FINAL REPORT

STUDY OF PERCEIVED EFFICACY

OLIGO.DX® CELLULITE REDUCING GEL

DS LABORATORIES

#10-2275-01-08-10-S01-V01

REPORT ATTACHMENT 1 –
(7/15/2011)
MAIN REPORT - OLIGO.DX® CELLULITE REDUCING AGENT

PERCEPTION Pesquisa em Análise Sensorial Ltda.
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CEP 13084-520. Campinas. São Paulo. Brazil

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1.IDENTIFICATION

1.1. Study Sponsor

DS LABORATORIES

Address: Rua Visconde de Inhaúma, 64 sala 404

Centro- Rio de Janeiro - RJ

Telephone: (21) 3546 2943

1.2. Organization in Charge of Study

PERCEPTION PESQUISA EM ANÁLISE SENSORIAL LTDA.

Address: Avenida Dr. Romeu Tórtima, 739

Campinas - SP - Brazil

Telephone: (19) 3749 8300

1.3. People in Charge of the Study

In Charge of Study Regina Lúcia F. de Noronha, Ph. D

Statistician in Charge: Leonardo Rangel Alves, M.Sc.

Technician in Charge: Lígia Domingues Ferreira

1.4. Product Tested

NAM	PERCEPTION CODE
OLIGO.DX® CELLULITE REDUCING GEL	10-2275-01

A sample of the product was catalogued and will be kept on file at Perception for one year.

2 OBJECTIVE

The objective of this study was to verify the efficacy of **OLIGO.DX® CELLULITE REDUCING GEL using sensory testing under real conditions** based upon guidelines described in the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products" (COLIPA, 2008).

3 LENGTH OF STUDY

Duration: This report presents the results obtained after using the product for 28 days.
Study start date: 18/Aug/2010 (start of first group)
Study end date: 15/Sept/2010 (end of last group)

4.TEST CONDITIONS

The test was conducted according to the following stages:

Day One:

- The subjects filled out the Free and Clear Consent Form (Attachment 02);
- The subjects were numbered according to order of arrival;
- Before applying the product (T0), the subjects evaluated their skin's initial state (Subjects' Profile Questionnaire) (Attachment 04);
- The products were distributed to the subjects to be used at home for a 28 day period.

Day Twenty-eight:

- After twenty-eight days of product use (T28), the subjects completed the Questionnaire of Evaluation of Perceived Efficacy (Attachment 04).

Directions for use:

For intensive use, apply to the desired areas once a day after bathing. It does not need to be massaged in.

Frequency of Use:

Daily

Application Area:

Body

Amount of Product Applied:

Apply the amount deemed necessary according to the directions for use.

Use Restrictions:

Do not use other cosmetic products in the area of product use during the study period, except for your commonly used soap.

5 EVALUATION OF PERCEIVED EFFICACY

5.1. Panel

Of the 36 subjects initially recruited, 35 were selected and 1 were rejected for not having the specific inclusion criteria (subject number 021).

Of the 35 subjects selected, 30 completed the study.

The panel was comprised of female subjects between the ages of 18 and 60, of any skin color and type who complain of cellulite in at least one of the following areas: thighs and/or hips and/or abdomen and who have not been excluded based upon the specific exclusion criteria.

The exclusion criteria are as follows: pregnancy, breastfeeding, history of adverse reactions on the body where the test-product is to be applied, illnesses and medications that could interfere with the test results or place the health of the subject

at risk, as well as body esthetics or weight loss treatments within the past three months.

5.2. Methodology

The methodology used to evaluate the Perceived Efficacy was created in accordance with the "Standard Guide for Sensory Claim Substantiation" (ASTM 1958-06, 2006).

The subjects were instructed to evaluate their skin using the Subjects' Profile Questionnaire (Attachment 4), at the following time:

- T0: On the first day of the study, before using the product.

The subjects were instructed to evaluate their skin using the Perceived Efficacy Questionnaire (Attachment 4) at the following time:

- T28: After using the product for 28 days.

