DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202833/S-002

SUPPLEMENT APPROVAL

LEO Pharma A/S
C/o LEO Pharma Inc.
Attention: Jane Aoyagi
Director, Regulatory Affairs
1 Sylvan Way
Parsippany, NJ 07054

Dear Ms. Aoyagi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 7, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Picato® (ingenol mebutate) gel, 0.015% and 0.05% for topical treatment of actinic keratosis.

We acknowledge receipt of your amendment dated October 28, 2013.

This "Changes Being Effected" supplemental new drug application provides for an increase in the prominence of the existing storage condition by adding the statement "Must Be Refrigerated" in several new locations on the product cartons.

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 with the enclosed, agreed-upon carton labels.

CARTON LABELS

Submit final printed carton labels that are identical to the enclosed carton labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton Labels for approved NDA 202833/S-002."** Approval of this submission by FDA is not required before the labeling is used.

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Carton Labeling

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
03/12/2014