

JERUSSI CONSULTING, INC.

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November 12, 2004

Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration, HFD-600
7500 Standish Place
Rockville, MD 20855-2773

Docket No. 2003P-0365/CPI

Dear Gary Buehler:

Reference is made to your letter of October 15, 2004 informing me that my petition dated August 13, 2003 requesting permission to file an Abbreviated New Drug Application for: Hydroquinone and Tretinoin Topical Solution, 4%/0.01% for the listed drug product Solage (Mequinol and Tretinoin) Topical Solution, 2%/0.01% manufactured by Galderma has been denied.

You mention that in considering this petition the comments submitted by Galderma dated November 13, 2003 were considered. Not mentioned in your letter were Jerussi Consulting comments of January 16, 2004 submitted to this docket in rebuttal to Galderma's comments. Would you please confirm whether or not you considered our Galderma rebuttal comments in arriving at your decision. If they have not been considered, I formally request a reconsideration of your denial. If a reconsideration is not possible because the Galderma rebuttal material was not part of the original petition, I do not understand how Galderma's comments, also not part of the original petition, could be considered.

Sincerely,


Robert A. Jerussi, Ph.D.

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