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Sun Protection Factor Final Report

Report Date: 2/02/18	**FSTI Study #: 17-786**
Sponsor Study No.: N/A	**FSTI Sample #: 17-786**
Sponsor: BOV Solutions Inc. 1105 E. Garner Baynal Blvd. Statesville, NC 28677	**Sponsor Formula #: 60-RF50FRF-00 Sample Description: SPF 50 Continuous Spray**

Summary:

The sponsor test product sample, Formula # 60-RF50FRF-00, was tested under FSTI (Florida Suncare Testing, Inc.) SOP # 2011-01, 80 Minute Water Resistant SPF Testing, as set forth by the FDA, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Final Monograph, Federal Register, Vol. 76, No. 117, June 17, 2011.

The ten (10) subject test panel study yielded a mean 80 Minute Water Resistant SPF value of **63.59** (**Label SPF 61**). See Page 9 (Table 1) of this report for a summary of all test results obtained in this study.

The FDA Standard Sunscreen Product tested concurrently with the experimental test sample yielded a mean Static SPF value of 15.30, within the allowable guidelines of 16.3 ± 3.43.

Approvals:

Sherriel Wallace **Sherriel Wallace** **FSTI Clinical Director**	2/2/18 **Date**
JP MD **Jeffrey Parks M.D.** **Board Certified Dermatologist**	2/2/2018 **Date**

FSTI STUDY NUMBER: 17-786

SPONSOR: **BOV Solutions Inc.**
1105 E. Garner Baynal Blvd.
Statesville, NC 28677

SPONSOR FORMULA NUMBER: 60-RF50FRF-00 **DATE RECEIVED:** December 7, 2017

FSTI SAMPLE NUMBER: 17-786 **DATE COMPLETED:** January 30, 2018

I. OBJECTIVE

To measure the Sun Protection Factor (SPF) value for a sunscreen formula following 80 minutes water immersion and the Static SPF value of the FDA standard sunscreen product using FDA, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Final Monograph, Federal Register, Vol. 76, No. 117, June 17, 2011.

II. STUDY TYPE

Ten (10) subject 80 Minute Water Resistant SPF study, with a final report furnished to the sponsor, which includes the mean SPF values and Label SPF values.

III. SAMPLE DESCRIPTION

SPF 50 Continuous Spray, Formula # 60-RF50FRF-00, Lot # 112017, FSTI Sample # 17-786

IV. TEST MATERIAL HANDLING

The BOV Solutions Inc. sample labeled Formula # 60-RF50FRF-00, was assigned Florida Suncare Testing, Inc. sample number 17-786 and entered into the SPF test submission log. The FDA standard 15 SPF sunscreen, as described in FDA, 21 CFR, Sec. 201.327, subpart (i) (2), SPF Standard, was used concomitantly as the control test product for this study.

V. ARCHIVING

All original protocols, raw data sheets, and copies of final reports are maintained on the premises of Florida Suncare Testing, Inc., in limited access storage files in accordance with FSTI SOP# 2008-10. A duplicate copy of all final reports is kept on a secured, password-protected, Florida Suncare Testing, Inc. computer hard drive.

VI. PANEL DESIGN

Number of Subjects enrolled 10

Number of Subjects completing study 10

Age Range .....20 – 66

Male .....2 Female 8

Skin Types: I (7) II (3) III (0)

VII. PANEL COMPOSITION

A. Fair-skinned subjects, male and female, eighteen years of age or older, of skin types I, II, or III as defined in FDA, 21 CFR, Sec. 201.327, subpart (i), SPF Test Procedure, (3) Test Subjects, (ii) Medical History, (B) Skin Type, June 17, 2011.

Type I - Always burns easily; never tans (sensitive)

Type II - Always burns easily; tans minimally (sensitive)

Type III - Burns moderately; tans gradually (normal)

B. The test panelists were selected based on the following criteria:

a. Inclusion Criteria

1. Individuals eighteen years of age or older.

2. Individuals with fair, uniformly-colored skin on the lower area of the back which would allow a discernable erythema.

3. Individuals free of any dermatological or systemic disorder which, in the opinion of the testing personnel, would interfere with the results of the study.

4. Individuals in good health who have completed a preliminary medical history.

5. Individuals who have read, understood and signed a consent document in compliance with 21 CFR 50.

b. Exclusion Criteria

1. Individuals with any visible skin disease at the study site, which in the opinion of the investigative personnel would, interfere with the study results.

2. Individuals taking medications which might affect study results, e.g.,.photosensitizers, antihistimines, analgesics or anti-inflammatory drugs.

3. Females who are pregnant, planning a pregnancy or nursing a child

4. Individuals with a history of skin cancer.

5. Individuals with a history of hepatitis or other blood disease.

6. Individuals with a known sensitivity to cosmetics, skin care products or topical drugs as related to product(s) being evaluated.

7. Individuals with recent sun exposure on the areas to be tested.

VIII. INFORMED CONSENT

An informed consent was signed by each volunteer prior to initiating the study describing the purpose of the study, the test procedure, potential risks and benefits of participating, as well as the limits of liability. Each subject completed an extensive medical history form and was assigned a subject identification number. These forms are available for inspection on the premises of Florida Suncare Testing, Inc. only.