The attributes evaluated by the subjects on the first day of the study, prior to the first application of the product, were as follows: *Softness, Firmness, Cellulite, Localized Fat* and *Overall Appearance.*

The attributes evaluated by the subjects after using the product for twenty-eight days (T28) were as follows: *Softness, Firmness, Cellulite, Localized Fat* and *Overall Appearance.*

5.3. Type of Test:

The test used to evaluate Perceived Efficacy was a single-blind monadic test.

5.4. Efficacy Evaluation/Criteria

Improvements to the skin were evaluated by the subjects based upon the attributes given in the table below:

ATTRIBUTE	DEFINITIO N	TYPE OF EVALUATION	SCALE
Softness	Sense of skin softness, the opposite of roughness	Touch, fingers run across it smoothly	Category (intensity - 7 points)

ATTRIBUTE	DEFINITION	TYPE OF EVALUATI	SCALE
Firmness	Degree of skin tone (rigidity) maintained , the opposite of flaccid	Touch and stretchiness of the skin	Category (intensity - 7 points)
Cellulite	Irregularity of the cutaneous surface where nodules and dimples are found, creating the "orange peel" effect on the skin.	Appearance and Touch	
Localized Fat	Degree of adipose-tissue accumulation in the evaluated region. Varies between very light to	Appearance	
Overall Appearance	Skin conditions with respect to Cellulite and Localized Fat. Remarks: An improvement need not be seen in each of these attributes to be considered an improvement in Overall Appearance	Appearance	

5.5. Adherence to the Study

Thirty subjects completed the twenty-eight days of the study. Four subjects (009, 013, 014, 025 and 030) withdrew from the research for personal reasons unrelated to product use and one subject (013) had his/her data rejected for incorrect use of the product.

6. STATISTICAL ANALYSES

Evaluation of Perceived Efficacy:

An exploratory analysis of the data was performed (frequencies, percentages, pie charts and bar graphs).

The number of subjects who completed the study was equal to 30 (HOUGH et. al., 2006 and STONE & SIDEL, 2004).

Software used for the statistical analysis included STATA 10.0, XLSTAT 2010, MINITAB 14 and FIZZ 2.40A.

7 RESULTS

During the study, it was noted that:

On 15/Sept/2010, **subject 013** arrived at the Institute for a final visit, complaining of intense pain and redness in the abdominal region, as well as on the front and back of the trunk nine hours after application on the twenty-fifth day of product use. The subject further stated that on that day she wore a tight belt after applying the product, and kept this belt on for nine hours.

A test was run to determine skin sensitivity to lactic acid, and the result was positive. A clinical dermatological exam noted moderate to intense inflammation, with some patches of rash on the abdomen, back and sides of the trunk.

