



OCT 15 2004

Jerussi Consulting, Inc.
Attention: Robert A. Jerussi, Ph.D.
3314 Midland Road
Fairfax, VA 22031

Docket No. 2003P-0365/CP1

Dear Dr. Jerussi:

This is in response to your petition filed on August 13, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydroquinone and Tretinoin Topical Solution, 4%/0.01%. The listed drug product to which you refer in your petition is Solagè® (Mequinol and Tretinoin) Topical Solution, 2%/0.01%, manufactured by Galderma.

Your request involves a change from one active ingredient to another active ingredient in the same pharmacologic or therapeutic class from that of the listed combination drug product (i.e., from Mequinol 2% to Hydroquinone 4%). The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) and (ii) of the Act, such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug products, or of any of the active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug products; or that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application. In addition, we have also considered the comments submitted by Galderma, USA dated November 13, 2003.

The Agency has determined that your proposed change in active ingredient raises questions of safety and effectiveness, and has concluded that clinical trials are required for these specific drug products. The FDA has determined that hydroquinone and mequinol do not have equivalent efficacy and safety profiles. Differences in both efficacy and safety of these two substances were demonstrated in the limited studies that are available. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) and (ii) of the Act because investigations are necessary to show the safety and effectiveness of the proposed drug product.

This petition is being denied because clinical trials are required for the approval of the requested change to the drug product. Therefore, the question of whether pediatric studies are necessary under the Pediatric Research Equity Act (PREA) has not been evaluated. Please contact the

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Division of Dermatologic and Dental Drug Products at 301-827-2020 if you wish to pursue approval of your product under Section 505(b) of the Act.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research