ASSESSMENT OF THE ACCEPTANCE OF A SUPPLEMENT AND EFFICACY ASSESSMENT THROUGH SELF-ASSESSMENT PERFORMED BY THE STUDY SUBJECTS AND IMAGE CAPTURE FOR RECORD PURPOSES, UNDER NORMAL USE CONDITIONS

DRAFT REPORT

INVESTIGATIONAL PRODUCT TYPE: Supplement
INVESTIGATIONAL PRODUCT NAME: Renew Glow - Hair and Nail Supplement

INSTITUTE INVESTIGATIONAL PRODUCT CODE: E001184A-01
STUDY CODE: All-SE-ES-E001184A-01-11-22
REPORT CODE: All-SE-ES-E001184A-01-11-22- RDV01-Rev01

REPORT DATE: 08/17/2023

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ASSESSMENT OF THE ACCEPTANCE OF A SUPPLEMENT AND EFFICACY ASSESSMENT THROUGH SELF-ASSESSMENT PERFORMED BY THE STUDY SUBJECTS AND IMAGE CAPTURE FOR RECORD PURPOSES, UNDER NORMAL USE CONDITIONS

SUMMARY

Investigational Product Name	Renew Glow - Hair and Nail Supplement
Institute Investigational Product Code	E001184A-01
Study Code	All-SE-ES-E001184A-01-11-22
Report Code	All-SE-ES-E001184A-01-11-22-RDV01-Rev01
Sponsor	TH GENESIS
OBJECTIVE OF THE STUDY	The objectives of this study were: • To verify the acceptance of a supplement by observing the non-occurrence of adverse events and discomfort sensations; • To evaluate investigational product efficacy through the following methodologies: ○ Subjective self-perception of the study subject by Self-Assessment Questionnaires, under normal use conditions; ○ Image capture, with a professional digital camera, for recording purposes.
METHODOLOGY	On the initial visit, the subjects were evaluated by a dermatologist to confirm the inclusion and non-inclusion criteria. Subjects included were submitted to a dermatological clinical assessment performed by the dermatologist and an initial digital imaging of hair was carried out by a technician (T0). Subjects received the investigational product for use at home, under normal conditions of use, for 180 ± 2 days and the product daily log. After 90 (T90) and 180 (T180) days of investigational product use, subjects returned to the institute and a dermatological clinical assessment was performed by the dermatologist. A new digital imaging was done by a technician and the subjects were also instructed to answer to a self-assessment questionnaire. In all visits, subjects underwent an acclimatization period of at least 30 minutes, under controlled environmental conditions.
PRINCIPAL INVESTIGATOR	Gabrielli Brianezi
STUDY LENGTH	180 ± 2 days.
FREQUENCY OF USE	Two capsules per day.
INCLUDED STUDY POPULATION DESCRIPTION	Male and female subjects, aged between 18 and 60 years old (mean age: 47 years old), presenting telogen effluvium hair loss, at the inclusion visit – proved by dermatologist, hair length longer than 3.5 cm, complaining of thin hair, weak hair strands and lack of hair volume.
NUMBER OF SUBJECTS	Included in the study: 40 subjects Finished the study: efficacy assessment - 38 subjects / safety assessment – 39 subjects
ETHICS	This study was conducted in accordance with the principles of the Declaration of Helsinki, applicable regulatory requirements, including the

Resolution CNS nº 466/12, and according to ICH E6: Good Clinical Practices and Document of the Americas.

Dermatological Clinical Assessment

During the study, 01 subject presented moderate subjective sensations of discomfort related to the intolerance to the odor of the investigational product, comprising 2.5% of the final population considered in the safety assessment (n=39). Since subject reported having already felt similar symptom with the use of other products of the same category, the investigational product was considered safe under the evaluated conditions.

Self-Assessment Questionnaire Performed by the Study Subjects

Statement	T90	T180
1) Reduces the appearance of thinning hair	71.1%	73.7%
2) Improves thinning hair	71.1%	71.1%
3) Improves hair density	76.3%	84.2%
4) Increases thickness	71.1%	89.5%
5) Increases hair strength	84.2%	86.8%
6) Helps promote fuller looking hair	73.7%	84.2%
7) Helps promote thicker looking hair	68.4%	81.6%

CONCLUSION

Therefore, the following claims can be supported:

- *Dermatologically tested* supported by the Dermatological Clinical Assessment;
- *Clinically Tested* supported by the Dermatological Clinical Assessment;
- *Reduces the appearance of thinning hair* supported by the Self-Assessment;
- *Improves thinning hair* supported by the Self-Assessment;
- *Improves hair density* supported by the Self-Assessment;
- *Increases thickness* supported by the Self-Assessment;
- *Increases hair strength* supported by the Self-Assessment;
- *Helps promote fuller looking hair* supported by the Self-Assessment;
- *Helps promote thicker looking hair* supported by the Self-Assessment.

QUALITY ASSURANCE

The study was conducted according to the Resolution CNS nº 466/12, the Good Clinical Practices and in conformity with the Standard Operating Procedures of the Institute.

Data quality is assured, considering that our personnel is trained according to the requirements of the study to be carried out, our equipment is always duly calibrated, and the methods used are recognized and/or validated.

The Quality Assurance Department is responsible for the Management System auditory; and it is completely available for any specific study monitoring performed by the sponsor.

The signature below indicates that the study was performed as above described and that the results were verified in comparison with the source documents.

Audited by: Cristiane Nunes Coelho Moreira
08/17/2023

SUMMARY

1 ABBREVIATION LIST

°C	Celsius Degrees
ASTM	American Society for Testing and Materials
cm	Centimeter
CNS	Brazilian National Health Council (*Conselho Nacional de Saúde*)
CRM	Regional Council of Medicine (*Conselho Regional de Medicina*)
Dr.	Doctor
e.g.	Example
etc.	*Et Cetera*
ICF	Informed Consent Form
ICIR	Informed Consent for Image Release
i.e.	id est (that is)
JPEG	Joint Photographic Experts Group
LTDA.	Limited
nº/n	Number
pH	Hydrogen Potential
RH	Relative Humidity
SP	State of São Paulo
St.	Standard
TX	Study Assessment Time-Points

2 INTRODUCTION

Over the last few years, the cosmetic industry has grown considerably, same as its concern in developing safe and effective products. Industry awareness and consumer's and regulatory agencies requirements caused cosmetic manufacturers to adopt procedures that lead them to know better their products: to conduct clinical tests on safety and efficacy, which are coordinated by expert physicians, before marketing a product. These procedures provide cosmetic companies with greater safety, credibility and reliability among their consumers.

