EltaMD Response to Consumer Reports
Sunscreen Evaluation Article - May 18, 2017

Again this year Consumer Reports (CR) has tested a collection of sunscreens and assigned arbitrary categories of performance to 66 sunscreen products. EltaMD® UV Aero Broad-Spectrum SPF 45 earned a “Good” UVB (SPF) Sun Protection Factor rating in the Consumer Reports 2017 sun protection report. However, CR rated UV Aero poor with respect to UVA protection and UVB accuracy.¹ We at EltaMD believe that there were two primary reasons for these poor evaluations.

First, unlike last year CR was more forthcoming with an admission that they do not use the FDA testing protocol as EltaMD is required to do, and that CR uses its own testing procedure. A Personal Care Products Council representative (Beth Jonas, Ph.D.) was quoted as saying that she disagreed with the findings of CR due to this differentiation in testing protocol.²

U.S. Federal Drug Administration (FDA) regulations provide that SPF values on sunscreen labels must be derived using the FDA-mandated testing protocol. No other testing method is approved by the FDA, not even CR’s.

Reliable and expert organizations familiar with the FDA-mandated protocol, such as The Skin Cancer Foundation and the American Melanoma Foundation, as well as thousands of practicing physicians, regularly recommend EltaMD sunscreens. They are confident doing so because they know that the SPF values on EltaMD are derived from testing by independent, FDA-registered laboratories with long experience testing sunscreen products in strict conformity with the FDA-mandated protocol. Read the Personal Care Council’s statement about SPF testing at http://www.personalcarecouncil.org/newsroom/20170518.

EltaMD sunscreens are all tested as required by FDA regulations with their performance validated by independent organizations:

- SPF Determination reports by independent laboratories are available for all EltaMD sunscreens at eltamd.com/SPF. The SPF rating documented in the SPF determination report is the SPF rating printed on the product packaging.
- All EltaMD sunscreens have earned the Skin Cancer Foundation’s Seal of Recommendation.

Secondly, the CR article again recommends that consumers should use sunscreens that contain, “…chemical active ingredients such as avobenzone rather than “natural” or mineral active ingredients such as zinc oxide.”³ The Environmental Working Group (EWG) directly contradicts this suggestion writing, “Zinc oxide is EWG’s first choice for sun protection.”⁴ Also, Dr. Dawn Davis, a dermatologist at the Mayo Clinic suggests that people with skin allergies or sensitive skin should "look for a sunscreen that contains zinc oxide and titanium oxide, which are physical blockers and tend to be hypoallergenic.”⁵
According to the Center for Disease Control, titanium dioxide and zinc oxide “…are effective, broad-spectrum sunscreens that protect against both UVA and UVB radiation.” 6

Zinc Oxide is not only the EWG’s choice for sun protection, it is less irritating to those with certain types of skin conditions and protects against a wide range of UV radiation.

Additionally, this CR suggestion is puzzling given the risk from some chemical active ingredients. Oxybenzone, an ingredient being outlawed in Hawaii due to the damage it can cause to ocean reefs, is one of those chemical ingredients indirectly recommended by CR.

Again this year CR has evaluated sunscreens without conducting FDA approved testing and made product recommendations that are counter to known clinical ingredient attributes, even to the point of putting the environment at risk.

EltaMD is very proud of all its sunscreen products and stands behind their efficacy and claims.

EltaMD UV Aero SPF 45 Validation Testing
Independent laboratory results on pages 11 and 28

- EltaMD only utilizes reputable, independent laboratories to conduct thorough, scientific and FDA-defined and required practices.

- The results of two independent laboratory tests that validate the SPF 45 rating of UV Aero are attached.

- EltaMD® UV Aero is recommended by The Skin Cancer Foundation and the American Melanoma Foundation, as well as hundreds of practicing physicians.
EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 80 MINUTE WATER RESISTANT

AMA Ref. No.: MS15.SPF.O0958.SAP.80MINWR10

Date: June 11, 2015

Sponsor: Swiss-American Products, Inc.
2055 Luna Road
Carrollton, Texas 75006

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as defined by the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018](formerly Docket No. 1978N-0038), RIN 0910-AF43, Labeling and Effectiveness Testing; Sunscreen Drug Products For Over-the-Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011] using Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 80 minute water immersion experiment which was carried out under controlled conditions as described in the above mentioned FDA Sunscreen Final Rule and Section 6.0 herein.

2.0 Sample Description:

On June 1, 2015 one test sample labeled Elta MD UV Aero (Lot # 45998R/1) was received from Swiss-American Products, Inc. and assigned AMA Lab No.: O-0958.

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material 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.

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.
4.0 Panel Demographics:

Number of subjects enrolled .................................................. 10
Number of subjects completing study ...................................... 10
Age Range ................................................................. 20 - 53
Sex .................................................................
    Male ........................................................... 10
    Female .......................................................... 8
Race .................................................................
    Caucasian ...................................................... 8
    Hispanic ....................................................... 2
    Asian ........................................................... 0

4.1 Standards For Inclusion In A Study:

a. Individuals eighteen years of age or older.

b. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.

c. Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.

d. Individuals with Fitzpatrick Skin Type I, II, and III only.

e. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with SPF determination.

f. Individuals who complete a preliminary medical history form mandated by AMA Laboratories, Inc. and are in general good health.

g. Individuals who will read, understand and sign an informed consent document relating to the specific type of study they are subscribing. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc. only.

h. Individuals able to cooperate with the Investigator and research staff, be willing to have test materials applied according to the protocol, and complete the full course of the study.

i. Individuals willing to refrain from using any sunscreen products, sunbathing or tanning bed use, 24 hours prior to study initiation and the entire duration of the study.

j. Individuals with excessive hair on their back who are willing to have hair removed by AMA technicians prior to commencement of study.
4.2 Standards For Exclusion From The Study:

   a. Individuals who are under a doctor's care.

   b. Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results.

   c. Subjects 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.

   d. Individuals diagnosed with chronic skin allergies.

   e. Individuals with a history of adverse effects upon sun exposure.

   f. Female volunteers who indicate that they are pregnant or lactating.

   g. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions or uneven pigmentation in the test sites.

   h. Individuals with known hypersensitivity to any sunscreen products.

4.3 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. 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.

A trained technician performed a physical examination of the panelist’s back to determine if study eligibility criteria were satisfied.

