mdpen
PROFESSIONAL SKINCARE FORMULATIONS

# CLINICAL STUDY EVALUATION

*Professional Skin Care Formulations*

## Quality Assurance Statement

This study (ETC Panel No.: 15377; ETC Entry No.: 28635) was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects — Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

**For purposes of this clinical study:**

- [x] Informed Consent was obtained.
- [ ] Informed Consent was not obtained.
- [x] An IRB review was not required.
- [ ] An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This report is considered a true and accurate reflection of the testing methods and source data.

Sherri L Sayles 18 Sep 2015

Sherri L. Sayles, MS — Date

Sherri L. Sayles, MS
- Magager, Quality Assurance

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**TABLE 1 - INDIVIDUAL SCORES**

## 1.0 OBJECTIVE

The objective of this study was to determine the irritation and/or sensitization potential of the test article after repeated application under semi-occlusive patch test conditions to the skin of human subjects (non-exclusive panel).

## 2.0 SPONSOR

Total Body Contouring
2727 Paces Ferry Road SE
Building ONE, Suite 750
Atlanta, GA 30339

## 3.0 CLINICAL TESTING FACILITY

The study was conducted by:
Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

## 4.0 CLINICAL INVESTIGATORS

Study Director: Annemarie E. Hollenback, BA
Principal Investigator: Toni F. Miller, PhD, DABT, BCFE
Medical Investigator: John A. Erianne, MD,
Board-Certified Dermatologist

## 5.0 STUDY DATES

Study initiation: July 29, 2015
Final evaluation: September 4, 2015

## 6.0 ETHICS

### 6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures.

### 6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

## 7.0 TEST MATERIAL

The test article used in this study was provided by:
Susan Raffy Consulting, Inc.
3420 W. Mac Arthur Blvd. Suite C
Santa Ana, CA 92704

It was received on July 20, 2015 and identified as follows:
ETC Entry No. 28635
Test Article ID: MDPen Skincare Formulation
Description: Transparent Colorless Viscous Liquid

## 8.0 TEST SUBJECTS

| No. of Subjects | Gender | Age Range | Stipulation |
|---|---|---|---|
| 50 | Male & Female | 18 - 79 | No dermatologic Conditions |

The subjects chosen were to be dependable and able to read and understand instructions. The subjects were not to exhibit any physical or dermatologic condition that would have precluded application of the test article or determination of potential effects of the test article.


**Tighten + Lift Serum**

MDPen Tighten + Lift Serum features the IntegriACTIVE Firmlift ™ conditioning blend with sweet almond seed extract, which helps to lift and fi rm the skin, making it an excellent addition to an anti-aging skincare regimen.


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Spending time in the sun increaases ayour risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. - 2 p.m.; wear lomg sleeve shirts, pants, hats and sunglasses; for children under 6 months: ask a doctor.


**Hydrating Cleanser**

Hydrating Cleanser Our Hydrating Cleanser is a gentle, foaming cleanser fonnulated to remove makeup and surface impurities without drying the skin. Our Cleanser contains Hyaluronic Acid to hydrate and botanical extracts of Aloe, Green Tea, Chamomile and Marigold to soothe, calm and nourish the skin.


**Moisture + Recovery Gel Mask**

Moisture+ Recovery Gel Mask
Our Moisture + Recovery Gel Mask contains Tremella Fuciformis Sporocarp Extract, a humectant which acts to reduce moisture loss, while the MariMoist® blend of Chondrus Crispus Extract and Sodium Hyaluronate instantly hydrates and softens. The Conditioned Stem Media contains Epidermal Growth Factors that help promote skin health and youthful appearance. With the addition of Calendula, Aloe and Oat Kernel, the mask is designed to provide the nourishment and calming agents needed to restore the skin after treatment.

## 9.0 TEST PROCEDURE

The 9 Repeated Insult (semi-occlusive) Patch Test (9-RIPT) I was conducted as follows:

### 9.1 Induction Phase

A sufficient amount of the test article (approximately 0.2 mL) was placed onto a 2 cm x 2 cm square of Webril@ cotton fabric (approximately 0.05 mL/cm2 of test material) affixed to Scanpor (Allerderm) semi-occlusive surgical tape. The patch was then applied to the back of each subject between the scapulae and waist, adjacent to the spinal mid-line. This procedure was performed by a trained technician/examiner and repeated every Monday, Wednesday and Friday until 9 applications of the test article had been made.
The subjects were instructed to remove the patch 24 hours after application. Twenty-four hour rest periods followed the Tuesday and Thursday removals and 48-hour rest periods followed each Saturday removal. Subjects returned to the Testing Facility and the site was scored by a trained examiner just prior to the next patch application.
If a subject developed a positive reaction of a level 2 erythema or greater during the Induction phase or if, at the discretion of the Study Director, the skin response warranted a change in site, the patch was applied to a previously unpatched, adjacent site for the next application. If a level 2 reaction or greater occurred at the new site, no further applications were made. However, any reactive subjects were subsequently Challenge patch tested.
9.2 Challenge

