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## AN INVESTIGATION INTO THE EFFICACY OF AN EYE CREAM PRODUCT

AMA Ref. No.: MS06.INUSE.K9735.REP.UNI

Date: November 22, 2006

Sponsor: Unimed International, Inc.  
105 Newfield Ave  
Edison, New Jersey 08837

### 1.0 Objective:

The purpose of this study is to evaluate the efficacy of a topically applied eye cream product intended to reduce the appearance of fine lines and wrinkles in the area around the users' eyes. Assessments of fine lines and wrinkles were conducted visually, within five minutes of application.

### 2.0 Sample Description:

On October 31, 2006 test samples labeled Chamonix Jeunesse Eye Crème, No. JC-110 were received from Unimed International, Inc. and assigned AMA Lab No.: K-9735.

### 2.1 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 4.4.

2.1.1 Sponsor purports that prior to sample submission to AMA the following tests were conducted with no adverse results and that 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
- 90 Day Accelerated Stability and Container Compatibility Study
- Fifty (50) person Repeat Insult Patch Test (RIPT) or equivalent

### 3.0 Test Material Handling:

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

### 4.0 Population Demographics:

Number of subjects enrolled.....	20
Number of subjects completing study.....	20
Age Range.....	24 - 61
Sex.....	
Male.....	0
Female.....	20
Race.....	
Caucasian.....	16
Hispanic.....	4

### 4.1 Standards For Inclusion In a Study:

1. Individuals between the ages of 21 and 65.
2. Individuals in general good health and free of any dermatological or systemic disorder that would interfere with the results or increase the risks of study participation, at the discretion of the Investigator.
3. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with instrumental readings.
4. Individuals who have completed a preliminary medical history and screening document mandated by AMA Laboratories, Inc.
5. Individuals who have read, understood and signed an informed consent document required by CFR Title 21, Part 50, Subpart B regulations.
6. Individuals able to cooperate with the Investigator and the research staff and are willing to complete the full course of the study.

7. Individuals who understand the instructions for use and are willing to cooperate with the program as stated.
8. Individuals with no known abnormal responses to topically applied products.
9. Individuals who have abstained from using any topical treatment products for a period of 72 hours prior to study commencement and during the test period.

#### 4.2 Standards For Exclusion From a 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, have been pregnant, 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 Informed Consent and Medical History:

Prior to initiating the study, a signed informed consent was obtained, in accordance with CFR Title 21, Part 50, Subpart B, from each panelist, describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms are available for inspection on the premises of AMA Laboratories, Inc. only.

#### 4.4 Recruitment:

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

#### 4.4 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc., consists of five or more individuals, chosen from within the company for technical expertise and also 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.

#### 5.0 Methodology:

Twenty healthy females between the ages of 24 and 61 were inducted into this study. The subjects were pre-qualified for participation based on the presence of fine lines and wrinkles, in the area under and around the eyes. In order to pre-condition the test sites and keep all topical treatments consistent during the study, the panelists were required to abstain from using any topical treatment products, including lotions creams and gels, for a period of 72 hours prior to study commencement and to use only the assigned test material for the study.

For the purpose of this study, wrinkles were defined as any small ridges and/or furrows formed on the surface of the skin, specifically around and under the eyes.

All participants were instructed to use the test material as they are normally accustomed to using such eye products.

The following distinct noninvasive method was employed as the sole evaluation parameter:

##### Wrinkle Reduction

Quantification of the wrinkle condition was performed by a trained technician, using a modified and expanded version of the Fitzpatrick Wrinkle Evaluation Scale (ten point monadic scale), with one (1) representing the least visible wrinkles and ten (10) being the maximum condition in the region selected. Each woman had the left and right eye area of her face evaluated and graded, prior to the test product being applied. The product was then applied in accordance with the previously stated directions and allowed to dry. The same eye area of the subjects' face was re-evaluated and graded within five (5) minutes.

The expanded 10-point monadic scaling method allows for the quantification and measurements of the efficacy of the product. This is expressed as a percentage of wrinkle reduction for each subject.

All technical employees of AMA Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published; which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.

