Scalp and Hair Therapeutics Final Report
October 20, 2013

Evaluation of a Regimen for Scalp Itch Reduction and Hair Beautification

STUDY NUMBER: DCS-62-13

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STUDY TITLE: Evaluation of a Regimen for Scalp Itch Reduction and Hair Beautification Evaluation of the Tolerance and Skin Improvement Properties of a Moisturizing Cream in Subjects with Eczema Correct study title?

Signatures of the noted individuals indicate that this document represents the final report.

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Rebecca Kazin, MD Date
President
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Zoe Diana Draelos, M.D. Date
Primary Investigator
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1.PROTOCOL SYNOPSIS

Title of Study:	Evaluation of a Regimen for Scalp Itch Reduction and Hair Beautification
Study Period:	4 weeks
Test Product and Application Instructions:	Cleansing Scalp & Hair Treatment, Nourishing Scalp and Hair Masque, Scalp Itch Eraser Apply a quarter-sized amount of the scalp cleansing shampoo to the top of the head and another quarter-sized amount to the sides on wet hair and scalp. Massage lather into scalp and rinse thoroughly with warm water. Squeeze out excess water after washing and gently massage nourishing scalp and hair mask into scalp and work through hair to ends. Leave on 30 seconds for normal hair and 2-3 minutes for damaged and/or processed hair. Rinse with warm water. Dry and style as usual. This procedure was performed at least 3 times weekly. Use scalp itch eraser as needed by applying a few drops to itchy scalp areas directly up to 3-4 times daily as needed.
Objectives:	1. To determine if the study scalp and hair care regimen is effective in reducing scalp itch and dryness/flaking while beautifying the hair. 2. To determine if the study scalp regimen provides superior scalp itch reduction. 3. To determine if the study scalp regimen provides superior hair beautification.
Design:	Subjects with mild to moderate itch of the scalp and/or mild scalp dryness/flaking presented to the research center for evaluation for study entry. If found to be suitable, subjects underwent the baseline investigator assessment, subject self-assessment, and received the study product for use 3 times weekly. The subjects were instructed on product use by the study coordinator. All subjects were compared to baseline as a historical control. Investigator and subject assessments were obtained at baseline, week 1, week 2, and week 4.

Study Population:	Male or female subjects 18+ years of age with mild dandruff accompanied by mild to moderate scalp itching. Subjects were enrolled with the following hair/scalp conditions: 1. Chemically processed hair, to include permanent dyeing, permanent waving, and hair straightening 2. Sensitive skin/scalp 3. Unsuccessful experiences with other products designed for dandruff and scalp itch
Number of Subjects:	30 subjects (5 males, 25 females)
Inclusion Criteria:	1. Males or females 18+ years of age. 2. Mild scalp flaking/dryness and/or 3. Mild to moderate scalp itch. 4. Subjects must be willing to use only the provided shampoo, conditioner, and scalp care products. 5. Subjects must be in general good health as determined from a medical history. 6. Subjects must read and sign the informed consent form after the nature of the study has been fully explained.
Exclusion Criteria:	1. Subjects with known allergies or sensitivities to ingredients contained in the test products. 2. Subjects who are required to spend excessive time in the sun (i.e. lifeguards, other outdoor workers). 3. Subjects who are pregnant or nursing or planning to become pregnant during the course of the study. 4. Subjects who are currently participating in any other clinical study (i.e., dermal patch, use tests, investigational drug or devices, etc.). 5. Subjects viewed by the investigator as not being able to complete the study. 6. Subjects who have scalp or hair cosmetic issues that could interfere with study assessment procedures. 7. Subjects with any other concomitant skin disease in addition to mild dandruff. 8. Subjects using any systemic or topical treatment for a skin condition. 9. Subjects with skin conditions that could interfere with an accurate assessment of scalp itch.

Endpoints:	Primary Efficacy Endpoint: Statistically significant (p=0.05 or less) improvement in global investigator scalp assessment. Secondary Efficacy Endpoint: Statistically significant (p=0.05 or less) improvement in global hair appearance subject assessment with the study regimen. Safety Endpoints: The safety endpoints were the investigator and subject assessed study product tolerability and the absence of adverse events.
Measures:	Investigator Scalp Assessments: irritation, erythema, desquamation, visible flaking, dryness, and global scalp skin appearance. The investigator queried the subjects for the following sensory attributes: stinging, burning, and itching. Assessments will be conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments will be conducted at baseline, 1 week, 2 weeks, and 4 weeks. Investigator Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and global hair appearance. Assessments will be conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments will be conducted at baseline, 1 week, 2 weeks, and 4 weeks. Subject Scalp Assessments: irritation, redness, scale, visible flaking, dryness, stinging, burning, itching and overall scalp skin appearance. Assessments will be conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments will be conducted at baseline, 1 week, 2 weeks, and 4 weeks. Subject Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and overall hair appearance. Assessments will be conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe. Assessments will be conducted at baseline, 1 week, 2 weeks, and 4 weeks.