The parties agree to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

4.4 Panel Composition:

Healthy volunteers over the age of 18 years were recruited for this study. The panel consisted of fair-skin individuals with Fitzpatrick Skin Types I, II or III defined as follows (Federal Register Vol. 64, No. 98: 27690, 1999):
Type I - Always burns easily; never tans*

Type II - Always burns easily; tans minimally*

Type III - Burns moderately; tans gradually*

* Based on the first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4.5 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.

5.0 Artificial Light Source:

The light source employed was a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S, Model 15S or Model 16S) having a continuous emission spectrum from 290 to 400 nanometers. Xenon arc was selected on the basis of its black body radiation temperature of 6000°K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight\(^1\).

This device was equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG-320 filter (which absorbs all radiation below 290nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remained visible radiation. UVB radiation was monitored continuously during exposure using a Model DCS-1 Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter). Measurements were taken at a position within 8mm from the surface of the skin. The size of the exposure site is ≥ 1cm\(^2\). The solar simulator was allowed a warm up time of at least 15 minutes before use and power supply output was recorded.

Realignments of the Light Sources and calibration of the sunburn meters are conducted semi-annually by independent certification facilities and more often as necessary at the discretion of the operating technician or Investigator. A certificate for the Solar Simulator Emission Spectrum compliance is on file at AMA Laboratories, Inc. The spectroradiometric measurements are performed at least annually.

6.0 Procedure:

(A) STATIC SPF DETERMINATION (INCLUDING 7% PADIMATE O/3% OXYBENZONE STANDARD)

The infrascapular area of the back to the right and left side of the midline was used. Within this area, 30 cm² rectangular test sites were delineated with a gentian violet surgical skin marker. Sites were observed to ensure uniform pigmentation, skin tone and texture, and absence of warts, moles, nevi, scars, blemishes and active dermal lesions. Any areas that might be expected to produce erratic results were not used for UV exposures.

The procedure for this study is outlined in the Federal Register / Vol.76, No.117, 21 CFR Parts 201 and 310 published on Friday June 17, 2011. One test site area served to determine each subject's Minimal Erythema Dose (MED).

A minimum of five UV exposures was administered within this site. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation.

The test material and 7% Padimate O/3% Oxybenzone standard were shaken and/or swirled with a glass rod before use and were evenly applied using plastic volumetric syringes to rectangular areas measuring 3 cm x 10 cm (30 cm²) for a final concentration of 2.0 mg/cm². Evenness of application was verified by observation with a Wood's Lamp. An adjacent test site was then selected to perform a static determination on the test substance, as above, prior to the immersion test.

Fifteen minutes after application, a protected site received a series of five UV exposures based upon previously determined MED.

All immediate responses were recorded after UV radiation exposure from the solar simulator.

The UV exposures for 7% Padimate O/3% Oxybenzone, in-house water resistant control and test material were calculated from previously determined MED and the intended SPF as follows:

SPF 16.3: MED times 0.76x, 0.87x, 1.00x, 1.15x and 1.32x

SPF 15: MED times 0.69x, 0.83x, 1.00x, 1.20x and 1.44x

SPF 45: MED times 0.76x, 0.87x, 1.00x, 1.15x, and 1.32x

where x equals the expected SPF of the product.
(B) **80 MINUTE WATER RESISTANT DETERMINATION (INCLUDING IN-HOUSE WATER RESISTANT CONTROL)**

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. On the day of the test, following exposure of the 7% Padimate O/3% Oxybenzone standard, MED’s and static determination, another test site was designated. One other adjacent site was selected to perform a water resistant determination of an in-house 80 minute water resistant standard with a known SPF as a control.

The water resistant SPF value was determined by the product’s ability to resist an 80-minute period of water immersion, achieved through the following test regimen: After application of the sunscreen product followed by the waiting period, a total of 80 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying). Immersion was achieved indoors in a whirlpool tub with water circulating by a 1 h.p. pump at 3450 RPM. Each panelist spent twenty minutes in the water, immediately followed by a fifteen minute rest period out of the water until a total of eighty minutes in the water were achieved. The whirlpool bath was set at 23°C to 32°C at moderate agitation. The water and air temperatures and relative humidity were recorded. After the last immersion, the test sites were air dried without toweling for at least fifteen minutes prior to exposure of treated areas to the solar simulation. The protected sites received a series of five UV exposures based upon previously determined MED.

### 7.0 Evaluation Of Responses:

Sixteen to twenty-four hours post exposure, the subjects are instructed to return to the testing facility for evaluation of delayed erythemic responses. The technician who evaluates the MED did not know the identity of the test product application sites and UV exposures. Also he/she was not the same person to have applied the sunscreen product to the test site or administered the doses of UV radiation.

\[
SPF = \frac{Protected\ MED}{Final\ unprotected\ MED}
\]

Visual grading scale:

- 0 = No Erythema
- ? = Questionable Erythema
- 1 = Minimal Erythema
- 2 = Slight Erythema
- 3 = Well-Defined Erythema
- 4 = Erythema and Edema
- 5 = Erythema and Edema in vesicles

### 7.1

All technical employees of AMA Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published which determines a person’s ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.
8.0 Determination of the Test Product’s SPF Value and PCD:

Calculation of SPF— According to the reference, the mean SPF value (x) is calculated using a minimum of 10 evaluable subjects per formulation. The standard deviation was determined (s). The upper 5% point was obtained from the t distribution table with n-1 degrees of freedom (t). The standard error (SE) was calculated by (s)/√n (where n equals the number of subjects who provided valid test results).

Therefore, the label SPF value for panels using a minimum of 10 evaluable subjects is the largest whole number less than the mean SPF minus (t x SE).

\[ Label \ SPF = Mean \ SPF - (t \times SE) \]

9.0 Rejection Criteria:

Panelist’s results were rejected and the panelist replaced if:

1. An exposure series fails to elicit an MED response on the untreated skin. The test is considered a technical failure even if the MED response is observed in the protected site.

2. The responses on the protected area are randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.

3. All exposures in a series elicit responses – thus prohibiting any MED calculation.

4. The subject was non-compliant (e.g. subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined.)

10.0 Results:

Please see attached Table.

11.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

12.0 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.
13.0 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 intact will be recognized by AMA Laboratories Inc. as a certified original.
14.0 Conclusions:

The Sun Protection Factor (SPF) of the above test material (AMA Lab No.: O-0958; Client No.: Elta MD UV Aero (Lot # 45998R/1)) when tested on ten subjects as described herein under static and 80 minute water resistant conditions yielded the mean SPF values of 49.05 and 47.70 and the label SPF’s of 47 and 45 respectively.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.28 and was within the standard deviation range of the expected SPF of 16.3 +/- 3.43. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.20.

