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Disparate SPF testing methodologies generate similar SPFs

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Synopsis

Regulatory agencies throughout the world have developed exclusive methodologies for assessing and classifying sunscreen product efficacy in their respective markets. Three prevalent methods, the Food and Drug Administration-Final Monograph (FDA-FM) method, the Australia/New Zealand (Aus/NZ) method, and the COLIPA International (International) method, contain procedural and statistical dissimilarities with undefined significance. The objective of our clinical trials was to evaluate the influence of these disparities on sun protection factor (SPF) values. Our clinical trials evaluated the SPF of 59 test materials, using two or all three of the aforementioned methods in simultaneous trials, providing two or three SPF values for each formulation. A total of 135 trials were conducted. The consequent mean SPF values generated per trial were used to compare methods in a correlation and variance analysis. The correlation coefficients for each method pair, International vs. FDA-FM, Aus/NZ vs. FDA-FM, and International vs. Aus/NZ, were each ≥0.94. The difference in least square mean SPF for each method pair was 0.12, 0.62, and 0.81, respectively. Our juxtaposition of the mean SPFs produced by these methods clearly illustrate that any disparities between average SPF values produced by these methods are not clinically or statistically significant and that using one method should be sufficient for SPF labeling in all three respective markets.

INTRODUCTION

The universal demand for reliable sunscreen products that protect users from the short-term and long-term consequences of ultraviolet (UV) radiation has led to the development of regional standards in sun protection factor (SPF) evaluation test methodologies. Sunscreen products sold in American markets must comply with the current Food and Drug Administration (FDA) Over-the-Counter (OTC) monograph (1–3), whereas identical formulations sold in Australia and New Zealand are generally evaluated with the method developed by the Joint Australia and New Zealand Standards Committee (4). Japan, Korea, and other Asian countries frequently evaluate the efficacy of sunscreen products with the COLIPA International method (5,6). Since these clinical trials were completed, the FDA has published the Labeling and Effectiveness Testing: Sunscreen Drug Products for OTC Human Use or Final Rule (3) on June 17, 2011. The International Organization for Standardization (ISO) produced a new method (7). Australia/New Zealand(Aus/NZ) published a revised method (8) that mirrors the ISO method (7). None

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of the research published herein used the FDA's Final Rule, the ISO standard, or the revised Aus/NZ methods to evaluate SPF.

Differences in these methodologies, including panel size, time frame for erythemal evaluation, geometric progression of UV dose, reference sunscreen formulations, and statistical criteria have been noted (9) and are shown in Table I. The mere existence of these differences has prevented international harmonization of SPF testing. However, the actual impact of these methodological variations on SPF values has not yet been reported. Herein, we report SPF values on the same formulations using the COLIPA International (International) method, the Aus/NZ method, and the FDA Final Monograph (FDA-FM) method. The statistical analysis of the disparities between SPF values generated by these three methodologies shows that no statistically significant differences exist.

MATERIALS AND METHODS

METHODS

Protocols based on the COLIPA International SPF test method (5,6), the FDA-FM SPF test method (1) and the Aus/NZ standard SPF test method (4) were approved by Allendale Institutional Review Board and used to evaluate the SPF of sunscreen formulations. Selected details for each method are listed in Table I. Using the FDA and Aus/NZ, 28 formulations were evaluated; 36 formulations were evaluated using the International and FDA method; and 29 formulations were evaluated using the International and Aus/NZ Method. Formulations designated numbers 1 through 17 were evaluated by all three methods. A total of 59 formulations were evaluated in the course of 135 clinical trials (Table II).

The trials were conducted between October 10, 2005, and May 20, 2011, in harmony with the World Medical Association Declaration of Helsinki (as amended), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Good Clinical Practice and Standard Operating Procedures at Consumer Product Testing Company, Inc. Potential subjects were recruited from the database at Consumer Product Testing Company, Inc.

Potential subjects were given a verbal description of the risks and benefits of the trial. They were allowed to ask questions to which they received answers in terminology that they understood. Upon completion of the informed consent process, each potential subject executed an informed consent form by signing and dating the document. The potential subject then became a subject in the trial.