Statistical Methods:	A Mann-Whitney two-tailed t-test was used to analyze the nonparametric data from the investigator and subject assessments.

2.STUDY VISIT SCHEDULE

Procedures	Visit 1 Baseline	Visit 2 Week 1	Visit 3 Week 2	Visit 4 Week 4
Dermatologic Evaluation for Suitability (mild dandruff and mild to moderate scalp itching)	X			
Product Dispensing	X		X	
Informed Consent	X			
Subject Scalp and Hair Evaluation	X	X	X	X
Investigator Scalp and Hair Evaluation	X	X	X	X
Study Closeout and Product Accountability				X

3.INTRODUCTION

Scalp health and protection from common scalp problems, such as itching and dandruff, are important hygiene and appearance needs. Shampoo is a product that can significantly affect the appearance of the hair shaft from a cosmetic standpoint, but also insure scalp health. Since the hair is nonliving, damage to the protein structure of the hair is permanent requiring carefully formulated shampoos to achieve and maintain the cosmetic value of the hair fiber. The scalp, on the other hand, is skin covering the head and functioning much like any other area with turnover of the epidermis occurring every 2 weeks with continuous sloughing of the stratum corneum. While on other body areas the skin scale is easily sloughed, the hair covered the scalp skin makes desquamation more challenging. It is the retention of the old stratum cornuem that leads to dandruff, a condition characterized by scaling, sebum retention, fungal overgrowth, and itching. Scalp scratching from uncontrolled itch can damage both the scalp and the hair shafts resulting in both functional and cosmetic issues. This study is aimed at understanding the benefits of a novel hair and scalp care regimen on scalp itching.

4.STUDY HYPOTHESIS

The objectives of this study were as follows:

1. To determine if the study scalp and hair care regimen is effective in reducing scalp itch and dryness/flaking while beautifying the hair.
2. To determine if the study scalp regimen provides superior scalp itch reduction.
3. To determine if the study scalp regimen provides superior hair beautification

5.STUDY DESIGN OVERVIEW

Subjects with mild to moderate itch of the scalp and/or mild scalp dryness/flaking presented to the research center for evaluation for study entry. If found to be suitable, subjects underwent the baseline investigator assessment, subject self-assessment, and received the study product for use 3 times weekly. The subjects were instructed on product use by the study coordinator. All subjects were compared to baseline as a historical control. Investigator and subject assessments were obtained at baseline, week 1, week 2, and week 4.

6.STUDY POPULATION

6.1NUMBER OF SUBJECTS

30 subjects (5 males, 25 females)

6.2SUBJECT POPULATION

Male or female subjects 18+ years of age with mild dandruff accompanied by mild to moderate scalp itching. Subjects were enrolled with the following hair/scalp conditions:

1. Chemically processed hair, to include permanent dyeing, permanent waving, and hair straightening
2. Sensitive skin/scalp
3. Unsuccessful experiences with other products designed for dandruff and scalp itch

6.3INCLUSION CRITERIA

The following items represented the inclusion criteria:

1. Males or females 18+ years of age.
2. Mild scalp flaking/dryness and/or
3. Mild to moderate scalp itch.
4. Subjects must be willing to use only the provided shampoo, conditioner, and scalp care products.
5. Subjects must be in general good health as determined from a medical history.
6. Subjects must read and sign the informed consent form after the nature of the study has been fully explained.

6.4EXCLUSION CRITERIA

The following represented the exclusion criteria:

1. Subjects with known allergies or sensitivities to ingredients contained in the test products.
2. Subjects who are required to spend excessive time in the sun (i.e. lifeguards, other outdoor workers).
3. Subjects who are pregnant or nursing or planning to become pregnant during the course of the study.
4. Subjects who are currently participating in any other clinical study (i.e., dermal patch, use tests, investigational drug or devices, etc.).
5. Subjects viewed by the investigator as not being able to complete the study.
6. Subjects who have scalp or hair cosmetic issues that could interfere with study assessment procedures.
7. Subjects with any other concomitant skin disease in addition to mild dandruff.
8. Subjects using any systemic or topical treatment for a skin condition.
9. Subjects with skin conditions that could interfere with an accurate assessment of scalp itch.

6.5CONCOMITANT MEDICATIONS & RESTRICTIONS

No prescription or nonprescription medications for dandruff were allowed during the study. Subjects did not change any other prescription medications or any of their own self-selected hair care products during the study. Only the study shampoo and accompanying itch products were used on the scalp.

