



NDA 21-142/S-007

Eleanor V. Chiu
Director, Regulatory Affairs
Connetics Corporation
3490 West Bayshore Road
Palo Alto, CA 94303

Dear Ms. Chiu:

Please refer to your supplemental new drug application dated January 20, 2003, received January 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Olux (clobetasol propionate) Foam, 0.05%.

This supplemental new drug application provides for DPT Laboratories, Inc., San Antonio, TX, to be an alternate contract manufacturer for the drug product for the 100g and 50 g can sizes, and for an alternate analytical testing site.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. The package insert, immediate container and carton labels should be revised to show the manufacturer as DPT Laboratories, Inc., San Antonio, TX, or other equivalent wording as permitted by 21 CFR 201.1.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the approved labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). These revisions are terms of the approval of this/these application(s).

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, call Kalyani Bhatt, Regulatory Project Manager, at (301) 2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry III
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
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approved