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January 15, 2014

Susan J. Walker, MD, FAAD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
59010-B Ammendale Road
Beltsville, MD 20705-1266

RE: RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUEST
NDA 022408 / IND 66657

Dear Dr. Walker,

ParaPRO received a Notification of Non-compliance with PREA letter, dated December 3, 2013, for Natroba (spinosad) Topical Suspension, 0.9%. The non-compliance letter states that ParaPRO has not met the requirements of PREA because we have not submitted the pediatric assessment that was deferred until March 31, 2012.

We were surprised to receive the non-compliance letter because we believed we had complied with all PREA requirements, as described in the approval letter for Natroba. As you may recall, the Natroba approval letter granted ParaPRO a deferral for submission of results of a pharmacokinetic and safety study in pediatric patients aged 6 months to 4 years because Natroba was ready for approval for use in adults and older children. According to the approval letter, ParaPRO was required to:

"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."

Furthermore, the NDA approval letter also indicated ***"All submissions, including supplements, relating to these postmarketing studies should be prominently labeled "Postmarketing Requirement Protocol," Postmarketing Requirement Final Report," or "Postmarketing Requirement Correspondence."***

ParaPRO completed the required study, and on May 29, 2012, submitted the results of the study to the NDA with the designation "**Postmarketing requirement final report**." ParaPRO received written confirmation from FDA, dated June 1, 2012, that the study was received by the Agency and had been forwarded to the team for review set to be completed by May 29, 2013. For your reference, a copy of this information is attached to this letter.

After further review into this matter, including a discussion with Rosemary Addy, Supervisory Consumer Safety Officer, Pediatric and Maternal Health Staff, we now understand that PREA requires the study we submitted as a "**Postmarketing Requirement Final Report**" in May of 2012 to be submitted as an "**Efficacy Supplement**" so that label changes may be implemented. Ms. Addy recommended we request a Deferral Extension in our response letter for a sufficient amount of time required to complete a new submission as an efficacy supplement and indicated that if the deferral extension was granted neither the PREA non-compliance letter nor this response letter would be posted on the FDA website.

DEFERRAL EXTENSION REQUEST

As explained above, ParaPRO has conducted the required postmarketing study and submitted it to FDA as directed in the Natroba approval letter, substantially in compliance with the time frames of the initial deferral. Based on the information included in the approval letter, we did not understand that an efficacy supplement was required. We now intend to submit the study results as an efficacy supplement. It is our understanding, based on the Guidance Document "Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees," that our pharmacokinetic study is not considered clinical data for user fee purposes, and therefore, that no user fee is payable with this efficacy supplement.

ParaPRO requests a deferral extension until April 30, 2014. Since the study has already been completed and submitted, ParaPRO expects to be able to quickly resubmit as an efficacy supplement as soon as the proposed label changes have been added to the document. We fully expect the submission to take place prior to the April 30, 2014 date requested.

If you have any questions or additional recommendations please feel free to call me at 317.810.6202 or via email to billc@parapro.com.

Thank you for your consideration of this matter.

Sincerely,

William H. Culpepper, III
President, ParaPRO LLC

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