DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-644

Galderma Laboratories, L.P.
Attention: Susan Pickrel
Regulatory Affairs Associate
14501 N. Freeway
Fort Worth, TX 76177

Dear Ms. Pickrel:

Please refer to your new drug application (NDA) dated May 2, 2003, received May 6, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Clobex™ (clobetasol propionate) Shampoo, 0.05%.

We acknowledge receipt of your submissions dated June 13, 26, August 8, 18, September 25, 30, November 14, 20, 21, December 19, 23(2), 24 and 30 (facsimile), 2003.

This new drug application provides for the use of Clobex™ (clobetasol propionate) Shampoo, 0.05%, for the topical treatment of moderate to severe forms of scalp psoriasis.

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, text for the 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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-644.**" Approval of this submission by FDA is not required before the labeling is used.

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 are deferring submission of your pediatric study for ages 12 to 17 years until April, 2006.

Your deferred pediatric study required under section 2 of the Pediatric Research Equity Act (PREA) is considered a required postmarketing study commitment. The status of the postmarketing study shall be reported annually according to 21 CFR 314.81. The commitment is listed below.

Deferred pediatric study under PREA for the topical treatment of moderate to severe forms of scalp psoriasis in pediatric patients ages 12 to 17.

Final Report Submission: April, 2006

Submit final study reports to this NDA. For administrative purposes, all submissions related to the pediatric postmarketing study commitment must be clearly designated "Required Pediatric Study Commitments".

We remind you of your postmarketing study commitment in your submission dated December 23, 2003.

1. Commits to performing dermal carcinogenicity testing of the drug product.

   Commitment Category: NON-CLINICAL TOXICOLOGY

   Protocol Submission: Within 4 months of the date of this letter
   Study Start: Within 6 months of the date of approval of the protocol
   Final Report Submission: Within 12 months after the study completion

2. Commits to evaluate the potential of the drug product to modify UV-induction of skin cancer. This might be evaluated by examining appropriate markers of UV exposure or UV damage in the skin (see CDER Photosafety Testing Guidance).

   Commitment Category: NON-CLINICAL TOXICOLOGY

   Protocol Submission: Within 4 months of the date of this letter
   Study Start: Within 6 months of the date of approval of the protocol
   Final Report Submission: Within 12 months after the study completion

3. Agrees to conduct a nonclinical study to evaluate the impact of clobetasol propionate on fertility.

   Commitment Category: NON-CLINICAL TOXICOLOGY

   Study Start: Within 10 months of the date of this letter
   Final Report Submission: Within 12 months after the study completion

4. Commits to performing an HPA axis suppression study in no less than 60 evaluable subjects (30 adults and 30 adolescents 12 to 17 years of age) using cosyntropin stimulation testing conducted as labeled with pre- and exactly-30-minutes-post-stimulation levels obtained at baseline and 4 weeks. Enrolled subjects should have at least 25% scalp surface area involvement and normal baseline stimulated cortisol levels, and any suppressed subjects should be followed to recovery.

Commitment Category:	CLINICAL SAFETY ASSESSMENT
Protocol Submission:	Within 4 months of receipt of approval letter
Study Start:	Within 6 months of the date of approval of the protocol
Final Report Submission:	Within 16 months after date of approval of the protocol

5. Commits to performing a safety and efficacy study in non-Caucasian subjects, with particular attention to subjects of African-American and Asian ethnicity.

Commitment Category:	CLINICAL SAFETY ASSESSMENT
Protocol Submission:	Within 4 months of receipt of approval letter
Study Start:	Within 6 months of the date of approval of the protocol
Final Report Submission:	Within 24 months after date of approval of the protocol

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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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 Dermatologic and Dental Drug Products 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, MD 20857

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

If you have any questions, call Jacquelyn Smith, Regulatory Project Manager, at (301) 827-2020

Sincerely,

{See appended electronic signature page}

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

Enclosure (Labeling)

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Clobex™ Shampoo for a condition for which it was not prescribed. Do not give Clobex™ Shampoo to other people, even if they have the same symptoms you have. It may harm them. This leaflet summarizes the most important information about Clobex™ Shampoo. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Clobex™ Shampoo that is written for health professionals.

What are the Ingredients in Clobex™ Shampoo?

Active ingredient: clobetasol propionate

Excipients (shampoo base): ethyl alcohol, citric acid monohydrate, coco-betaine, polyquaternium-10, purified water, sodium citratedihydrate, and sodium laureth sulfate.

Rx only