Efficacy studies allow us to assess the product's characteristics, detecting complaints and comments regarding its performance, as well as testing the quality control and the assured quality, analysis of competitors and claims support (what the product offers). In order to evaluate if a claim is appropriate, it is necessary to take into account the general consumers' impression concerning the presentation or the product advertisement (COLIPA, 2008). The claims must be supported by solid, clear and relevant evidences. Such evidences may result from experimental studies (biochemical / instrumental methods, sensory evaluations, technical evaluations and evaluations without the participation of study subjects, in vitro testing in cell cultures, use of hair locks, etc.), and consumers evaluations (ASTM E 1958-06, 2006).

For the efficacy assessment of products, clinical and/or self-assessment studies and instrumental studies can be used. The Self-Assessment by the study subjects is performed by following the "Standard Guide for Sensory Claim Substantiation" (ASTM E 1958-06, 2006), by using questionnaires. The ASTM (American Society for Testing and Materials) standards organization has been developed for over a century and represents one of the greatest voluntary organizations for standards development in the world, being a reliable source of technical standards of material, products, systems and services. Known by their high technical quality and relevance on market, ASTM standards have an important role in the infrastructure of the information guiding the study design, product manufacturing and commerce in global economy. The "Standard Guide for Sensory Claim Substantiation" is an ASTM standard that aims to disclose the good practices in sensory studies, approaching reasonable practices for executing sensory studies to validate product claims.

3 OBJECTIVE

The objectives of this study were:

- To verify the acceptance of a supplement by observing the non-occurrence of adverse events and discomfort sensations;
- To evaluate investigational product efficacy through the following methodologies:
    - Subjective self-perception of the study subject by Self-Assessment Questionnaires, under normal use conditions;
    - Image capture, with a professional digital camera, for recording purposes.

4 STUDY DESIGN

Non comparative clinical study.

5 APPLICATION SITE

The investigational product was ingested by the study subjects.

6 INVESTIGATIONAL PRODUCT

The investigational product was provided by the sponsor and was labeled with adequate codes and use directions. All products sent by the sponsor were initially stored in the sample room at the study center, with controlled temperature and restricted access. The products release was controlled by the principal investigator or by a previously designated technical staff. At the moment of receiving the product, the subjects were instructed on how to correctly store it, emphasizing the importance to keeping them out of reach of children and/or animals.

Product information, as declared by the sponsor, are described in APPENDIX 4. One sample of the product was cataloged and can be found in the institute's archive, for a period of one month after the end of the study.

6.1 Identification

Table 1 Investigational Product Identification

Product Name	Product Type	Product Code	Batch	Expiration Date
Renew Glow - Hair and Nail Supplement	Supplement	E001184A-01	395062	06/01/2024

6.2 Use Directions of the Investigational Product

Subjects were instructed to use the product exactly as follows:

Take two (2) capsules per day, before or after the meal.

6.2.1 Investigational Product Use Compliance Checking

Subject's compliance with the investigational product's use was checked by verifying the completion of the daily log of use of the investigational product by the subjects.

7 STUDY PERIOD

The total duration of the study per subject was 180 ± 2 days.

- **Start of the First Group:** 01/20/2023;
- **End of the Last Group:** 07/26/2023.

8 STUDY SUBJECTS

8.1 Study Subjects Recruitment

The study subjects were recruited by the recruitment department of the study center that has a computerized and updated register system. Subjects registered in this system are interested in taking part of clinical trials. Subjects were contacted to participate in the selection process and, having all the necessary criteria, they were included in the study in compliance with applicable laws Resolution CNS nº 466/12 and General Data Protection Law (13709:2018).

The study was performed at one of Allergisa's facilities, and subjects were informed about the address/site when they were contacted.

8.2 Selection and Admission of Study Subjects

During the subjects' selection to this study, the physician in charge certified that the subjects did not present pathologies that could interfere on the study results. The physician is also responsible for the information on the study subject evaluation form, checking all the inclusion and non-inclusion criteria for admission of the subject in the study.

8.3 Study Population

The population sample size predicted to be enrolled on the protocol was 40 subjects, aiming complete the study with 25 answers.

8.4 Inclusion Criteria

- Healthy study subjects;
- Intact skin on test site – except for the loss of hair;
- Agreement to adhere to the procedures and requirements of the study and to report to the institute on the day(s) and at the time(s) scheduled for the assessments;
- Ability to provide a consent for participating in the study;
- Aged from 18 to 60 years old;
- Subjects vaccinated for COVID-19;
- Subjects of any gender;
- Presenting telogen effluvium hair loss, at the inclusion visit – proved by dermatologist;
- Hair length longer than 3.5 cm (to be maintained during the study);
- Subjects willing not to change the hairstyle throughout the study period;
- Subjects willing not to change the hair dye routine throughout the study. If the subject does have this habit, the dyeing will be made 7-4 days before the visits T0, T90 and T180;
- Subjects willing not to use hair treatments (i.e., against hair loss, anti-dandruff, supplements, etc.) throughout the study;

- Subjects complaining of thin hair;
- Subjects complaining of weak hair strands;
- Subjects complaining of lack of hair volume.

8.5 Non-Inclusion Criteria

- Pregnancy or breastfeeding;
- Subjects diagnosed with cicatricial alopecia;
- Moderate to intense dandruff;
- White hair (more than 50%) or light blonde;
- Moles, tattoos, scars, irritated skin, etc. on the test sites that could influence the assessments/measurements;
- Pathological hair loss such as scalp disease (like alopecia areata, universalis or totalis) and chemotherapy;
- Skin pathology on the area of product application – except for the loss of hair;
- Type 1 Diabetes Mellitus: insulin-dependent diabetes, presence of complications resulting from diabetes (retinopathy, nephropathy, neuropathy), presence of dermatosis related to diabetes (lipoidic necrobiosis, plantar ulcer, ring granuloma, opportunistic infections); antecedents of episodes of hypoglycemia, diabetic ketoacidosis and/or hyperosmolar coma;
- Immune insufficiency;
- Use of systemic corticosteroids or immunosuppressant drugs;
- Skin diseases: vitiligo, psoriasis, atopic dermatitis;
- Antecedents of reaction to the category of product tested;
- Other diseases or medications that might directly interfere in the study or put the subject's health under risk.

