DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-142/S-012

Connetics Corporation
Attention: Katy Morton, Senior Director, Regulatory Affairs
3160 Porter Drive
Palo Alto, CA 94304

Dear Ms. Morton:

Please refer to your supplemental new drug application dated January 10, 2006, received January 11, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for OLUX® (clobetasol propionate) Foam, 0.05% for the relief of inflammatory and pruritic manifestations of moderate to severe corticosteroid responsive dermatoses of the scalp and for mild to moderate plaque type psoriasis of non-scalp regions excluding the face and intertriginous areas.

This supplemental new drug application provides for reformatting the product description to provide a consistent labeling format across all Connetics foam products and updating the VersaFoam® logo. The VersaFoam Logo is trademarked by Connetics. 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 package insert, immediate container and carton labels).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-142/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 Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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
7/11/2006 05:23:55 PM
sign off for Susan Walker, Division Director