DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020554/S-12
NDA 020273/S-13

SUPPLEMENT APPROVAL

LEO Pharma A/S
c/o LEO Pharma Inc.
Attention: Lori A. Palmer
Director, U.S. Regulatory Affairs
1 Sylvan Way
Parsippany, NJ 07054

Dear Ms. Palmer:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 15, 2014, received September 15, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dovonex (calcipotriene cream) Cream, 0.005% and Dovonex (calcipotriene) Ointment, 0.005%.

We acknowledge receipt of your amendments dated October 6, 2014 and January 27 (2), 2015.

These "Prior Approval" supplemental new drug applications propose updates to the Warnings and Postmarketing Experience sections of product labeling regarding contact dermatitis, including allergic contact dermatitis.

APPROVAL & LABELING

We have completed our review of this supplemental application, 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.

- In the label for Dovonex Cream, the product name should appear as Dovonex (calcipotriene cream) Cream, 0.005%, not Dovonex (calcipotriene) Cream, 0.005%. Revise the product name in the Dovonex Cream label.

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, the enclosed labeling (text for

the 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 indicated above 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 Cristina Attinello, Senior Regulatory Project Manager, at (301) 796-3986.

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

ENCLOSURE:
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
03/11/2015