



2011 FDA Changes to Sun Protection Factor Labeling Rules

SPF changes: SPF Value & Testing Subjects

- Previously, testing was required on 20 Subjects per the 1999 rule.
 - Testing has changed to 10 to 13 subjects per FDA 301.327(i). 10 subjects must be valid.
- A numerical SPF value can be listed up to 50. If greater than 50, then only 50+ can be listed (not the actual number).

SPF changes: Broad Spectrum or UVA Claims

- Previously, there was no mention of Broad Spectrum or UVA claims.
 - In addition to the in-vivo testing listed above, the product must pass the new FDA Critical Wavelength test listed in section 301.327(j).
 - Must meet 370 nm² to pass.

SPF changes: Claims

- “Help Reduce Skin Cancer and Premature Skin aging”
 - Must be SPF 15 or greater and have Broad Spectrum protection.
- “Helps prevent Sunburn”
 - Both Non-broad spectrum and broad spectrum products with SPF value of 2 to 14.

SPF changes: UVA star Rating

- The 2007 proposed rule listed a UVA star Rating. This is no longer required.

SPF changes: Waterproof, Sweatproof or Sunblock Claims

- Claims using the words: Waterproof or Sweatproof or Sunblock
 - You are no longer allowed to make these claims.

SPF changes: Water Resistance or Very Water Resistant

- Water Resistant or Very Water Resistant
 - Must meet a 40 minute for or 80 minute test to make this claim.

SPF changes: Drug Facts

- Drug Facts Label on product
 - Must include “Drug Facts” label on the product.

SPF changes: Implementation Dates

- Implementation Dates
 - New Formulations must meet these new rules by June 18, 2012. If sales are less than \$25,000 then by June 17, 2013.
 - Existing formulations must be tested to the new procedure within 2 years of the date of publication of monograph which is June 17, 2011, so the due date is June 17, 2013.

For more information or a quote for testing of Sun Protection Products, please visit our quote request form at:

<http://www.bioscreen.com/forms-a-quotes>

Or contact Customer Service at (310) 214-0043 or info@bioscreen.com.

SPF Helpful links

The following links to the FDA website provide answers to frequently asked questions:

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm258468.htm#Q1_Why_is_FDA

(please copy and paste the following link into your browser)

Final Rule

<http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14766.pdf>

Label

<http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM258718.pdf>

Enforcement Policy

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf>

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