



NDA 20-934/S-012

Connetics Corporation
Attention: Eleanor V. Chiu
Director, Regulatory Affairs
Connetics Corporation
3290 West Bayshore Road
Palo Alto, CA 94303

Dear Ms. Chiu:

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 Luxiq (clobetasol propionate) Foam, 0.12 %.

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 acknowledge receipt of your submissions dated October 10 and December 24, 2003.

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

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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 Melinda Harris, 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
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/s/

Wilson H. DeCamp
12/29/03 02:24:14 PM
approved with phase 4 commitment