



NDA 22-013/S-001

Connetics Corporation  
Attention: Rebecca Mock  
Associate Director, Regulatory Affairs  
3160 Porter Drive  
Palo Alto, CA 94304

Dear Ms. Mock:

Please refer to your supplemental new drug application dated January 16, 2007, received January 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Olux-E™ (clobetasol propionate) Foam, 0.05%

This new drug application provides for the addition of 10 g and 50 g package sizes.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 16, 2007.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 22-013/S-001.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

*{See appended electronic signature page}*

James D. Vidra, Ph.D.  
Branch Chief  
Branch VII, Division of Post-Marketing Evaluation  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

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/s/

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Jim Vidra  
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