DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-185/S-003

LEO Pharmaceutical Products Ltd.
US Agent: Warner Chilcott (US), LLC
Attention: Taryn E. Macones, Associate, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Macones:

Please refer to your supplemental new drug application dated November 6, 2008, received November 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taclonex® (calcipotriene and betamethasone dipropionate) Suspension.

This "Prior Approval" supplemental new drug application provides for addition of 4 g sample size (b) (4)

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-185/S-003**." Approval of this submission by FDA is not required before the labeling is used.

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 Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Jim Vidra

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