IX. LIGHT SOURCE

A Xenon Arc Solar Simulator lamp, which has a continuous light spectrum in the UVA and UVB range (290-400 nanometers) was utilized. The spectral output of the solar simulator was filtered so that it meets the spectral output requirements for testing Sunscreen Drug Products for over-the-counter human use; FDA Final Monograph, 21 CFR Part 201.327 (i)(1), UV Source, Federal Register, Vol. 76, No. 117, June 17, 2011 and the International Sun Protection Factor (SPF) Test Method, May 2006.

X. GENERALTESTING PROCEDURE

Day 1

Subject Enrollment

The test subjects reported to the testing laboratory and received a complete explanation of the study procedures. Those who participated signed a written, witnessed consent form, and a permission to release personal health information form and provided a brief medical history. The technician did a final examination of the subject's back, between the belt-line and shoulder blades and determined their suitability to participate in this study.

MEDu UV Dose Administration

1. A series of 5 UV radiation doses expressed as Joules/square meter, increasing in 25% increments, was administered to two unprotected separate locations on the test subject's back, just below the shoulder blades and above the belt-line, to determine the initial unprotected MED (MEDu).

2. The test subjects were instructed to avoid additional UV exposure, and to avoid taking any photosensitizing medications until the conclusion of the study.

3. The MEDu was administered in the following 5 dose series, with X representing the amount of UV energy projected to produce the test subject's MEDu.

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.64X	0.80X	1.00X	1.25X	1.56X

Day 2

MEDu Determination

1. Subjects returned to the testing laboratory within 16 to 24 hours following completion of the MEDu doses for evaluation of their responses, and to determine each subject's unprotected MED (MEDu).
2. The subject's Minimal Erythemal Dose (MED) was the quantity of erythema effective energy, or dose corresponding to the first site that produced the first unambiguous erythema reaction with clearly defined borders. Table A below shows the grading scale used in this study for determining a MED (+) response.

Table A

-	No perceptible erythemal response
?	Barely perceptible erythemal response
+	Unambiguous erythema reaction with clearly defined borders (MEDu)
++	Moderate erythema with sharp borders
+++	Dark red erythema with sharp borders

Application of Product for SPF Determination

Two test areas (10 cm x 5 cm), 50 square centimeter rectangles, were drawn in the designated locations on the subject's back, (between the beltline and the shoulder blade) using a template and an indelible marker. The technician applied the test formula in one of the test areas and the FDA standard sunscreen in the adjacent test area. The sunscreens were applied by "spotting" the product across the test area and gently spreading, using a finger cot (as specified in FDA, 21 CFR 201.327, subpart (4)(iii), until a uniform film was applied to the entire test area. A product density of 2 mg/cm2 was delivered to the test area. To accomplish this, the technician weighed an amount in excess of 100 mg, to allow for the residual amount left on the finger cot (approximately 10%). The test products were permitted to dry a minimum of 15 minutes prior to the Static UV exposures on the standard sunscreen and the 80 minute water immersion of the test formula.

80 Minute Water Immersion Sequence

1. An indoor fresh water Jacuzzi maintained at 23 to 32 deg. Celsius was used in this testing procedure. Fresh water is clean drinking water that meets the standards in 40 CFR part 141.
2. The pool and air temperature, as well as the relative humidity was recorded prior to testing.
3. The SPF values for the test product submitted by the sponsor was determined after 80 minutes of water immersion using the following procedure as specified in FDA, 21 CFR 201.237, subpart (i) (7) (ii), Determination of Water Resistance:
   a. Apply sunscreen product. (Followed by a minimum 15 minute waiting period after application).
   b. Twenty minutes of moderate activity in the water.
   c. Fifteen minute rest period. (Do not towel test sites)
   d. Repeat steps b. and c. until a total of 80 minutes of water immersion is achieved.
   e. Conclude water test. (Air dry test sites completely without toweling)

4. Begin light source exposures to the 80 minute water resistant test site areas in accordance with FDA, 21 CFR 201.327, subpart (5), UV Exposure.

MEDp UV Dose Administration

The technician administered a series of 5 UV radiation doses expressed as Joules/square meter, as specified in FDA, 21 CFR, Sec. 201.327, subpart (5)(iii), progressively increasing in increments of 15 or 20 percent, determined by the previously established MEDu (unprotected MED) from Day 1 and the expected SPF range of the test product. The MEDp was administered in the following 5 dose series with X representing the expected amount of UV energy required to produce a MEDp.

