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CONTROLLED USE STUDY - EYE AREA PRODUCT

AMA Ref. No.: MS12.OPHTHAL.M3851.REP.D.PCY.REV

Date: March 23, 2012

Sponsor: Photomedex, Inc.
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Objective:

This panel has been convened to evaluate the safety of an eye area product under conditions of exaggerated use.

2.0 Sample Description:

On January 23, 2012 test samples labeled Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36 were received from ProCyte, a Photomedex Company and assigned AMA Lab No.: M-3851.

2.1 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material is assigned unique laboratory code numbers 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.

2.2 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.

2.2.1 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 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 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 Demographics:

Number of subjects enrolled		60
Number of subjects completing study		60
Age Range		32 - 64
Sex	Female	60
Race	Caucasian	54
	Hispanic	3
	Asian	0
	African-American	3

4.1 Standards For Inclusion In A Study:

1. 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.

2. Individuals with no history of sensitivity to cosmetics in general and eye area products in particular.
3. Individuals who have completed a preliminary medical history and screening document as mandated by AMA Laboratories, Inc.
4. Individuals who have read, understood and signed an informed consent document as required by CFR Title 21, Part 50, Subpart B regulations. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc., only.
5. Individuals able to cooperate with the Investigator and research staff, and are willing to have the test materials applied according to the protocol, and complete the course of study.

4.2 Standards For Exclusion From The Study:

1. Individuals who are under the care of a physician.
2. Individuals diagnosed with chronic skin allergies.
3. Individuals currently taking medication that may mask or interfere with the test results.
4. Individuals 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.
5. Individuals with known allergies or skin and/or eye conditions, which would interfere with the study at the discretion of the Study Director.
6. Females who are pregnant, lactating, have been pregnant, or given birth within the six month period immediately preceding study commencement.

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 And Medical History Forms:

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.

5.0 Procedure:

A minimum of sixty female subjects willing to use the test product daily for 28 days were recruited for this study. The demographic data is shown in Section 4.0.

The study was conducted according to the sponsor requested design wherein all subjects were instructed to use the test material according to the following sponsor supplied use directions:

"Apply test product (AMA Lab No.: M-3851; Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36) gently to area around the eyes after morning and evening cleansing. Avoid getting into eyes."

The application regimen was conducted for a period of 28 consecutive days.

Panelists returned to the laboratory 7, 14, 21 and 28 days post commencement for evaluation. Participants were also instructed to keep a daily log for each product noting the date and time of each application together with any subjective comments relating to product use. Upon commencement and on day 28 of study panelists were examined by an Optometrist or an Ophthalmologist. Evaluations were performed by a trained Technician on Days 7, 14 and 21. Signs and symptoms of objective irritation and/or sensitization were scored. Panelists also reported subjective comments relating to product use and user perceived feel, after application.

Subject's eyes and eye area, including eyelids, were checked for irritation, scaling and edema according to the following scheme:

* Skin Grading (Eye Area):
0 - no reaction
1+ - Weak (non vesicular) showing erythema, infiltration and possible papules
2+ - Strong reaction with vesicles in addition to erythema and infiltration
3+ - Extreme reaction, bullous or ulcerative

*Wilkinson, et al: Terminology of Contact Dermatitis, ACTA Dermatovener (Stockholm) 50:287-292, 197

** Eye Grading:
0 - no reaction
1+ - conjunctivae (palpebral and bulbar) injected above normal with possible chemosis (swelling); no discharge
2+ - conjunctivae injected above normal; obvious swelling; possible discharge
3+ - conjunctivae more diffuse, deeper crimson red, individual vessels not easily discernible; excessive swelling and/or discharge

** Patterned after scoring criteria of Draize, J.H. et al, Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Other Mucous Membranes, Div. Pharmacology, Food and Drug Administration, Federal Security Agency, Washington D.C. Nov. 1944.

Scoring was reported based on the bilateral conditions of the eyes and eye area.

Any adverse reaction to the test products was recorded in detail on the Adverse Condition Report. Adverse findings might include, but not be limited to eye stinging/burning, rash, irritation, sensitization and physical discomfort (lashes clinging together, excessive lacrimal secretion, etc.)

On each evaluation day panelists reported any irritation or itching of the eyes or anatomical location surrounding the eyes, relating to product use. Any perceived response was graded according to the subjective scale of none, slight, moderate or severe.

6.0 Results:

Please refer to attached Tables.

7.0 Observations:

No reactions of any kind were noted during the course of the study.

8.0 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.

9.0 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 will be recognized by AMA Laboratories Inc. as a certified original.

10.0 Conclusions:

The test material (AMA Lab No.: M-3851; Client No.: Neova Refining Eye Lift; Lot #: 1258; Formula #: 110909-36), when tested as described herein, may be considered **NON-IRRITATING** to the eyes and related eye area skin under exaggerated use conditions and suitable for use in contact lens wearers.