Donna Muratschew, M.D.
Study Director

Kaitlyn Gold, B.S. (Candidate)
Technician

Jaime M. Reidy, A.A.
Technician

Tara Grube, B.S.
Technician

Katharine Lipnicky, B.S.
Technician

David R. Winne, B.S.
Technical Director

Date 11/15

The AMA family of laboratories (AMA) represents fully independent testing facilities committed to the highest standards of unbiased testing and reporting. AMA is not in partnership, affiliation and/or association, in any way, with any other corporation, company, sole proprietorship, partnership, client, laboratory, and/or any other business entity (collectively, Business Associate(s)). Should any Business Associate(s) indicate via literature, advertising, promoting, publications, raw data, reports, correspondence and/or any other documentation that they are in any way in partnership, use partnership language or indicate they are otherwise affiliated with AMA, this shall serve as formal notice that AMA shall in no event be legally bound by such claim(s) and any Business Associate(s) representing such affiliation shall, by this instrument, hold AMA harmless and indemnify AMA against and from, without limitation, legal responsibility, damages, lawsuits, actions, claims, proceedings, arbitrations, and the like which may arise against AMA from said Business Associate(s) claim of affiliation. Your possession of this fully executed, signed and dated, final report shall signify your acknowledgment, agreement and acceptance of and compliance with all of the foregoing.

All Services Undertaken Subject to the following General Policy: AMA reports are submitted for exclusive use of the clients to whom they are addressed. Their significance is subject to the adequacy and representative character of the samples and to the comprehensiveness of the test, examination or surveys made. No quotations from AMA reports, or use of AMA names or the names of staff members or sub-contractors is permitted except as expressly authorized in writing. The liability of AMA with respect to services rendered shall in no event exceed the amount of one hundred dollars. Wherein this report is used to support commercial claims, the Sponsor is directed to provide said report in its entirety only.

MS15.SPF.O0958.SAP.80MINWR10 9  AMA LABORATORIES, INC.
# EVALUATION OF SUN PROTECTION
**BY SPF DETERMINATION (FDA) - WATER RESISTANT - 80 MINUTE WATER IMMERSION**

**Table**

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Sex</th>
<th>MED/II Hr</th>
<th>(Amps)</th>
<th>Skin I Type</th>
<th>MED I J/M²</th>
<th>MED II J/M²</th>
<th>STD (7%PadO/3%Oxyb)</th>
<th>WR Control</th>
<th>WR Static</th>
<th>WR SPF Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>41 2167</td>
<td>F</td>
<td>128.5</td>
<td>6.3</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>68 8379</td>
<td>F</td>
<td>128.3</td>
<td>6.5</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>68 2304</td>
<td>F</td>
<td>125.5</td>
<td>6.6</td>
<td>III</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>84 5583</td>
<td>M</td>
<td>126.8</td>
<td>6.1</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>80 4194</td>
<td>F</td>
<td>127.1</td>
<td>6.5</td>
<td>III</td>
<td>55.55</td>
<td>55.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>58 5653</td>
<td>F</td>
<td>129.3</td>
<td>6.5</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>80 3646</td>
<td>M</td>
<td>128.4</td>
<td>6.4</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>76 5957</td>
<td>F</td>
<td>126.3</td>
<td>6.0</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>58 9750</td>
<td>F</td>
<td>129.4</td>
<td>5.9</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>82 8976</td>
<td>F</td>
<td>128.7</td>
<td>6.0</td>
<td>III</td>
<td>55.55</td>
<td>55.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
</tbody>
</table>

**MEAN (x)**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17.28</td>
<td>16.20</td>
<td>49.05</td>
<td>47.70</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**STANDARD DEV (s)**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.27</td>
<td>1.55</td>
<td>3.49</td>
<td>3.49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**STD. ERROR**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.40</td>
<td>0.49</td>
<td>1.10</td>
<td>1.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**S.E. % OF MEAN**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.31</td>
<td>3.02</td>
<td>2.24</td>
<td>2.31</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**N**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**UPPER 5% t DIST.**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.2622</td>
<td>2.2622</td>
<td>1.8331</td>
<td>1.8331</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**A VALUES**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.9051</td>
<td>1.1082</td>
<td>2.0206</td>
<td>2.0206</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LABEL SPF**

<p>| | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>15</td>
<td>47</td>
<td>45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MED:** Minimal Erythemal Dose

**I:** Intensity of light source

**Evaluation Period:** This study was conducted from June 1, 2015 through June 10, 2015.
15.0 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:

Christian Gorglione, B.S.
Quality Assurance Supervisor

[Signature]

6/11/15
Date
EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 80 MINUTE WATER RESISTANT

AMA Ref. No.: MS15.SPF.00958.SAP.80MINWR10

Date: June 11, 2015

Sponsor: Swiss-American Products, Inc.
2055 Luna Road
Carrollton, Texas 75006

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as defined by the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018](formerly Docket No. 1978N-0038), RIN 0910-AF43, Labeling and Effectiveness Testing; Sunscreen Drug Products For Over-the-Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011] using Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 80 minute water immersion experiment which was carried out under controlled conditions as described in the above mentioned FDA Sunscreen Final Rule and Section 6.0 herein.

2.0 Sample Description:

On June 1, 2015 one test sample labeled Elta MD UV Aero (Lot # 45998R/1) was received from Swiss-American Products, Inc. and assigned AMA Lab No.: O-0958.

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material 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.

