

# IS THE FINAL MONOGRAPH THE NEW METRIC SYSTEM?

SEE YOU IN SEPTEMBER! The hopeful song plays on... But September has come and gone and neither the Final Monograph nor the Time and Extent Application (TEA) for sorely

needed UVA filters in the U.S. has been issued or finalized. How long will we wait?

Our current predicament conjures images of another time in this country's history when resistance and delay stunted progress indefinitely.

The U.S. Metric Act of 1866, a resolution introduced by Congressman John Kesson of Iowa, stated, "It shall be lawful throughout the United States of America to employ the weights and measures of the metric system."

This standardization

A mere 150 years have elapsed since Congressman Kesson's proposal and still, the U.S. has not joined the rest of the world in adopting the metric system. The decision has left us encumbered and out-of-step with the international community. I hope the same fate won't befall the U.S. Sunscreen Final Monograph.

We must remember that it is possible for a prolonged delay to extend ad infinitum. Remember George Santayana's Law of Repetitive Consequences, "Those who cannot remember the past are condemned to repeat it."

Sure, Congress has other major issues to deal with; I am aware that FDA Commissioner Dr. Marjorie Hamburg has her hands full with pressing food and drug concerns. Of course, it goes without saying that the issues of the Sunscreen Monograph are complex and awkward to condense into one final regulation—but this is no way to live! The lack of regulations is a serious matter that is destabilizing commerce. It undermines the livelihoods of individuals and companies in this business and directly impacts the health and lives of U.S. consumers. A lack of regulation breeds uncertainty and invites criticism.

Each year, there are 1.5 million new cases of skin cancer in the U.S.; 60,000 die from this disease, coinciding with weekly reports on the impact of sunscreens on individuals or the environment. Still, products are appearing in the U.S. that are not in compliance with one or more aspect of our old regulations, current regulations, proposed regulations or even new and final ones!

A glimmer of hope appeared on the horizon two months ago when an FDA spokesperson declared that the Sunscreen Monograph and the TEA

regulations would definitely be issued in September 2009. In fact, it seemed possible that the announcement would be made on Sept. 10, when a panel of experts in sunscreen science (Dr. Robert Sayre, Dr. Curtis Cole, David Steinberg, John Staton, Joe Stanfield, Mike Brown, Uli Osterwalder, Dennis Lott and myself) would join FDA's Matt Holmann at the Florida Chapter of the Society of Cosmetic Chemists to debate issues relating to testing protocols and provide him with a podium for his announcement. After 31 years of waiting, the Final Monograph was going to be law and we, the people, would finally have peace and order in sunscreen land.

## FDA Remains Silent

Instead, we heard very little from Mr. Holmann during the panel discussion and when asked about the day the regulation would be announced, his answer was clearly sometime before the end of September. Legally, he informed us, he could not make the announcement at the Sunscreen Symposium. But what better platform deserved this honor? After the last 25 years of pioneering involvement in sunscreens, the Florida Sunscreen Symposium seemed like the perfect place to me. Rather, we were told that it would be announced at the Federal Register and perhaps at the White House that month. With deflated hope we continued to wait.

September has come and gone 31 times since the proposed Sunscreen monograph in 1978 and if the metric system debacle is an indication, perhaps another 150 more years may pass before we have a new Sunscreen Monograph.

On the bright side, however, September was a month full of meetings offering insight into new devel-



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had been proposed in France in 1791 and championed later by none other than Napoleon Bonaparte. It is practiced today in most countries.

opments in sunscreens. During the HBA Global Expo in September, a lively debate ensued during a panel discussion with representatives from Intelligent Nutrients, Burt's Bees, Weleda and Revolution Organics about so-called "natural" sunscreens. It was pointed out that the FDA still does not allow the claim of sunscreens as "natural" since no Category I UV approved filters are classified as natural. The debate illustrated how a lack of regulations leads to unnecessary industry confusion and stunts achievable progress.

