DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-087 **NDA APPROVAL**

Galderma Laboratories, L.P.
ATTENTION: Paul Clark
Director, Regulatory Affairs
14501 N. Freeway
Fort Worth, TX 76177

Dear Mr. Clark:

Please refer to your new drug application (NDA) dated, December 21, 2007 received December 27, 2007, submitted under section 505(b) (1) of the Federal Food, Drug, and Cosmetic Act for Vectical (calcitriol) Ointment, 3 mcg/g.

We acknowledge receipt of your submissions dated September 25, November 7, and 20, December 1, and 14, 2006; January 22, and 30; March 20, December 21, 2007; February 12, 14, and 20, April 15, and 29, June 23 and 25, July 10 and 18, August 11, 13, and 26, September 2, 8, and 26, October 17, 20, 24, 27, and 29, November 4 and 12, December 4, 2008; January 5, 12, and 15, 2009.

This new drug application provides for the use of Vectical (calcitriol) Ointment, 3 mcg/g indicated for the treatment of plaque psoriasis.

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.

CONTENT OF LABELING

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)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-087."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).*

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 and Container Labels for approved NDA 22-087**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product 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.

We are waiving the pediatric study requirements for ages 0 months to 2 years because necessary studies are impossible or impracticable. This is because there are too few children with the condition to study.

We are deferring submission of your pediatric studies for ages 2 to 17 years for this application, because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. The required studies are listed below.

1. Conduct PK/PD study of Vectical Ointment under maximum use conditions in 25 evaluable pediatric subjects with psoriasis aged 12 to 17 years. The study protocol has been submitted and initiated.

   Study Start: June 2006
   Final Report Submission: March 2010

2. Conduct a PK/PD study of Vectical Ointment under maximum use conditions in pediatric subjects with psoriasis aged 2 to 12 years; the number of subjects enrolled should be sufficient to detect a 10% change in serum ionized calcium from baseline with 90% confidence or a minimum of 25 evaluable subjects, whichever is larger.

   Protocol Submission: April 2009
   Study Start: July 2009
   Final Report Submission: March 2012

3. Conduct a vehicle-controlled study of the safety and efficacy of Vectical Ointment in pediatric subjects with psoriasis 2 to 12 years of age with a minimum of 100 evaluable subjects exposed to active.

Protocol Submission:	April 2009
Study Start:	July 2009
Final Report Submission:	July 2011

4. Conduct a long-term safety study of Vectical Ointment in 100 evaluable pediatric patients 2 to 17 years of age.

Protocol Submission:	April 2009
Study Start:	October 2009
Final Report Submission:	January 2012

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Emelia Annum, Regulatory Project Manager, at (301) 796-2223.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Labeling, Carton and Immediate Container Labels

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

/s/

Susan Walker
1/23/2009 05:46:40 PM