CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022408Orig1s000

Trade Name: Natroba Topical Suspension 0.9%

Generic Name: Spinosad

Sponsor: ParaPRO, LLC

Approval Date: January 18, 2011

Indications: Topical treatment of head lice infestation in patients 4 years of age and older

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022408

NDA APPROVAL

ParaPRO, LLC
Attention: William Culpepper, III
President
11550 N. Meridian St., Suite 600
Carmel, IN 46032

Dear Mr. Culpepper:

Please refer to your New Drug Application (NDA) dated January 21, 2009, received January 22, 2009, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Natroba (spinosad) Topical Suspension, 0.9%.

We acknowledge receipt of your amendments dated February 25, March 10 and 31, May 1, June 29, July 9 and 16, August 21, September 8 and 24, December 11 and 30, 2009; January 26, April 16, May 25, June 14, July 23, September 14 and 23, November 23, December 16, 2010, and January 11, 2011.

The July 23, 2010, submission constituted a complete response to our November 18, 2009 action letter.

This new drug application provides for the use of Natroba (spinosad) Topical Suspension, 0.9% for the topical treatment of head lice infestation in patients 4 years of age and older.

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, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 16, 2010, submission containing final printed carton and container labels.

Your application for Natroba (spinosad) Topical Suspension, 0.9% was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues in the intended population.

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 requirement for ages 0 months to 6 months because this product would be unsafe in this pediatric subpopulation, since it contains benzyl alcohol and there is a risk of benzyl alcohol toxicity. This product is not recommended for use in neonates and infants below the age of 6 months. In addition, necessary studies are impossible or highly impracticable because there are too few children with the condition to study. This product also does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this pediatric subpopulation and is not likely to be used in a substantial number of pediatric patients in this subpopulation

We are deferring submission of your pediatric studies for ages 6 months to 4 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed in those patients with head lice infestation.

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

Your deferred pediatric study under PREA is as follows:

1711 A pharmacokinetic and safety study in pediatric patients ages 6 months to 4 years of age with active head lice infestation. This study should be conducted under maximum use conditions and include a minimum of 24 evaluable patients who will undergo pharmacokinetic sampling and assessments of local and systemic safety at appropriate time points.

The timetable you submitted on September 14, 2010 states that you will conduct this study according to the following schedule:

Final Protocol Submission: March, 2011

Study Completion: December, 2011

Final Study Report Submission: March, 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**".

Submit clinical protocols to your IND 066657 for this product. 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/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing studies should be prominently labeled "**Postmarketing Requirement Protocol**," "**Postmarketing Requirement Final Report**," or "**Postmarketing Requirement Correspondence**."

This product is appropriately labeled for use in ages 4 to 16 years for this indication. Therefore, no additional studies are needed in this pediatric age group.

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 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, 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 http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues

Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm.

POST-ACTION FEEDBACK MEETING

New molecular entities qualify for a post-action feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application. If you have any questions, call Dawn Williams, Regulatory Project Manager, at (301) 796-5376.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Carton and Container Labeling

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

/s/

JULIE G BEITZ
01/18/2011
Change the set number to 1711-1