UV RADIATION SOURCE

Xenon Arc Solar Simulators from Solar Light Company, Philadelphia, PA, (150 Watt or 300 Watt) were used as the source of UV radiation (10). The spectral output for the 150 W and the 300 W was essentially identical (11). The lamp output was measured with a UV intensity meter (Model PMA2100, Solar Light Company, Philadelphia, PA) before and after the test period. Solar simulators were equipped with 1-mm UG11 and WG320 filters, providing a spectral output in the UV range (290–400 nm) comparable to that of

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Table I
Comparison of SPF *in vivo* Methods(7)

Parameters	International 2006		Australia 1998	FDA 1999	FDA 2011	
Source of UV radiation						
Acceptance Limits %RCEE UVAII/UVAI	% RCEE defined in different bands					
	λ range (nm)	RCEE%			λ range (nm)	Erythemal Effective Radiation (%)
	≤290	<0.1			≤290	<0.1
	290–300	1.0 – 8.0			290–300	1.0–8.0
	290–310	49.0–65.0	<0.01% < 290 nm	290 nm to 400 nm	290–310	49.0–65.0
	290–320	85.0–90.0	"red" and "blue" acceptance limits (±4 nm): graph	<1% energy < 290 nm	290–320	85.0–90.0
	290–330	91.5–95.5		≤5% energy > 400 nm	290–330	91.5–95.5
	290–340	94.0–97.0			290–340	94.0–97.0
	290–400	99.9–100			290–400	99.9–100
	UVAII 20% UVAI 60% of the total UV irradiance to ensure that appropriate amounts of UVA radiation are included				UVAII 20% UVAI 60% of the total UV irradiance to ensure that appropriate amounts of UVA radiation are included	
UV exposures						
Progression of UV dose	Geometric progression of either (1.25″) or (1.12″) for the unprotected area. For the protected areas, a minimum of five subsites centered on the expected SPF × MEDu shall be exposed with a geometric progression of either (1.25″) or (1.12″)		Unprotected MED re-determined with a dose range of ≈ 0.6 to 1.5 provisional MEDu	Geometric progression (1.25″) for the unprotected area	Geometric progression (1.25″) for the unprotected area	

Table I
Continued

Parameters	International 2006	Australia 1998	FDA 1999	FDA 2011
	A maximum progression of 1.12^n must be used for expected SPF > 25	For protected skin the dose range is multiplied by the expected SPF	For the protected areas geometric series of five exposure where the middle exposure is placed to yield the expected SPF plus two other exposures placed around the middle exposure	For the protected areas geometric series of five exposure where the middle exposure is placed to yield the expected SPF plus two other exposures placed around the middle exposure
		Increments between subsites no more than 1.35	According to the expected SPF (×)	According to the expected SPF (×)
			SPF < 8: 0.64×, 0.80×, 0.90×, 1.00×, 1.10×, 1.25×, 1.56×	SPF < 8: 0.64×, 0.80×, 1.00×, 1.25×, 1.56×
		≤1.118 for SPF ≥ 25	SPF 8 to 15: 0.69×, 0.83×, 0.91×, 1.00×, 1.09×, 1.20×, 1.44×	SPF 8 to 15: 0.69×, 0.83×, 1.00×, 1.20×, 1.44×
			SPF > 15: 0.76×, 0.87×, 0.93×, 1.00×, 1.07×, 1.15×, 1.32×	SPF >15: 0.76×, 0.87×, 1.00×, 1.15×, 1.32×
Reference sunscreen formulations				
Reference sunscreen formulations used	Expected SPF < 20: P2 or P3 or P7	On each subject either:	Homosalate 8% with SPF 4.47 (SD: 1.279)	P3 (Padimate O 7.0% + Oxybenzone 3.0%) with SPF 16.3 (SD: 3.43)
	Expected SPF ≥ 20: P2 or P3	Homosalate 8% with SPF 4.47		
	The same reference has to be tested on every subject in the same series of at least 10 subjects	P3 with SPF 15.5		
		Or values derived from the laboratory's historical record on its test results		