6.0 References:

Fitzpatrick, R.E., Goldman, M.P., Satur, W.D., and Tope, W.D., Pulsed carbon dioxide resurfacing of photo-aged facial skin. Archives of Dermatology, 132 (1996) 395-402

Westerink, J.H.D.M., Assessment of Visibility of Facial Wrinkle Reduction by Various Types of Observers, J. of International Federation of Society of Cosmetic Chemists, (IFSCC Vol. 7 No.1 January/March 2004)

Krantz, D.H., Luce, R.D., Suppes, P., and Tversky, A. Foundations of Measurement (1971) Vol. I – Vol. II San Diego Academic Press

7.0 Results: Please refer to the attached Tables and Charts.

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.

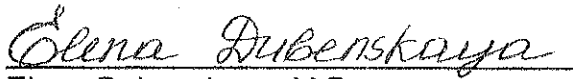
10.0 Conclusions:


Within the limits imposed by the conduct and population size of the study described herein, a single use of the test product (AMA Lab No.: K-9735; Client No.: Chamonix Jeunesse Eye Crème, No. JC-110) resulted in a visual reduction of fine lines and wrinkles in the left and right eye area of the test subjects.

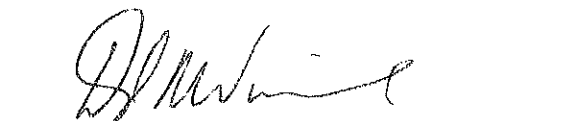
- The following data collected on 20 female subjects was observed in the treatment areas:

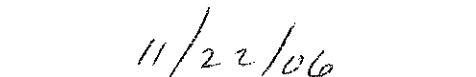
Visual Fine Lines and Wrinkles of the Eye Area		
	Pre Treatment	Post Treatment
Mean	5.90	4.20
% Difference		-28.81%*
* Statistically Significant		

A single use of the test product reduced the appearance of fine lines and wrinkles, in and around the eyes, within five (5) minutes of applying the product. The results are considered to be statistically significant.

  
Elena Dubenskaya, M.D.  
Study Director

  
Alex G. Letizia  
Technician

  
David R. Winne, B.S  
Technical Director

  
Date

Note: All Services Undertaken Subject to the following General Policy: AMA Laboratories, Inc. Reports are submitted for exclusive use of the clients to whom they are addressed. Their significance is subject to the adequacy and representative character of the samples and to the comprehensiveness of the test, examination or surveys made. No quotations from AMA Laboratories, Inc., reports, or use of AMA Laboratories, Inc., name or names of staff members or sub-contractors is permitted except as expressly authorized in writing. The liability of AMA Laboratories, Inc. with respect to services rendered shall in no event exceed the amount of one hundred dollars. Any indemnification agreement attached to or included in the embodiment of this report shall, if sent by certified mail, return receipt requested, be deemed to be properly served, executed, notarized and accepted by virtue of the signature appearing on the return certified claim. Wherein this report is used to support commercial claims, the Sponsor is directed to provide said report in its entirety.

