AMA LABORATORIES, INC.
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18 MINUTE OSTEO-ARTHRITIS PAIN RELIEF STUDY

AMA Ref. No.: MS10.PAINRELIEF18MIN.L7930.REP.GKL

Date: November 4, 2010

Sponsor: Greek Island Labs

1.0 Objective:

This panel has been convened to evaluate the test formula intended to reduce the pain associated with osteo-arthritis. Pain relieving properties were evaluated using VAS (Visual Analog Scale) scoring method (0~10 scale).

2.0 Test Material:

2.1 Test Sample Description:

On June 10, 2010 test samples labeled Joint Mud, was received from from Greek Island Labs and assigned AMA Lab No. L-7930.

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.

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 a Study:

1. Males and Females actively experiencing hands/wrists pain associated with osteo-arthritis.
2. Individuals 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 will abstain from using any pain relief products at least 48 hours prior to test period.
6. Individuals able to cooperate with the Investigator and research staff, willing to have the test material(s) applied according to the protocol, and complete the full course of study.

4.2 Standards for Exclusion from a Study:

1. Individuals who are under the care of a physician.
2. Individuals currently taking medication that may mask or interfere with the test results.
3. Individuals diagnosed with chronic skin allergies.
4. Females who are pregnant, lactating, have been pregnant, or given birth within the six month period immediately preceding study commencement.
5. Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes, or any disease that would increase the risk associated with study participation.
6. Individuals with irritation or sensitivity to lotion products.
7. Individuals with known allergies or skin conditions, which would interfere with the study at the discretion of the Study Director.

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 panelist was also given a copy of the informed consent for his records. 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.

5.0 Population Demographics:

Age Range ..... 26 - 55

6.0 Procedure:

1. Subjects were mandated to adhere to all the restrictions mentioned in the inclusion/exclusion section (refer to Section 4.1 and 4.2).
2. Upon arrival to the laboratory panelists were examined by a trained technician.
3. Based on an interview with panelist, one test site located on hand/wrist affected by osteo-arthritis pain was selected.
4. The application of the test product was made by trained technician.
5. Panelists were asked to rate the pain on a Visual Analog Pain Rating Scale at Baseline and at 18 minutes post application.

VISUAL ANALOG PAIN RATING SCALE											
No Pain	0	1	2	3	4	5	6	7	8	9	The Worst Imaginable Pain

Osteo-Arthritis Pain – VAS (Visual Analog Scale) The Visual Analog Scale (Jenson & Karoly, 1992; McCaffery & Pasero, 1999) allows the patient to determine his or her own level of pain by using descriptors or visual aids. The numeric scale is most often used in clinical practice because it is fast and easy. Patients rate their pain on a scale of 0–10, with 0 being no pain and 10 the worst imaginable pain (McCaffery & Pasero, 1999).

7.0 Results:

Please refer to attached Chart and 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 Conclusions:

The test material: Joint Mud, when used in accordance with package directions demonstrated statistically significant reduction in joint pain by an average of 74% within the first eighteen minutes with a maximum of 89% improvement reported after a single application. Further, this phenomenon was documented and confirmed during the course of the study.

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11/4/10

Date

11.0 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:

Kamil Wojtowicz
Kamil Wojtowicz, M.S.
Quality Assurance Supervisor

11/4/10
Date