CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-852

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-852

PAREXEL International, PAREXEL Consulting
Attention: Alberto Grignolo, PhD
Corporate Vice President and General Manager
Drug Development Consulting Practice
195 West Street
Waltham, MA 02451-1163

Dear Dr. Grignolo:

Please refer to your new drug application (NDA) dated March 9, 2005, received March 9, 2005, submitted pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment.

We acknowledge receipt of your submissions dated March 14, May 4 and 23, June 23, July 5, and 13, August 2, 11 and 29, September 12, 16, and 21, October 12 and 31, November 2, 3, 13, 21, and 29, and December 9 (facsimile), 2005; January 5 and 6 (facsimile), 2006.

This new drug application provides for the use of Taclonex® (calcipotriene 0.005% and betamethasone dipropionate 0.064%) Ointment, for the topical treatment of psoriasis vulgaris in adults aged 18 years and above.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and container labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-852**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are

waiving the pediatric study requirement for ages 0 to 11 years and deferring pediatric studies for ages 12 to 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of the postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

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

Final Report Submission: 01/09

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "Required Pediatric Study Commitment".

In addition, we remind you of your postmarketing study commitments in your facsimile dated January 5, 2006. These commitments are listed below.

1. Evaluation of the carcinogenicity of calcipotriene (which is currently being evaluated as a post-approval commitment to NDA 20-273).

   Final Report Submission: 07/06

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

4. Evaluation of betamethasone dipropionate for effects upon female fertility, including prenatal and postnatal function.

   Study Start: 07/06
   Final Report Submission: 12/07

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

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Dermatology & Dental Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

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

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, please call Felecia Curtis, 301-796-0877.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, MD
Acting Division Director
Division of Dermatology & Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (Labeling)

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

/s/

Jill Lindstrom
1/9/2006 03:00:39 PM