8.6 Restrictions During the Study

- Do not apply any product to the test site, which may interfere with the study assessment;
- Do not change any cosmetic habits, including personal hygiene;
- Do not perform chemical treatments on the hair (smoothing, relaxing, progressive straightening, etc.) throughout the study period;
- Do not change the hair dye routine during the study period. If the subject does have this habit, the dyeing will be performed 7-4 days before the visits T0, T90 and T180;
- Do not cut the hair so that it is shorter than 3.5 cm.

9 METHODOLOGY

9.1 Materials and Equipment

- Acclimatized room;
- Professional digital camera (Canon 60D);
- Thermohygrometer;
- Tripod.

9.2 General Procedures

On the initial visit, the subjects were informed about the study objective, its methodology and duration, also about the possible expected benefits and constraints related to the study and they signed the Informed Consent Form (ICF) and the Informed Consent for Image Release (ICIR). The study subjects were evaluated by a dermatologist to confirm the inclusion and non-inclusion criteria.

Subjects included were submitted to dermatological clinical assessment performed by the dermatologist and an initial digital imaging of the hair was carried out by a technician (T0). Subjects received the investigational product for use at home, under normal conditions of use, for 180 ± 2 days and the product daily log. During this period, subjects were instructed to record in the daily log of the product used for all the ingestions performed.

After 90 (T90) and 180 (T180) days of investigational product use, subjects returned to the institute and a dermatological clinical assessment was performed by the dermatologist. A new digital imaging was done by a technician and the subjects were also instructed to answer to a self-assessment questionnaire. At the final visit (T180) a technician collected the investigational product and the filled daily log.

In all visits, subjects underwent an acclimatization period of at least 30 minutes, under controlled environmental conditions (20ºC ± 2ºC and 50% ± 5 RH).

9.3 Study Schedule

Table 2 Study Schedule

Phases	T0	T90	T180
Signature of the ICF and ICIR	X	-	-
Dermatological Clinical Assessment - Eligibility of the inclusion/non-inclusion criteria	X	-	-
Dermatological Clinical Assessment	X	X	X
Image capture of the hair with professional digital camera for recording purposes	X	X	X
Distribution (D) / Restitution (R): • Investigational Product; • Daily log of use.	D	-	R
Self-assessment by the study subject at the institute	-	X	X
Verification of investigational product daily log, filled at home by study subjects	-	X	X
Assessment of Adverse Events (if applicable)	-	X	X

9.4 Methods Used in the Study

9.4.1 Dermatological Clinical Assessment

Study subjects were assessed by a dermatologist at the initial visit (T0) before investigational product use to check the inclusion and non-inclusion criteria of the study and after 90 (T90) and 180 (T180) days of investigational product use to verify possible adverse events, discomfort sensations and to confirm the accurate use of the product. They were also supervised by a dermatologist throughout the study and also assessed in case there was any symptom or sign.

The subjects were instructed to contact the study coordinator at any time, in case they had any complaints. In these cases, they would be assessed and instructed by the dermatologist in charge, who would perform the dermatological exams, classify the reaction and decide the appropriate procedure to be followed.

9.4.2 Digital Imaging

During the study, subjects had digital photographs of their hair taken. Images of the subjects were acquired with a professional digital camera. Resulting images were delivered as JPEG files.

Images were taken at the following time-points:

- T0 - before investigational product use;
- T90 – after 90 ± 2 days of investigational product use;
- T180 – after 180 ± 2 days of investigational product use.

9.4.3 Self-Assessment Questionnaire Performed by the Study Subjects

Subjective questionnaires allow the sponsor to gauge the subjects' perceptions of the investigational product and its effects.

Questions were asked for subjects' agreement to a statement with a five-point scale, according to the table below:

Table 3 Time-points, Statements and Scales of the Self-Assessment Questionnaire

Time-point	Statement	Scale
T90 / T180	1) Reduces the appearance of thinning hair	5. Totally Agree 4. Agree 3. Neither agree, nor disagree 2. Disagree 1. Totally Disagree
	2) Improves thinning hair	
	3) Improves hair density	
	4) Increases thickness	
	5) Increases hair strength	
	6) Helps promote fuller looking hair	
	7) Helps promote thicker looking hair	

9.5 Statistical Analysis

The self-assessment results were reported through percentages and frequencies of positive answers.

The detailed description of the treatment applied to the data is presented in the table below.

Table 4 Detailed Statistical Analysis

Data Type	Statistical Methods	Data Reported	Sample Size
Subjective Questionnaire	Descriptive statistics	Percentage and frequency of positive answers	38

Software: XLSTAT and MINITAB.

9.6 Criteria and Procedures for Study Subjects Withdrawal

The removal of a study subject by the principal investigator could occur due to the following reasons:

- Study subjects not included: subjects who signed the ICF, but who did not meet the inclusion and non-inclusion criteria of the study;
- Subjects who present complications that affect their eligibility after the study consent;
- Subjects who presented - at the principal investigator's discretion - any problem that prevented product applications from continuing, at any time during the study;
- Consent withdrawal by the study subject, regardless of the reason;
- Lack of adhesion of the study subject to the study. A significant lack of adhesion was recorded if the subject did not visit the study center for assessments;
- Serious Adverse Event;
- Concurrent disorder or treatment: any pathological process or treatment that occurred during the study period and that might interfere with the study product, such as a medication interaction or masking of results.

If the subject was withdrawn from the study by the principal investigator, he or she would be followed up in case of any event possibly related to the study, even after withdrawal. If the subject was withdrawn due to presenting an adverse event, he or she would be followed up until the complete resolution of the condition.

Those subjects who were removed from study after the inclusion stage were not replaced.

10 ADVERSE EVENTS

An adverse event is any untoward medical occurrence in a patient or clinical investigation subject administered a product and that does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory

finding), symptom, or disease temporally associated with the use of the investigational product (adapted from ICH, 2016).

