DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-821/S-012

Connetics Corporation
Attention: Sharon L. Hall
Senior Director, Regulatory Affairs
3290 West Bayshore Road,
Palto Alto, CA 94303

Dear Ms Hall:

Please refer to your supplemental new drug application dated April 29, 2004, received May 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Soriatane® (acitretin) Capsules, 10 and 25 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the Pregnancy Prevention Program (PPP) brochure for Soriatane (acitretin) Capsules, 10 mg and 25 mg. These changes identify the name, address, logo, trademark, copyright and contact information for Connetics Corporation as the owner of Soriatane Capsules 10 and 25 mg.

Furthermore, it was discussed during the meeting of October 19, 2004, between the Agency and Connetics Corporation that the current Risk Management Program for Soriatane, the Soriatane Pregnancy Prevention Program (PPP), needs to be augmented.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text for the Pregnancy Prevention Program (PPP) brochure.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the Pregnancy Prevention Program (PPP) brochure submitted on April 29, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-821/S-012." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatologic and Dental Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Kalyani Bhatt, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich
11/4/04 11:17:57 AM
Sign off for Dr. Jonathan Wilkin, Division Director