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INVESTIGATION INTO THE EFFICACY OF A PAIN CONTROL PRODUCT

AMA Ref. No.: MS16.WRIST.O8170.REP.SSL

Date: August 25, 2016

Sponsor: SkinScience Labs, Inc.
725 Grand Avenue, Suite 201
Ridgefield, New Jersey 07657

1.0 Objective:

The purpose of this study is to evaluate the efficacy of a pain control wrist brace. Effectiveness of the test material was evaluated on a group of 10 subjects using subjective panelist self-assessment via questionnaire responses.

2.0 Test Material:

2.1 Test Sample Description:

On July 25, 2016 test samples labeled SILVERPROTM style 6195 were received from SkinScience Labs, Inc. and assigned AMA Lab No. O-8170.

2.2 Handling:

Upon arrival at AMA Laboratories, Inc., the test material is assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and test requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

2.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, toxicology, microbiology or in-vitro performance spectra may be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in Section 3.0.

2.3.1 Sponsor purports that prior to sample submission to AMA the samples were received and approved by the Sponsor's Safety Group for inclusion in this protocol.

The following tests were conducted with no adverse results and the test data are on file at their premises and have not been made available to AMA personnel:

- USP or CTFA Preservative Efficacy Test or equivalent
- Fifty (50) person Repeat Insult Patch Test (RIPT) or equivalent

3.0 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc. consists of 5 or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file at AMA Laboratories, Inc., and is available for inspection during the hours of operation.

4.0 Panel Selection:

4.1 Standards for Inclusion in the Study:

1. Individuals experiencing regular wrist pain due to Carpal Tunnel Syndrome or pain from tendon overuse or any other diagnosis that results in wrist pain.
2. Individual who will complete a preliminary medical history and screening document as mandated by AMA Laboratories, Inc.
3. Individuals, who will read, understand and sign an informed consent document as required by CFR Title 21, Part 50, Subpart B regulations. Consent forms will be kept on file and are available for examination on the premises of AMA Laboratories, Inc., only.
4. Individuals in general good health and free of any health problems, including neurological, dermatological, or systemic disorder that would interfere with the results, at the discretion of the Study Director.
5. Individuals who understand the instructions for use and are willing to cooperate with the program as stated.

4.2 Standards for Exclusion from the Study:

1. Individuals who are under the care of a physician.
2. Individuals who are currently taking any medication that may mask or interfere with the test results at the discretion of the Study Director.
3. Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes or any disease that would increase risk associated with study participation.
4. Females who are pregnant, lactating, or given birth within the six month period immediately preceding study commencement. Females who intend to become pregnant over the study period.
5. Individuals diagnosed with chronic skin allergies or with history of hypersensitivity to cosmetics in general.

4.3 Recruitment:

Panel selection is accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

4.4 Informed Consent Document:

An informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form and screening form. These forms, along with the signed consent forms, are available for inspection on the premises of AMA Laboratories, Inc., only. Reference 21 CFR Ch.1 Part 50, Subpart B.

The parties agreed to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

5.0 Panel Demographics:

Number of subjects enrolled		10
Number of subjects completing study		10
Age Range		24 – 67
Sex	Female	9
	Male	1
Race	Caucasian	7
	Hispanic	2
	African American	1

6.0 Procedure:

Ten panelists were inducted into this study. The demographic data is shown in Section 5.0.

On the day of the test, panelists reported to the test facility and were examined by a trained technician.

All participants were instructed to use the test material as a part of their daily routine according to the following sponsor-supplied use instructions:

Use brace daily for minimum of 30 minutes but there is no upper limit, you can use it as long as you want.

Subjects completed a self-assessment questionnaire addressing consumer perception after 14 days of daily use of the test product.

7.0 Results:

Please refer to attached Table.

8.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

9.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

10.0 Security Label Disclosure:

To prevent loss of and protect intellectual property, original, certified documents issued by AMA Laboratories, Inc. can be identified by a proprietary, tamper evident security hologram affixed to all Conclusion/Signature pages on final reports. Any attempt to remove the hologram will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the AMA LABS, INC. hologram intact will be recognized by AMA Laboratories Inc. as a certified original.

11.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, the test product (AMA Lab No.: O-8170; Client No.: SILVERPROTM style 6195) was reported by the majority of test panelists to be effective in reducing wrist pain after 14 days of daily use.

Mayya Tatsene, M.D.
Study Director

Patrycja Wojtowicz, M.S.
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Technician

David R. Winne, B.S.
Technical Director

8/25/16
Date

Pain Control Product Questionnaire Summary – Day 14

AMA Lab No.: O-8170
Client No.: SILVERPROTM style 6195

Question	Agree	Disagree
1. I felt a warm sensation at the site almost immediately:	20.00%	80.00%
2. I felt pain relief almost immediately:	60.00%	40.00%
3. I felt pain relief within a few minutes:	40.00%	60.00%
4. I felt pain relief shortly:	70.00%	30.00%
5. I felt a dramatic improvement in pain:	60.00%	40.00%
6. I felt an undeniable improvement in pain:	60.00%	40.00%
7. I no longer need my pain killer pills:	40.00%	60.00%
8. I need much less pain killer pills now:	80.00%	20.00%
9. I no longer need pain killer pills at all:	40.00%	60.00%
10. The test product saved me from surgery:	30.00%	70.00%
11. The test product saved me from pain pills:	50.00%	50.00%
12. My pain is dramatically less without any pain pills:	80.00%	20.00%
13. My doctor says, I do not need surgery any more:	40.00%	60.00%
14. I may not need surgery any more:	60.00%	40.00%
15. I do not need surgery any more:	40.00%	60.00%
16. My pain is significantly less:	80.00%	20.00%
17. Without a doubt, my pain is significantly less:	70.00%	30.00%
18. My pain is dramatically less:	70.00%	30.00%
19. My pain is less than half of what it used to:	60.00%	40.00%
20. My pain is almost completely gone:	40.00%	60.00%
21. My pain is completely gone:	30.00%	70.00%
22. The test product is pain control:	90.00%	10.00%
23. I have never experienced pain control this effective:	70.00%	30.00%
24. The test product is better than pain killer pills:	70.00%	30.00%
25. The test product is the best thing for my pain:	60.00%	40.00%
26. The test product equals pain relief:	100.00%	0.00%
27. The test product means no surgery for me:	40.00%	60.00%
28. The test product means freedom from pain:	50.00%	50.00%
29. I will never be without my the test product:	60.00%	40.00%
30. The test product changed my life:	60.00%	40.00%
31. The test product changed my life from constant pain to no pain at all:	40.00%	60.00%
32. The test product made me pain free:	50.00%	50.00%
33. The test product dramatically improved my pain:	80.00%	20.00%
34. I do not need physical therapy any more:	40.00%	60.00%
35. I do not need therapy any more:	50.00%	50.00%

12.0 Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Report reviewed by:

Tasmiya Masud, B.A.
Quality Assurance Supervisor

8/25/16
Date