### 9.2 Challenge Phase

After a rest period of approximately 2 weeks (no applications of the test article), the Challenge patch was applied to a previously unpatched (virgin) test site. The site was scored 24 and 72 hours after application. All subjects were instructed to report any delayed skin reactivity that occurred after the final Challenge patch reading. When warranted, selected test subjects were called back to the Clinic for additional examinations and scoring to determine possible increases or decreases in Challenge patch reactivity.

Dermal responses for both the Induction and Challenge phases of the study were scored according to the following 6-point scale:

| Scale | | | | | |
|---|---|---|---|---|---|
| **0=** | **+=** | **1=** | **2=** | **3=** | **4=** |
| **No evidence of any effect** | Barely perceptible (Minimal, faint, uniform or spotty erythema) | Mild (Pink, uniform erythema covering most of the contact site) | Moderate (Pink-red erythema uniform in the entire contact site) | Marked (Bright red erythema with/without petechiae or papules) | Severe (Deep red erythema with/without vesiculation or weeping) |

Al other observed dermal sequelae (eg, edema, dryness, hypo- or hyperpigmentation) were appropriately recorded on the data sheet and described as mild, moderate or severe.

1 MarzulJi FN, Maibach HI. (1976) Contact allergy: predictive testing in man. Contact Dermatitis. 2, 1-17.
Essex Testing Clinic, Inc.

## 9.0 TEST PROCEDURE (CONT'D)

### 9.3 Data Interpretation

Edema, vesicles, papules and/or erythema that persist or increase in intensity either during the Induction and/or Challenge phase may be indicative of allergic contact dermatitis. Allergic responses normally do not resolve or improve markedly at 72-96 hours.

Exceptions to typical skin reactions may occur. These may include, but not be limited to, symptoms of allergic contact sensitivity early in the Induction period to one or more test products. When this occurs in one subject, such a reaction usually suggests either an idiosyncratic response or that the subject had a preexposure/sensitization to the test material or component(s) of the test material or a cross-reactivity with a similar product/component. Data for such reactions will be included in the study report but will not be included in the final study analysis/conclusion of sensitization.

### Induction Phase Summary

| Test Article | Induction Scores Number of Res onses | | | | | | Evidence of Irritation |
|---|---|---|---|---|---|---|---|
| | 1 | | | | 4 | Other | |
| MDPen Skincare Formulation | 0.5 | | 2 | 3 | | | |

### Challenge Phase Summary

| Test Article | Challenge Scores Number of Res onses | | | | | | Evidence of Sensitization |
|---|---|---|---|---|---|---|---|
| | | | | | | Other | |
| MDPen Skincare Formulation | | | | | | | |
| | | | | | | | |

There was no skin reactivity observed at any time during the course of the study.

## 10.0 RESULTS AND DISCUSSION

(See Table 1 for Individual Scores)

A total of 58 subjects (12 males and 46 females ranging in age from 18 to 79 years) were empanelled for the test procedure. Fifty (50/58) subjects satisfactorily completed the test procedure on Test Article: MDPen Skincare Formulation. Eight (8/58) subjects discontinued for personal reasons unrelated to the conduct of the study. Discontinued subject data are shown up to the point of discontinuation, but are not used in the Conclusions section of this final report.

## 11.0 CONCLUSIONS

Under the conditions of a repeated insult (semi-occlusive) patch test procedure conducted in 50 subjects, Test Article: MDPen Skincare Formulation was "Dermatologist-Tested" and was not associated with skin irritation or allergic contact dermatitis in human subjects.

## **TABLE 1: INDIVIDUAL SCORES** REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVE

Test Article: MDPen Skincare Formulation

| Subj. No. | Induction Evaluation Number | | | | | | | | | Challenge Vir in Site | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 24hr | 72hr |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 | 0 | Discontinued | | | | | |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9 | 0 | Discontinued | | | | | | | | | |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Discontinued | | | |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | Discontinued | | | | | |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

