DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-142/S-003

Connetics Corporation
Attention: Linda Fenney, MD
Senior Vice President
3400 West Bayshore Road
Palo Alto, CA 94303

Dear Dr. Fenney:

Please refer to your supplemental new drug application dated September 12, 2001, received September 20, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for OLUX (clobetasol propionate) Foam, 0.05%.

We acknowledge receipt of your submissions dated September 12, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of a smaller packaging size (50 g can size).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Please add the new 50 g can size to the labeling, under “How Supplied”.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the original labeling. These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-142/S-003." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
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/

Wilson H. DeCamp
3/13/02 04:44:39 PM
approved