DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-142/S-004

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

Dear Ms. Hall

Please refer to your supplemental new drug application dated October 31, 2002, received November 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OLUX ® (clobetasol propionate) Foam, 0.05%.

We acknowledge receipt of your submission for NDA 21-142/S-004 dated December 10, 2002.

Your submission of October 31, 2002, constituted a complete response to our October 24, 2002, action letter.

This supplemental application proposes the use of OLUX ® (clobetasol propionate) Foam, 0.05%, for an expanded labeling of the Indications & Usage Section which includes the original labeled wording along with the statement "and for short term topical treatment of mild to moderate plaque-type psoriasis of non-scalp regions".

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. We note that during the teleconference of December 16, 2002, you have agreed to print the footnote to table 3, of page 9, of the label in full font size in your final printed label. Following is the footnote text:

"OLUX Foam is not indicated for non-scalp atopic dermatitis, as the safety and efficacy of OLUX Foam in non-scalp atopic dermatitis has not been established. Use in children under 12 years of age is not recommended."

In addition, during the teleconference of December 10, 2002, the Agency noted that we still believe that the Patient Package Insert (PPI) is a valuable means of conveying safety information for patients. The Agency acknowledges that you have chosen to retire the PPI and move the Instructions for Applying Olux Foam to the package insert. These instructions do not convey any safety or efficacy information to the patients.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) and must be formatted in accordance with the requirements of 21 CFR 201.66. 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 ten of the copies on heavy-weight paper or similar material.

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 this Division 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, HF-2
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/

Jonathan Wilkin

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