According to the Good Clinical Practices (ICH, 2016), a Serious Adverse Event is any medical occurrence that results in:

- death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- persistent or significant disability/incapacity;
- congenital anomaly/birth defect.

Thus, any clinical sign, discomfort sensation, disease, or clinically significant worsening compared to the condition at the first visit, should be considered an Adverse Event. Lack of clinical or self-assessment efficacy of a cosmetic product or drug is not considered an Adverse Event.

Clinical signs and dermatological or systemic diseases observed during the selection process of the study subjects are not considered as Adverse Events. This information is recorded in the subject's assessment form as a reason for non-inclusion and the subject is not included in the study.

The case of adverse events occurred as a result of incorrect product use (either cosmetics or drug products) - such as inappropriate frequency or incorrect application - are considered as adverse events that do not interfere with the product evaluation, since the subject - in this situation - does not follow the correct use directions stated on the product label.

In case there is an adverse event with doubtful causal nexus, an investigation process is initiated in order to determine if such event is or is not related to the study or investigational product.

The procedures adopted during the adverse event investigation are defined by the physician in charge, based on the nature of the reaction, the subject's medical history and on factors that may interfere with the occurrence of the event, such as medication or other concomitant disorders.

For the conclusion of the final diagnosis, the relation of an Adverse Event can be defined using the decision tree COLIPA, 2016, according to the following description:

• Very likely: Only cases in which the clinical condition is considered to be evocative are classified as a very likely nexus, the following conditions occurring together: (i) the temporality of the facts is compatible with an adverse reaction to cosmetics and (ii) there is a laboratory test that confirm the relationship with the investigational product (e.g., positive patch test for the investigational product).

• Likely: The cases in which the clinical condition is considered to be evocative are classified as likely causal nexus, occurring with the following conditions together: (i) the temporality of the facts is compatible with an adverse reaction to cosmetics and (ii) there is no laboratory test to confirm the relationship with the investigational product (e.g. diagnosis of contact dermatitis, without patch test, cosmetic acne - there are no laboratory tests to confirm the relationship with the investigational product).

• Not clearly attributable: Cases in which the clinical scenario is not considered to be evocative or the chronology is not clearly compatible or unknown, are classified as nexus not clearly attributable.

• Unlikely: The following two cases are associated with an unlikely nexus: the clinical scenario is not considered to be evocative, the chronology is not clearly compatible or unknown, and the result of the investigation with the investigational product is negative (patch test or re-exposure).

• Excluded: The cases in which the diagnosis corresponds to a dermatosis of well-known cause and/or known to be caused by the use of products are classified as excluded nexus (e.g. vitiligo, tineas, pityriasis rosea, pityriasis versicolor, psoriasis, folliculitis, solar melanosis, ephelides, among others), when there is no correlation between the subject's complaint and the use of a product (for example: muscle pain, lack of appetite, stomach pain, diarrhea, insect bites, among others) or the chronology is clearly incompatible with an adverse reaction to the investigational product (for example: there is no improvement in the scenario, even with the interruption of the product; there is relapse of the scenario, without the reintroduction of the product; the signs and symptoms started before the start of product use).

11 APPLICABLE ETHICAL REMARKS

This study was conducted in compliance with the Declaration of Helsinki principles, the applicable regulatory requirements, including Resolution CNS nº 466/12, and according to the Good Clinical Practices (Document of the Americas and ICH E6: Good Clinical Practices).

Before the study starts, the subjects were informed about the study objective, its methodology and length, and about the possibly expected benefits and the constraints related to the study. Subjects who agreed to participate in the study signed the Informed Consent Form (ICF) (APPENDIX 1) and the Informed Consent for Image Release (ICIR) (APPENDIX 2), prepared in accordance with the Declaration of Helsinki and Resolution CNS nº 466/12. The process of obtaining the consent confirmed the voluntary nature of subjects' participation in the study.

In order to maintain confidentiality of subjects' data, study subjects were identified through a three-digit inclusion number. No personal information was disclosed in all data analyses. If necessary, the principal investigator must allow the study monitor to access study-related subject records. This includes all documents containing the subject's clinical history for checking suitability for the study, diagnoses and any other document concerning the subject in the study.

All data found or proven by the study results are considered as being confidential information and sponsor's property. No information - as well as all documents generated during the study - will be copied or disclosed without previous written consent of the sponsor. All information will be kept confidential until the results are published.

The study technical documentation is in the institute's archives, where it will be stored for a 5-year period.

12 RESULTS

12.1 Protocol Deviations

Subject 027 did not comply with restrictions during the study and performed chemical treatments on the hair (hair straightening) throughout the study period. Therefore, subjects' data were not considered in the study. The protocol deviation did not affect the product's safety and efficacy assessment since the sample size still attended the minimum required by the protocol.

Subject 039 did not use the investigational product according to the instructions, as evidenced by review of the information entered by the subject in the daily log of investigational product use. For 21 days (not consecutive), during the study period, she took one capsule per day. The protocol deviation did not present an impact in the study results since the subjects' data were similar to the data of subjects without deviation.

12.2 Study Population Description and Study Adherence

Forty (40) subjects were included in the study, from them, 38 completed the efficacy assessments and 39 completed the safety assessments. The study achieved its objective to obtain, at its final, a minimum of 25 answers. A summary description of the population and adherence to the study are available in the table below. The detailed description of the population can be found in APPENDIX 3.

Table 5 Population Included and Adherence to the Study

Population Included									Adherence		
Recruited[1]	**Not Included[2]**	**Withdrawn[3]**	**Included[4]**	**Gender (F)**	**Gender (M)**	**Minimum Age (years)**	**Maximum Age (years)**	**Mean Age (years)**	**Absences[5]**	**Removed[6]**	**Finished the Study[7]**
45	05	00	40	39	01	18	60	47	00	02	Safety assessment: 39 Efficacy assessment: 38
Subjects									-	027 and 028	

[1]Subjects who attended the Institute and signed the ICF.
[2]Subjects who did not meet the inclusion criteria or presented any of the non-inclusion criteria.
[3]Subjects who withdrew from the study after the study consent for personal reasons and were not included.
[4]Subjects who were approved in the study.
[5]Subjects who were absent in the study for personal reasons unrelated to the study and to the investigational product.
[6]Subjects removed from the study are characterized as protocol deviations or another reason recorded by the principal investigator.
[7]Subjects considered in the total who finished the study.
Caption: F=Female; M=Male

Subject 027 was removed from the study for characterizing as protocol deviation as described in item 12.1. Subject 028 was removed from the efficacy assessment for presenting adverse event as described in item 12.3.