Mayya Tatsene, M.D.
Study Director

Lopa Y. Gupta, M.D.
Ophthalmologist

Marilyn Mann, O.D., M.S.
Optometrist

Patrycja Wojtowicz, M.S.
Technician

Christine A. Garon, B.S. Candidate
Technician

David R. Winne, B.S.
Technical Director

3/23/12
Date

Table 1

AMA Lab No.: M-3851
Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36

Day: 0

Product No.	Subject ID	Skin Eye Area	Eye	Irritation	Itching
1	44 7255	0	0	0	0
2	56 9114*	0	0	0	0
3	38 2811	0	0	0	0
4	94 7230*	0	0	0	0
5	52 6562	0	0	0	0
6	50 1729*	0	0	0	0
7	50 3737	0	0	0	0
8	46 4934	0	0	0	0
9	60 4516	0	0	0	0
10	54 7647	0	0	0	0
11	56 1236	0	0	0	0
12	50 2664	0	0	0	0
13	46 8520	0	0	0	0
14	60 7847	0	0	0	0
15	64 0508	0	0	0	0
16	48 1258*	0	0	0	0
17	06 0729*	0	0	0	0
18	62 8235	0	0	0	0
19	68 2333*	0	0	0	0
20	54 3226*	0	0	0	0
21	58 1747*	0	0	0	0
22	62 5693	0	0	0	0
23	62 2696*	0	0	0	0
24	68 2617*	0	0	0	0
25	66 9198	0	0	0	0
26	60 6194*	0	0	0	0
27	64 8484*	0	0	0	0
28	52 9994*	0	0	0	0
29	70 3975	0	0	0	0
30	50 9640*	0	0	0	0
31	58 5342*	0	0	0	0
32	74 3708*	0	0	0	0
33	56 8631	0	0	0	0
34	50 1699*	0	0	0	0
35	56 7056*	0	0	0	0
36	62 3461*	0	0	0	0
37	68 7790	0	0	0	0
38	64 7220	0	0	0	0
39	58 0925*	0	0	0	0
40	64 6029	0	0	0	0
41	68 9062*	0	0	0	0
42	62 0996*	0	0	0	0
43	66 5140	0	0	0	0
44	60 3135	0	0	0	0
45	00 0006*	0	0	0	0
46	54 4259	0	0	0	0
47	60 8476*	0	0	0	0
48	52 0789*	0	0	0	0
49	62 2960*	0	0	0	0
50	67 7361	0	0	0	0
51	46 5842*	0	0	0	0
52	56 9608*	0	0	0	0
53	60 4294	0	0	0	0
54	60 8461*	0	0	0	0
55	54 9327	0	0	0	0
56	44 0340*	0	0	0	0
57	66 0675*	0	0	0	0
58	68 4403	0	0	0	0
59	50 6005*	0	0	0	0
60	56 7022	0	0	0	0

*Contact lens wearer

Table 1

AMA Lab No.: M-3851
Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36

Day: 7

Product No.	Subject ID	Skin Eye Area	Eye	Irritation	Itching
1	44 7255	0	0	0	0
2	56 9114*	0	0	0	0
3	38 2811	0	0	0	0
4	94 7230*	0	0	0	0
5	52 6562	0	0	0	0
6	50 1729*	0	0	0	0
7	50 3737	0	0	0	0
8	46 4934	0	0	0	0
9	60 4516	0	0	0	0
10	54 7647	0	0	0	0
11	56 1236	0	0	0	0
12	50 2664	0	0	0	0
13	46 8520	0	0	0	0
14	60 7847	0	0	0	0
15	64 0508	0	0	0	0
16	48 1258*	0	0	0	0
17	06 0729*	0	0	0	0
18	62 8235	0	0	0	0
19	68 2333*	0	0	0	0
20	54 3226*	0	0	0	0
21	58 1747*	0	0	0	0
22	62 5693	0	0	0	0
23	62 2696*	0	0	0	0
24	68 2617*	0	0	0	0
25	66 9198	0	0	0	0
26	60 6194*	0	0	0	0
27	64 8484*	0	0	0	0
28	52 9994*	0	0	0	0
29	70 3975	0	0	0	0
30	50 9640*	0	0	0	0
31	58 5342*	0	0	0	0
32	74 3708*	0	0	0	0
33	56 8631	0	0	0	0
34	50 1699*	0	0	0	0
35	56 7056*	0	0	0	0
36	62 3461*	0	0	0	0
37	68 7790	0	0	0	0
38	64 7220	0	0	0	0
39	58 0925*	0	0	0	0
40	64 6029	0	0	0	0
41	68 9062*	0	0	0	0
42	62 0996*	0	0	0	0
43	66 5140	0	0	0	0
44	60 3135	0	0	0	0
45	00 0006*	0	0	0	0
46	54 4259	0	0	0	0
47	60 8476*	0	0	0	0
48	52 0789*	0	0	0	0
49	62 2960*	0	0	0	0
50	67 7361	0	0	0	0
51	46 5842*	0	0	0	0
52	56 9608*	0	0	0	0
53	60 4294	0	0	0	0
54	60 8461*	0	0	0	0
55	54 9327	0	0	0	0
56	44 0340*	0	0	0	0
57	66 0675*	0	0	0	0
58	68 4403	0	0	0	0
59	50 6005*	0	0	0	0
60	56 7022	0	0	0	0

