Certification

The undersigned certifies, that, to the best of his knowledge and belief, 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,



Todd L. Maibach