12.3 Dermatological Clinical Assessment

The following table presents the frequency and percentage of study subjects who had objective and/or subjective clinical signs/discomfort sensations related to the investigational product use. The detailed description is available in item 12.4.

Table 6 Frequency and Percentage of Subjects who Showed Objective and/or Subjective Signs (n=39)

Evaluation	Objective Sign	Subjective Sign
Dermatological	-	Intolerance to the odor of the investigational product/Malaise – 1 (2.5%)

12.4 Adverse Events

During the study, 04 subjects experienced adverse events, 01 being related to the investigational product use, comprising 2.5% of the safety assessment population that completed the study. Adverse events are described in the table below.

Table 7 Adverse Events

Subject Number	Day of Study	Adverse Event Description	Intensity	Site of the Event	Frequency	Action Taken	Hypothesis or Rational + Diagnosis	Causal Nexus	Data considered in the study?
008	T180	Flu symptoms Pharyngitis	Mild	Systemic	Single Episode	Maintenance of investigational product use	Considering subject's statement, and the medical assessment, the case was closed. It was a case of Flu symptoms and pharyngitis. Subject reported that on 07/18/2023 (T180) began to present hoarse voice, speech loss and sore throat, all with mild intensity. She sought medical attention on the same day, was diagnosed with flu symptoms and pharyngitis, and was prescribed the use of medication "Nimesulida", "Seki" and "Dipyrone". Subject informed that on 07/19/2023 (T181) presented improvements of the scenario, following in follow-up. In face-to-face return, during the final visit, relocated to 07/26/2023, subject reported complete remission of symptoms on 07/21/2023 (T183). She denied complaints about the investigational product and continued making use of it, ending the study. The adverse event had not caused the subject removal from the study.	Excluded	Yes

Table 7 Adverse Events

Subject Number	Day of Study	Adverse Event Description	Intensity	Site of the Event	Frequency	Action Taken	Hypothesis or Rational + Diagnosis	Causal Nexus	Data considered in the study?
028	T1 until T90	Intolerance to the odor of the investigational product Malaise	Moderate	Systemic	Continuous	Not applicable - Final Date of the Study	Considering subject's statement, and the medical assessment, the case was closed. It was a case of intolerance to the odor of the investigational product. Subject found the smell of the product uncomfortable causing malaise. The complaint occurred both in fasting and after meals on all days of use (T1 to T90) immediately after opening the bottle and having contact with the supplement lasting 5 minutes and spontaneous remission. Subject permanently suspended the use of the investigational product on her own in T91. Reported that the complaint was limited only to the odor denying other complaints after ingestion. Subject reported having already felt similar symptom with the use of supplement of another brand. She denied suspicion of pregnancy, she uses contraceptive. Clinical examination performed on 07/19/2023 without alterations. The adverse event caused the subject removal from the study.	Very Likely	No
029	T162	Wisdom tooth removal	Moderate	Dental arch	Single Episode	Not applicable - Final Date of the Study	Considering subject's statement, and the medical assessment, the case was closed. It was a case of wisdom tooth removal to the right on 06/29/2023. She used amoxicillin and anti-inflammatory for five days, and dipyrone when she had pain. She's done the stitches removal. She continued to use the investigational product, not presenting any complaints. The adverse event has not caused the subject removal from the study.	Excluded	Yes

Table 7 Adverse Events

Subject Number	Day of Study	Adverse Event Description	Intensity	Site of the Event	Frequency	Action Taken	Hypothesis or Rational + Diagnosis	Causal Nexus	Data considered in the study?
032	T1 and T2	Abdominal discomfort	Moderate	Systemic	Intermittent	Maintenance of investigational product use	Considering subject's statement, and the medical assessment, the case was closed. It was a case of temporary abdominal discomfort. Subject reported that in the first two days of the study, she had abdominal discomfort (feeling of fullness) approximately 4 hours after ingestion of the investigational product, lasting ± 1 hour and spontaneous remission. After these days, she had no recurrence of the scenario. Therefore, compatible chronology and negative re-exposure were considered.	Not Clearly Attributable	Yes
	T3	Burning when urinating	Intense				Considering subject's statement, and the medical assessment, the case was closed. The diagnostic hypothesis is vulvovaginitis. It was a case of intense burning sensation when urinating on the third day of the study, which persisted for approximately 5 days. After 3 days of symptoms, subject underwent a gynecological consultation, where a urine test was performed with a negative result for urinary infection. The gynecologist considered the hypothesis of a change in pH due to the beginning of use of the investigational product, but in an assessment with the doctor at the institute, the subject reported that she had sexual relation in the days before the complaint, which led the doctor to the diagnostic hypothesis mentioned above. Subject reported that the scenario regressed spontaneously, she did not use medication and only increased the daily consumption of water. Therefore, partially compatible chronology and negative re-exposure were considered.	Unlikely	

12.5 Self-Assessment Questionnaire Performed by the Study Subjects

The table below presents the percentage of subjects who were in agreement (responding “agree” or “totally agree”) to the statements presented after 90 and 180 days of product use.

Table 8 Percentage and Frequency of Positives Answers (n=38)

Statement	T90	T180
1) Reduces the appearance of thinning hair	71.1% (27)	73.7% (28)
2) Improves thinning hair	71.1% (27)	71.1% (27)
3) Improves hair density	76.3% (29)	84.2% (32)
4) Increases thickness	71.1% (27)	89.5% (34)
5) Increases hair strength	84.2% (32)	86.8% (33)
6) Helps promote fuller looking hair	73.7% (28)	84.2% (32)
7) Helps promote thicker looking hair	68.4% (26)	81.6% (31)

13 CONCLUSION

According to the methodology used to assess the safety and efficacy of the product **Renew Glow - Hair and Nail Supplement**, forwarded by the company **TH GENESIS**, it is possible to conclude that:

13.1 Dermatological Clinical Assessment

During the study, 01 subject presented moderate subjective sensations of discomfort related to the intolerance to the odor of the investigational product, comprising 2.5% of the final population considered in the safety assessment (n=39). Since subject reported having already felt similar symptom with the use of other products of the same category, the investigational product was considered safe under the evaluated conditions.