The Florida Sunscreen Symposium was attended by more than 300 top scientists and marketers in the sunscreen industry. Although there was no announcement regarding the Final Monograph, there were some exceptional speakers, most notably Craig Bonda of Hallstar, who gave a half-day course on sunscreen photostability. He was followed by a UVA mini-conference chaired by Christine Mendrock-Edinger of DSM. Speakers included John Staton (Dermatest), Julian Hewitt (Croda), Mike Brown (Boots) and Dr. Hani Fares (ISP). On subsequent days, Dr. Steven Wang, director of Dermatology and Dermatologic Surgery at Memorial Sloan-Kettering Cancer Center, Basking Ridge, NJ, spoke very eloquently on "Behavioral Patterns of US Consumers Regarding Sun Protection." Also, Dr. Karen Burke from the Mt. Sinai Medical Center Dermatology department spoke on a lively topic, "Sunscreens May Not Be Enough." (For more on the meeting, see the October issue of HAPPI.)

Once again, the Florida Chapter of the SCC put together an exceptional symposium that allowed for the free exchange of ideas.<sup>1</sup>

## A Vital Information Exchange

During the meeting in Florida a plea was made to reach out to environmental organizations and other concerned NGOs to include them in the current dialogue concerning the testing, safety, efficacy and regulations of sunscreen products. Any exchange of information between these consumer groups and the sun care industry can only lead to a better-informed public.

Dr. Steve Wang and I met in New York to see what can be accomplished on that issue. As a dermatologist and a surgeon, Dr.



Steve Wang

Wang has a ring-side seat to the tangible damage of excessive sun exposure. He has written extensively on a number of topics in sunscreens<sup>2</sup> and has made timely and insightful comments on excessively high SPF products that have proliferated the market recently. Excerpts from his article are provided below:

## Avoid High SPFs

"So, what is the harm in having products with very high SPF values? Three answers come to mind. First, a product with a very high SPF value may result in unbalanced, non-uniform UV protection, providing high UVB but low UVA protection. Ideally, sunscreens should reduce the magnitude of UVB and UVA transmission equally, as do other photoprotection strategies, such as wearing hats and clothing and seeking shade. A second reason to eschew ultra-high SPF values is that they reinforce misprioritized photoprotective behavior. Most public health organizations issue their photoprotection directives in the following order: sun avoidance, seeking shade, wearing clothing and hats, and last, using sunscreen. However, the public tends to reverse this, using sunscreen first, then thinking about wearing sun-protective clothing, sunglasses, and hats, with shade-seeking and sun avoidance bringing up the rear. In fact, many people use sunscreen as their only sun protection strategy at outdoors. The availability of high SPF sunscreen may push people even further in this direction. It may create a false sense of security, prompting some to stay out in the sun longer. The truth is, high-SPF products can delay sunburn, but there is strong evidence showing that DNA and other cellular damage can take place with sub-erythral doses of UV exposure. A third rationale

against very high-SPF sunscreens is that introduction of innovative sun protection products to the market may be delayed as long as the industry continues to concentrate on SPF values. If SPFs are capped at 50+ as suggested in the FDA's proposed final monograph, companies must rely on other strategies to distinguish their products from those of their competitors. The shift in focus might drive product improvements, such as more balanced UVA and UVB protection and enhanced photostability. Resources could be devoted to developing new formulations that are less oily or greasy, thereby increasing user compliance. And just maybe, limiting SPF values might turn research in new directions, catalyzing efforts to provide DNA and cellular repair functions in sunscreen rather than just UV protection."<sup>3</sup>

In conclusion, there clearly seem to be some "legal" issues that need to be addressed prior to the issuance of the Final Monograph by the FDA. I am not underestimating the pressure the FDA is under to finalize regulations, but the current situation is intolerable. What do we advise our constituents to do in the meantime? Many unresolved questions remain: Is an SPF over 30+ allowed? Can we use the combinations of zinc oxide with avobenzone? What about quenchers or natural sunscreen claims? Will we label our products with photostability ratings? Should we label our products with UVA stars? We can only answer these pressing questions with another urgent question: If not September, then when? Maybe this month or next or...?!? Stay tuned. ●

## References

1. A flash drive with all of the proceedings of the meeting is available for \$15. More info: [www.flsc.org/sunscreensymposium.html](http://www.flsc.org/sunscreensymposium.html).
2. Wang SQ, Stanfield JW, Osterwalder U. In vitro assessments of UVA protection by popular sunscreens available in the United States. *J Am Acad Dermatol* 2008; 59:934-42.
3. For the full article, contact Dr. Steven Wang at [sqwang01@yahoo.com](mailto:sqwang01@yahoo.com) or email me, [alphanrd@aol.com](mailto:alphanrd@aol.com).