



DermaTest

Newsletter

FDA June 2011

FDA - FINAL-ly crosses the Finish Line



June 17th

Executive Summary.

1. No confusing labeling now - only requires ...
 - a. the SPF number.
 - b. the words "Broad Spectrum" (if above SPF 15).
 - c. The statement "Water Resistant (40 minutes)" or "extra Water Resistant" (80 minutes) as relevant.
 *A number of additional mandatory statements are also required.)
2. FDA has also removed the confusion between SPF and UVB which was evident in the 2007 proposal.
3. The UVA/UVA1 test requirement has been replaced with a test similar to COLIPA/ISO.
4. 10 to 13 test subjects for SPF test.
5. There is no requirement for UVA in-vivo testing.

SPF

The number of test subjects is reduced from 20 to a min of 10.

A new higher SPF Reference Sunscreen is specified - the equivalent of the ISO and COLIPA "P2".

The test protocol parameters are aligned to COLIPA and allow for compliance for both to be derived from the same test. Label SPF can be any number between 2 and 50 is permitted, with "50+" applying for any above 50. [FDA has called for submissions on clinical efficacy support for SPF above 50.] This is at variance with the requirements for other protocols, were 50+ requires an in-vivo SPF greater than 60.

UVA - Broad Spectrum.

The claim of "Broad Spectrum" is allowed when SPF is 15 or more, AND Critical Wavelength reaches 370 nm. FDA has that aligned the method with the COLIPA UVA in-vitro method (2009) - but not the improved ISO 24443 which is mostly referenced in the updated COLIPA (2011). So, whilst the critical wavelength does not need to be measured separately, the test is not harmonised as would be ideal. (see spreadsheet on p2). As well, test parameters-

given by FDA do not tie down the potential for lab to lab variability, as there is less attention to instrument calibration by FDA and PMMA substrate plate roughness range is high.

Expression of compliance as "Broad Spectrum" in place of "UVA" is in line with what is currently proposed for Australia. This puts the two therapeutically regulated markets in line.

Water Resistance

The two levels of claim are "Water Resistant (40 minutes)" and "Water Resistant (80 minutes)". Both are with reference to the SPF measured at the end of the test period. Again, this is in line with Australia, but not the E.U. 50% allowed "discount" for post-immersion SPF.

Compliance Deadline

FDA are proposing that marketed products must comply by the deadline of 12 mths from publication i.e. 17th June 2012.

Testing

DermaTest Pty Ltd can conduct testing for compliance to all of the new FDA or any other recognised protocol requirements.

In-Vitro UVA			
Test Parameter	ISO & Aust Prop March 2011	COLIPA March 2011	FDA FINAL June 2011
Plates	6 um PMMA plates	6 um PMMA plates	2 to 7 um PMMA plates
Plate Surface Characteristics	Moulded	Moulded	Etched or moulded
Application Rate	1.3 mg/sq cm	1.3 mg/sq cm	0.75 mg/sq cm
Drying Time	Temp of exposure min 15 min	min 15 min	15 min
Pre-irradiation Dose	Pre-irradiation 1.2 J x UVAPFo	Pre-irradiation 1.2 J x UVAPFo	Fixed Pre-irradiation 4 MED's
Pre-irradiation Spectrum	UVA Irradiance Spectrum	UVA Irradiance Spectrum	SPF Irradiance Spectrum
SPF used in exposure Calculation	in-vivo SPF	in-vivo SPF	in-vivo SPF
Ratio Calculation (UVAPFDx/label SPF)	Ratio minimum 0.33	Ratio minimum 0.33	n/a
Critical Wavelength	TBD	min 370 nm	min 370 nm
Final Expression	Aust "Broad Spectrum" - ISO n/a	E.U. interprets Pass/Fail	"Broad Spectrum"
Replicates	4 Measurements on 4 plates	3 Measurements on 4 plates	5 Measurements on 3 plates

Australia

Europe

FDA

Towards Harmonised Labeling

As can be seen from the attached example, although the sunscreen front labels are almost the same, subtle differences are still present. Some elements of the FDA label are compatible with the Australian label, but the E.U. uses "UVA" as the label claim in place of "Broad Spectrum"

As the requirements for labeling are substantially in the hands of regulators and not standards authorities, there is really no mechanism for negotiation. Success is more likely to arise when regulators allow flexibility to provide additional consumer information which can be reflect alternative interpretation e.g. adding the words "UVA" or "UVA/UVB" as well as "broad spectrum".



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