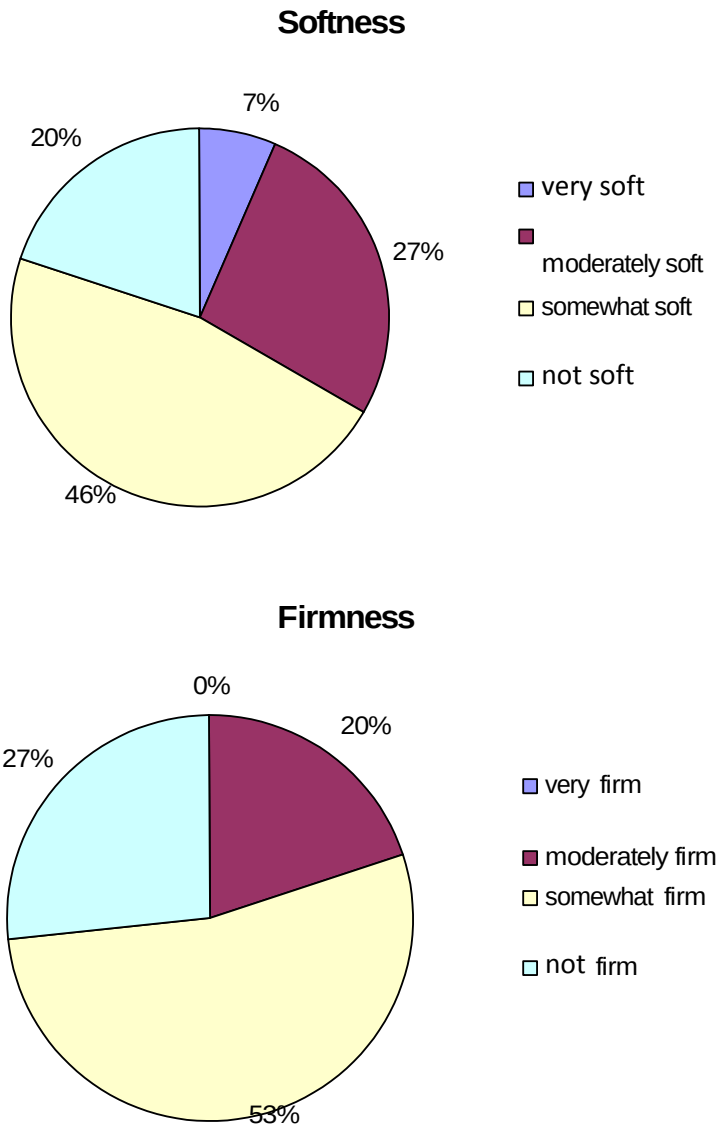
The subject was instructed to apply hydrocortisone cream twice a day and return 22/Sept/2010 to continue the study.

The subject returned to the Institute for reassessment 22/Sept/2010 with no complaints or signs of rash.

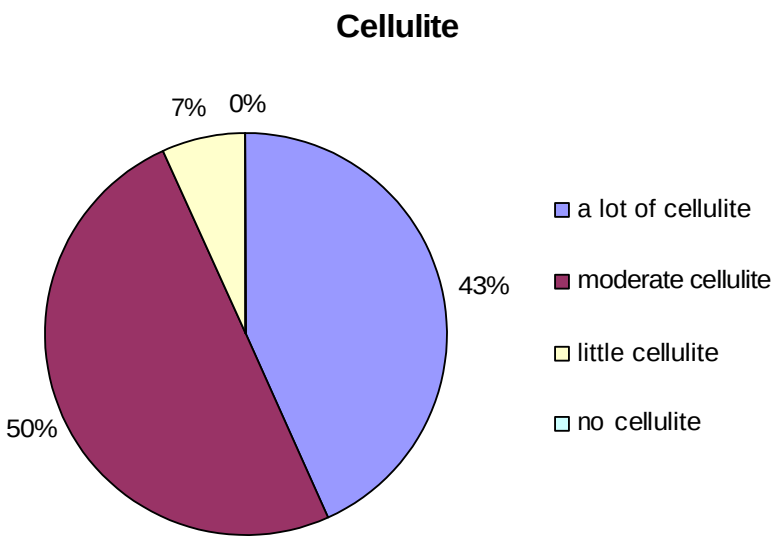
The case was closed as contact dermatitis, irritated by blockage. Use of the product was not determined to be the cause.

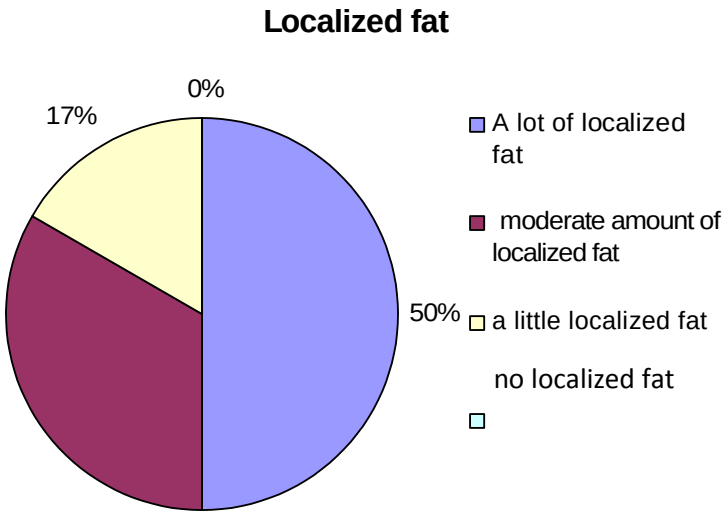
7.1. Evaluation of the skin before product use - Subject Profiles

The figure below (pie chart) shows the judges' evaluation before using the product.

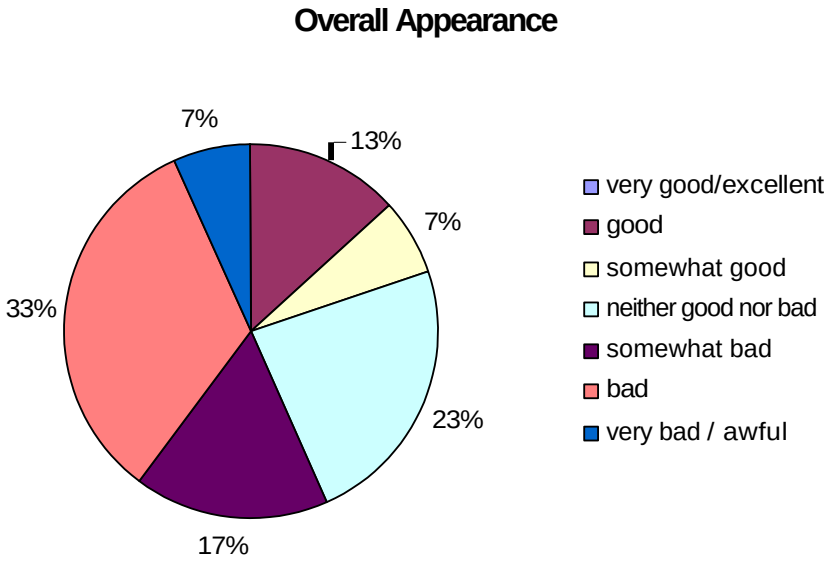


JUDGES' PROFILE





JUDGES' PROFILE



7.2. Skin evaluation after use of the product - Perceived Efficacy

The following tables and figures present the results obtained after using the product for 28 days:

SOFTNESS

With use of the product, the **SOFTNESS** of your skin:	n	%
7 - increased a lot	6	20.0
6 - increased moderately	5	16.7
5 - increased a little	13	43.3
4 - is the same, I didn't notice a change	6	20.0
3 - decreased a little	0	0.0
2 - decreased moderately	0	0.0
1 - decreased a lot	0	0.0
Acceptance	**24**	**80.0**
Rejection	**0**	**0.0**

FIRMNESS

With use of the product, the **FIRMNESS** of your skin:	**T28**	
	n	**%**
7 - increased a lot	3	10.0
6 - increased moderately	9	30.0
5 - increased a little	12	40.0
4 - is the same, I didn't notice a change	6	20.0
3 - decreased a little	0	0.0
2 - decreased moderately	0	0.0
1 - decreased a lot	0	0.0
Acceptan	**24**	**80.0**
Rejectio	**0**	**0.0**

CELLULITE

With use of the product, the **CELLULITE** on your skin:	**T28**	
	n	**%**
7 - decreased a lot	5	16.7
6 - decreased moderately	3	10.0
5 - decreased a little	16	53.3
4 - is the same, I didn't notice a change	6	20.0
3 - increased a little	0	0.0
2 - increased moderately	0	0.0
1 - increased a lot	0	0.0
Acceptan	**24**	**80.0**
Rejectio	**0**	**0.0**

LOCALIZED FAT

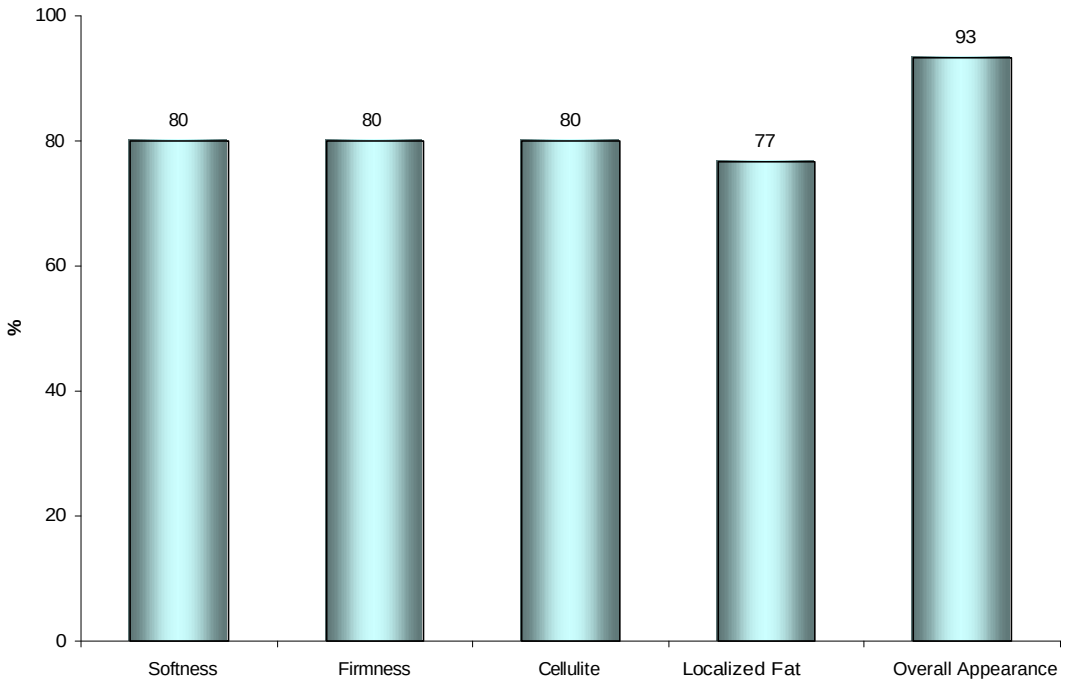
With use of the product, the **LOCALIZED FAT** on your thighs and/or hips and/or abdomen:	**T28**	
	n	**%**
7 - decreased a lot	5	16.7
6 - decreased moderately	6	20.0
5 - decreased a little	12	40.0
4 - is the same, I didn't notice a change	7	23.3
3 - increased a little	0	0.0
2 - increased moderately	0	0.0
1 - increased a lot	0	0.0
Acceptanc	**23**	**76.7**
Rejection	**0**	**0.0**

OVERALL APPEARANCE

With use of the product, the **OVERALL APPEARANCE** of your skin:	**T28**	
	n	**%**
7 - improved a lot	8	26.7
6 - improved moderately	7	23.3
5 - improved a little	1	43.3
4 - is the same, I didn't notice a change	2	6.7
3 - worsened a little	0	0.0
2 - worsened moderately	0	0.0
1 - worsened a lot	0	0.0
Acceptance	**2**	**93.3**
Rejection	**0**	**0.0**

PERCEIVED EFFICACY

The figures below show a summary of the percentages of acceptance for the Perceived Efficacy attributes evaluated after using the product for 28 days.



PERCEPTION

11. CONCLUSION

According to the methodology used to evaluate the product **OLIGO.DX® CELLULITE REDUCING GEL,** ordered by **DS LABORATORIES**, one may conclude that:

Evaluation of Perceived Efficacy by Judges

After using the product 28 days (T56), the following results were obtained:

- 80.0% of subjects noticed increased Softness of their skin;
- 80.0% of subjects noticed increased Firmness of their skin;
- 80.0% of subjects noticed a decrease in Cellulite on their skin;
- 76.7% of subjects noticed a decrease in Localized Fat on their skin;
- 93.3% of subjects noticed an improvement in Overall Appearance of their skin.

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In Charge of Study

Leonardo Rangel Alves, M.Sc.
Statistician In Charge

Lígia Domingues Ferreira
Technician in Charge

Fátima Ap. Ortigoza de Lima
Quality Assurance

9/24/2010

REBLAS

PERCEPTION

ANALI - 025

Analytical Laboratory licensed by ANVISA

See the scope on ANVISA's website:
http://www.a nvisa.gov.br/reblas/bio/anali/index.htm

9 REFERENCES

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MONTGOMERY, D. C. 1991. Design and analysis of experiments. New York : John Wiley and Sons pp 110-114.

SAMPAIO, S.A.P. & COL. Dermatologia Básica. São Paulo: 2nd edition, Artes Médicas, 1989.

STONE, H & SIDEL, J.L. Sensory Evaluation Practices. Redwood City: 3rd Edition, Elsevier Academic, 2004. p.247-272.

PERCEPTION

ATTACHMENT 1 – SUBJECTS WHO PARTICIPATED IN THE STUDY

Subject	Initials	Age	Sex	Status
1		2	F	
2	MGO	2	F	A
3	MIP	5	F	A
4	RCRM	5	F	A
5	MDS	3	F	A
6	RRG	4	F	A
7	TRL	5	F	A
8	MDS	3	F	A
9	SFF	4	F	A
1	JAG	2	F	A
1	MSS	2	F	A
1	LLS	5	F	A
1	LRG	2	F	A
1	MOB	1	F	A
1	SDS	4	F	A
1	LKAP	3	F	A
1	MSS	3	F	A
1	C	2	F	A
1	EAO	3	F	A
2	C	5	F	A
2	LBST	4	F	FS
2	LAPS	3	F	A
2	AMV	4	F	A
2	NMOP	5	F	A
2	R	3	F	A
2	MFG	5	F	A
2	P	4	F	A
2	MAS	5	F	A
2	J	4	F	A
3	MVS	2	F	A
3	TDTM	2	F	A
3	SMB	5	F	A
3	MCG	4	F	A
3	JMEV	3	F	A
3	JCM	5	F	A
3	RCPF	4	F	A

FS: Selection Failure; A: Approved

ATTACHMENT 2 – FREE AND CLEAR CONSENT FORM

• You have been invited to participate in a study. We ask that you thoroughly understand all stages, and if you agree, sign this consent form;

• Perceived efficacy evaluation under real conditions of use. You will receive the product to be tested to use at home for 28 days, and a home product-use diary to be filled out regarding frequency of product use and any complaints about its use that you deem necessary. By signing this consent form you will guarantee the veracity of the information reported; at the end of the study, you will bring the test products and the duly completed diary. You will answer the questionnaire prior to using the product and after using the product 28 days. Directions for use: For intensive use, apply once a day after bathing to the desired areas. It does not need to be massaged in.

• You will be evaluated prior to the study by a trained technician and monitored during the study. Any questions that arise during and after the study will be promptly answered;

• Your contribution will ensure a safe and effective product for the community;

• According to current legislation, you will receive no cash payment, and your transportation expenses will be reimbursed;

•You may withdraw from the study at any time you so desire, or if necessary, at the researcher's discretion.

• The study will be conducted on 35 volunteers;

- The study's duration will be 28 days / 4 weeks;

• Your voluntary collaboration will be of great importance to our work; therefore, we ask that you arrive on time and on the dates listed over the course of the study.

• If there is any change to your habits, we ask that you please tell us for better interpretation of the results;

• Do not use any type of product (deodorant or antiperspirant, talcum powder, bath oils, creams, lotions, perfumes, colognes, or topical medications) on the areas adjacent to the test area. If you use any of these products or take systemic medication, please let us know;

ATTACHMENT 2 – CONTINUED

• In the event of intense itching or other strong signs of irritation, immediately report it and come to the test-application location, or call us at 19-3789-8615.

