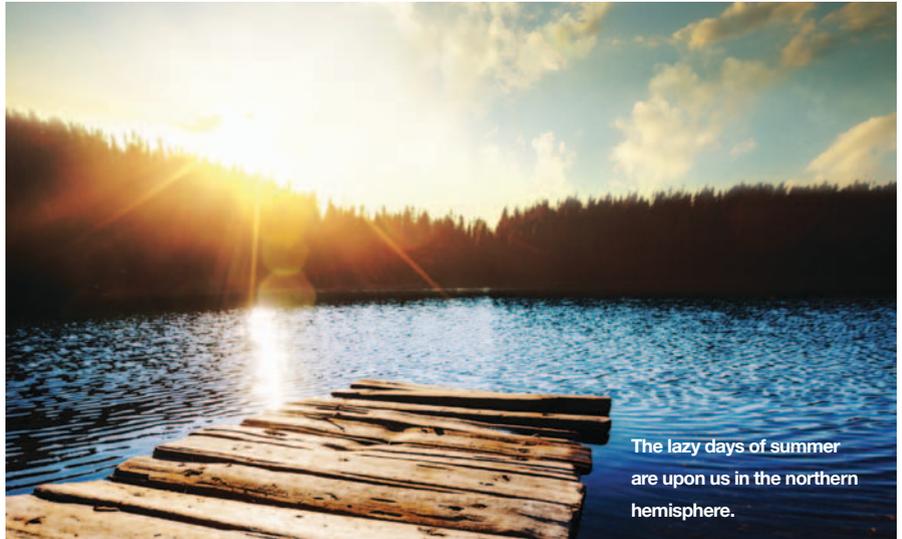


WE'RE RIGHT IN THE MIDDLE OF A BUSY SUNSCREEN SEASON

MUCH of the country endured record-setting cold this past winter and rain this spring. No wonder, then, that many consumers will try to spend as much time outside as possible this summer, which unofficially began in May in the US. May, which also happens to be the busiest month of the year for sunscreen sales, has been designated as Skin Cancer Awareness Month and Melanoma Monday fell on May 6 this year. On that day, clinics and detection centers are set up around the country to screen individuals for early signs of skin cancers and melanomas.

May is also the month that *Consumer Reports* issues its annual survey of best sunscreens on the market and the Environmental Working Group (EWG) publishes its annual report on sunscreens. *Consumer Reports* revealed that price does not mean quality and that some products on the market do not meet the SPF claims on the bottle. The group tested 12 broad-spectrum sunscreens and found that some of the least expensive brands, including Target's Up and Up and Walmart's Equate, were the most effective. Pricier



The lazy days of summer are upon us in the northern hemisphere.

sunscreens that fell short included All Terrain Aquasport SPF 30 and Badger Unscented SPF 34, which did not live up to the SPF on their labels.¹ The EWG issued its 2013 Guide on 1,467 Sunscreens in May with conclusions that were quite similar to their 2012 Guide!²

On June 3, in a publication in the *Annals of Internal Medicine*, Dr. Adele Green from the University of Queensland in Brisbane, Australia, published her results on 900 Australians who applied a daily dollop of sunscreen (SPF 15+). They had fewer wrinkles on their skin than those who did not use sunscreens daily. This is an extremely important study since you can now claim that sunscreens are the only true anti-aging ingredient on the market today.³ Dr. Green had reported earlier in 2011 in the *Journal of Clinical Oncology* that melanoma in adults might be preventable with the regular use of sunscreens.⁴ I trust that credible studies like these will dispel any rumors or myths concerning the effectiveness of sunscreen use!

Also in June, a series of developments took place on Capitol Hill and within the Food and Drug Administration. A number of meetings have been held in Congress with the Public Access to Sunscreens (PASS) Coalition members that included staff members from dozens of Senators and House Representatives.

In fact, on May 21 the PASS Coalition members met with the staffers of Senators Hatch (R-UT), Casey (D-PA), Pryor (D-AR), Shelby (R-AL) and Representatives Latta (R-OH/5), Blackburn (R-TN/7), DeGette (D-CO/1) and Dingell (D-MI/12). Representative Sam Farr (D-CA), ranking Democrat on the House Appropriations Subcommittee that funds the FDA, raised the need for the FDA to approve pending sunscreen applications directly with the FDA Commissioner Margaret Hamburg.⁵ Commissioner Hamburg responded by stating that approving TEA sunscreen applications was a priority, but she did not have an update regarding what the FDA was doing to resolve the issue. In the May 27 issue of *The Wall Street Journal*, entitled "European Sunscreen Roadblock on US Beaches" supported the PASS Coalition's efforts to pressure the FDA into releasing the eight TEA applications to the public.⁶ On June 2, Senator Chuck Schumer (D-NY) urged FDA to approve more effective sunscreens by making TEA ingredients available.⁷

