CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 22-185

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	February 13, 2008
To:	Susan Walker, M.D., Director Division of Dermatology and Dental Products
Through:	Jodi Duckhorn, M.A., Team Leader Patient Labeling and Education Team Division of Risk Management
From:	Sharon R. Mills, BSN, RN, CCRP Patient Product Information Specialist Patient Labeling and Education Team Division of Risk Management
Subject:	DRM Review of Patient Labeling (Patient Package Insert)
Drug Name(s):	Taclonex Scalp (calcipotriene 0.005% and betamethasone dipropionate 0.064%) gel
Application Type/Number:	NDA 22-185
Applicant/sponsor:	LEO Pharmaceutical Products Ltd.
OSE RCM #:	2007-2031

1 INTRODUCTION

PAREXEL International (PAREXEL), acting as U.S. agent on behalf of LEO Pharmaceutical Products Ltd., submitted New Drug Application (NDA) #22-185 for Taclonex Scalp (calcipotriene 0.005% and betamethasone dipropionate 0.064%) gel on June 19, 2007. The proposed indication for Taclonex Scalp gel is for the topical treatment of psoriasis vulgaris of the scalp in adults 18 years and above.

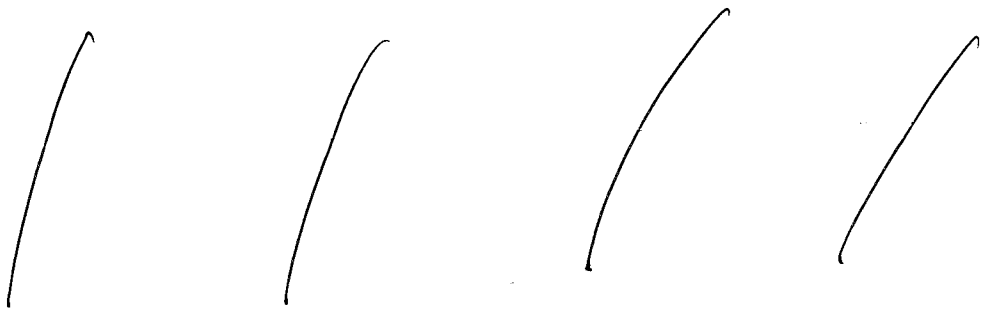
The submitted labeling for the above referenced NDA includes patient labeling in the form of a Patient Package Insert. DRM has been requested to review the Patient Package Insert for this application.

2 MATERIAL REVIEWED

Professional Information (PI) and Patient Package Insert (PPI) submitted on June 19, 2007

3 DISCUSSION

The purpose of patient information leaflets is to enhance appropriate use and provide important risk information about medications. Our recommended changes are consistent with current research to improve risk communication to a broad audience, including those with lower literacy.



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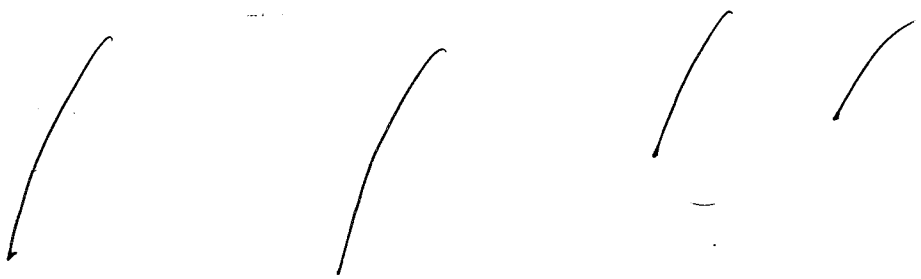
See the attached document for our recommended revisions to the PPI. Comments to the review division are ***bolded, underlined and italicized***.

We are providing the review division a marked-up and clean copy of the revised PPI. We recommend using the clean copy as the working document.

All future relevant changes to the PI should also be reflected in the PPI.

4 CONCLUSIONS AND RECOMMENDATIONS



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_____ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Sharon Mills
2/13/2008 02:33:46 PM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
2/13/2008 02:43:07 PM
CSO