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.
4.0 Panel Demographics:

Number of subjects enrolled .............................................. 10
Number of subjects completing study .................................. 10
Age Range ........................................................................... 20 - 53
Sex ................................................................................. Male ........................................ 2
........................................................................ Female ................................... 8
Race ................................................................................. Caucasian ................................ 8
........................................................................ Hispanic ......................... 2
........................................................................ Asian .................................... 0

4.1 Standards For Inclusion In A Study:

a. Individuals eighteen years of age or older.

b. Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the Investigator.

c. Individuals free of any acute or chronic disease that might interfere with or increase the risk of study participation.

d. Individuals with Fitzpatrick Skin Type I, II, and III only.

e. Individuals with no uneven skin tones, pigmentation, scars, other irregularities or hair in test site areas that would interfere with SPF determination.

f. Individuals who complete a preliminary medical history form mandated by AMA Laboratories, Inc. and are in general good health.

g. Individuals who will read, understand and sign an informed consent document relating to the specific type of study they are subscribing. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc. only.

h. Individuals able to cooperate with the Investigator and research staff, be willing to have test materials applied according to the protocol, and complete the full course of the study.

i. Individuals willing to refrain from using any sunscreen products, sunbathing or tanning bed use, 24 hours prior to study initiation and the entire duration of the study.

j. Individuals with excessive hair on their back who are willing to have hair removed by AMA technicians prior to commencement of study.
4.2 Standards For Exclusion From The Study:

a. Individuals who are under a doctor's care.

b. Individuals who are currently taking any medication (topical or systemic) that may mask or interfere with the test results.

c. Subjects 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.

d. Individuals diagnosed with chronic skin allergies.

e. Individuals with a history of adverse effects upon sun exposure.

f. Female volunteers who indicate that they are pregnant or lactating.

g. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions or uneven pigmentation in the test sites.

h. Individuals with known hypersensitivity to any sunscreen products.

4.3 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. 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.

A trained technician performed a physical examination of the panelist's back to determine if study eligibility criteria were satisfied.

The parties agree to comply with applicable state and federal privacy laws for the use and disclosure of a subject's personal health information by taking reasonable steps to protect the confidentiality of this information. This obligation shall survive the termination or expiration of this Agreement.

4.4 Panel Composition:

Healthy volunteers over the age of 18 years were recruited for this study. The panel consisted of fair-skin individuals with Fitzpatrick Skin Types I, II or III defined as follows (Federal Register Vol. 64, No. 98: 27690, 1999):
Type I - Always burns easily; never tans*

Type II - Always burns easily; tans minimally*

Type III - Burns moderately; tans gradually*

* Based on the first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4.5 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.

5.0 Artificial Light Source:

The light source employed was a 150 watt Xenon Arc Solar Simulator (Solar Light Co., Philadelphia, Pennsylvania, Model 14S, Model 15S or Model 16S) having a continuous emission spectrum from 290 to 400 nanometers. Xenon arc was selected on the basis of its black body radiation temperature of 6000° K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight.

This device was equipped with a dichroic mirror (which reflects all radiation below 400nm) and works in conjunction with a 1 mm thick Schott WG-320 filter (which absorbs all radiation below 290nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter (black lens) was added to remove reflected (infra-red, greater than 700 nm) heat and remained visible radiation. UVB radiation was monitored continuously during exposure using a Model DCS-1 Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter). Measurements were taken at a position within 8mm from the surface of the skin. The size of the exposure site is ≥ 1cm². The solar simulator was allowed a warm up time of at least 15 minutes before use and power supply output was recorded.

Realignement of the Light Sources and calibration of the sunburn meters are conducted semi-annually by independent certification facilities and more often as necessary at the discretion of the operating technician or Investigator. A certificate for the Solar Simulator Emission Spectrum compliance is on file at AMA Laboratories, Inc. The spectroradiometric measurements are performed at least annually.

6.0 Procedure:

(A) STATIC SPF DETERMINATION (INCLUDING 7% PADIMATE O/3% OXYBENZONE STANDARD)

The infrascapular area of the back to the right and left side of the midline was used. Within this area, 30 cm² rectangular test sites were delineated with a gentian violet surgical skin marker. Sites were observed to ensure uniform pigmentation, skin tone and texture, and absence of warts, moles, nevi, scars, blemishes and active dermal lesions. Any areas that might be expected to produce erratic results were not used for UV exposures.

The procedure for this study is outlined in the Federal Register / Vol.76, No.117, 21 CFR Parts 201 and 310 published on Friday June 17, 2011. One test site area served to determine each subject's Minimal Erythema Dose (MED).

A minimum of five UV exposures was administered within this site. The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation.

The test material and 7% Padimate O/3% Oxybenzone standard were shaken and/or swirled with a glass rod before use and were evenly applied using plastic volumetric syringes to rectangular areas measuring 3 cm x 10 cm (30 cm²) for a final concentration of 2.0 mg/cm². Evenness of application was verified by observation with a Wood's Lamp. An adjacent test site was then selected to perform a static determination on the test substance, as above, prior to the immersion test.

Fifteen minutes after application, a protected site received a series of five UV exposures based upon previously determined MED.

All immediate responses were recorded after UV radiation exposure from the solar simulator.

The UV exposures for 7% Padimate O/3% Oxybenzone, in-house water resistant control and test material were calculated from previously determined MED and the intended SPF as follows:

SPF 16.3: MED times 0.76x, 0.87x, 1.00x, 1.15x and 1.32x

SPF 15: MED times 0.69x, 0.83x, 1.00x, 1.20x and 1.44x

SPF 45: MED times 0.76x, 0.87x, 1.00x, 1.15x, and 1.32x
where x equals the expected SPF of the product.
(B) **80 MINUTE WATER RESISTANT DETERMINATION (INCLUDING IN-HOUSE WATER RESISTANT CONTROL)**

This test is employed to determine the substantivity of a test product and its ability to resist water immersion. On the day of the test, following exposure of the 7% Padimate O/3% Oxybenzone standard, MED's and static determination, another test site was designated. One other adjacent site was selected to perform a water resistant determination of an in-house 80 minute water resistant standard with a known SPF as a control.

The water resistant SPF value was determined by the product's ability to resist an 80-minute period of water immersion, achieved through the following test regimen: After application of the sunscreen product followed by the waiting period, a total of 80 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying). Immersion was achieved indoors in a whirlpool tub with water circulating by a 1 h.p. pump at 3450 RPM. Each panelist spent twenty minutes in the water, immediately followed by a fifteen minute rest period out of the water until a total of eighty minutes in the water were achieved. The whirlpool bath was set at 23°C to 32°C at moderate agitation. The water and air temperatures and relative humidity were recorded. After the last immersion, the test sites were air dried without toweling for at least fifteen minutes prior to exposure of treated areas to the solar simulation. The protected sites received a series of five UV exposures based upon previously determined MED.

7.0 **Evaluation Of Responses:**

Sixteen to twenty-four hours post exposure, the subjects are instructed to return to the testing facility for evaluation of delayed erythemic responses. The technician who evaluates the MED did not know the identity of the test product application sites and UV exposures. Also he/she was not the same person to have applied the sunscreen product to the test site or administered the doses of UV radiation.

\[
SPF = \frac{\text{Protected MED}}{\text{Final unprotected MED}}
\]

Visual grading scale:

0 = No Erythema  
? = Questionable Erythema  
1 = Minimal Erythema  
2 = Slight Erythema  
3 = Well-Defined Erythema  
4 = Erythema and Edema  
5 = Erythema and Edema in vesicles

7.1 All technical employees of AMA Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.
8.0 Determination of the Test Product’s SPF Value and PCD:

**Calculation of SPF**— According to the reference, the mean SPF value (x) is calculated using a minimum of 10 evaluable subjects per formulation. The standard deviation was determined (s). The upper 5% point was obtained from the t distribution table with n-1 degrees of freedom (t). The standard error (SE) was calculated by \((s)/\sqrt{n}\) (where n equals the number of subjects who provided valid test results).

Therefore, the label SPF value for panels using a minimum of 10 evaluable subjects is the largest whole number less than the mean SPF minus \((t \times SE)\).

\[
Label \ SPF = Mean \ SPF - (t \times SE)
\]

9.0 Rejection Criteria:

Panelist’s results were rejected and the panelist replaced if:

1. An exposure series fails to elicit an MED response on the untreated skin. The test is considered a technical failure even if the MED response is observed in the protected site.

2. The responses on the protected area are randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.

3. All exposures in a series elicit responses – thus prohibiting any MED calculation.

4. The subject was non-compliant (e.g. subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined.)

10.0 Results:

Please see attached Table.

11.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

12.0 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.
13.0 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 intact will be recognized by AMA Laboratories Inc. as a certified original.
14.0 Conclusions:

The Sun Protection Factor (SPF) of the above test material (AMA Lab No.: O-0958; Client No.: Elta MD UV Aero (Lot # 45998R/1)) when tested on ten subjects as described herein under static and 80 minute water resistant conditions yielded the mean SPF values of 49.05 and 47.70 and the label SPF's of 47 and 45 respectively.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.28 and was within the standard deviation range of the expected SPF of 16.3 ± 3.43. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.20.

Donna Muratschew, M.D.
Study Director

Jaime M. Reidy, A.A.
Technician

Katherine Lipnicky, B.S.
Technician

Kaitlyn Gold, B.S. (Candidate)
Technician

Tara Grube, B.S.
Technician

David R. Winne, B.S.
Technical Director

Date

The AMA family of laboratories (AMA) represents fully independent testing facilities committed to the highest standards of unbiased testing and reporting. AMA is not in partnership, affiliation and/or association, in any way, with any other corporation, company, sole proprietorship, partnership, client, laboratory, and/or any other business entity (collectively, Business Associate(s)). Should any Business Associate(s) indicate via literature, advertising, reporting, publications, raw data, reports, correspondence and/or any other documentation that they are in any way in partnership, use 'partnership' language or indicate they are otherwise affiliated with AMA, this shall serve as formal notice that AMA shall in no event be legally bound by such claim(s) and any Business Associate(s) representing such affiliation shall, by this instrument, hold AMA harmless and indemnify AMA against and from, without limitation, legal responsibility, damages, lawsuits, actions, claims, proceedings, arbitrations, and the like which may arise against AMA from said Business Associate(s) claim of affiliation. Your possession of this fully executed, signed and dated, final report shall signify your acknowledgment, agreement and acceptance of and compliance with all of the foregoing.

All Services Undertaken Subject to the following General Policy: AMA reports are submitted for exclusive use of the clients to whom they are addressed. Their significance is subject to the adequacy and representative character of the samples and to the comprehensiveness of the test, examination or surveys made. No quotations from AMA reports, or use of AMA names or the names of staff members or sub-contractors is permitted except as expressly authorized in writing. The liability of AMA with respect to services rendered shall in no event exceed the amount of one hundred dollars. Wherein this report is used to support commercial claims, the Sponsor is directed to provide said report in its entirety only.
**EVALUATION OF SUN PROTECTION**
**BY SPF DETERMINATION (FDA) - WATER RESISTANT - 80 MINUTE WATER IMMERSION**

Table

<table>
<thead>
<tr>
<th>Subject</th>
<th>Sex</th>
<th>MED/</th>
<th>I</th>
<th>Skin</th>
<th>MED I</th>
<th>MED II</th>
<th>STD (7%PadO/3%Oxyb)</th>
<th>WR</th>
<th>SPF Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID #</td>
<td></td>
<td>Hr (Amps)</td>
<td>(Type)</td>
<td>J/M²</td>
<td>J/M²</td>
<td></td>
<td>Control</td>
<td>Static</td>
<td>WR</td>
</tr>
<tr>
<td>41 2167</td>
<td>F</td>
<td>128.5</td>
<td>6.3</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
</tr>
<tr>
<td>68 8379</td>
<td>F</td>
<td>128.3</td>
<td>6.5</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
</tr>
<tr>
<td>68 2304</td>
<td>F</td>
<td>125.5</td>
<td>6.6</td>
<td>III</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
</tr>
<tr>
<td>84 5583</td>
<td>M</td>
<td>126.8</td>
<td>6.1</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
</tr>
<tr>
<td>80 4194</td>
<td>F</td>
<td>127.1</td>
<td>6.5</td>
<td>III</td>
<td>55.55</td>
<td>55.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
</tr>
<tr>
<td>58 5653</td>
<td>F</td>
<td>129.3</td>
<td>6.5</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>45.00</td>
</tr>
<tr>
<td>80 3646</td>
<td>M</td>
<td>128.4</td>
<td>6.4</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
</tr>
<tr>
<td>76 5957</td>
<td>F</td>
<td>126.3</td>
<td>6.0</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
</tr>
<tr>
<td>58 9750</td>
<td>F</td>
<td>129.4</td>
<td>5.9</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
</tr>
<tr>
<td>82 8976</td>
<td>F</td>
<td>128.7</td>
<td>6.0</td>
<td>III</td>
<td>55.55</td>
<td>55.55</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
</tr>
</tbody>
</table>

**MEAN (x)**
- 17.28

**STANDARD DEV (s)**
- 1.27

**STD. ERROR**
- 0.40

**S.E. % OF MEAN**
- 2.31

**N**
- 10

**UPPER 5% t DIST.**
- 2.2622

**A VALUES**
- 0.9051

**LABEL SPF**
- 16

MED: Minimal Erythemal Dose
I: Intensity of light source

Evaluation Period: This study was conducted from June 1, 2015 through June 10, 2015.
15.0 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:

Christian Gorglione, B.S.
Quality Assurance Supervisor

6/11/15
Date
REPORT #2 ON NEXT PAGE
EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – 80 MINUTES WATER RESISTANT

FINAL REPORT

June 26, 2015

SPONSOR: Swiss American Products, Inc.
2055 Luna Road, #126
Carrollton, TX 75006

TEST PRODUCT: EltaMD UV Aero

PROJECT -ACCESSION NUMBER: 902730 – 902730
RESEARCH STANDARD

This clinical study was conducted in accordance with standard practices of BioScreen Testing Services and as defined by the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018](formerly Docket No. 1978N-0038), RIN 0910-AF43, Labeling and Effectiveness Testing; Sunscreen Drug Products For Over-the Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011] using Xenon arc solar simulator as the UV source.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. STUDY CONCLUSIONS</td>
<td>4</td>
</tr>
<tr>
<td>II. RESULTS</td>
<td>4</td>
</tr>
<tr>
<td>III. STUDY OBJECTIVE</td>
<td>5</td>
</tr>
<tr>
<td>IV. TEST PRODUCT</td>
<td>5</td>
</tr>
<tr>
<td>V. TEST PRODUCT HANDLING</td>
<td>5</td>
</tr>
<tr>
<td>VI. STUDY PARTICIPATION RECRUITMENT</td>
<td>5</td>
</tr>
<tr>
<td>VII. INFORMED CONSENT AND MEDICAL HISTORY FORMS</td>
<td>5</td>
</tr>
<tr>
<td>VIII. SUBJECT DEMOGRAPHICS</td>
<td>6</td>
</tr>
<tr>
<td>IX. INCLUSION CRITERIA</td>
<td>6</td>
</tr>
<tr>
<td>X. EXCLUSION CRITERIA</td>
<td>6</td>
</tr>
<tr>
<td>XI. ARTIFICIAL LIGHT SOURCE</td>
<td>7</td>
</tr>
<tr>
<td>XII. PROCEDURE</td>
<td>7</td>
</tr>
<tr>
<td>XIII. REJECTION CRITERIA</td>
<td>11</td>
</tr>
<tr>
<td>XIV. SPF CALCULATIONS</td>
<td>11</td>
</tr>
<tr>
<td>XV. ADVERSE EVENTS</td>
<td>12</td>
</tr>
</tbody>
</table>
I. STUDY CONCLUSIONS

The Sun Protective Factor (SPF) of EltaMD UV Aero when tested on ten (10) subjects as described herein under static and 80 minute water resistant conditions yielded the mean SPF values of 49.05 and 47.70 and the label SPF’s of 47 and 45, respectively.

The mean SPF of the 7% Padimate O/3% Oxybenzone standard on the same panel was 17.53 and was within the standard deviation range of the expected SPF of 16.3 ± 3.43. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 16.50.

II. RESULTS

Under conditions of the study a total of 10 healthy subjects, 25-59 years of age, completed the clinical study evaluating the Sun Protective Factor (SPF) of EltaMD UV Aero.

<table>
<thead>
<tr>
<th>SUBJECT ID</th>
<th>SEX</th>
<th>MED/Hr</th>
<th>I (Amps)</th>
<th>SKIN TYPE</th>
<th>MED I J/M²</th>
<th>MED II J/M²</th>
<th>STD (7% PadO/3%O xyb)</th>
<th>WR CONTROL</th>
<th>SPF VALUE STATIC</th>
<th>SPF VALUE WR</th>
</tr>
</thead>
<tbody>
<tr>
<td>58 5653</td>
<td>F</td>
<td>129.3</td>
<td>6.5</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>40 5720</td>
<td>F</td>
<td>128.0</td>
<td>6.1</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>72 4447</td>
<td>M</td>
<td>125.8</td>
<td>6.0</td>
<td>II</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>50 2448</td>
<td>M</td>
<td>126.9</td>
<td>6.4</td>
<td>II</td>
<td>35.55</td>
<td>35.55</td>
<td>16.30</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>78 8873</td>
<td>M</td>
<td>128.2</td>
<td>6.4</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>15.00</td>
<td>51.75</td>
<td>45.00</td>
</tr>
<tr>
<td>62 5537</td>
<td>F</td>
<td>126.9</td>
<td>6.6</td>
<td>III</td>
<td>55.55</td>
<td>55.55</td>
<td>18.75</td>
<td>18.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
<tr>
<td>64 0805</td>
<td>F</td>
<td>126.6</td>
<td>6.0</td>
<td>III</td>
<td>44.44</td>
<td>44.44</td>
<td>16.30</td>
<td>15.00</td>
<td>51.75</td>
<td>45.00</td>
</tr>
<tr>
<td>70 6417</td>
<td>F</td>
<td>126.1</td>
<td>6.0</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>58 7541</td>
<td>F</td>
<td>127.6</td>
<td>6.8</td>
<td>II</td>
<td>28.44</td>
<td>28.44</td>
<td>18.75</td>
<td>18.00</td>
<td>51.75</td>
<td>51.75</td>
</tr>
<tr>
<td>68 6886</td>
<td>F</td>
<td>129.4</td>
<td>6.3</td>
<td>I</td>
<td>28.44</td>
<td>28.44</td>
<td>16.30</td>
<td>15.00</td>
<td>45.00</td>
<td>45.00</td>
</tr>
</tbody>
</table>

**MEAN**

<table>
<thead>
<tr>
<th>MEAN</th>
<th>17.53</th>
<th>16.50</th>
<th>49.05</th>
<th>47.70</th>
</tr>
</thead>
</table>

**STANDARD DEVIATION**

| 1.29 | 1.58 |

**STANDARD ERROR**

| 0.41 | 0.50 |

**STANDARD ERROR % OF MEAN**

| 2.34 | 3.03 |

**NUMBER OF SUBJECTS (N)**

| 10   | 10   |

**UPPER 5% t-DISTRIBUTION**

| 2.2622 | 2.2622 |

**A VALUES**

| 0.9237 | 1.1311 |

**LABEL SPF**

| 16   | 15   | 47   | 45   |

F = Female, M = Male, MED = Minimal Erythema Dose, I = Intensity of Light Source, STD = Standard, SPF = Sun Protection Factor, WR = Water Resistant
III. STUDY OBJECTIVE

The objective of the study was to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as defined by the FDA Sunscreen Final Rule; 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018](formerly Docket No. 1978N-0038), RIN 0910-AF43, Labeling and Effectiveness Testing; Sunscreen Drug Products For Over-the-Counter Human Use [FR Doc. 2011-14766 Filed 06/16/2011; Publication Date: 06/17/2011] using Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a 80 minute water immersion experiment which was carried out under controlled conditions as described in the above mentioned FDA Sunscreen Final Rule and Section 6.0 herein.