13.2 Self-Assessment Questionnaire Performed by the Study Subjects

Statement	T90	T180
1) Reduces the appearance of thinning hair	71.1%	73.7%
2) Improves thinning hair	71.1%	71.1%
3) Improves hair density	76.3%	84.2%
4) Increases thickness	71.1%	89.5%
5) Increases hair strength	84.2%	86.8%
6) Helps promote fuller looking hair	73.7%	84.2%
7) Helps promote thicker looking hair	68.4%	81.6%

Therefore, the following claims can be supported:

- *Dermatologically tested* supported by the Dermatological Clinical Assessment;
- *Clinically Tested* supported by the Dermatological Clinical Assessment;
- *Reduces the appearance of thinning hair* supported by the Self-Assessment;
- *Improves thinning hair* supported by the Self-Assessment;
- *Improves hair density* supported by the Self-Assessment;
- *Increases thickness* supported by the Self-Assessment;
- *Increases hair strength* supported by the Self-Assessment;

- *Helps promote fuller looking hair* supported by the Self-Assessment;
- *Helps promote thicker looking hair* supported by the Self-Assessment.

Gabrielli Brianezi
Principal Investigator
08/17/2023

Edlaine C. Tolari Hamzé
Dermatologist (CRM 150655)
08/17/2023

José Marcos M. Vendramini
Statistician in Charge
08/17/2023

14 REFERENCES

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APPENDIX 1. INFORMED CONSENT FORM

Subj No.: _____

INFORMED CONSENT FORM

TITLE OF THE STUDY PROJECT: ACCEPTANCE AND EFFICACY ASSESSMENT OF A SUPPLEMENT THROUGH THE STUDY SUBJECTS' SELF-ASSESSMENT AND IMAGES CAPTURING FOR RECORD, UNDER NORMAL USE CONDITIONS

NAME OF THE INVESTIGATOR IN CHARGE: Gabrielli Brianezi

STUDY SITE: Allergisa Pesquisa Dermato-Cosmética Ltda.

You are being invited to join a study that will be carried out by Allergisa's team together with the company that is sponsoring this study.

Before any decision, it is important that you read attentively all information presented, and if you decide to join, you will be requested to sign two originals of this informed consent form and one original will be given to you.

Your participation in this study is completely voluntary and it depends only on your will, and you are also free to withdraw from the study at any time.

Any doubts you might have before, during, or after the study will be promptly solved.

This study is being done with all the safety measures necessary to avoid contamination by coronavirus, which causes the disease COVID-19. If you agree in taking part of this study, please follow the instructions below to keep your own safety.

What are the objectives of this study?

The objective of the study is to check the acceptance of an oral hair supplement through the absence of adverse reactions and discomfort sensations when used under normal use conditions. This assessment will be supervised by a dermatologist.

In addition, the product efficacy will be assessed through self-assessment questionnaires and image capturing of the hair for record purposes.

Can I join the study?

For participating in the study, firstly you must present good health and meet other requirements called inclusion and non-inclusion criteria, that will be assessed and discussed by the dermatologist.

You can even be dismissed by the dermatologist, after signing the informed consent form, if you present any of the non-inclusion criteria of the study, also in case the total amount of subjects was already reached.

How many people will join this study? The study will be conducted with up to 40 subjects. **Where will the study be conducted?**

The study will be conducted in the headquarter of ALLERGISA pesquisa dermato-cosmética ltda, located at 452/466, Dr. Romeu Tórtima Avenue – Barão Geraldo – Campinas – SP, with all precautions for your safety and the safety of the team.

What are the study procedures? What will I have to do?

Your participation in the study will last 180 (± 2) days. During this period, 03 visits will be made.

- **On visit 1:**

You will be informed about the study objective, its methodology and duration, and about the possibly expected risks and benefits, as well as the constraints related to the study and, if you agree, you will sign this Informed Consent Form (ICF) and the Informed Consent for Image Release (ICIR).

You will undergo a dermatological clinical assessment.

If you are approved, images of your hair will be captured with the photographic camera for record purposes.

You will receive the test-product to use at home for 180 ± 2 days.

You must use the product as it follows: **Take 2 capsules a day with or without any food.**

You will receive a daily log with the use instructions described on it and you must fill it according to the product use.

By signing this informed consent, you will guarantee the truthfulness of information provided.

You will remain up to 04 hours in this visit.

- **On visit 2:**

You will undergo a dermatological clinical assessment.

Images of your hair will be captured with a photographic camera for record purposes.

You must bring the daily log to check the product use at home and checking of the document filling.

You will answer a questionnaire at the institute with instructions of the study technician.

You will remain up to 04 hours in this visit.

- **On visit 3:**

You will undergo a dermatological clinical assessment.

Images of your scalp will be captured with a photographic camera for record purposes. You must return the test-product.

You must return the daily log filled with the applications performed at home. You will answer a questionnaire at the institute with instructions of the study technician.

You will remain up to 04 hours in this visit.

IMPORTANT!!!

During these returns, all the precautions recommended by health experts will be taken to ensure your safety and the safety of the study team to avoid the contamination of the COVID-19 disease. Masks will be provided by the Institute for use during your stay at the Institute and during the whole study, and there will be gel alcohol hand sanitizer available. The rooms will be cleaned and disinfected with 70% alcohol, there will be appropriate distancing between people, scheduled and individual appointments and a measurement of your temperature at a distance always when necessary.

We ask you to be at the Institute ONLY at the time informed to you, in order to avoid crowds. If you present any symptoms related to the disease (runny nose, headache, sore throat, fever, shortness of breath, etc.), do not attend the institute. You must call us so we can schedule a teleconsultation with a physician, we will inform you about the procedures to be followed.

The teleconsultation is a remote appointment performed by a doctor through a telephone call or video conference. During the teleconsultation, you will be ensured of the confidentiality of the medical attention, that is, that it was done in a place where only the physician and the authorized person of the technical department were present during the call.

