DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-821/S-011

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 6, 2004, received April 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SORIATANE® (acitretin) Capsules, 10 and 25 mg.

We acknowledge receipt of your submission dated July 29, 2004.

This "Changes Being Effected" supplemental new drug application provides for changes to the capsule shells, bottle labels, package insert and medication guide for Soriatane (acitretin) Capsules, 10 mg and 25 mg. These changes are implemented because of change in ownership of Soriatane NDA 19-821 from Hoffman-La Roche, Inc. to Connetics Corporation.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the patient package insert, medication guide, and immediate container labels submitted on April 6, 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-011." 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

Please submit one market package of the drug product when it is available.

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

Enclosure

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
10/8/04 01:38:56 PM
Sign off for Dr. Wilkin, Division Director