7.CONDUCT OF STUDY: METHODS AND PROCEDURES

7.1SUBJECT IDENTIFICATION

A study subject number was assigned based on the order in which the subjects presented to the research center. This number was placed on all study documents and used for randomization purposes.

7.2SUBJECT SUITABILITY EVALUATION

7.2.1INFORMED CONSENT

A signed, Institutional Review Board (IRB) approved informed consent form was obtained from each subject prior to performing any study procedures. No study related procedures or activities were performed until each subject was fully informed and the consent form was signed and dated.

7.2.2MEDICAL HISTORY

A brief medical history was recorded.

7.2.3INCLUSION /EXCLUSION CRITERIA

Subjects were questioned and assessed to determine eligibility for the study

7.2.4DERMATOLOGICAL EXAMINATION

A dermatological scalp evaluation for mild dandruff and mild to moderate scalp itching was performed to determine if the subjects met the entry criteria. Only subjects who possessed these findings were enrolled.

7.3BASELINE VISIT

Subjects with mild to moderate itch of the scalp and/or mild scalp dryness/ flaking were enrolled. They underwent the baseline investigator assessment, subject self-assessment, and received the study product for use 3 times weekly. The subjects were instructed on product use by the study coordinator. At baseline, the following scalp and hair assessments were conducted:

Investigator Scalp Assessments: irritation, erythema, desquamation, visible flaking, dryness, and global scalp skin appearance. The investigator queried the subjects for the following sensory attributes: stinging, burning, and itching. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Investigator Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and global hair appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Subject Scalp Assessments: irritation, redness, scale, visible flaking, dryness, stinging, burning, itching and overall scalp skin appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Subject Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and overall hair appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

7.4WEEK 1, 2, 4 VISITS

Subjects returned to the research center at weeks 1, 2, and 4. The study concluded at week 4 and all study products were collected. Subjects were resupplied with study products as necessary during the study. The following scalp and hair assessments were conducted:

Investigator Scalp Assessments: irritation, erythema, desquamation, visible flaking, dryness, and global scalp skin appearance. The investigator queried the subjects for the following sensory attributes: stinging, burning, and itching. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Investigator Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and global hair appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Subject Scalp Assessments: irritation, redness, scale, visible flaking, dryness, stinging, burning, itching and overall scalp skin appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

Subject Hair Assessments: manageability, frizziness, dryness, roughness, shine, split ends, and overall hair appearance. Assessments were conducted on the following ordinal grading scale: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe.

8.SUBJECT COMPLIANCE

Subjects were asked to complete a diary to insure compliance with study product use.

9.FINAL SUBJECT STATUS

A study termination form was completed for each study subject who underwent study procedures. This included subjects who completed the study or who withdrew or were withdrawn from study. 30/30 subjects successfully completed the study.

10.STUDY TEST MATERIALS

10.1DOSAGE AND FORMULATIONS

The test materials consisted of a Cleansing Scalp & Hair Treatment, Nourishing Scalp and Hair Masque, Scalp Itch Eraser.

10.2STUDY TEST MATERIALS ADMINISTRATION

Subjects were instructed to apply a quarter-sized amount of the scalp cleansing shampoo to the top of the head and another quarter-sized amount to the sides on wet hair and scalp. Massage lather into scalp and rinse thoroughly with warm water. Squeeze out excess water after washing and gently massage nourishing scalp and hair mask into scalp and work through hair to ends. Leave on 30 seconds for normal hair and 2-3 minutes for damaged and/or processed hair. Rinse with warm water. Dry and style as usual. This procedure was performed at least 3 times weekly. Use scalp itch eraser as needed by applying a few drops to itchy scalp areas directly up to 3-4 times daily as needed.

10.3PACKAGING, LABELING, DISTRIBUTION

Test materials were packaged and labeled by the sponsor.

10.4 STORAGE AND ACCOUNTABILITY OF STUDY TEST MATERIALS

The study product was stored at room temperature in a locked, limited access area at the study site. Access to the study test materials was limited to the investigator and staff members designated to dispense study test materials.

11. ADVERSE EVENTS

11.1ADVERSE REACTIONS PREVIOUSLY REPORTED

The study shampoo and scalp products could rarely cause scalp dryness and irritation. The shampoos are not intended for oral consumption or installation into the eyes. The study products all contained currently marketed ingredients

and did not represent a risk to subjects above and beyond that in the present shampoo and scalp treatment marketplace.

