DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 15 2006

Michael Eison, Ph.D
Vice President, Regulatory Affairs
Connetics Corporation
3160 Porter Drive
Palo Alto, California 94304

Re: Docket No. 2006P-0140/CP1

Dear Dr. Eison:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition that you submitted on behalf of Connetics Corporation (Connetics) dated March 24, 2006. In the petition you request that the FDA withhold approval of any abbreviated new drug application (ANDA) for Soriatane (acitretin) capsules until the sponsor of the proposed ANDA meets certain "sameness" and "bioequivalence" criteria, and until FDA determines that the risk minimization action plan ("RiskMAP") devised by Connetics is effective and that the generic sponsor's RiskMAP is at least as effective as Connetics' RiskMAP.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities and the complexity of the issues raised by your petition, which require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0140

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