By Rada K. Tierney

The way we choose and use sunscreen is about to change dramatically. For more than 30 years, consumers have been able to identify a sunscreen’s level of ultraviolet B (UVB) protection using SPF (sun protection factor) values. When finalized, the new U.S. Food and Drug Administration’s proposed sunscreen monograph will amend the agency’s 1999 final rule on sunscreen products and incorporate new testing and labeling requirements for products that protect against ultraviolet A (UVA) rays. Simultaneously, scientists are finding new protective ingredients and better formulations that could mean not only fewer skin cancers but less photoaging.
Sunscreen is an advanced sunblock formulated by a physician. It combines silica-coated, micronized zinc and powerful antioxidants to protect the skin without irritation. 877.777.2305, osmosisskincare.com

Kinerase Daily Defense Lotion SPF 30 includes Kinetin, the proprietary ingredient in Kinerase skincare products, and a photosensitized combination of UVA and UVB absorbers in a luxurious moisturizer. Avobenzone, homomentyl salicylate, octocrylene, oxybenzone, hexyl salicilate, octinoxate, oxybenzone. 800.321.4576, kinerase.com

Mesoestetic Dermatological Complete Sunscreen SPF 50 not only protects against UVB but carries the FDA’s four-star rating, the highest UVA protection available on the market today. A combination of organic ingredients that absorb UV radiation and titanium dioxide is encapsulated in micro pearls to prevent the occlusive effects on skin pores produced by liposoluble organic filters. 888.498.3842, mesoestheticusa.com

G.M. Collin Mineral Sun Veil offers complete protection against sunburn and skin damage in a refreshing, hydrating lotion. Zinc oxide, cyclopentasiloxane and antioxidants. 800.341.1531, gmcollin.com

The proposed changes to the FDA sunscreen monograph require that the primary display panel include dual ratings for UVA and UVB protection. SPF is revised to mean “sunburn protection factor” instead of “sun protection factor” and products are labeled as providing low (2-14 SPF), medium (15-29 SPF), high (30-50 SPF) or highest (50+ SPF) results. Values higher than SPF 50 cannot be substantiated with current testing methods.

Near the UVB SPF rating, labels will include an easy-to-understand, four-star UVA rating system: low (one star), medium (two stars), high (three stars) or highest (four stars). Sunscreen products found to provide no UVA protection will state “No UVA Protection” near the SPF value. The UVA rating will be determined by using a combination of two tests: an in vitro spectro-photometric test to determine a sunscreen’s ability to reduce the amount of UVA light that passes through it, and an in vivo clinical test to determine a sunscreen’s ability to prevent tanning. The results will be combined to generate a single UVA rating, which will be the lower of the two values.

Other proposed changes include:
- The term “waterproof” is revised to “water resistant” and “very water resistant” since no sunscreen is completely waterproof. Additional in vivo testing is mandated to determine whether a water-resistant product can remain effective after 40 minutes of water immersion, and whether a very water-resistant product can remain effective after 80 minutes of water immersion.
- Manufacturers are required to print the following warning statement in the drug facts box on all over-the-counter sunscreens, except lip protection products: UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing and using a sunscreen.
- Sunscreen product labels will instruct consumers to apply sunscreens “liberally” or “generously” and to reapply frequently, at least every two hours, “to avoid lowering protection.”
- The rule will allow manufacturers to formulate their products with avobenzone in combination with either zinc oxide or ensulizole.

Of course, as of press time the finalized monograph had not been released and some industry insiders are hoping for some changes. Bill Kling, CEO of Swiss-American Products, makers of Elta and EltaMD skin and wound care products, believes connecting UBV and UVA in the proposed ratio penalizes effective UVA ingredients. “In other words, a product with an SPF of 15 can get a high star rating on UVA coverage much more easily than a product with an SPF of 40. This can be misleading to the consumer, since the SPF 40 product could easily be protecting at a higher level in the UVA range as well,” he explains.

Because of the potential risk of nanoparticle ingredients penetrating consumers’ skin, the FDA is soliciting public comment on the safety and effectiveness of sunscreen ingredients formulated in particle sizes as small as a few nanometers. J.F. Nash, PhD, principal scientist at Procter & Gamble (P&G) Beauty, has no concerns about nanotechnology in sunscreen formulations. “Human safety testing of micronized zinc oxide and titanium dioxide has proven them to be safe,” says Nash. “The reported nanotechnology is exemplary of these ingredients.” While John Kulesza, president of Young Pharmaceuticals, doesn’t dispute the safety record of nanoparticles,
he does believe that with sunscreens, bigger may be better. “It may be better when using inorganic sunscreens to use larger particles to properly reflect UV rays away from the body.” These significant proposed changes come as the result of a growing body of scientific evidence that UVA exposure is as damaging to the skin as UVB exposure. Although scientists have long recognized that UVA penetrates the skin more deeply than UVB, they believed DNA absorbed less of it, triggering fewer harmful mutations. A joint U.S./Australian study revealed that UVA actually causes more DNA damage than UVB in cells where most skin cancers originate—keratinocytes in the basal layer of the epidermis. UVB, on the other hand, incites damage in more superficial epidermal layers. Dermatologist Carl Thornfeldt, MD, president and chief scientific officer of Episciences, believes that introducing more stringent labeling guidelines will give consumers better skin protection tools. “This information is supposed to allow the consumer to select more protective products, especially against UVA. This spectrum accounts for most of the visible changes of extrinsic skin aging and photoaging,” explains Dr. Thornfeldt.

