DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021852/S-006 **SUPPLEMENT APPROVAL**

LEO Pharmaceuticals Products Ltd.
c/o PAREXEL Consulting (US Agent)
Attention: Lori A. Palmer
Director
72 Burr Road
Higganum, CT 06441

Dear Ms. Palmer:

Please refer to your supplemental new drug application dated June 30, 2009, received July 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment.

We acknowledge receipt of your submission dated August 26, 2009, January 6, February 3, and March 19, 2010.

This "Prior Approval" supplemental new drug application provides for the revision of the Taclonex® Ointment 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.

CONTENT OF LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to enclosed labeling (text for the package insert and text for the patient package insert. For administrative purposes, please designate this submission, "SPL for approved NDA 021852/S-006.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch

Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

POSTMARKETING COMMITMENTS

We remind you of your postmarketing commitments provided in the January 9, 2006, approval letter. These commitments are listed below.

2. Evaluation of the carcinogenicity of betamethasone dipropionate in mice.

   Protocol Submission: 10/06
   Study Start: 07/07
   Final Report Submission: 10/10

3. Evaluation of the carcinogenicity of betamethasone dipropionate in rats.

   Protocol Submission: 10/06
   Study Start: 07/07
   Final Report Submission: 10/10

5. Deferred pediatric study under PREA for the treatment of psoriasis vulgaris in pediatric patients ages 12 to 17.

   Final Report Submission: 01/09

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/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

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 Nichelle Rashid, Regulatory Project Manager, at (301) 796-3904.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, M.D., M.P.H.
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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21852	SUPPL-6	LEO PHARMACEUTICAL PRODUCTS LTD	TACLONEX OINTMENT

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
03/30/2010