Dr. Robert Sayre's Citizen Petition to the FDA requesting the Commissioner to formally withdraw approval of the anti-inflammatory sunscreen ingredients dioxybenzone, oxybenzone, trolamine salicylate, homosalate and octisalate has drawn considerable



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interest in the industry.⁸ This will surely be a topic of discussion at the Florida Sunscreen Symposium in September⁹ especially since it is rumored that Dr. Sayre and Dr. Reynold Tan from the FDA may attend the meeting. I have received a number of interesting comments on the petition from my colleagues Dr. Curtis Cole (J&J), Dr. Olga Dueva-Koganov (Akzo Nobel) and others.

Cole cited several arguments against the “anti-inflammatory” hypothesis including that in-vitro SPF is not always lower than in-vivo, and it is totally invalidated and unreliable to predict SPF. He further suggested that the model used by Couteau et al,¹⁰ that Sayre relies upon, is immune modulated inflammation—not a UV prostaglandin and leucotriene modulated inflammation, which is very difficult to suppress. He also pointed out that Sayre assumes the salicylates are penetrating 100%, which they do not, and also that the sunscreens work best when on the surface of the skin.

Dueva-Koganov contends that Sayre’s patent references are not directly applicable for the support of his petition. One contains data from the experimental inflammation models that do not involve UV irradiation; another uses a “treatment” approach on rabbits, which differs from the “prevention” model used in SPF in-vivo testing, when sunscreen is applied before irradiation and UV-induced erythema response is determined 24 hours post irradiation. Dueva-Koganov also contended that the animal experimental model used by Couteau et al is chemically induced edema and does not involve UV irradiation. She voiced her concerns regarding the possibility of the transdermal delivery of sunscreen actives. Personally, I have decided to do a series of tests that will shed light on Sayre’s claims and any recent counter claims. Hopefully, these results will be ready to present at the Florida Sunscreen Symposium in September 2013.

On the subject of zinc oxide approval in Europe, the Scientific Committee on Consumer Safety (SCCS) of the EU published an opinion (COLIPA 576) on zinc oxide (nanoform) on Sept. 18, 2012.¹¹ The SCCS study addressed the following question: Does the SCCS consider zinc oxide in its nano-form safe for use as a UV filter with

a concentration up to 25% in cosmetic products taking into account the scientific data provided? Their conclusion was that “there is no evidence for the absorption of ZnO nanoparticles through skin and via the oral route. Even if there was any dermal and/or absorption of ZnO nanoparticles, continuous dissolution of zinc ions would lead to complete solubilization of the particles in the biological environment.”

Hopefully, we will hear a positive response soon for including ZnO on the approved list of ingredients in Europe. For the record, I had reported in my October 2012 column on the controversy surrounding the Australian manufacturer Antaria, makers of Zinclair IM non-nanoparticle dispersion.¹² Dow, distributor of the product, has declared recently that Zinclair contains a measurable population of nanoparticles.¹³ Considering the positive conclusions arrived at by the SCCS on nanoparticles, this issue of nanoparticles in sunscreens would not be a major factor in determining ingredients for sunscreens.

New FDA rules on sunscreen labeling are now in effect. Products with SPF 15 or lower must have a warning that states it will not protect users against skin cancer. All products using the label “broad spectrum protection” must protect against UVA and UVB rays and must have passed the critical wavelength of >370nm. Products can no longer use the terms “waterproof” or “sweat-proof.” Instead, they must be characterized as “water-resistant” stating the number of minutes as 40 or 80. Terms such as “sun-block” or offers “instant protection” are no longer allowed. Re-application every two hours is also required. More importantly, June 17, 2013 is the final date by which testing of OTC sunscreen products must comply with the SPF testing requirements described 21 CFR 201.327(i) that were published on June 17, 2011.

With exciting developments like Dr. Green’s remarkable study in Australia and



sun safety awareness by the general public, it is enticing to overlook the negatives concerning compliance and other controversies in the industry; but that is hardly possible. The industry is experiencing growing pains and we must throw our energy behind efforts to relieve these pains. There are so many contributors to this project: citizens and politicians, scientists and business people; it is exciting to be a part of a vital, growing industry. Here’s wishing us more busy months. •

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