

R&D EFFORTS MOVE ALONG EVEN AS REGULATORS STALL

I AM GETTING TIRED of reporting on the developments—more accurately, the lack of developments—on sunscreen regulations in the US! The snail-paced movement toward final regulations is only contributing to the lack of reporting on the progress for superior safety protocols and products to protect the consumer from the ravaging rays of the sunlight. The House of Representatives and the Senate are still debating legislation to reform the US Food and Drug Administration's Over-The-Counter (OTC) monograph process. On Jan. 16, 2018, the House released its draft of the OTC reform legislation and to date neither the House nor the Senate have completed their deliberations. On Feb. 21, 2018, the Public Access to Sunscreens (PASS) coalition visited the offices of several House and Senate members on Capitol Hill. The meetings are always encouraging and informative but, unfortunately, finalization of this reform bill is still a long way off. More importantly, the way this bill is written, it will not have a major impact on sunscreen legislation. The call for superior sunscreen filters and, in particular, the call

for finalizing the sunscreen monograph, is so vague and nebulous that we will not be any closer to a Final Monograph than we have been for the past three dozen years!

Focusing on regulations, especially since Congress has re-entered this arena of presumably regulating the FDA's role in finalizing sunscreens, has distracted me from the recent developments in the field of protection and sunscreen research. Several recent articles address various aspects of this topic. Research on producing sunscreens from marine algae that I reported on in past columns seems to have sparked more interest in several laboratories worldwide. A recent study from the University of Florida published in the American Chemical Society Synthetic Biology magazine, reports on a bio-degradable sunscreen compound called Shinorine that is produced naturally by cyanobacteria and marine algae.¹

These researchers devised a reliable source of Shinorine by bringing production out of the wild and into the laboratory. They selected a strain of fresh water cyanobacteria, *Synethocystis*, as a host cell for shinorine expression because it grows quickly and it is easy for scientists to alter its genes. Next, they mined the cluster of genes responsible for the synthesis from a native producer, the filamentous cyanobacterium *Fischerella*. Researchers then inserted these genes into *Synethocystis*. Finally, the team exposed control cells and those expressing Shinorine to UV radiation. No growth differences were observed with UVA light. But control cells experienced an obvious decline in population from UVB exposure. The researchers say that in the other cells Shinorine acted as a sunscreen against UVB light, which helped the cells live and grow better.

A number of reports surfaced on the effect of blue light emanating from our cell phones, tablets and computer devices. This High Energy Visible Light (HEV) accelerates

the oxidation process, which elicits inflammation and damages the skin barrier.² HEV makes skin more prone to signs of aging such as wrinkles, fine lines, uneven skin tone and pigmentation. Sunscreens tinted with iron oxides, zinc oxides and antioxidants create barriers against pollutants and low energy radiation. A Harvard study compared the effects of 6.5 hours of exposure to blue light vs green light and found that the blue light suppressed melatonin for about twice as long as the green light and shifted circadian rhythms by twice as much (3 hours vs 1.5 hours). As a result, Harvard researchers made recommendations on better light sources for many of our gadgets.³

The Wild Blue Yonder

In a previous column, I reported on a study published by the Journal of the American Medical Association of Dermatology (JAMA) that airline pilots were more at risk from sunlight damage in the cockpit while flying in high altitudes.⁴ Recently, the British Association of Dermatologists (BAD) reported that even passengers sitting in window seats are exposed to more UVA rays in high altitudes close to the ozone layer.⁵ The exposure to radiation was compared to a tanning bed session and the authors recommended the use of sunscreens for air travelers. Pulling down the window shades during intense sun-exposure would be prudent too!

A recent paper published in SOFW Journal discusses advanced light protection with titanium dioxide.⁶ The additional performance of UV filter grade TiO₂ in High Energy Visible light (HEV) and IR-A light was investigated by photometric in-vivo measurements on different substrates. The paper provided information on types of TiO₂ that are suitable for optimizing sunscreen cosmetic formulations and providing advanced light protection in the HEV and IRA ranges. On the topic of TiO₂ safety, the Scientific Committee on



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Consumer Safety (SCCS) of the European commission published its opinion on TiO₂ (nanoform) as a UV filter in sprays.⁷ SCCS concluded that the inclusion of nanoparticle TiO₂ in sprayable sunscreen products could potentially be unsafe due to “insufficient information” provided by the industry to allow proper safety assessment tests.

I am not sure why Australian scientists seem to lead the way on reducing melanoma rates with regular sunscreen use. The work by Professor Adele Green and her associates was clearly demonstrated in my previous columns. A current review by Robyn Lucas from the Australian Natural University published in SOFW Journal addresses the protocols for minimizing the dangers of sun exposure.⁸ Recently, a study by QIMR Berghofer Medical Research Institute in Australia found that regular use of sunscreens reduced melanoma rates by a third (34%). The study by Professor David Whitman and his colleagues, published



The regular use of sunscreen would dramatically reduce incidence of melanoma in the US.

in the British Journal of Dermatology, determined that since UV radiation from sunlight is the main environmental cause of melanoma, the use of broad spectrum sunscreen provides protection from the sun's harmful rays and, if applied daily, can significantly reduce the risk of developing melanoma.⁹ The study also predicted the impact of regular sunscreen use by the Caucasian population of the US would lead to 796,872 fewer cases of melanoma!

Measuring UV

Two recent studies developed new protocols for the analysis of ultraviolet filters and their metabolites. A study by Dr. Abdel Ghany from Ain Shams University in Egypt developed a sensitive synchronous spectrofluorimetric study of UV filters using fluorescence enhancers in cosmeceutical formulations.¹⁰ The procedure was successful in the simultaneous determination of octinoxate, avobenzene, octyltri-azone and phenyl benzimidazole sulfonic acid in moisturizing sunscreen lotion utilizing β -CD as a fluorescence enhancer. Also, the determination of avobenzene, homosalate, Tinosorb M and phenyl benzimidazole sulfonic acid in the presence of octocrylene in whitening sunscreen cream, using micellar medium of sodium dodecyl sulfate to enhance fluorescence intensity, was accomplished. The proposed methods were validated according to ICH guidelines and successfully applied

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to determine sunscreens in both pure form and in cosmeceutical formulations.

A method determining exposure to sunscreen ingredients by German scientists, led by Daniel Bury at Ruhr University in Germany, was recently published.¹¹ The German Federal Ministry for the Environment had identified octocrylene as a substance for which exposure

levels needed to be determined.

Bury and his colleagues used turbulent flow chromatography (TFC), liquid chromatography (LC) and mass spectrometry (MS) for their analysis. They found that they could detect the three octocrylene metabolites in the urine at sub-microgram per liter concentrations.

Finally, would you try sunscreen

pills? According to Kalpesh Gawade, director of Skinovation, this product has been launched in India. Gawade explains that Heliocare oral has been extensively tested and researched for safety and efficacy.¹² He cites 12 years of research and clinical investigations conducted in conjunction with the Harvard Medical School and leading experts in the field of sun protection.

Until testing with and without the use of the pills demonstrates clearly a multi-fold sun protection factor (SPF), I presume the overburdened FDA will not be inclined to sanction their use as effective protocols for sun protection.

It is liberating to be able to write a column focusing on sunscreen research developments rather than dwelling on the snail-paced regulatory developments with the FDA and Congress in the US! •

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