DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-934/S-006

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

Dear Ms. Chiu:

Please refer to your supplemental new drug application dated April 15, 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, 0.12%.

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

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new package size (15 g can) of Luxiq® (betamethasone valerate) Foam, 0.12% and labeling to reflect this change.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 15, 2002.

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 the requirements for an approved NDA set forth under 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
10/9/02 03:00:20 PM
approved