DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021535/S-003
NDA 021644/S-003

SUPPLEMENT APPROVAL

Galderma Laboratories, LP
Attention: Richard Almond, MBA, RAC
Senior Manager, Regulatory Affairs
14501 N. Freeway
Fort Worth, TX 76177

Dear Mr. Almond:

Please refer to your Supplemental New Drug Applications (sNDA's) dated and received March 26, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Clobex® (clobetasol propionate) Lotion, 0.05% and Clobex® (clobetasol propionate) Shampoo, 0.05%.

We acknowledge receipt of your amendments dated October 26, and November 20, 2012.

These "Prior Approval" supplemental new drug applications provide for the revision of the full prescribing information to meet the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57.

We have completed our review of these supplemental applications, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and indicated in track changes in the enclosed labeling.

Clobex® Shampoo

1. Move the last paragraph"If irritation develops . . .", in HIGHLIGHTS/WARNINGS AND PRECAUTIONS section to the second to last paragraph of that section.

2. In the Table of Contents, the title of subsection 5.1 was changed to match the title of subsection 5.1 in the Full Prescribing Information, "Effects on the Endocrine System".

3. The cross reference of the second paragraph in the INDICATIONS AND USAGE section of the Full Prescribing Information has been italicized.

4. In subsection 8.5 Geriatric Use, the first line "Clobetasol Propionate" has been changed to "CLOBEX".

5. In the Patient Information section, You should not use CLOBEX Shampoo subsection, the sentence (b) (4) has been deleted.

6. The revised date at the end of the Instructions for Use section has been deleted.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions listed above and indicated in the enclosed labeling (text for the package insert, text for the patient package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Dawn Williams, Regulatory Project Manager, at (301) 796-5376.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

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

/s/

TATIANA OUSSOVA
11/30/2012