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COSMETICS, PERSONAL CARE AND HOUSEHOLD

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US FDA EXTENDS DEADLINE FOR NEW SUNSCREEN LABELING REQUIREMENTS

The U.S. Food and Drug Administration (FDA) announced the delay of the compliance dates for the new sunscreen labeling requirement by 6 months. The new implementation date for products with annual sales less than US \$25,000 is December 17, 2013 and that for all other products is December 17, 2012¹.

On June 14, 2011, the U.S. Food and Drug Administration (FDA) announced significant changes on OTC (over-the-counter) sunscreen product labeling. The new rules established labeling and effectiveness testing requirements for OTC sunscreen products which enable consumers to identify and select suitable sunscreen products. It was planned to be effective one year from the date of publication - June 18, 2012 for OTC sunscreen products with annual sales higher than US \$25,000 and June 17, 2013 for those with sales less than US \$25,000.

FDA concurs with the request from the associations and industries; and finally decided to extend the implementation period for 6 months from the original compliance date.

Summary of the New Final Rule² and Proposed Rule³ is showed in Table 1:



¹ [Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates](#)

² [The Proposed Rule](#)

³ [FDA Regulatory Action on Sunscreen](#)

TABLE 1.

Broad Spectrum designation	With measurement of both ultraviolet A (UVA) protection relative to its ultraviolet B (UVB) protection
Use claims	<p>"Broad Spectrum" sunscreens with an SPF value ³15 can claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures</p> <p>Non-Broad Spectrum sunscreens and Broad Spectrum sunscreens with an SPF value between 2 and 14 can only claim to help prevent sunburn</p>
"Waterproof," "sweatproof" or "sunblock" claims	Not allowed
Water resistance claims	"Water resistance" claims on the front label must indicate whether the sunscreen remains effective for 40 minutes or 80 minutes while swimming or sweating, based on standard testing
Drug Facts	All sunscreens must include standard "Drug Facts" information on the back and/or side of the container
Maximum SPF value on sunscreen labels to "50 +"	A Proposed Rule to limit the maximum SPF value to "50+". It is available for public comment until September 15, 2011

If you have any questions about Sunscreen Over-the-Counter (OTC) labels, SPF & Broad Spectrum claims or testing, don't hesitate to contact SGS.



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