Expected SPF 15 (FDA Standard Static)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.69X	0.83X	1.00X	1.20X	1.44X

Expected SPF 50.0 (Test Product following 80 min Water Immersion)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.76X	0.87X	1.00X	1.15X	1.32X

MEDu Repeat UV Dose Determination

On Day 2, the technician administered a second timed series of 5 UV doses, increasing in 25% increments to an unprotected area of the subject's back to determine the subject's second day MEDu. The series of 5 doses included the original MEDu from Day 1 in the center as follows:

Multiple of Original MEDu (X)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.64X	0.80X	1.00X	1.25X	1.56X

Day 3

Evaluation of Responses to UV Doses for Static & 80min WR SPF and Repeat MEDu

1. Subjects returned 16 to 24 hours following completion of the UV doses from Day 2. The MED for all sites that received UV doses, both protected and unprotected areas was evaluated.

2. The study was conducted in a double-blinded manner. Neither the test subjects nor the designated staff member who evaluated the MED responses knew which sunscreen formulation was applied to which site or what doses of UV radiation were administered, as he was not the technician who applied the sunscreen test products or administered the doses of UV radiation.

3. The grader evaluated and recorded the MED responses on both the unprotected and protected test sites under the following conditions:

a. The source of illumination was a warm white fluorescent light bulb that provides a level of illumination of at least 450 lux at the test site.

b. The test subject was seated when evaluated, the same as when the test sites were irradiated.

XI. CALCULATION OF SPF VALUES

SPF values were calculated for both the test product and the FDA standard using FDA, 21 CFR 201.327, subpart (i) (6), Determination of SPF, by calculating the ratio of the MEDp value produced in the sunscreen protected sites to the MEDu produced in the unprotected test area, for each individual using the following calculation:

MEDp / MEDu = SPF value

Data from ten (10) subjects was used for calculating the test product's Label SPF value. The mean SPF value (x) and the Standard Deviation (s) for these subjects was computed. Based on a full 10 subject test panel, the upper 5-percent point from the student distribution table (denoted by t) with n-1 degrees of freedom was obtained. The quantity A was computed using the formula A = ts/Square root n (with n representing the number of test subjects (10) in a full study). A label SPF value was calculated by determining the largest whole number less than X – A. Any test product with a label SPF less than 2 is not a sunscreen drug product and will not display an SPF value.

XII. REJECTION OF STUDY DATA

There are three (3) primary reasons for rejection of study data as noted in 21 CFR, Sec. 201.327, subpart (5)(v), Invalid Test Data. The exposure series fails to elicit an MED response on either the protected or unprotected test sites; an MED response was noted on all the protected test sites, or the test subject was non-compliant (failed to follow instructions or withdrew from the study).

XIII. RESULTS

A total of ten (10) healthy subjects who fulfilled the test panel participation criteria were inducted into this investigation. The demographic data is shown in Section V., Panel Design. The individual, mean and label SPF values of the BOV Solutions Inc. test product, SPF 50 Continuous Spray, Formula # 60-RF50FRF-00, Lot # 112017, FSTI Sample # 17-786, are shown in Table 1, page 9.

XIV. ADVERSE EXPERIENCES

No adverse experiences were reported during this study.

XV. CONCLUSIONS

The Sun Protection Factor (SPF) of the above sample described herein; tested under 80 Minute "Water Resistant" conditions, yielded the following SPF values:

Sponsor Formula Number	FSTI Sample Number	Mean 80min WR SPF	Label SPF
60-RF50FRF-00	17-786	63.59	**61**

The FDA standard for this study had a mean static SPF value of 15.30 and satisfied all statistical criteria as specified in FDA, 21 CFR, Sec. 201.327, subpart (6)(i).

References:

U.S. Food and Drug Administration, Sunscreen Drug Products for Over-The-Counter Human Use; Final Monograph, 21 CFR Sec. 201.327, subpart (i), SPF Test Procedure, Sunscreen Drug Products for Over-the-Counter Human Use, Federal Register, Vol. 76, No. 117, June 17, 2011.

FLORIDA SUNCARE TESTING, INC.

FDA 2011 80 Min WR SPF Testing Summary

Table 1

Study No.: 17-786

Date: February 2, 2018

Sponsor: BOV Solutions

Sponsor Formula #: 60-RF50FRF-00

Sample Code: 112017

Sample Description: SPF 50 Continuous Spray

FSTI Sample No.: 17-786

Subjects Tested: 10

Subject ID Number	Sex	Age	Skin Type	Base MEDu Joules/M2	1902I FDA Std. Static SPF	17-786 112017.00 80 Min WR SPF
2268	F	51	II	59.50/59.50	15.00	57.50
2075	F	66	II	59.50/59.50	15.00	66.17
2214	F	58	II	59.50/59.50	15.00	66.17
2227	F	61	I	49.58/49.58	18.00	66.20
2226	M	70	I	49.58/49.58	18.00	57.60
1794	F	51	I	49.58/49.58	15.00	66.20
2164	F	47	I	49.58/49.58	15.00	66.20
1195	F	53	I	49.58/49.58	15.00	66.20
1636	F	52	II	59.50/59.50	15.00	57.50
2291	F	20	I	49.58/49.58	15.00	66.20
				AVERAGE:	15.60	63.59
				STD DEVIATION:	1.26	4.18
				A = ts / sq root n	0.73	2.42
				X - A	14.87	61.17
				LABEL SPF	14	**61**