IV. TEST PRODUCT

Accession No. 902730 was assigned to EltaMD UV Aero which was received from Swiss American Products, Inc. on June 3, 2015.

The study began on June 4, 2015 and was completed on June 17, 2015.

7% Padimate O/3% Oxybenzone Standard was used as the control.

V. TEST PRODUCT HANDLING

Test product that had been reviewed and approved for use by the Regulatory and Safety representatives of Swiss American Products, Inc. was tested.

Upon arrival at BioScreen 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.

VI. STUDY PARTICIPATION RECRUITMENT

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

VII. INFORMED CONSENT 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 form 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. These forms along with the signed consent forms will be available for inspection on the premises of BCS only. Reference 21 CFR Ch. 1 Part 50, Subpart B.
VIII. SUBJECT DEMOGRAPHICS

Number of subjects enrolled.......................................................... 10
Number of subjects completing study........................................... 10
Age Range...................................................................................... 25-59
Sex............................................. Male ........................................ 3
............................................. Female ......................................... 7
Race............................................ Caucasian ................................ 10
............................................. Hispanic ................................... 0
............................................. Asian ................................... 0

IX. INCLUSION CRITERIA

1. Sex: Male and Female
2. Age Range: 18-65
3. Race: Unrestricted
4. Fitzpatrick Skin Type I, II and III
5. Individuals who were free of any dermatological or systemic disorder, which could interfere with the results, at the discretion of the Investigator.
6. Individuals who were in good general health.
7. Individuals who completed a preliminary medical history.
8. Individuals who were free of any acute or chronic disease that might interfere with or increase the risk of study participation.
9. Individuals with uneven skin tones, pigmentation, scars, other irregularities or hair in the test site areas that would interfere with SPF determination.
10. Individuals who read, understood and agreed to sign an informed consent document.
11. Individuals who were able to cooperate with the Investigator and research staff, were willing to have test materials applied according to the protocol, and completed the full course of the study.
12. Individuals who were willing to refrain from using any sunscreen products, sunbathing, or tanning bed use, 24 hours prior to study initiation and the for the entire duration of the study.
13. Individuals with excessive hair on their back who were willing to clip or shave their hair.

X. EXCLUSION CRITERIA

1. Individuals who were under a Physician’s care.
2. Individuals who were taking any medication (topical or systemic) that could mask or interfere with the test results.
3. 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.
4. Individuals with an active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema).
5. Individuals with damaged skin at or in close proximity to test sites (e.g., sunburn, tattoos, scars, excessive hair or other disfigurements).
6. Individuals with a history of adverse effects upon sun exposure.
7. 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.
8. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
9. Individuals who used injectable insulin to control their diabetes.
10. Individuals with blemishes, nevi, sunburn, suntan, scars, moles, active dermal lesions, or uneven pigmentation in the test sites.
11. Individuals who had a known history of hypersensitivity to any cosmetics, personal care products, fragrances and/or sunscreen products.

XI. ARTIFICIAL LIGHT SOURCE

The light source, a 150 watt Xenon Arc Solar Stimulator (Solar Light Co., Philadelphia, PA, Model 14S or 16S) with a continuous emission spectrum in the UVB range of 290 to 320 nm will be used. Xenon arc is selected on the basis of its black body radiation temperature of 6000° K which produces continuous UV spectra (all wavelengths) substantially equivalent to that of natural sunlight.1

This device is equipped with a dichroic mirror (reflects all radiation below 400nm) and which works in conjunction with a 1mm thick Schott WG-320 filter (absorbs all radiation below 290 nm) to produce simulation of the solar UVA-UVB spectrum. A 1 mm thick UG 11 filter is attached to remove reflected (infra-red, greater than 700nm) heat and remaining visible radiation. UVB radiation will be monitored continuously during exposure using a Model DCS-a Sunburn UV Meter/Dose Controller System (Solar Light Co.) formerly known as the Robertson-Berger Sunburn Meter (R-B meter).

Measurements were taken at a position within 8mm from the surface of the skin. The size of the exposure site was ≥ 0.5 cm². Each exposure site was separated from the next exposure site by at least 0.8 cm. The solar stimulator was allowed a warm up time of at least 15 minutes before use and the power supply output was recorded.

Realignment of the light sources and calibration of the sunburn meters are conducted semi-annually by independent certification facilities and more often as necessary at the discretion of the operating technician or investigator. A certificate for Solar Stimulator Emission Spectrum compliance is on file. The spectroradiometric measurements are performed at least annually.


XII. PROCEDURE

1. Prospective subjects reported to the facility on the start of the study.
2. Prior to beginning all study related activities, prospective subjects completed an informed consent form, medical history form and a HIPPA form.
3. Subjects were screened based on the Federal Register Vol. 64, No. 98:27690,1999*:

   Type I – Always burns easily; never tans
   Type II – Always burns easily; tans minimally
   Type III – Burns moderately; tans gradually

* Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.

4. Subjects with Fitzpatrick Skin Types greater than III were not enrolled in the study.

5. The infrascapular area of the back to the right and left of the midline was used.

6. A trained staff member observed the test sites to ensure uniform pigmentation, skin tone, and texture, and absence of warts, moles, nevi, scars, blemishes, and active dermal lesions using a Woods Lamp

7. Any areas that could be expected to produce erratic results were not used for UV exposures.

8. A 50 cm² rectangular test site was wiped down and cleaned prior to delineation with a skin pen. This test site was used to determine the Minimal Erythema Dose (MEDₙ) of untreated and unprotected skin.

9. A minimum of five UV exposures were administered within this site to determine the subject’s inherent MEDu. UV exposures were calculated using a geometric progression of 1.25².

10. Each exposure site was at least 0.5 cm² and was separated from the next exposure site by at least 0.8 cm.

11. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.

12. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.

13. Subjects returned the facility approximately 16 to 24 hours after UV exposure.

14. A trained staff member visually graded the exposure sites based on the following scale:

   0 = No Erythema
   ? = Questionable Erythema
   1 = Minimal Erythema
   2 = Slight Erythema
   3 = Well-Defined Erythema
   4 = Erythema and Edema
5 = Erythema and Edema in vesicles

15. All visual grading was conducted under same lighting conditions and in the same position in which the UV dose was given to the panelist.