*Contact lens wearer

Table 1

AMA Lab No.: M-3851
Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36

Day: 14

Product No.	Subject ID	Skin Eye Area	Eye	Irritation	Itching
1	44 7255	0	0	0	0
2	56 9114*	0	0	0	0
3	38 2811	0	0	0	0
4	94 7230*	0	0	0	0
5	52 6562	0	0	0	0
6	50 1729*	0	0	0	0
7	50 3737	0	0	0	0
8	46 4934	0	0	0	0
9	60 4516	0	0	0	0
10	54 7647	0	0	0	0
11	56 1236	0	0	0	0
12	50 2664	0	0	0	0
13	46 8520	0	0	0	0
14	60 7847	0	0	0	0
15	64 0508	0	0	0	0
16	48 1258*	0	0	0	0
17	06 0729*	0	0	0	0
18	62 8235	0	0	0	0
19	68 2333*	0	0	0	0
20	54 3226*	0	0	0	0
21	58 1747*	0	0	0	0
22	62 5693	0	0	0	0
23	62 2696*	0	0	0	0
24	68 2617*	0	0	0	0
25	66 9198	0	0	0	0
26	60 6194*	0	0	0	0
27	64 8484*	0	0	0	0
28	52 9994*	0	0	0	0
29	70 3975	0	0	0	0
30	50 9640*	0	0	0	0
31	58 5342*	0	0	0	0
32	74 3708*	0	0	0	0
33	56 8631	0	0	0	0
34	50 1699*	0	0	0	0
35	56 7056*	0	0	0	0
36	62 3461*	0	0	0	0
37	68 7790	0	0	0	0
38	64 7220	0	0	0	0
39	58 0925*	0	0	0	0
40	64 6029	0	0	0	0
41	68 9062*	0	0	0	0
42	62 0996*	0	0	0	0
43	66 5140	0	0	0	0
44	60 3135	0	0	0	0
45	00 0006*	0	0	0	0
46	54 4259	0	0	0	0
47	60 8476*	0	0	0	0
48	52 0789*	0	0	0	0
49	62 2960*	0	0	0	0
50	67 7361	0	0	0	0
51	46 5842*	0	0	0	0
52	56 9608*	0	0	0	0
53	60 4294	0	0	0	0
54	60 8461*	0	0	0	0
55	54 9327	0	0	0	0
56	44 0340*	0	0	0	0
57	66 0675*	0	0	0	0
58	68 4403	0	0	0	0
59	50 6005*	0	0	0	0
60	56 7022	0	0	0	0

*Contact lens wearer

Table 1

AMA Lab No.: M-3851
Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36

Day: 21

Product No.	Subject ID	Skin Eye Area	Eye	Irritation	Itching
1	44 7255	0	0	0	0
2	56 9114*	0	0	0	0
3	38 2811	0	0	0	0
4	94 7230*	0	0	0	0
5	52 6562	0	0	0	0
6	50 1729*	0	0	0	0
7	50 3737	0	0	0	0
8	46 4934	0	0	0	0
9	60 4516	0	0	0	0
10	54 7647	0	0	0	0
11	56 1236	0	0	0	0
12	50 2664	0	0	0	0
13	46 8520	0	0	0	0
14	60 7847	0	0	0	0
15	64 0508	0	0	0	0
16	48 1258*	0	0	0	0
17	06 0729*	0	0	0	0
18	62 8235	0	0	0	0
19	68 2333*	0	0	0	0
20	54 3226*	0	0	0	0
21	58 1747*	0	0	0	0
22	62 5693	0	0	0	0
23	62 2696*	0	0	0	0
24	68 2617*	0	0	0	0
25	66 9198	0	0	0	0
26	60 6194*	0	0	0	0
27	64 8484*	0	0	0	0
28	52 9994*	0	0	0	0
29	70 3975	0	0	0	0
30	50 9640*	0	0	0	0
31	58 5342*	0	0	0	0
32	74 3708*	0	0	0	0
33	56 8631	0	0	0	0
34	50 1699*	0	0	0	0
35	56 7056*	0	0	0	0
36	62 3461*	0	0	0	0
37	68 7790	0	0	0	0
38	64 7220	0	0	0	0
39	58 0925*	0	0	0	0
40	64 6029	0	0	0	0
41	68 9062*	0	0	0	0
42	62 0996*	0	0	0	0
43	66 5140	0	0	0	0
44	60 3135	0	0	0	0
45	00 0006*	0	0	0	0
46	54 4259	0	0	0	0
47	60 8476*	0	0	0	0
48	52 0789*	0	0	0	0
49	62 2960*	0	0	0	0
50	67 7361	0	0	0	0
51	46 5842*	0	0	0	0
52	56 9608*	0	0	0	0
53	60 4294	0	0	0	0
54	60 8461*	0	0	0	0
55	54 9327	0	0	0	0
56	44 0340*	0	0	0	0
57	66 0675*	0	0	0	0
58	68 4403	0	0	0	0
59	50 6005*	0	0	0	0
60	56 7022	0	0	0	0

