CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-142

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-142

Connetics Corporation
Attention: Ms. Claire Lockey
Vice President, Regulatory Affairs
3400 West Bayshore Road
Palo Alto, CA 94303

MAY 26 2000

Dear Ms. Lockey:

Please refer to your new drug application (NDA) dated July 28, 1999, received July 29, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for OLUX™ (clobetasol propionate) Foam, 0.05%.

We acknowledge receipt of your submissions dated September 15 and 27, October 27 and 29, November 29, December 17, 1999; February 4 and 16, March 21, April 27, and May 23, 24, 25 (facsimile) and 26 (facsimile), 2000.

This new drug application provides for the use of OLUX™ (clobetasol propionate) Foam, 0.05%, for short-term topical treatment of the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text with revisions listed on your submission dated May 24, 2000, regarding the carton and container labeling. These revisions are listed below. Accordingly, the application is approved effective on the date of this letter.

1. The drug name and strength will be located more towards the center on the label and will be given greater prominence.
2. The trade dress will be modified so that there can be no confusion with the controlled substance symbol which is overlayed on scheduled drugs,
3. The "Rx Only" statement will be moved to the primary display panel.
4. All inactive ingredients will be listed on the both the container and the carton in alphabetical order.
5. The prominence of the net quantity statement will be diminished such that it is not more prominent than the product strength.
6. The large "foam" icon will not appear at the proprietary name.

The final printed labeling (FPL) must be identical, and should include the revisions listed above, to the enclosed labeling (package insert, patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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, this submission should be designated "FPL for approved NDA 21-142." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application for short-term topical treatment of the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp as the necessary studies are impossible or highly impractical to conduct because the number of pediatric patients under 12 years of age with these conditions is too small.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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 Kalyani Bhatt, Project Manager, at (301) 827-2020.

Sincerely,

/S/

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure