



**EVALUATION OF A LIP PRODUCT IN IMPROVING THE APPEARANCE OF  
LIP PLUMPING**

**FINAL REPORT**

**June 9, 2016**

**SPONSOR:** IP Brands  
20-21 Wagaraw Road  
Fair Lawn, NJ 07410

**TEST PRODUCT:** WunderKiss Lip Gloss  
WunderKiss Booster

**STUDY NUMBER:** BCS 16-049

**PROJECT NUMBER:** 949500

## **RESEARCH STANDARD**

This clinical study was conducted in accordance with the International Conference of Harmonization Tripartite Guideline on Good Clinical Practice, applicable FDA regulations/guidelines set forth in 21 CFR Parts 11, and 50 and standard practices of BioScreen Testing Services.

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## I. STUDY CONCLUSIONS

Under the conditions of the study and based on the study results, the following claims were substantiated for Test Product: WunderKiss Lip Gloss and WunderKiss Booster:

- 1) Improved appearance of lip plumping

Test Product: WunderKiss Lip Gloss and WunderKiss Booster provided the following statistically significant improvements 30 minutes after test product use:

- **46.46%** improvement in the appearance of lip plumping.
- **100.00%** of subjects demonstrated an improvement in the appearance of lip plumping

## II. SUMMARY OF RESULTS

Under conditions of the study a total of 33 healthy female subjects, 18-62 years of age, completed the clinical study evaluating the efficacy of Test Product: WunderKiss Lip Gloss and WunderKiss Booster to improve the appearance of lip plumping.

### A. Lip Plumping by Clinical Grading

Note: Negative difference indicates an increase in the appearance of lip plumping.

Parameter	30 Minute
Mean Percent Difference from Baseline	<b>-46.46%</b>
Percent of Subjects Improved	<b>100.00%</b>

BOLD values indicate statistical significance ( $p \leq 0.05$ ).

#### *Clinical Findings:*

- There was a statistically significant improvement in the appearance of lip plumping from baseline at the 30 minute post-treatment interval.
- A statistically significant number of subjects demonstrated improvement in the appearance of lip plumping at the 30 minute post-treatment interval.

### B. Post-Treatment Questionnaires

Scale: 1 = Strongly Agree, 2 = Agree, 3 = Disagree, 4 = Strongly Disagree

Statement	% of subjects with favorable response	
	2 Minute	30 Minute
1. The test product helped to plump the appearance of my lips within 2-minutes of application.	<b>87.88%</b>	<b>87.88%</b>
2. The test product helped to plump the appearance of my lips even more after 30-minutes of application?	<b>78.79%</b>	<b>96.97%</b>
3. The test product helped provide high shine to the appearance of my lips.	<b>100.00%</b>	<b>100.00%</b>
4. The test product helped my lips feel hydrated.	<b>96.97%</b>	<b>100.00%</b>
5. The test product helped give a fuller appearance to the appearance of my lips.	<b>90.91%</b>	<b>100.00%</b>
6. The test product helped give a smoother appearance to the appearance of my lips.	<b>87.88%</b>	<b>93.94%</b>

7. The test product helped my lips to appear younger.	<b>84.85%</b>	<b>90.91%</b>
8. The plumping effects of the test products lasted for hours after application?	<b>78.79%</b>	<b>93.94%</b>
9. The test product was the best lip plumper I have ever tried?	<b>87.88%</b>	<b>96.97%</b>
10. I would recommend the test product to a friend?	<b>90.91%</b>	<b>100.00%</b>
11. The test product was easy to apply?	<b>100.00%</b>	<b>100.00%</b>
12. The test product glided onto my lips?	<b>100.00%</b>	<b>100.00%</b>
13. The test product felt luxurious on my lips?	<b>100.00%</b>	<b>96.97%</b>
14. The test product exceeded my expectations?	<b>87.88%</b>	<b>93.94%</b>
15. The test product improved the overall appearance of my lips?	<b>96.97%</b>	<b>96.97%</b>
16. I experienced tingling after application of the test product.	<b>100.00%</b>	<b>100.00%</b>
17. The test product was comfortable on my lips?	<b>96.97%</b>	<b>100.00%</b>
18. The test product left my lips feeling soft.	<b>96.97%</b>	<b>100.00%</b>
19. I liked how the test product tingled on my lips.	<b>87.88%</b>	<b>87.88%</b>
20. The test product gave me added confidence.	<b>75.76%</b>	<b>90.91%</b>
21. My lips look more supple.	<b>90.91%</b>	<b>96.97%</b>
22. My lips look healthier.	<b>90.91%</b>	<b>93.94%</b>
23. This test product is different than any other lip product I have used.	<b>93.94%</b>	<b>100.00%</b>

BOLD values indicate statistical significance ( $p \leq 0.05$ ).

### III. STUDY OBJECTIVE

To evaluate the efficacy of a body product for the following attributes:

- 1) Appearance of lip plumping

### IV. STUDY DATES

The study began and ended on June 1, 2016

### V. TESTING FACILITY

BioScreen Clinical Services Division  
BioScreen Testing Services, Inc.  
3305 N. 2nd Street,  
Phoenix, AZ 85012

### VI. TEST PRODUCT

Test Product	# of Samples	Date Received	Accession Number
WunderKiss Lip Gloss	35	05/13/2016	949500
WunderKiss Booster	35	05/13/2016	949501

### VII. TEST PRODUCT HANDLING

The test product had been reviewed and approved for use by the Regulatory and Safety representatives of IP Brands was tested.

Upon arrival at BioScreen Clinical Services (BCS) the test product 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. Sample will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

### VIII. STUDY PARTICIPATION RECRUITMENT

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

## **IX. INFORMED CONSENT, PHOTOGRAPHY RELEASE AND MEDICAL HISTORY FORMS**

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 and a photography release form to indicate their authorization to proceed and acknowledged their understanding of the contents. 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 BCS only.<sup>1</sup>

## **X. INCLUSION CRITERIA**

- a. Sex: Female
- b. Age: 18- 65 years of age
- c. Race: Unrestricted
- d. Individuals who were in good general health.
- e. Individuals who were free of any dermatological or systemic disorder, which would interfere with the results, at the discretion of the Investigator.
- f. Individuals who completed a preliminary medical history and who read, understood and signed an informed consent document.
- g. Individuals who were able to cooperate with the Investigator and research staff, had test product applied according to the protocol, and completed the full course of the study.
- h. Individuals who had not participated in any other clinical study involving the same test sites (lips) for the past 15 days.
- i. Individuals who had average-sized lips.
- j. Individuals who agreed to not use any lip products (e.g. balms, chapstick, lip gloss, lipstick, etc.) 24 hours prior to their visit.

## **XI. EXCLUSION CRITERIA**

- a. Individuals who had a history of any acute or chronic disease that could interfere with or increase the risk on study participation.
- b. Individuals who had an active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema), or had recently treated skin cancer (within the last 12 months).
- c. Individuals who had damaged skin at or in close proximity to test site (e.g., sunburn, tattoos, scars, piercings or other disfigurements).
- d. Individuals who had any history, which, in the Investigator's opinion, indicated the potential for harm to the subject or placed the validity of the study in jeopardy.
- e. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
- f. Individuals who had a known history of hypersensitivity to any cosmetics, personal care products and/or fragrances.



- g. Individuals who were employees of BioScreen.

## **XII. EXPERIMENTAL TECHNIQUES AND PRINCIPLES:**

### **Clinical Photography for Expert Grading of Lip Plumping<sup>2-4</sup>**

Photographs are taken in accordance with regulations provided by consumer protection agencies such as the Federal Trade Commission, the Food and Drug Administration and several other regulatory authorities. The following guidelines are followed: 1) Head position is the same in before and after photos, 2) Same lighting conditions are used and the distance from the camera is same for both, before and after picture, and 3) Same room and background is used for both before and after picture.

Clinical photographs of subjects' faces (frontal) were taken and evaluated with Canfield VISIA CR system using the Standard 1 modalities.

Photographs obtained were evaluated for lip plumping using a 0-3 scale category for the following parameters (Half point increments were allowed):

Overall Scale: 3=No Change, 2=Mild Plumping, 1=Moderate Plumping, 0=Extreme Plumping

### ***Self-Assessment Questionnaire***

Each subject was instructed to complete a self-assessment questionnaire, provided by the Sponsor, at the Immediate (2 Minute) and 30 Minute post-treatment intervals.

## **XIII. PROCEDURE**

1. Prospective subjects reported to the facility at the start of the study.
2. Subjects were instructed to not use any lip products (e.g. balms, chapstick, lip gloss, lipstick, etc.) 24 hours prior to their visit.
3. Prior to beginning all study related activities, prospective subjects completed an informed consent form, medical history form, photography release, and a HIPAA form.
4. Subjects were enrolled on the basis of the subject selection criteria. Subjects failing to meet criteria were dismissed from the study.
5. Enrolled subjects was instructed to use a makeup remover wipe on their lips to ensure there were no products on their lips that would interfere with the test product.
6. Subjects then had the below procedures/measurements performed by trained BCS staff:

### **Baseline (pre-treatment)**

- a. Close-up facial photography

7. Subjects were instructed to apply the test product to their lips per Sponsor use instructions.
8. At 2 minutes post-application, subjects were instructed to complete a post-treatment questionnaire.
9. Subjects were then instructed to reapply the test product per Sponsor use instructions.
10. At 30 minutes ( $\pm$  5 minutes) post application, subjects had the below procedures/measurements performed by trained BCS staff
  - 30 Minute ( $\pm$  5 minutes) (post-treatment)
    - a. Close-up facial photography
    - b. Post-treatment questionnaire
11. Subjects were dismissed after the 30 minute questionnaire had been completed.

#### **XIV. ADVERSE EVENTS**

There were no adverse events reported during the study period.

## XV. STUDY RESULTS AND ANALYSIS

### A. Study Subjects

A total of 33 healthy female subjects consented, enrolled and completed the clinical study.

**Table 1. Subject Demographics.**

No.	Subject ID	Subject Initials	Age	Race
1	824	S-S	51	H
2	1506	VLC	58	C
3	3894	LAW	54	C
4	4607	MJD	39	C
5	6467	SME	36	C
6	8110	F-G	39	C
7	8940	LCD	36	C
8	9457	KJL	33	C
9	10892	DAT	56	C
10	12937	MAC	21	H
11	14060	RAW	32	C
12	14258	LKT	62	C
13	17220	AMA	38	H
14	18033	CIC	23	C
15	18462	DMB	56	H
16	18756	CMC	50	C
17	18786	LDD	44	C
18	19916	TKH	45	C
19	20218	ESK	45	AA
20	20567	CLD	50	C
21	20675	IMD	18	C
22	21240	A-R	45	H
23	21388	EJR	34	AA
24	22182	CRM	53	AA
25	22249	MPC	49	C
26	22457	MEB	23	H

<b>No.</b>	<b>Subject ID</b>	<b>Subject Initials</b>	<b>Age</b>	<b>Race</b>
27	22941	ENM	20	C
28	23179	LMT	30	C
29	23292	AVB	21	H
30	23540	JLP	44	C
31	23603	LHL	40	H
32	23607	SLV	22	H
33	23730	GTR	36	H

AA=African American, C=Caucasian, H=Hispanic

**B. Lip Plumping by Clinical Grading**

**Table 2. Mean appearance of lip plumping values.**

Scale: 3=No Change, 2=Mild Plumping, 1=Moderate Plumping, 0=Extreme Plumping

Interval	Mean	SD
Baseline	3.00	0.00
30 Minute	1.61	0.65

**Table 3. Descriptive statistics of appearance of lip plumping differences from baseline.**

Note: Negative difference indicates improvement in the appearance of lip plumping.

Interval	Parameter	Lip Plumping Differences from Baseline
30 Minute	Mean	-1.39
	SD	0.65
	%Change	<b>-46.46%</b>
	<i>p</i>	≤0.001
	%Improvers	<b>100.00%</b>
	<i>p</i>	≤0.001

Bold values indicate statistical significance ( $p \leq 0.05$ ).

## APPENDIX

### A) Lip Plumping by Clinical Grading

Overall Scale: 3=No Change, 2=Mild Plumping, 1=Moderate Plumping, 0=Extreme Plumping

Subject ID	Baseline	30 Minute
824	3.0	1.0
1506	3.0	1.5
3894	3.0	2.0
4607	3.0	1.0
6467	3.0	2.0
8110	3.0	2.0
8940	3.0	1.5
9457	3.0	1.5
10892	3.0	2.5
12937	3.0	1.5
14060	3.0	0.5
14258	3.0	2.5
17220	3.0	1.5
18033	3.0	1.0
18462	3.0	2.0
18756	3.0	2.0
18786	3.0	2.5
19916	3.0	1.5
20218	3.0	2.0
20567	3.0	2.0
20675	3.0	2.5
21240	3.0	1.0
21388	3.0	1.0
22182	3.0	0.5
22249	3.0	1.5
22457	3.0	1.0
22941	3.0	1.5
23179	3.0	2.5
23292	3.0	1.5
23540	3.0	0.0
23603	3.0	2.5
23607	3.0	1.5
23730	3.0	2.0

## B) Post-Treatment Questionnaire (2 Minute)

Scale: 1 = Strongly Agree, 2 = Agree, 3 = Disagree, 4 = Strongly Disagree

ID	1. The test product helped to plump the appearance of my lips within 2-minutes of application.	2. The test product helped to plump the appearance of my lips even more after 30-minutes of application?	3. The test product helped provide high shine to the appearance of my lips.	4. The test product helped my lips feel hydrated.	5. The test product helped give a fuller appearance to the appearance of my lips.	6. The test product helped give a smoother appearance to the appearance of my lips.	7. The test product helped my lips to appear younger.	8. The plumping effects of the test products lasted for hours after application?	9. The test product was the best lip plumper I have ever tried?	10. I would recommend the test product to a friend?	11. The test product was easy to apply?	12. The test product glided onto my lips?	13. The test product felt luxurious on my lips?	14. The test product exceeded my expectations?	15. The test product improved the overall appearance of my lips?	16. I experienced tingling after application of the test product.	17. The test product was comfortable on my lips?	18. The test product left my lips feeling soft.	19. I liked how the test product tingled on my lips.	20. The test product gave me added confidence.	21. My lips look more supple.	22. My lips look healthier.	23. This test product is different than any other lip product I have used.
824	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	3	2	3	3	2	3	2	
1506	2	2	1	1	2	1	2	2	1	1	1	1	1	1	1	1	1	2	2	2	2	1	
3894	1	1	1	1	1	2	2	2	2	1	1	1	1	2	1	1	1	1	3	1	2	2	
4607	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	2	1	2	2	1	2	2	
6467	2	2	1	1	2	2	3	2	3	2	1	1	1	2	2	2	1	1	1	3	2	3	
8110	1	1	2	2	2	2	2	2	2	1	2	1	1	1	2	2	2	3	2	2	2	2	
8940	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	
9457	2	1	1	1	1	1	1	2	1	1	2	1	2	1	1	1	2	1	2	1	2	3	
10892	3	4	1	1	3	1	1	4	4	1	1	1	1	2	2	1	1	1	3	1	1	1	

12937	2	2	2	2	2	1	2	2	2	2	1	1	2	2	2	1	2	2	2	2	2	1
14060	1	2	1	1	1	1	1	2	1	1	1	1	2	1	1	1	2	1	1	1	1	1
14258	2	3	2	2	2	2	2	3	2	3	2	2	2	3	2	1	2	2	1	4	2	2
17220	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
17795	3	2	1	1	1	1	2	2	1	1	1	1	1	2	2	1	2	2	2	2	2	1
18033	2	2	2	2	2	2	2	2	1	2	1	1	1	1	2	1	2	2	2	2	2	2
18462	2	2	1	2	2	2	2	2	2	2	2	2	1	2	2	1	1	1	1	2	2	1
18756	2	3	1	2	2	3	3	3	2	2	2	2	2	3	2	2	2	2	2	2	3	2
18786	1	1	1	1	1	2	2	2	1	1	1	1	1	1	2	1	2	1	2	2	1	1
19916	2	4	1	1	1	1	1	3	2	1	1	1	1	1	1	2	1	1	1	2	1	2
20218	3	3	1	1	3	2	3	3	3	2	2	2	2	3	2	2	2	2	2	3	3	2
20567	2	3	1	3	2	3	3	3	2	3	1	1	2	2	2	2	2	2	2	3	2	2
21240	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
21388	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22182	2	2	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22249	1	1	1	1	1	1	2	1	1	2	1	1	1	2	2	1	2	1	3	2	2	1
22457	2	2	1	1	1	2	1	2	1	1	1	1	1	1	1	2	1	1	1	1	1	1
22941	2	2	2	2	1	2	2	2	2	1	1	1	1	2	1	2	2	2	3	2	2	2
23179	1	2	1	2	1	3	2	2	1	1	1	1	1	1	1	1	2	2	1	2	1	2
23292	4	4	1	1	4	4	4	4	4	4	1	1	1	4	4	1	1	3	2	4	4	1
23540	2	2	1	1	2	2	2	2	2	2	2	2	2	2	2	1	1	2	2	2	2	2
23603	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
23607	2	2	2	2	1	1	1	2	1	1	1	1	1	1	1	1	2	2	1	1	1	1
23730	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2



### C) Post-Treatment Questionnaire (30 Minute)

Scale: 1 = Strongly Agree, 2 = Agree, 3 = Disagree, 4 = Strongly Disagree

ID	1. The test product helped to plump the appearance of my lips within 2-minutes of application.	2. The test product helped to plump the appearance of my lips even more after 30-minutes of application?	3. The test product helped provide high shine to the appearance of my lips.	4. The test product helped my lips feel hydrated.	5. The test product helped give a fuller appearance to the appearance of my lips.	6. The test product helped give a smoother appearance to the appearance of my lips.	7. The test product helped my lips to appear younger.	8. The plumping effects of the test products lasted for hours after application?	9. The test product was the best lip plumper I have ever tried?	10. I would recommend the test product to a friend?	11. The test product was easy to apply?	12. The test product glided onto my lips?	13. The test product felt luxurious on my lips?	14. The test product exceeded my expectations?	15. The test product improved the overall appearance of my lips?	16. I experienced tingling after application of the test product.	17. The test product was comfortable on my lips?	18. The test product left my lips feeling soft.	19. I liked how the test product tingled on my lips.	20. The test product gave me added confidence.	21. My lips look more supple.	22. My lips look healthier.	23. This test product is different than any other lip product I have used.
824	3	1	1	2	1	2	3	2	2	2	2	2	2	2	1	2	2	3	2	2	2	2	
1506	1	1	1	1	1	1	2	2	1	1	1	1	2	1	1	1	1	1	2	1	1	1	
3894	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	
4607	1	1	1	1	1	1	2	1	2	1	1	1	1	2	1	1	2	1	2	2	1	2	2
6467	2	1	1	1	1	1	2	2	2	1	1	1	1	2	2	2	1	1	1	2	2	2	2
8110	2	2	2	1	2	1	2	2	2	1	1	1	2	2	2	2	2	2	2	2	2	2	2
8940	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
9457	1	1	1	1	1	1	2	1	1	1	2	2	3	1	2	1	1	1	1	2	1	2	2
10892	3	2	1	1	2	1	1	4	1	1	1	1	1	1	1	1	1	1	2	1	1	1	

12937	1	1	1	2	1	2	2	2	1	1	1	1	2	1	1	1	2	2	1	2	1	2	1
14060	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1
14258	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	3	4	2	2	2	2
17220	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
17795	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
18033	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1
18462	2	2	1	1	1	2	1	2	1	1	1	1	1	2	2	1	1	1	1	2	1	1	1
18756	2	2	2	2	2	3	3	2	2	2	2	2	2	3	2	2	2	2	2	2	2	3	2
18786	1	1	1	1	1	1	1	2	2	1	1	1	1	1	1	1	1	1	2	2	1	1	1
19916	1	1	1	1	1	1	1	2	2	1	1	1	1	2	1	1	1	1	1	2	1	1	2
20218	3	3	1	1	2	2	3	3	3	2	2	2	2	3	3	1	1	2	1	3	3	3	2
20567	2	2	1	2	2	1	2	2	1	2	1	1	2	2	2	1	1	2	2	3	2	2	2
21240	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
21388	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22182	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22249	1	1	1	1	1	1	1	1	1	2	1	1	1	2	1	1	2	2	3	2	1	1	1
22457	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22941	2	1	1	2	1	1	2	2	2	1	1	1	1	2	1	1	2	2	3	2	1	1	2
23179	1	2	1	2	1	3	2	2	1	1	1	1	1	1	1	1	2	1	2	2	2	2	1
23292	4	1	1	1	1	1	2	2	2	2	1	1	1	2	1	1	1	1	1	2	2	2	1
23540	1	1	1	1	1	2	2	2	2	2	2	2	2	2	1	1	1	2	1	2	1	1	1
23603	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
23607	1	1	1	1	1	1	1	1	1	1	2	2	2	2	1	2	2	2	1	1	2	1	1
23730	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1



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