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Table I
Continued

Parameters	International 2006	Australia 1998	FDA 1999	FDA 2011
Calculations and results				
Number of test subjects	Minimum of 10, Maximum of 25	Minimum of 10, Maximum undefined	At least 20 valid; Maximum of 25	At least 10 valid; no maximum
			Up to five subjects can be excluded	Up to three subjects can be excluded
Statistical criterion	95% confidence interval should fall within ±17% of mean SPF	SEM 7% of mean SPF for valid result	No	No

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Table II
Mean SPF Values For Formulations 1–59 by Method

	International	FDA-FM	Aus/NZ
1	16.5 ± 1.9 (n = 10)	18.0 ± 2.4 (n = 21)	17.3 ± 2.8 (n = 10)
2	24.3 ± 4.4 (n = 10)	22.3 ± 1.9 (n = 20)	21.7 ± 3.3 (n = 10)
3	18.0 ± 2.5 (n = 10)	17.3 ± 1.3 (n = 20)	18.4 ± 2.7 (n = 10)
4	18.2 ± 2.1 (n = 10)	17.3 ± 1.3 (n = 20)	19.6 ± 1.3 (n = 10)
5	16.1 ± 1.8 (n = 10)	16.0 ± 1.5 (n = 20)	16.1 ± 1.8 (n = 10)
6	17.7 ± 4.6 (n = 10)	18.2 ± 1.8 (n = 20)	17.6 ± 3.7 (n = 10)
7	17.3 ± 2.4 (n = 10)	16.8 ± 2.4 (n = 20)	18.3 ± 1.2 (n = 10)
8	17.6 ± 1.8 (n = 10)	16.0 ± 1.4 (n = 20)	16.9 ± 2.5 (n = 10)
9	15.7 ± 3.1 (n = 15)	16.4 ±.7 (n = 20)	17.2 ± 1.9 (n = 10)
10	26.4 ± 3.7 (n = 10)	22.7 ± 1.5 (n = 20)	25.3 ± 3.8 (n = 10)
11	10.3 ± 1.3 (n = 10)	8.7 ± 0.9 (n = 20)	9.9 ± 1.25 (n = 10)
12	17.6 ± 1.8 (n = 10)	15.7 ± 1.4 (n = 25)	18.1 ± 2.6 (n = 10)
13	9.8 ± 2.1 (n = 10)	8.4 ± 0.7 (n = 20)	9.7 ± 1.9 (n = 10)
14	10.5 ± 10.5 (n = 10)	8.6 ± 0.9 (n = 20)	9.0 ± 1.3 (n = 10)
15	18.0 ± 2.6 (n = 10)	17.6 ± 1.8 (n = 20)	16.6 ± 2.4 (n = 10)
16	17.2 ± 1.9 (n = 10)	17.5 ± 0.9 (n =20)	21.7 ± 3.1 (n = 10)
17	18.9 ± 2.8 (n = 10)	17.0 ± 1.0 (n = 20)	18.2 ± 3.3 (n = 10)
18		16.7 ± 1.7 (n = 20)	19.1 ± 4.0 (n = 10)
19		27.6 ± 1.6 (n = 20)	27.4 ± 2.0 (n = 10)
20		15.9 ± 1.8 (n = 20)	16.2 ± 2.4 (n = 10)
21		16.5 ± 1.6 (n = 20)	16.6 ± 2.4 (n = 10)
22		15.9 ± 2.3 (n = 20)	17.6 ± 1.8 (n = 10)
23		16.3 ± 1.8 (n = 20)	17.2 ± 1.9 (n = 10)
24		16.9 ± 2.0 (n = 20)	18.4 ± 2.3 (n = 10)
25		17.3 ± 1.9 (n = 20)	18.2 ± 3.3 (n = 10)
26		15.9 ± 0.8 (n = 20)	16.5 ± 1.9 (n = 10)
27		23.4 ± 2.2 (n = 20)	22.2 ± 3.2 (n = 10)
28		23.1 ± 1.7 (n = 20)	22.2 ± 2.4 (n = 10)
29	16.9 ± 2.0 (n = 10)	16.7 ± 1.6 (n = 20)	
30	18.2 ± 3.6 (n = 10)	16.8 ± 1.9 (n = 20)	
31	17.4 ± 3.2 (n = 10)	16.6 ± 1.8 (n = 20)	
32	17.0 ± 3.2 (n = 10)	16.8 ± 1.8 (n = 20)	
33	17.4 ± 3.2 (n = 10)	16.9 ± 1.9 (n = 20)	
34	19.0 ± 3.4 (n = 10)	16.8 ± 2.1 (n = 20)	
35	18.0 ± 1.6 (n = 10)	17.0 ± 2.2 (n = 20)	
36	16.5 ± 1.9 (n = 10)	16.7 ± 2.4 (n = 20)	
37	30.5 ± 3.8 (n = 10)	31.0 ± 3.3 (n = 20)	
38	33.9 ± 2.6 (n = 10)	33.3 ± 2.2 (n = 20)	
39	34.4 ± 3.1 (n = 10)	32.6 ± 2.2 (n = 20)	
40	33.6 ± 2.7 (n = 10)	33.6 ± 2.0 (n = 20)	