Your adherence to the visits schedule is important for the study results. In case you cannot come on the scheduled date, please, contact the investigator or the study team and check the possibility of returning as soon as possible for the visit.

What information will be obtained about me?

Personal information such as name, age, usual medications, etc., will be obtained.

For this study, information about your health will be obtained through clinical assessments about possible adverse reactions that the product might cause on your skin. If you present an adverse reaction with clinical sign on the skin (reaction that can be observed by the naked eye: irritation, redness, swelling, etc.), photos will be taken with the single purpose of investigation of the reaction and of record of these information. Your identity will be preserved.

The images obtained during the study, after edited, will be submitted to the study Sponsor and might become public for the study results or product's efficacy disclosure for advertising purposes (scientific articles, advertisements, training, educational materials and sales materials). Your signature will be required in an Informed Consent for Image Release.

The technical team will explain the images capturing process and will answer all questions that you might have.

For this study, answers will also be obtained through an applied questionnaire about the product qualities, as well as your opinion about it. You will not be identified in this questionnaire.

How will the information be protected to preserve my privacy?

All information obtained about you, from your participation in this study, will be treated confidentially, and your identity will be kept confidential, under all circumstances. The information collected about you will be used only for the purpose of this study.

Your identity will be kept confidential throughout the process and only the study investigator or people from the team delegated will have access to those records.

If the study results are published, your identity will remain confidential.

If necessary to perform the teleconsultation, it will be performed with a tool that presents data safety, ensuring confidentiality of the medical attention.

It is possible that in some occasions a representative of the sponsor company may be present to observe the study.

According to Law No. 13.709, of August 2018, concerning the General Data Protection Law, Allergisa Pesquisa Dermato-Cosmética LTDA, together with the sponsor, declares to be in compliance with all obligations applicable to the Personal Data Processing (including any and all obligations of information to the Data Subject). Allergisa Pesquisa Dermato-Cosmética LTDA guarantees the continuous monitoring of risks and failures of Information Security that may compromise your personal data (such as name, last name, ID, "CPF", address, etc.), and the sensitive personal data (personal information concerning health, ethnic group, racial origin, political party preferences, among others), through our platforms of digital information storage.

In case some of your registration information changes (e.g., telephone number, address, etc.), please ask the study organizers to have them updated.

What are my responsibilities in this study?

You should attend the institute on the days determined for each visit. In addition, there are some restrictions that you will follow, such as:

- Do not apply any other product to the test site which may interfere with the study assessment;
- Do not change any cosmetic habits, including personal hygiene.
- Do not perform chemical treatments on the hair (smoothing, relaxing, progressive straightening, etc.) throughout the study period;
- Do not change the hair dye routine during the study period; If the subject has this habit, the dying must be performed 7-4 days before the visits T0, T90 and T180;
- Do not cut the hair so that it is shorter than 3.5 cm.
- You cannot perform any dermatological treatment during the study. If the treatment is necessary, immediately inform the study center.
- We ask you to communicate the study center about any type of medication or external/skin use, or oral route tablets and liquids (solutions and syrups) or injections, such as cortisone, anti-allergic or any other.

The product must be used exclusively by yourself.

If you change any of your habits, we ask that you please keep us informed, so we can better interpret the results.

We ask you not to use any other kind of supplement while using this product. If you use any of these products or are taking any medication, please, let us know.

Can I withdraw from the study at any time?

Yes, you are completely free to withdraw from the study at any time, not having to worry with any negative consequences. You can also remove your data (information given, images/photographs taken) at any time, if you wish.

In case of new information available that can change your desire to continue your participation in the study, you will be timely communicated by the investigator and study team and you will be completely free to withdraw from the study. Just let us know about your wish of giving up.

What benefits will I have to join the study?

Studies in the cosmetic area aim to prove the safety and efficacy of those products.

By joining this study, you will be contributing that this product is used by the population with much lower risk of skin reactions and with an efficacy action of hair improvement confirmed. You will also undergo free medical assessments and instructions on how to use the product, in order to assure better results.

Is there any risk related to the study participation?

All raw materials used in the product are approved for topical use and are not toxic. However, same as with any other products, they might cause unexpected reactions such as "redness", "swelling", "itching", and "burning sensation" on the product application sites.

The risks presented are already known, and if they occur, they will be as minimized as possible. You will be clinically supervised by the study site, until your health clinical conditions are reestablished, regardless of the time that it might take.

Any health problems you might have during the study should be informed to the investigator or study team immediately. All immediate or late assistance will be provided.

Regarding the risk of contracting the COVID-19 disease, it exists apart from the participation in the study. If you are vaccinated, the risk of having strong symptoms is reduced. All necessary precautions will be taken at the Institute to ensure your safety. If you present any symptoms related to the disease such as cough, fever, sneezing, runny nose, body pain, among others, do not attend the institute and let us know immediately. In this case, a test for diagnosis of COVID-19 may be performed, as one more safety measure adopted by the Institute.

In case of suspect or confirmation of COVID-19, you must follow the recommendations that the Institute will provide based on the health organs. All immediate or full assistance will be provided and, if a diagnosis of COVID-19 is confirmed, all the instructions to perform a quarantine or seek hospital attention will be given according to the recommendations of the health organizations. You will be supervised by the Institute, until your health is reestablished.

What if I am pregnant or breastfeeding?

Pregnant or breastfeeding women, or women who are planning to get pregnant are not allowed to take part in this study.

If, despite the orientations given by the physician and the study team, you get pregnant and find yourself to be pregnant during the study, your participation will be terminated for your safety and the safety of the baby. Please inform the study investigator or study team immediately. They will make sure you get advising about what to do during pregnancy and you will be supervised during the pregnancy until the birth.

Will I have any type of reimbursement for the expenses for participating of this study?

As predicted by Brazilian laws, you will not have any type of financial compensation/payment for your participation in the study; however, you will receive a reimbursement in the end of the study due to expenses of your participation.

If you are removed from the study before its conclusion by the investigator in charge due to safety reasons, non-compliance of the study requirements, or even due to your own withdrawal, you will be reimbursed for expenses such as transportation and food regarding the days you participated, if there were any.

How can I know about the study results?

The study results will be assessed by the investigator in charge after it is completed. The results can be published, but your name will not be mentioned.