16. The lowest UV dose producing perceptible erythema with clearly defined borders determined the individual’s MED (grade 1). Any instance of painful erythema or severe erythema with a grade of 3 or greater was considered an adverse experience.

17. This MED was used in determination of the series of UV radiation exposures to be administered to the protected site in subsequent testing of standard, test sunscreens.

18. A series of 50 cm$^2$ rectangular test sites were wiped down and cleaned prior to delineation with a skin pen. A minimum distance of 1 cm will be maintained between the borders of adjacent test site application areas.

19. One rectangular test site served as the untreated and unprotected site.

20. A second rectangular test site served as the test product site and the third rectangular site served as the SPF Standard Sunscreen (7% Padimate O/3% Oxybenzone).

21. All products (oils, creams, and most lotions) were shaken and/or swirled with a glass rod before use. Products such as powders, pastes, and ointments that could not be drawn into a syringe, were weighed, and then applied by spreading on the test site.

22. The test product and 7% Padimate O/3% Oxybenzone standard sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites measuring 50 cm$^2$ in the amount of 2.0 mg/cm$^2$.

23. Evenness of application was verified by observation with a Wood’s Lamp and the product(s) were allowed to dry at least 15 minutes prior to UV exposure.

24. The untreated and unprotected site received a series of minimum five UV exposures based upon previously determined MED$_u$ such that the series of 5 doses included the previously determined MED$_u$ in the center using a geometric progression of 1.25$^5$.

25. The UV exposures for SPF Standard, PADIMATE O.OXYBENZONE SPF STANDARD were calculated from the previously determined MED$_u$ where a minimum of 5 doses were administered using a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X. X denotes the expected SPF.

26. The UV exposures for the test product was calculated from the previously determined MED$_u$ where a minimum of 5 doses were administered using a geometric progression of 25%, i.e. 0.64X, 0.80X, 1.00X, 1.25X and 1.56X for products with an expected SPF of 8, a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X for products with an expected SPF from 8 to 15 and a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X for products with an expected SPF higher than 15.
27. The middle dose in each of these dose series (i.e. the third dose) should equal the previously determined MEDₜₜ times the expected SPF.

28. Any immediate responses observed after UV exposure were recorded. These responses included several types of typical responses such as immediate darkening or tanning in 30 or 60 minutes and/or immediate reddening with rapid fading.

29. Following UV exposures to the test product site, untreated and unprotected site and the 7% Padimate O/3% Oxibenzon standard sunscreen site, two 50 cm² rectangular test sites were wiped down and cleaned before being delineated with a skin pen.

30. These test sites were selected to perform the 80 minute water resistant portion of the study.

31. The test product and in-house water resistant control sunscreen were evenly applied through plastic volumetric syringes to their respective rectangular test sites in the amount of 2.0 mg/cm².

32. Evenness of application was verified by observation with a Wood’s Lamp and the product(s) were allowed to dry at least 15 minutes.

33. Following the 15 minute waiting period, a total of 80 minutes water immersion was scheduled; 20 minute intervals in the water, followed by 15 minute rest intervals (without towel drying).

34. Immersion was achieved indoors in a circulating whirlpool maintained at 23°C to 32°C where pool and air temperature and the relative humidity were recorded.

35. Following the 80 minute water immersion/rest period cycle, the test sites were allowed to air-dry without toweling prior to exposure from the solar simulator.

36. The UV exposures for in-house water resistant control were calculated from the previously determined MEDₜₜ where a minimum of 5 doses were administered using a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X. X denotes the expected SPF.

37. The UV exposures for the test product was calculated from the previously determined MEDₜₜ where a minimum of 5 doses were administered using a geometric progression of 25%, i.e. 0.64X, 0.80X, 1.00X, 1.25X and 1.56X for products with an expected SPF of 8, a geometric progression of 20%, i.e. 0.69X, 0.83X, 1.00X, 1.20X and 1.44X for products with an expected SPF from 8 to 15 and a geometric progression of 15%, i.e. 0.76X, 0.87X, 1.00X, 1.15X and 1.32X for products with an expected SPF higher than 15.

38. Subjects were instructed to avoid UV exposure, tanning, photosensitizers, analgesics, antihistamines and anti-inflammatory medications.

39. Subjects returned to the facility approximately 16 to 24 hours after UV exposure.

40. A trained staff member visually graded the exposure sites based on the following scale. The technician who evaluated the MED did not know the identity of the test product application sites and UV exposures. Also he/she was not the same
person to have applied the sunscreen product to the test site or administered the doses of UV radiation.

0 = No Erythema  
? = Questionable Erythema  
1 = Minimal Erythema  
2 = Slight Erythema  
3 = Well-Defined Erythema  
4 = Erythema and Edema  
5 = Erythema and Edema in vesicles

41. Subjects were then dismissed from the study.

XIII. REJECTION CRITERIA

Panelist’s results were rejected and the panelist was replaced if:

1. An exposure series failed to elicit an MED response on the untreated skin. The test was considered a technical failure even if the MED response was observed in the protected site.

2. The responses on the protected area were randomly absent, indicating uneven product spreading, non-constant light irradiance or unstable product.

3. All exposures in a series elicited responses – thus prohibiting any MED calculation.

4. The subject was non-compliant (e.g. subject withdrew from the test due to illness or work conflicts or did not shield the exposed testing sites from further UV radiation until the MED was determined.)

XIV. SPF CALCULATIONS

SPF value for each test subject (SPFi) was calculated as follows:

\[ SPF_i = \frac{MED_p}{MED_u'} \]

The mean SPF, \( \overline{SPF} \) and standard deviation \( s \) were calculated. The standard error (SE) was determined by the following:

\[ SE = \frac{s}{\sqrt{n}} \]

Where \( n \) = the number of subjects.
The upper 5% point (A) was obtained from the Student’s t distribution table with n – 1 degrees of freedom (t). A was calculated as follows:

\[ A = t \times SE \]

The labeled SPF for panels using a minimum of 10 evaluable subjects was the largest whole number less than the mean SPF minus A. This number should be rounded down to the nearest whole number.

\[ SPF = \frac{SPF}{ } - A \]

For the study to be valid, the SPF value of the SPF Standard should fall within the standard deviation range of the expected SPF (i.e., 16.3 \pm 3.43). Additionally, a minimum of 10 subjects must complete the study with valid data for analysis.

**XV. ADVERSE EVENTS**

There were no adverse events reported during study period.