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Table II
Continued

	International	FDA-FM	Aus/NZ
41	32.8 ± 1.9 (n = 10)	33.4 ± 2.6 (n = 20)	
42	11.5 ± 1.3 (n = 10)	11.9 ± 1.2 (n = 20)	
43	17.6 ± 1.8 (n = 10)	16.9 ± 1.1 (n = 20)	
44	31.1 ± 1.7 (n=10)	33.2 ± 2.2 (n = 20)	
45	23.3 ± 4.0 (n = 10)	21.2 ± 2.0 (n = 20)	
46	26.4 ± 2.6 (n = 10)	26.9 ± 2.4 (n = 20)	
47	11.8 ± 1.8 (n = 10)	12.2 ± 1.3 (n = 20)	
48	21.6 ± 3.1 (n = 10)		22.1 ± 6.0 (n = 10)
49	23.2 ± 4.3 (n = 10)		22.6 ± 3.9 (n = 10)
50	28.1 ± 2.3 (n = 10)		28.7 ± 1.7 (n = 10)
51	23.1 ± 2.2 (n = 10)		25.4 ± 4.2 (n = 10)
52	16.2 ± 2.4 (n = 10)		15.6 ± 3.0 (n = 10)
53	18.5 ± 2.7 (n = 10)		16.5 ± 1.9 (n = 10)
54	18.2 ± 2.9 (n = 10)		17.6 ± 1.8 (n = 10)
55	17.0 ± 2.9 (n = 10)		19.9 ± 3.4 (n = 10)
56	16.9 ± 2.0 (n = 10)		17.4 ± 3.2 (n = 10)
57	16.9 ± 2.8 (n = 10)		15.7 ± 1.6 (n = 10)
58	16.0 ± 3.1 (n = 10)		14.5 ± 2.6 (n = 10)
59	22.5 ± 2.6 (n = 10)		24.1 ± 3.4 (n = 10)

natural sunlight and that meets international and FDA standards. Irradiation beams were a minimum of 1 cm^2 with a beam uniformity of 10%, and they exhibited less than 20% time-related fluctuation. All solar simulators were calibrated and adjusted to deliver energies within 10% variance.

SPF DETERMINATION

An individual sun protection factor (SPFi), defined as the ratio of the Minimal Erythemal Dose on protected skin (MEDp) to the Minimal Erythemal Dose on unprotected skin (MEDu) on the same subject, was calculated for each subject as follows:

$$SPFi = \frac{MEDi\ (protected\ skin)}{MEDi\ (unprotected\ skin)} = \frac{MEDpi}{MEDui}$$

The mean SPF for each trial, defined as the arithmetical mean of the individual SPFi values obtained from the total number (n) of subjects used, expressed to one decimal point, was calculated as follows:

$$\text{SPF} = \frac{(\sum \text{SPFi})}{n}$$

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STATISTICAL ANALYSES

Scatterplots of mean SPF values show each method pair, International vs. Aus/NZ, International vs. FDA-FM, and Aus/NZ vs. FDA-FM.