### Scale

**0=**
**No evidence of any effect**

**+=**
Barely perceptible (Minimal, faint, uniform or spotty erythema)

**1=**
Mild (Pink, uniform erythema covering most of the contact site)

**2=**
Moderate (Pink-red erythema uniform in the entire contact site)

**3=**
Marked (Bright red erythema with/without petechiae or papules)

**4=**
Severe (Deep red erythema with/without vesiculation or weeping)

## **TABLE 1 (CONT'D): INDIVIDUAL SCORES** REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVE

Test Article: MDPen Skincare Formulation

| Subj. No. | Induction Evaluation Number | | | | | | | | | Challenge Vir in Site | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 24hr | 72hr |
| 31 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 32 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 33 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 34 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 35 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 36 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 37 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 38 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 39 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 40 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 42 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 43 | 0 | 0 | 0 | Discontinued | | | | | | | |
| 44 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 45 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 46 | 0 | Discontinued | | | | | | | | | |
| 47 | 0 | 0 | Discontinued | | | | | | | | |
| 48 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 49 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 50 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 51 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 52 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 53 | Discontinued | | | | | | | | | | |
| 54 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 55 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 56 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 57 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 58 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

### Scale

**0=**
**No evidence of any effect**

**+=**
Barely perceptible (Minimal, faint, uniform or spotty erythema)

**1=**
Mild (Pink, uniform erythema covering most of the contact site)

**2=**
Moderate (Pink-red erythema uniform in the entire contact site)

**3=**
Marked (Bright red erythema with/without petechiae or papules)

**4=**
Severe (Deep red erythema with/without vesiculation or weeping)

**NOTES:**


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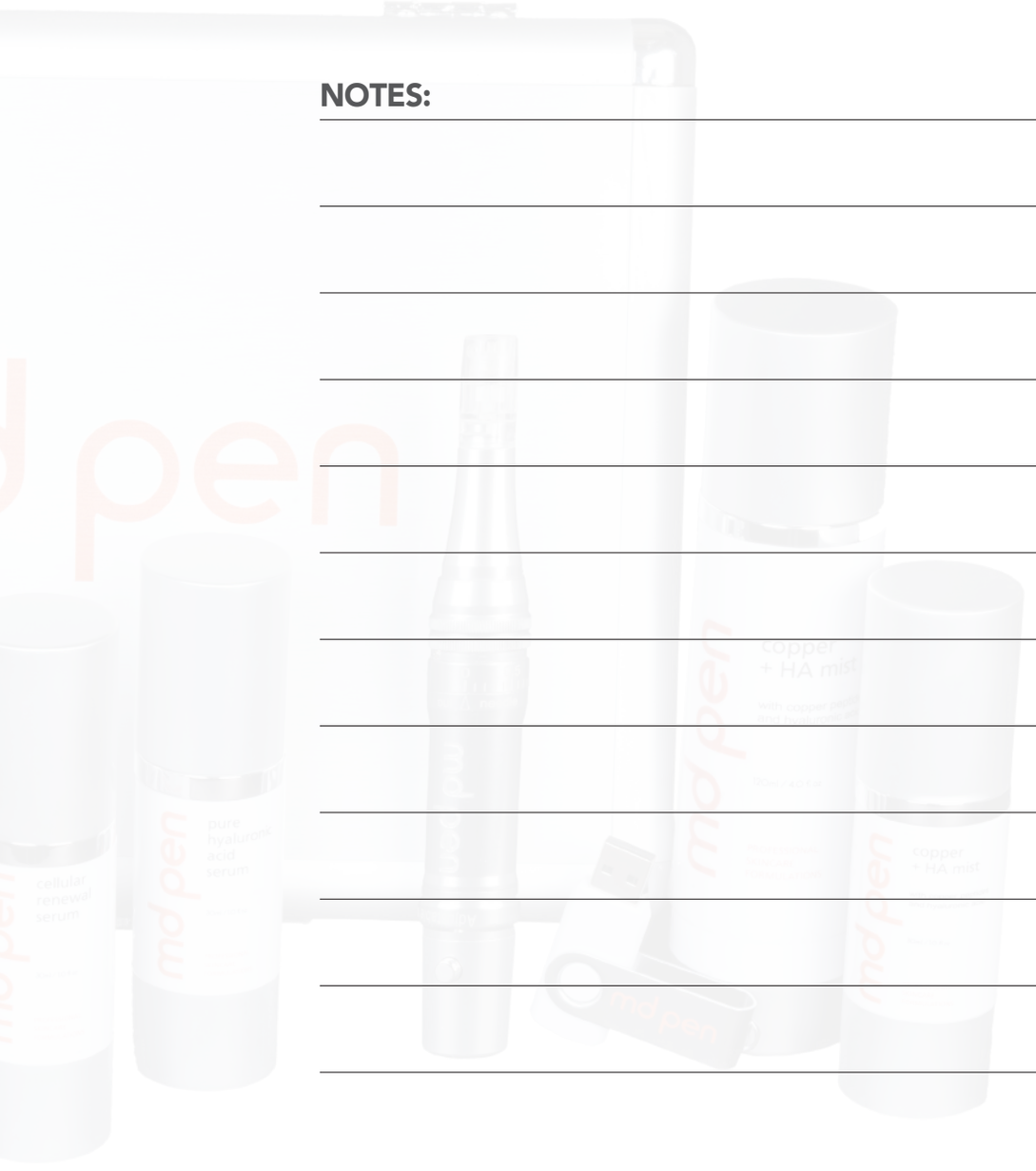
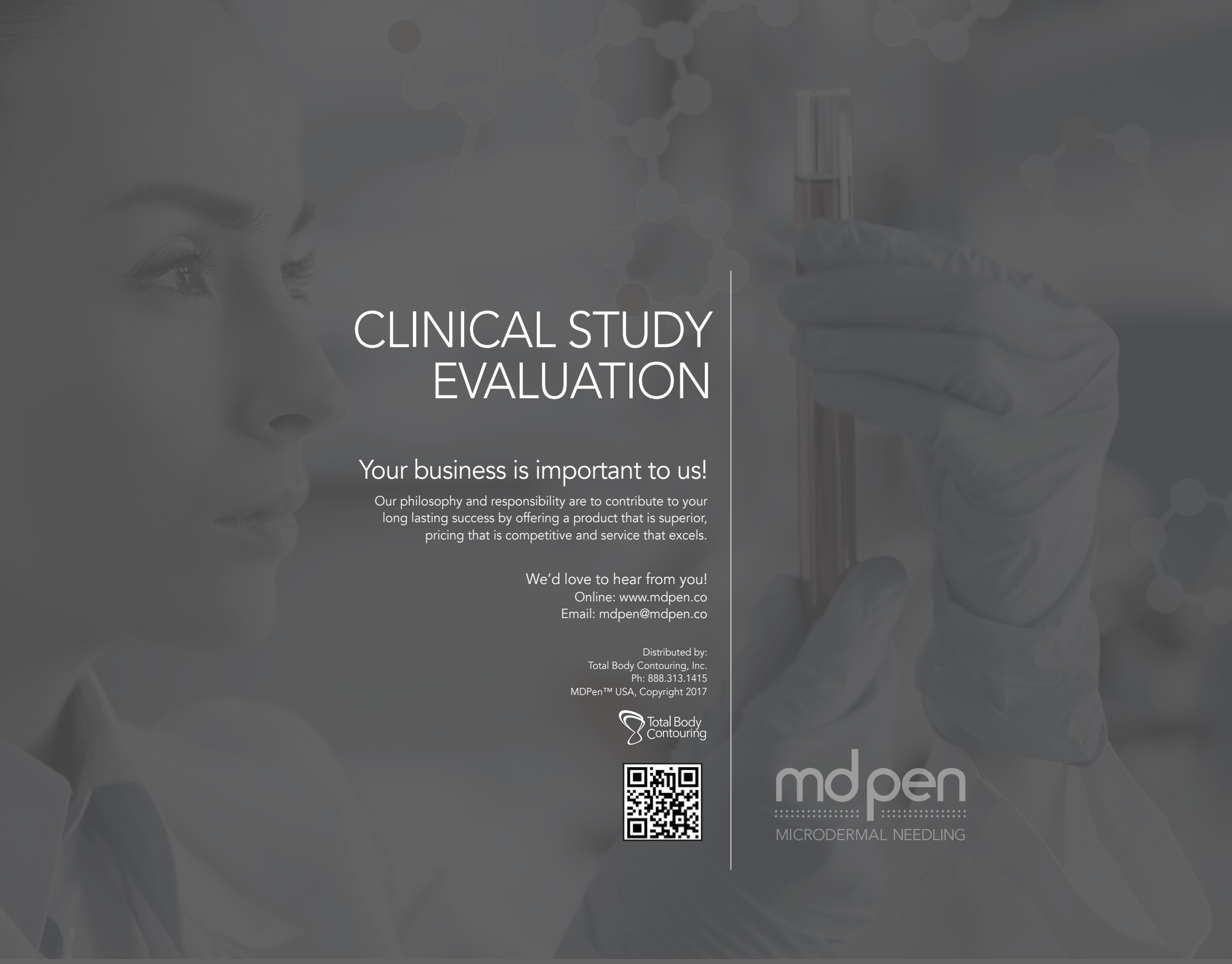

md pen
pure hyaluronic acid serum
cellular renewal serum
copper + HA mist

**NOTES:**



# CLINICAL STUDY EVALUATION

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