DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-934

Eleanor V. Chiu
Connetics
3290 West Bayshore Road
Palo Alto, CA 94303

Dear Ms. Chiu:

Please refer to your supplemental new drug application dated April 11, 2002, received April 15, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Luxiq® (betamethasone valerate) Foam, 0.012%.

We acknowledge receipt of your submission dated May 15, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (b)----------as an alternate manufacturer of the drug product.

We completed our review of these applications, as amended. These applications are 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.

Reflect "Manufactured by : (b)----------and "Manufactured for: Connetics Corporation, Palo Alto, CA 94303, USA".

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted May 15, 2002, patient package insert submitted May 15, 2002, immediate container and carton labels submitted May 15, 2002). These revisions are terms of the approval of these applications.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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, these submissions should be designated "FPL for approved supplement NDA 20-934/SCM-007, SCP-007." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Melinda Harris, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader

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
10/8/02 02:31:20 PM
approved