CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-978

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-978

Connetics Corporation
Attention: Michael Eison, Ph.D., Vice President, Regulatory Affairs
3160 Porter Drive
Palo Alto, CA 94304

Dear Dr. Eison:

Please refer to your new drug application (NDA) dated November 18, 2005, received November 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Verdeso (desonide) Foam, 0.05%.

We acknowledge receipt of your submissions dated March 15 (2), May 2 and 24, July 18 and 24, August 15, 22, 24 and 29, and September 11, 2006.

This new drug application provides for the use of Verdeso (desonide) Foam, 0.05% for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). 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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

We remind you of your CMC agreements made in your amendment dated May 24, 2006.

We also remind you of your postmarketing study commitments in your submission dated September 11, 2006. These commitments are listed below.

1. The applicant commits to conducting a dermal carcinogenicity study with Verdeso (desonide) Foam.

90-day dose range-finding study:	By April 1, 2008
Study protocol submission:	By October 1, 2008
Study start date:	By June 1, 2009
Final report submission:	By December 1, 2012

2. The applicant commits to conducting a study to determine the photoco-carcinogenic potential of Verdeso (desonide) Foam.

90-day dose range-finding study:	By April 1, 2008
Study protocol submission:	By October 1, 2008
Study start date:	By June 1, 2009
Final report submission:	By December 1, 2011

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be **prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Bauerlien, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Division Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich
9/19/2006 04:37:10 PM
Sign off for Dr. Susan Walker, Division Director