• We guarantee that any adverse reaction caused by the tested product will be monitored by the dermatologist and/or specialist in charge of the project, and if necessary, proper medication will be provided, and you will be notified of any other relevant information;

• All raw materials used in the product are approved for topical use and are non-toxic. However, like any product, it may cause unexpected reactions such as "reddening," "swelling," "itching," and "burning" in the areas where the product is applied

• Volunteers are duly insured through Mapfre Seguros, policy number 18/442/2001000095518

• All information collected from volunteers will be kept confidential;

• If you have any questions or problems, you may contact the medical team at 19 3789 8615 and at the address: Avenida Dr. Romeu Tórtima, 452 – Barão Geraldo, Campinas.

One copy of this form will remain on file at PERCEPTION, and another will be given to the volunteer.

All of the items were read aloud and explained to the volunteers.

01 I,

First and Last Names *(complete, no abbreviations)*

02 Date of Birth Telephone for Contact

03 Identification (R.G.) number

ATTACHMENT 2 – CONTINUED

I agree to participate in the study **"EVALUATION OF PERCEIVED EFFICACY UNDER REAL CONDITIONS OF USE"** and I declare that all of the aforementioned items have been explained to me.

04

Volunteer's Signature *(same as the R.G. or Driver's License C.N.H.)* Date

Witness *(complete first and last name, no abbreviations)*

Identification (R.G.) number

05

Witness' Signature *(same as the R.G. or Driver's License C.N.H.)* Date

Complete this section only if the volunteer is illiterate.

ATTACHMENT 3 – PRODUCT FORMULA

OLIGO.DX® CELLULITE REDUCING GEL

ATTACHMENT 4 – QUESTIONNAIRES FOR THE SUBJECTS' EVALUATION

SUBJECT PROFILE QUESTIONNAIRE

Classification of Skin Characteristics Before Using the Product – T0

01 - With respect to **SOFTNESS**, your skin:
(…) is very soft
(…) is moderately soft
(...) is a little soft
(...) is not soft

01 - With respect to **FIRMNESS**, your skin:
(…) is very firm
(...) is moderately firm
(...) is a little firm
(...) is not firm

03 - With respect to **CELLULITE**, your skin:
(…) has a lot of cellulite
(...) has moderate cellulite
(...) has a little cellulite
(...) has no cellulite

04 - With respect to **LOCALIZED FAT**, your skin:
(…) has a lot of localized fat
(...) has a moderate amount of localized fat
(...) has a little localized fat
(...) has no localized fat

5. With respect to **OVERALL APPEARANCE**, your skin is:
(…) very good/excellent
(…) good
(...) somewhat good
(...) neither good nor bad
(...) somewhat bad
(...) bad
(...) very bad/awful

ATTACHMENT 4 – CONTINUED

PERCEIVED EFFICACY QUESTIONNAIRE

Classification of Skin Characteristics After Using the Product – T28

01 - After using the product the **SOFTNESS** of your skin:
(…) increased a lot
(...) increased moderately
(...) increased a little
(...) is the same, I didn't notice a change
(...) decreased a little
(...) decreased moderately
(...) decreased a lot

02 - After using the product the **FIRMNESS** of your skin:
(…) increased a lot
(...) increased moderately
(...) increased a little
(...) is the same, I didn't notice a change
(...) decreased a little
(...) decreased moderately
(...) decreased a lot

03 - After using the product the **CELLULITE** on your skin:
(…) decreased a lot
(...) decreased moderately
(...) decreased a little
(...) is the same, I didn't notice a change
(...) increased a little
(...) increased moderately
(…) increased a lot

04 - After using the product, the **LOCALIZED FAT** on your skin:
(…) decreased a lot
(...) decreased moderately
(...) decreased a little
(...) is the same, I didn't notice a change
(...) increased a little
(...) increased moderately
(…) increased a lot

05 After using the product the **GENERAL APPEARANCE** of your skin:
(…) improved a lot
(...) improved moderately
(...) improved a little
(...) is the same, I didn't notice a change
(...) worsened a little
(...) worsened moderately
(...) worsened a lot