In June 2011, the U.S. Food and Drug Administration (FDA) announced new requirements for the labeling of over-the-counter (OTC) sunscreen products. For most OTC sunscreen products, the final rules were scheduled to go into effect on June 18, 2012. In May 2012, however, the FDA extended the compliance dates for the new requirements until December 17, 2012, for products with annual sales of over $25,000, and to December 17, 2013, for products with annual sale of less than $25,000.

**The Challenge:**

The use of the term “sunscreen” or similar sun protection terminology such as Sun Protection Factor (SPF) in a product’s labeling would cause the product to be classified as a drug. The new requirements would also apply to cosmetics and moisturizers labeled with SPF values.

The final regulations establish standards for testing the effectiveness of sunscreen products and require labeling that accurately reflects the test results. Key requirements under the final rule are as follows:

- **Broad Spectrum designation:** Sunscreens should provide protection against both ultraviolet A radiation (UVA) and ultraviolet B radiation (UVB) to be classified as “broad spectrum”. The final rule includes an in vitro broad spectrum test procedure for assessing protection across both UVA and UVB regions of the UV spectrum. Only products that make broad spectrum claims or suggest that they decrease the risk of skin cancer or premature skin aging are subject to these requirements.

- **Use claims:** Broad spectrum sunscreens with an SPF value of 15 or higher can claim: ‘reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures.’ Sunscreen products that are not broad spectrum, or that are broad spectrum with SPF values from 2 to 14, can only claim ‘help prevent sunburn’. Also, they would require a warning statement that reads: “Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.”

- **Prohibited claims:** Claims such as “waterproof”, “sweatproof”, “sunblock”, “all-day”, “extended wear”, and “instant-protectors” are not permitted.

- **Water Resistant claims:** “Water-resistant” claims are permitted. If this term is used, it should be indicated whether the sunscreen will remain effective for 40 or 80 minutes while swimming or sweating, based on standard testing.

- **Drug Facts:** All sunscreens must indicate standard “Drug Facts” information on the back and/or side of the container.

1. [http://www.fda.gov/forconsumers/consumerupdates/ucm258416.htm](http://www.fda.gov/forconsumers/consumerupdates/ucm258416.htm)
SPF testing: The final rule requires that labeling for covered OTC sunscreen products bear the SPF values determined in accordance with the new SPF testing requirements, which measure protection against sunburn caused by UVB radiation. FDA has allowed an additional year for manufacturers to test in accordance with the new SPF testing requirements.

In addition to the above final regulations, in June 2011 the FDA proposed a regulation that would limit the maximum SPF value on sunscreen labeling to “SPF 50+”.

The Solution:

Intertek offers tailored solutions that enable you to comply with the requirements under the new sunscreen regulations, including broad spectrum testing, labeling review services, determination of SPF values, and clinical studies for substantiating product claims.

Should you have any queries on the above news, please contact Ms. Nastaran Hashemi at: (nastaran.hashemi@intertek.com) or Mr. Denis Leung at: (denis.leung@intertek.com)