You can still ask to the investigator about the study results after the conclusion of the study.

Can I be removed from the study?

Yes, your participation in this study can finish earlier than predicted.

It is duty of the investigator, at any moment, to remove you from the study, if you present any reaction to the product or if your health has been affected for any reason and you are not in conditions to continue as a study subject.

You can also be removed from the study in case you do not fulfill your responsibilities, according to the study protocol.

What if my participation in the study interferes with any other medication I am currently taking? It is highly important that you inform the investigator in charge of the study about the use of usual medications, or use of any other different medication when you sign this document and during your participation.

In case you need to take a specific medication, not mentioned previously, you should communicate the study investigator immediately, because they will know how to give you instructions about the best conduct for your case.

Who will I be able to contact if I do not feel well during the study or present any reactions to the product?

If you do not feel well or in case of any irritation skin signs, immediately communicate, attending to the study: site or by telephone 19-3517-6800 (working hours). In case of any doubts or problems, you can contact the investigator in charge (Gabrielli Brianezi) or medical team through the same telephone numbers.

We assure that, for any complications or damages caused by the study, a full assistance will be given to the study subjects together with the sponsors of this study.

Eventual Indemnifications for damages caused by the study are assured.

We ask you to call the Institute at any moment if you feel symptoms such as cough, fever, runny nose, sore throat or shortness of breath, or if you would like to cancel your participation in the study, through the telephones 19-3517-6800 (business hours) or 19-99778-0204 (from 5 p.m. to 10 p.m.). Subjects who present these symptoms will not be allowed to participate in the study and if you arrive at the Institute with the symptoms, you will not be allowed inside and will be instructed to go home.

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Subj No.: _____

INFORMED CONSENT FORM

Important information!

If you have any question about the study that was not answered yet, you should ask the investigator or study team.

Please, keep this document for your information.

Signatures – ACCEPTANCE AND EFFICACY ASSESSMENT OF A SUPPLEMENT THROUGH THE STUDY SUBJECTS' SELF-ASSESSMENT AND IMAGES CAPTURING FOR RECORD, UNDER NORMAL USE CONDITIONS

I read and understood the information provided in this Informed Consent Form. I have obtained the answers for all my questions and I freely decided to join this study. I offer my consent, freely, to join this study, as explained in this document.

I am aware that the photos taken for the investigation procedure, in case of any reaction or for study data obtainment are part of the procedure of this study and I agree with those images capturing as long as my identity is preserved.

In addition, I agree that the sponsor of the study may use these photos or images to disclose study results or product's efficacy for advertising purposes. Therefore, in addition to signing this informed consent, I should sign another form authorizing the photos and images disclosure for advertising purposes.

By signing this document, I did not waive from any legal rights I have when I participate in a study, including the indemnification.

01									
	Initials of the study subject	Date (MM/DD/YYYY)							
	Signature of the Study Subject (as in the ID or Driver's License)								

02									
	Signature of the person in charge of explaining the ICF	Date (MM/DD/YYYY)							

APPENDIX 2. INFORMED CONSENT FOR IMAGE RELEASE

SUBJECT No. ___

INFORMED CONSENT FOR IMAGE RELEASE (ICIR)

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AUTHORIZATION FOR IMAGE RELEASE
STUDY: ACCEPTANCE AND EFFICACY ASSESSMENT OF A SUPPLEMENT THROUGH TJE STUDY SUBJECTS' SELF-ASSESSMENT AND IMAGES CAPTURE FOR RECORD, UNDER NORMAL USE CONDITIONS

I, hereby,
_____, ID No.:
_____, grant to ALLERGISA PESQUISA DERMATO-COSMÉTICA LTDA the permission to use **my image**, in picture of its authorship, for study results assessments, and in case of adverse events to the products, and in the advertising material of the sponsor, the permission to use the signature of this form.

This photographic material will be for ALLERGISA and study Sponsor use only. Your identity will be kept confidential during the photographic records performance.

The present concession does not generate either contract of employment nor functional, or any labor, administrative, social welfare liabilities, or others.

The use of the image mentioned above is granted in all national territory and abroad, to the purposes explained above.

It is also granted, in free will, for the same purposes, the cession to the rights of images exhibition without any kind of payment, for undetermined time. For it is the expression of my will, I declare I grant the use described above, with no reason to complain related to **my image** rights or any other right, and I sign the present concession in 02 (two) equal copies in content and form.

The parties herein agreed, sign the present document.

_____ Date: | | | | | | | | |
Signature of the Subject *(as in the ID or Driver's License)*

_____ Date: | | | | | | | | |
Signature of the person in charge of explaining the ICIR

Allergisa Pesquisa Dermato-Cosmética Ltda *All-SE-ES-E001184A-01-11-22*

F-SOP_15.04 – Rev.13 – 03/11/2022

APPENDIX 3. STUDY GROUP

SUBJECT	AGE (YEARS)	GENDER	STATUS
001	52	F	I
002	54	F	NI
003	56	F	I
004	43	F	I
005	59	F	I
006	58	F	I
007	58	F	I
008	57	F	I
009	51	F	I
010	50	F	I
011	44	F	I
012	57	F	I
013	41	F	I
014	27	F	NI
015	38	F	I
016	18	F	NI
017	60	F	I
018	49	F	I
019	47	F	I
020	59	F	I
021	51	F	I
022	42	F	I
023	42	F	I
024	39	F	I
025	60	F	I
026	41	F	NI
027	35	F	I
028	29	F	I
029	20	M	I
030	35	F	NI
031	48	F	I
032	42	F	I
033	27	F	I
034	46	F	I
035	60	F	I
036	58	F	I
037	44	F	I

STUDY GROUP (CONTINUATION)

SUBJECT	AGE (YEARS)	GENDER	STATUS
038	54	F	I
039	51	F	I
040	50	F	I
041	51	F	I
042	59	F	I
043	40	F	I
044	46	F	I
045	18	F	I

Caption:
F = Female;

M = Male;

I = Included;

NI = Not Included (presented any of the non-inclusion criteria and/or did not present some of the inclusion criteria).

APPENDIX 4. INVESTIGATIONAL PRODUCT INFORMATION

“FORMULA NOT SUBMITTED”