



January 29, 2018

Division of Dermatology and Dental Products  
FDA Office of Drug Evaluation III  
Center for Drug Evaluation and Research Central Document Room  
5901-B Ammendale Road  
Beltsville MD 20705-1266

**RE: DEFERRAL EXTENSION REQUESTED  
RESPONSE to PREA NON-COMPLIANCE LETTER  
NDA 022087/SN 0017/s004  
Vectical<sup>®</sup> (calcitriol) Ointment, 3 mcg/g**

Dear Susan Walker, M.D.,

Reference is made to the approved New Drug Application, NDA 22-087 for Vectical<sup>®</sup> (calcitriol) Ointment, 3 mcg/g sponsored by Galderma Laboratories, L.P. (GLLP). Cross-reference is made to Galderma Laboratories, L.P. (GLLP) initial Investigational New Drug Application, IND (b) (4) (Protocol (b) (4)) for Calcitriol Ointment 3 mcg/g, effective April 4, 2001.

Galderma is hereby requesting a deferral extension for the pediatric assessment. As previously indicated, the December 2017 clinical study report delivery date was missed due to difficulties in recruitment of applicable subjects (low prevalence of pediatric psoriasis, difficulty of physician diagnosis, parental refusal of study participation, etc.), which resulted in Galderma requesting a release from the post-marketing requirements. Based on the discussions during the teleconference on November 8, 2017, Galderma intends to submit an efficacy supplement as requested by the Agency wherein all data collected will be presented for evaluation.

In order to submit the efficacy supplement, the ongoing study will be terminated in June 2018 (Last Subject Out), enrollment activities will be stopped, and the ongoing subjects (7) will be followed to completion. A complete clinical study report will then be prepared along with integrated data from the prior studies, as requested by the Agency in the teleconference. The clinical study report is to be finalized in November 2018 with a submission of the efficacy supplement to the FDA in December 2018.

These electronic files were provided through the Electronic Gateway. All files were checked and verified to be free of viruses. If there are any questions, please contact me directly at 817-961-5079, by facsimile at 817-720-1040, or email at [steve.lautzenheiser@galderma.com](mailto:steve.lautzenheiser@galderma.com).

Sincerely,

**Steve Lautzenheiser** Digitally signed by Steve Lautzenheiser  
Date: 2018.01.29 09:20:18 -06'00'

Steve Lautzenheiser  
Regulatory Affairs Manager