The 29 test materials evaluated by the International method and the Aus/NZ method were designated a unique point and graphed in Figure 1 as follows:

$$\text{Point}_{\text{Material A}}\,(p_A) = (\text{SPF Aus/NZ}_n, \text{SPF}_{\text{International}})$$

The 36 test materials evaluated by the International method and the FDA-FM method were designated a unique point and graphed in Figure 2 as follows:

$$\text{Point}_{\text{Material A}}\,(p_A) = (\text{SPF}_{\text{FDA-FM}}, \text{SPF}_{\text{International}})$$

The 28 test materials evaluated by the FDA-FM and the Aus/NZ method were designated a unique point and graphed in Figure 3 as follows:

$$\text{Point}_{\text{Material A}}\,(P_A) = (\text{SPF}_{\text{Aus/NZ}}, \text{SPF}_{\text{FDA-FM}})$$

The correlation coefficients and best-fit line for each scatterplot were determined.
An Analysis of Variance was performed for each study pair to compare the overall mean of each method. The variability was considered statistically significant if $p < 0.05$.

RESULTS AND DISCUSSION

The data in Figures 1, 2, and 3 display the trial results for evaluating the SPF of test materials with two test methods, International vs. Aus/NZ, International vs. FDA-FM, and Aus/NZ vs. FDA-FM, respectively. The statistical analysis results are summarized in Table III. The correlation coefficents for International vs. Aus/NZ, International vs. FDA-FM, and Aus/NZ vs. FDA-FM, were 0.94, 0.99, and 0.95, respectively, illustrating

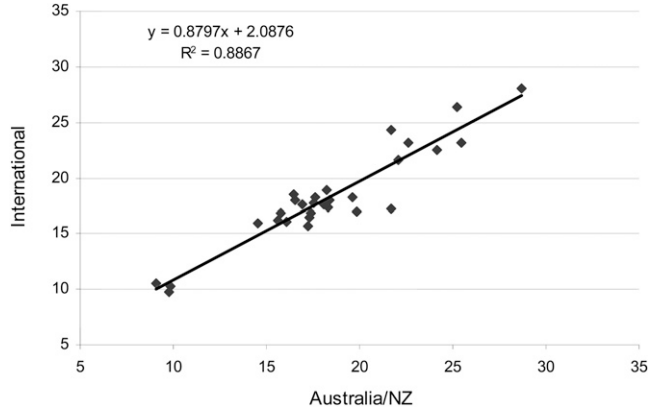

Figure 1. Correlation analysis of mean SPF values produced by international method and the Aus/NZ method.

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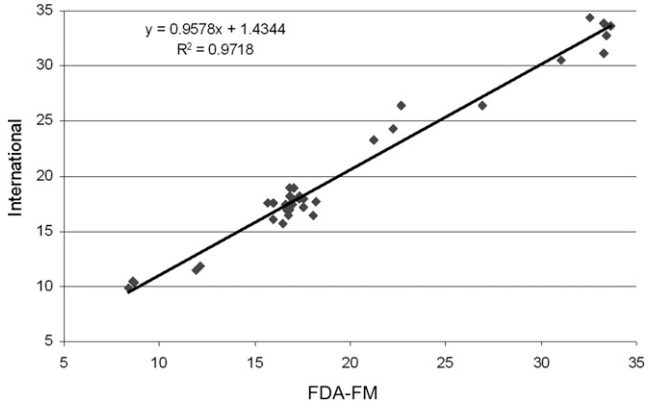

Figure 2. Correlation analysis of mean SPF values produced by international method and the FDA-FM.

a strong positive correlation between each pair. The differences in least square mean SPF for each method pair were 0.12, 0.62, and 0.81, respectively; these differences also show no statistically significant differences between the mean SPFs obtained using the different testing methods.

The use of 25% exposure increments or 15% exposure increments produce similar SPF values when utilizing the same test method (12). Our data illustrate that incremental doses in irradiation sites, ranging from 12% to 25%, in combination with the other methodology variables existing between the FDA-FM method, the Aus/NZ method, and the International method, have no significant impact on the mean SPF value produced.

