DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-142/S-010

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

Dear Ms. Hall:

Please refer to your supplemental new drug application dated September 3, 2003, received September 5, 2003, 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 October 10 and December 15 and 24, 2003.

This "Prior Approval" supplemental new drug application provides for the addition of a new 12 gm packaging can size to be distributed free of charge as an additional professional sample.

We have completed the review of this supplemental application, and it is approved, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the attached submitted labeling (package insert and immediate container and carton labels submitted October 10, 2003).

We remind you of your postmarketing study commitment in your submission dated December 24, 2003. This commitment is listed below.

1. The Applicant commits to submitting, within 60 days after the date of this approval letter, the results of tests on the 12 gm sample size to show the amount of the foam that is actually delivered.

Commitment Category: CHEMISTRY, MANUFACTURING, AND CONTROLS

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

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/s/

Wilson H. DeCamp
12/29/03 02:33:35 PM
approved with phase 4 commitment