**Table 1**  
**Wrinkle Reduction – Eye Area Visual Scoring**

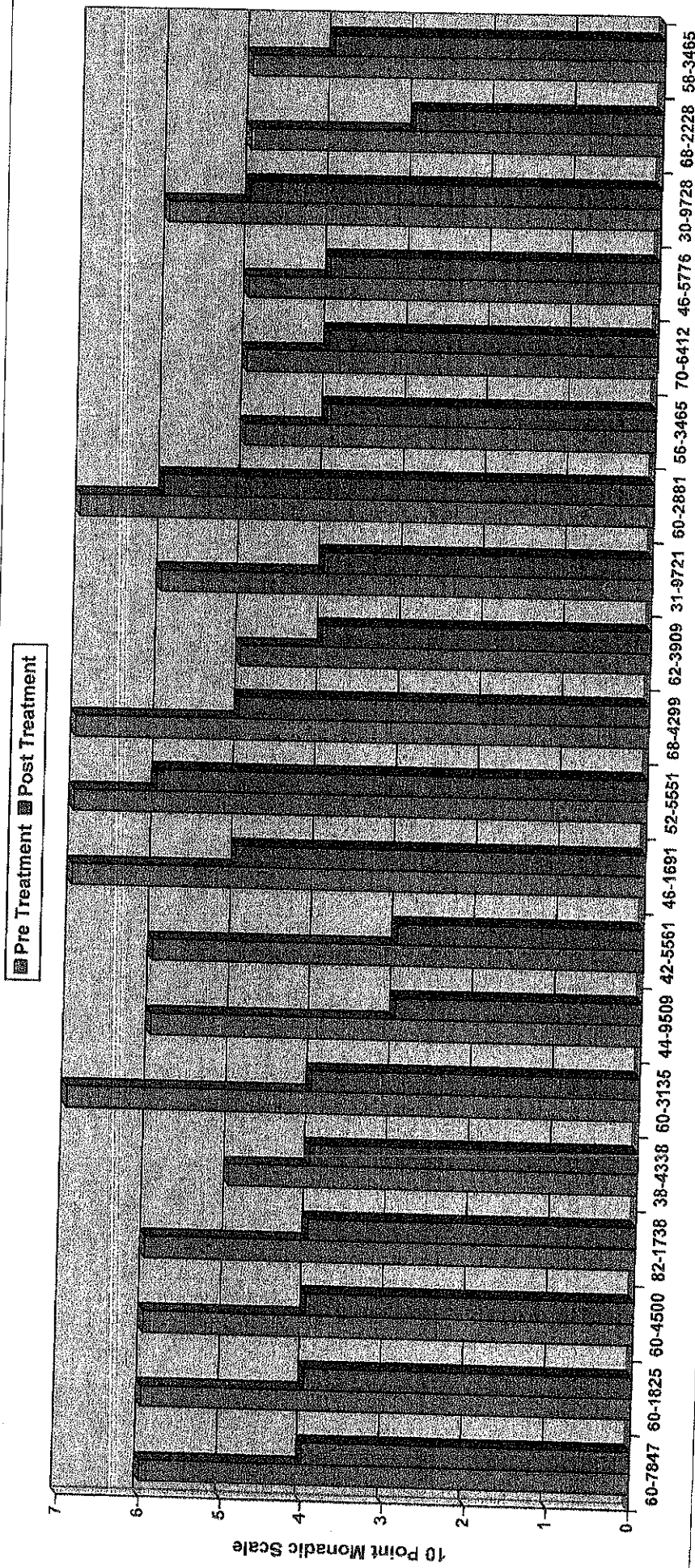
AMA Lab No.: K-9735      Client No.: Chamonix Jeunesse Eye Crème,  
 No. JC-110

Eye Area			
Panelist ID	Pre Treatment	Post Treatment	$\Delta$
60 7847	6	4	-33.33%
60 1825	6	4	-33.33%
62 4500	6	4	-33.33%
82 1738	6	4	-33.33%
38 4338	5	4	-20.00%
60 3135	7	4	-42.86%
44 9509	6	3	-50.00%
42 5581	6	3	-50.00%
46 1691	7	5	-28.57%
52 5551	7	6	-14.29%
68 4299	7	5	-28.57%
62 3909	5	4	-20.00%
31 9721	6	4	-33.33%
60 2881	7	6	-14.29%
56 3465	5	4	-20.00%
70 6412	5	4	-20.00%
46 5776	5	4	-20.00%
30 9728	6	5	-16.67%
68 2228	5	3	-40.00%
58 3465	5	4	-20.00%
<b>Mean</b>	<b>5.90</b>	<b>4.20</b>	<b>-28.81%</b>
<b>t</b>		<b>10.38</b>	
<b>p</b>		<b>0.00*</b>	

\*Statistically Significant

**Chart 1**  
**Wrinkle Reduction – Eye Area Visual Scoring**

AMA Lab No.: K-9735      Client No.: Chamonix Jeunesse Eye Crème,  
 No. JC-110





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:

*P. Elistratova*

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Polina Elistratova, M.A.  
Quality Assurance Supervisor

*11/22/06*

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Date