Likewise, statistically equivalent SPF values are produced by 10 subject trials as by 20 subject trials. Furthermore, using different sunscreen standards in a clinical trial induces no significant change in mean SPF value. We conclude that the procedure discrepancies

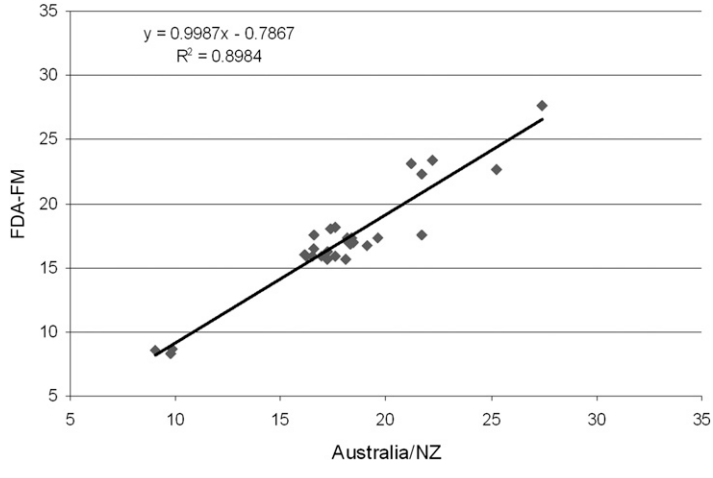

Figure 3. Correlation analysis of mean SPF values produced by FDA-FM and the Aus/NZ Method.

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Table III
Statistical Analysis Summary

Methods used	International method	Aus/NZ	International method	FDA-FM	FDA-FM	Aus/NZ
$N_{materials}$	29		36		28	
LSM SPF	18.22	18.34	19.93	19.31	17.12	17.93
$\lvert SPF_Y - SPF_X \rvert$	0.12		0.62		0.81	
R	0.94		0.99		0.95	

in FDA-FM method, Aus/NZ Method, and the International method are inconsequential; either the differences have no impact on mean SPF value, or, less likely, the differences produce equally and opposite changes in mean SPF, thus cancelling any effects.

Marketed sunscreens labeled according to the mean efficacy value as determined by any of these methods would produce a universally definable SPF. However; formulations evaluated with the International method (5,6) or Aus/NZ Method (4) are designated a label with the mean SPF value when it fits within statistical criterion testing for precision and accuracy. In contrast, the FDA-FM (1) method and the more recently published FDA Final Rule (3) subtract an "A" value from the mean SPF to calculate the SPF label. The A value is composed of the product of the upper 5% point of the t-distribution and the standard deviation, divided by $\sqrt{(n)}$, where n equals the number of subjects. The authors are not aware of any other drug that has a clinically determined efficacy value altered to a different label efficacy value. This calculation decreases the SPF determined by the FDA-FM and FDA Final Rule to a value that could be statistically different from the SPF value determined by either the International method or the Aus/NZ method, likely resulting in identical formulations labeled with different SPF values.

Recently, there has been a flurry of newly published sunscreen standards. The FDA published the Labeling and Effectiveness Testing: Sunscreen Drug Products for OTC Human Use or Final Rule (3) on June 17, 2011; the International Organization for Standardization produced a new method (7); and Aus/NZ published a revised method (8) that mirrors the ISO method (7). While we have no dataset to compare these methods to the FDA-FM method, we know of no reason to believe that these three new methods would produce SPF values with statistically significant differences from the three methods compared herein. One notable change implemented by the FDA, reduction of a panel size from 20 to 10, is substantiated by the data presented herein.

In conclusion, the contemporary method of being able to sell sunscreen products in all markets requires the concurrent utilization of all three methods. The data presented herein illustrates the equivalency of mean SPFs generated using each method. The differences inherent in each method, such as panel size, time frame for erythemal evaluation, geometric progression of UV dose, SPF of reference sunscreen formulations, and statistical criteria, do not have a significant impact on the mean SPF value produced. These compulsory testing standards are similar enough to render simultaneous use of all three as redundant; compliance with one should suffice for SPF labeling in all markets. This would reduce the number of subjects experiencing the risks of SPF trials unnecessarily (13) while also bringing the static sunscreen testing methodology to the brink of international

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harmonization; the disparate mathematical alteration of the mean SPF value, or lack thereof, is the only significant factor remaining to be resolved.

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