

FINAL RULE FOR SUNSCREENS IS NOW IN EFFECT

THE FIRST EVER sunscreen Final Rule in the US went into effect last month. According to the US Food and Drug Administration, sunscreen products marketed under the OTC Monograph System, the compliance date for products with sales of \$25,000 or more is Dec. 17, 2012. For products with sales of less than \$25,000, the compliance date is Dec. 17, 2013. The long-awaited Rule should not be confused with the illusive Final Monograph which has yet to be issued. The process leading to this point has been lengthy, and while this occasion marks a new stage, we are far from finalizing all outstanding issues.

The Final Rule means that most OTC sunscreen products introduced or delivered for introduction into interstate commerce, on or after Dec. 17, 2012, must comply with the testing and labeling requirements of the Sunscreen Final Rule published June 17, 2011.¹ The three most significant changes in the labeling requirements are with “broad spectrum” protection, the new requirement that the SPF must be above 15 to qualify as a sunscreen in order to make the claim that “sunscreen



The US Food and Drug Administration issued the Final Rule on sunscreens last month, but much more work remains.

reduces the risk of skin cancer and early skin aging when used as directed,” and the changes in the requirements of the Drug Facts box.

Two other documents were released with the Final Rule—the Proposed Rule and the Advanced Notice of Proposed Rulemaking (ANPR). The Proposed Rule limits the maximum SPF value on sunscreen labels to 50+. The FDA justifies this due to the fact that there is no sufficient data to show products with SPF values higher than 50 provide greater protection for users than products with an SPF of 50. The FDA is encouraging public comment on this document. However, any products labeled over SPF 50 (say 70 or 100) will not be subject to regulatory action until the Proposed Rule becomes a Final Rule.² The Advanced Notice of Proposed Rulemaking (ANPR) allows the public a period of time to submit data addressing the effectiveness of the safety of sunscreen sprays. The FDA also requests comments on the possible warnings and directions for spray usage and issues regarding dosage forms. Thus, two issues—sprays and SPF 50+ labels—are still subject to finalization pending the outcome of the comments period and evaluation. All reference to “sunblock,” “waterproof,” “sweatproof,” and “all day protection” will not be allowed after that date. Towelette and powder products are not eligible for consideration under the pending OTC Sunscreen Monograph and would therefore be subject to regulatory

action.

In the US, a number of litigation cases involving sunscreen manufacturers continue to be filed and settled. Merck Consumer Care recently settled the false advertisement lawsuit that dates back to Oct. 31, 2003 (plaintiff Joseph Goldstein filed an action against Merck/Coppertone in the superior court of the State of California, County of Los Angeles). Merck agreed to pay between \$3 and \$10 million in a New Jersey District Court and agreed to stop using the terms “sunblock,” “waterproof,” “sweatproof,” and “all day protection” in its labeling or advertising of Coppertone sunscreen products manufactured after June 22, 2012.³

In other developments, Andrea Franco, in a class action suit filed on Nov. 29, 2012, accused Neutrogena Corp. of violating the Unfair Competition Law and the Consumer Legal Remedies Act. Specifically, she claims that “sunblock,” “sweatproof,” and “waterproof,” particularly when coupled with the SPF 55 to 110 representation, lull consumers into a false sense of security.^{4,5} Meanwhile, the FDA has been taking aim at cosmetic firms that are marketing cosmetics with claims of biologically-enhanced benefits.⁶

Finally, to add to the woes of Energizer Holdings, the company had to expand its initial recall of Banana Boat sunscreens in Canada on Nov. 29, 2012. The initial recall was made back in October for some of their well-known products, since they potentially run the risk of catching fire if contact is made with open flames before they are completely dried onto the skin. According to Energizer, the issue is related to the product delivery system. The spray valve opening apparently dispenses more than is typical in the industry for continuous spray sunscreen.⁷

Interestingly, on Nov. 13, 2012, the Australian Therapeutic Goods Administration (TGA) revised how new



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sunscreen products are authorized for supply in Australia. The change allows for labeling of sunscreen products with a rating of up to SPF 50+ and sets stringent requirements for the “broad spectrum” performance.⁸ In Australia, sunscreens fall into two categories for regulatory purposes, namely “therapeutic sunscreens” and “cosmetic sunscreens” and are regulated by different government agencies. The “therapeutic sunscreens” (intended primarily for protection of the skin from the sun’s UV radiation) are regulated by the TGA, and “cosmetic sunscreens” (moisturizers with SPF of 15 or less, sunbathing products with SPF between 4 and 15, lip balms/lipsticks and makeup products with any SPF) are regulated by NICNAS (ingredients),⁹ and the ACCC (labeling).¹⁰ Perhaps, this may be a sensible way to address sunscreen regulations in the US as well.

Some Good News!

Now let’s move on to some positive news! The Society of Cosmetic Chemists held its annual scientific meeting and technology showcase on Dec. 6-7, 2012 at the NY Hilton in Manhattan (*see p. 00 in this issue for more SCC annual meeting coverage*). As usual, the attendance was excellent and the organization flawless. This event came at a time that the SCC offices in New York City were flooded during Superstorm Sandy. With no electricity, nor access to their files or computers, the SCC staff managed to pull this conference off without a hitch! Congratulations to all of those involved.

For me, the highlight of the meeting was the presentation by Richard Rox Anderson from the Wellman Center for Photomedicine at Harvard Medical School. His talk was entitled “Cosmegizmoceuticals—The Physics and Chemistry of Looking Better.”¹¹ Though I do not necessarily subscribe to the catchy title, his presentation was dynamic and refreshing. Anderson suggested alternative strategies based on physical properties for cosmetic preparations that change the appearance of the skin and can be used in combination with home-use devices for skin perfection.

Other sunscreen related presentations¹² that were delivered included Kobo’s Pascal



FDA has yet to address questions surrounding spray formulas.

Delrieu who spoke on the “Development of Non-Nano Composite UV Powders for Safer and Efficient Sunscreen.” Paul Staniland from Croda spoke on “Measurement of UV Initiated Radical Generation in Skin Substitute by ESR Spectroscopy.” Finally, Li Zhang from Dow Chemical made her presentation on new insights into “Water Resistant Polymers in Sunscreen Emulsion Formulations.” With plenty of time to field questions, the debate was lively and quite informative.

As I conclude my comments in this month’s column, I cannot help but reflect on the nearly 40 year journey of the sunscreen regulations—from assembling the expert panel in the early 1970s to the first ANPR on Aug. 25, 1978, which was almost considered law for a long time. We have passed many milestones along the way. These milestones included the Tentative Final Monograph on May 12, 1993, the Proposed Final Monograph on May 21, 1999 and, finally, the Final Rule that was released on June 17, 2011 and finalized on Dec. 17, 2012. To say it has been quite a process would be an understatement!

I noticed, too, that this retrospective listing parallels my own 40 year career and involvement with sunscreens. Today, I am

privately taking stock of my own achievements and contributions. Some of those years, for me personally, were filled with both upheaval and accomplishments, much like the journey of the sunscreen regulations in the US. My work, like the Final Monograph, is not done nor near completion, but as with all scientific endeavors, perhaps it never will be. Stay tuned to see what the New Year will bring! ●

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