*Contact lens wearer

Table 1

AMA Lab No.: M-3851
Client No.: Decreasing Eye Lift; Lot #: 1258; Formula #: 110909-36

Day: 28

Product No.	Subject ID	Skin Eye Area	Eye	Irritation	Itching
1	44 7255	0	0	0	0
2	56 9114*	0	0	0	0
3	38 2811	0	0	0	0
4	94 7230*	0	0	0	0
5	52 6562	0	0	0	0
6	50 1729*	0	0	0	0
7	50 3737	0	0	0	0
8	46 4934	0	0	0	0
9	60 4516	0	0	0	0
10	54 7647	0	0	0	0
11	56 1236	0	0	0	0
12	50 2664	0	0	0	0
13	46 8520	0	0	0	0
14	60 7847	0	0	0	0
15	64 0508	0	0	0	0
16	48 1258*	0	0	0	0
17	06 0729*	0	0	0	0
18	62 8235	0	0	0	0
19	68 2333*	0	0	0	0
20	54 3226*	0	0	0	0
21	58 1747*	0	0	0	0
22	62 5693	0	0	0	0
23	62 2696*	0	0	0	0
24	68 2617*	0	0	0	0
25	66 9198	0	0	0	0
26	60 6194*	0	0	0	0
27	64 8484*	0	0	0	0
28	52 9994*	0	0	0	0
29	70 3975	0	0	0	0
30	50 9640*	0	0	0	0
31	58 5342*	0	0	0	0
32	74 3708*	0	0	0	0
33	56 8631	0	0	0	0
34	50 1699*	0	0	0	0
35	56 7056*	0	0	0	0
36	62 3461*	0	0	0	0
37	68 7790	0	0	0	0
38	64 7220	0	0	0	0
39	58 0925*	0	0	0	0
40	64 6029	0	0	0	0
41	68 9062*	0	0	0	0
42	62 0996*	0	0	0	0
43	66 5140	0	0	0	0
44	60 3135	0	0	0	0
45	00 0006*	0	0	0	0
46	54 4259	0	0	0	0
47	60 8476*	0	0	0	0
48	52 0789*	0	0	0	0
49	62 2960*	0	0	0	0
50	67 7361	0	0	0	0
51	46 5842*	0	0	0	0
52	56 9608*	0	0	0	0
53	60 4294	0	0	0	0
54	60 8461*	0	0	0	0
55	54 9327	0	0	0	0
56	44 0340*	0	0	0	0
57	66 0675*	0	0	0	0
58	68 4403	0	0	0	0
59	50 6005*	0	0	0	0
60	56 7022	0	0	0	0

*Contact lens wearer

GRADING SCALE

Skin Grading (Eye Area):

0 - no reaction

1+ - Weak (non vesicular) showing erythema, infiltration and possible papules

2+ - Strong reaction with vesicles in addition to erythema and infiltration

3+ - Extreme reaction, bullous or ulcerative

Eye Grading:

0 - no reaction

1+ - conjunctivae (palpebral and bulbar) injected above normal with possible chemosis (swelling); no discharge

2+ - conjunctivae injected above normal; obvious swelling; possible discharge

3+ - conjunctivae more diffuse, deeper crimson red, individual vessels not easily discernible; excessive swelling and/or discharge

Response Definition:

On each evaluation day panelists reported any feeling of irritation or itching of the eyes or eye area relating to product use. Any perceived response was graded according to the subjective scale of none, slight, moderate or severe.

0 = None
S = Slight
M = Moderate
SE = Severe
D/C = Discontinued from the study

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:

Tasmiya Masud, B.A.
Quality Assurance Supervisor

3/23/12
Date