11.2ADVERSE EXPERIENCES

An adverse experience is defined as any untoward medical occurrence (sign, symptom or laboratory finding), regardless of severity and whether or not attributed to the study products. No adverse experienced occurred during the administration of the study.

12.STATISTICAL METHODS

A two-tailed Mann Whitney test for nonparametric data was used to evaluate the ordinal data for significant change using an intragroup analysis technique.

12.1SAMPLE SIZE RATIONALE

The sample size was determined based upon the wishes of the sponsor at 30 subjects.

12.2SIGNIFICANCE LEVEL

Significance was defined at the p=0.05 or less level.

13.RESULTS

The results are summarized for each of the data sets collected.
Table 1: Investigator Longitudinal Hair Assessment
Table 2: Investigator Longitudinal Scalp Assessment
Table 3: Subject Longitudinal Hair Assessment
Table 4: Subject Longitudinal Scalp Assessment

The data was analyzed longitudinally as compared to a historical control at baseline since all subjects used the active shampoo, conditioner, and scalp itch eraser. A lower score was indicative of a better score. The data is presented in all tables as percent change from baseline and the p value listed. A two tailed paired Mann Whitney nonparametric analysis technique was used with significance defined as $p<0.05$. All bolded numbers are statistically significant.

14.DISCUSSION

The results are discussed for each data set.
Table 1: Investigator Longitudinal Hair Assessment
The dermatologist investigator assessed excellent improvement in hair attributes at all evaluation time points (week 1, week 2, and week 4). There were highly statistically significant ($p<0.001$) improvements noted in manangeability, frizziness, dryness,

roughness, shine, and overall assessment at week 1. In addition, there was a statistically significant improvement in split ends ($p=0.006$) at week 1. All assessments became highly statistically significant at weeks 2 and 4. This is excellent performance for a medicated shampoo designed to reduce scalp itch while simultaneously beautifying the hair.

Table 2: Investigator Longitudinal Scalp Assessment
The investigator queried the subjects as to improvement in scalp stinging, burning, and itching at all visits. There was a statistically significant reduction in burning ($p=0.044$) and itching ($p<0.001$) at week 1. Scalp burning, stinging, and itching continued to improve throughout the study until week 4 where there was a highly statistically significant ($p<0.001$) reduction in all sensory parameters.

The investigator visually assessed scalp irritation, erythema, desquamation, flaking, dryness, and overall appearance at weeks 1, 2, and 4. All parameters showed a statistically significant reduction at week 1. Irritation, itching, desquamation, dryness, and overall appearance showed a highly statistically ($p<0.001$) reduction. By week 2 and continuing on into week 4, all parameters showed a highly statistically significant reduction. Again, the investigator noted dramatic improvement in scalp health as a result of the treatment regimen.

Table 3: Subject Longitudinal Hair Assessment
The subjects also rated strong improvement in hair attributes during the 4 week study. At week 1, subjects rated a statistically significant improvement in manageability ($p=0.035$), frizziness ($p=0.002$), dryness ($p=0.001$), roughness ($p=0.003$), shine ($p=0.011$), split ends ($p=0.011$), and overall appearance ($p=0.012$). Improvement continued on into week 2 where all parameters remained statistically significant, but by week 4 all parameters showed highly statistically ($p<0.001$) improvement. This result is consistent with the dermatologist investigator assessment demonstrating impressive subject perceived improvement in hair health.

Table 4: Subject Longitudinal Scalp Assessment
Subject assessed scalp improvement was also excellent. While subject assessed irritation and redness did not achieve statistical significant at the week 1 time point, statistically significant reductions in scalp symptoms were noted. There was a statistically significant reduction in scalp flakes ($p=0.002$), visible flaking ($p<0.001$), dryness ($p=0.012$), and overall scalp appearance ($p=0.015$) at week 1. The sensory symptoms of stinging ($p=0.049$), burning ($p=0.014$), and itching ($p=0.001$) were also statistically improved at week 1. By weeks 2 and 4, all subject assessed scalp parameters were highly statistically significant ($p<0.001$) also providing for a very strong subject assessed improvement in scalp health mirroring the dermatologist investigator assessments.

15.SUMMARY

15.1SAFETY ASSESSMENT

No safety issues arose during the administration of the study. The product was determined to be safe and without medical side effects.

15.2EFFICACY ASSESSMENT

15.2.1PRIMARY EFFICACY ENDPOINT

The primary efficacy endpoint was a statistically significant (p=0.05 or less) improvement in global investigator scalp assessment. The primary efficacy endpoint was met.

15.2.2SECONDARY EFFICACY ENDPOINT

The secondary efficacy endpoint was the statistically significant (p=0.05 or less) improvement in global hair appearance subject assessment with the study regimen. The secondary efficacy endpoint was met.