Seeking Better Actives
These long-awaited FDA advances open the door to an increasing variety of sunscreens. Currently, only 17 active ingredients are FDA-approved for sunscreen use in the U.S., placing us far behind Europe (with 29 approved ingredients), Australia (26) and Canada (21).

In the United States ingredients are divided into two classes: organic chemical ingredients that absorb UV radiation before it can penetrate the skin and inorganic physical ingredients (formerly called sunblocks) that scatter and reflect UV radiation. Most of these ingredients only protect against UVB radiation. “These filters have a wide range of UV absorbance profiles,” says P&G’s Nash. “Avobenzone and zinc oxide are the only long-wavelength UVA filters available.”

While seven UV filters listed in the U.S. monograph state that they actively screen UVA rays, closer examination reveals that some of these ingredients, such as sulisobenzone and dioxybenzone, are rarely used because they do not work well in solutions. Other chemical ingredients—oxybenzone and methyl anthranilate, for example—provide only partial broad-spectrum UVA protection. While the chemical avobenzone (Parsol 1789) does provide broad-spectrum UVA protection, it quickly loses potency when exposed to UV radiation unless it is combined with a photostabilizing ingredient. Both physical sunscreen ingredients, titanium dioxide and zinc oxide, provide excellent UVA and UVB protection, and are often blended with their chemical counterparts to create cosmetically elegant formulations that are easy to apply, feel good on the skin and provide broad-spectrum protection.

Ecamule (Mexoryl), approved by the FDA in July 2006, is the most recent addition to the list of sunscreen ingredients. This short-wavelength UVA absorber has been a popular photostabilizer in European sunscreens for years, allowing fragile ingredients like avobenzone to go from losing potency within 20 minutes of sun exposure to providing UVA protection for up to three hours. Nash adds that more UV filters are on the horizon, including Bemotrizinol (Tinosorb), which has been available in Europe since 2000. This highly photostable broad-spectrum UV filter is effective on its own or as a stabilizer for other more photosensitive ingredients.
UV antioxidant benefits of PhytoMelanin.

PhytoMelanin offers broad-spectrum Daily Face Protectant SPF 30 with Jan Marini Skin Research.

LUCA Solar Protection is the only U.S. sunscreen with its critical wavelength value (an internationally recognized UVA rating system) printed on the label. It effectively shields the skin from UVB and UVA for up to six hours. Avobenzone and a Polycrylene booster. 866.377.5822, lucasunscreen.com

SkinCeuticals Active UV Defense SPF 15 is sweat and water resistant, and offers powerful, everyday protection from both UVA and UVB rays. Mesoryl SX, avobenzone, octocrylene. 800.811.1660, skinceuticals.com

The search for new sunscreen ingredients has uncovered a promising class of botanical-based photoprotective actives that complement classical sunscreens by strengthening the skin’s immune response to photodamage and reversing residual damage from previous UV exposure.

Carotenoids are antioxidants present in a variety of plants and are particularly abundant in the micro algae Dunaliella. Two carotenoids, phytoene and phytofluene, were originally marketed by Israeli Biotechnology Research as antiaging ingredients. Now the company is promoting its patented technology for use in sunscreen products. In vitro studies revealed that phytoene absorbs light in the UVB range, and phytofluene in the UVA range. Both compounds have demonstrated protection against oxidative damage and inflammation, as well as the ability to inhibit melanin synthesis in skin exposed to UVA radiation.

Bran extracts, known as inositol and inositol hexaphosphate, protected both human skin cells and skin of cancer-prone mice from UVB radiation in a study conducted by scientists at the University of Maryland. Both inositols proved to be capable of preventing reactive molecules from injuring DNA. “These antioxidants have been shown to have broad-spectrum anti-tumor capabilities, and now our studies confirm the degree to which these molecules protect against the DNA damaging effects of ionizing radiation,” said Abulkalam M. Shamsuddin, MD, professor of pathology at Johns Hopkins University, and his colleagues more than 15 years ago and has been shown to prevent tumor development in a number of animals treated with cancer-causing chemicals. Talalay’s research emphasizes that the bran extract is not a sunscreen. Instead of absorbing UVR, it works inside skin cells, boosting production of enzymes that protect against UVR. Its effect lasts for several days, even after the extract has vanished from the skin surface.

Coffee seems to be creating the biggest buzz in sunscreen research. Scientists at the University of Washington and Rutgers University are working jointly to study the effects of topical caffeine on UV exposure. In one study, caffeine and caffeine sodium benzoate applied to mouse skin after UV exposure resulted in a significant decrease in UV-induced roughness and wrinkles,
Remergent High Intensity DNA Repair + SPF 30 harnesses the best of two worlds: DNA repair technology and broad-spectrum sunscreen protection. Photosomes, ultra- somes, vitamins C and E, and micronized titanium dioxide and zinc oxide. AGI Derma- tics, 800.590.4244, remergentskin.com

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hexyl salicylate, oxybenzone and Octyl methoxycinnamate, ethyl-

oligopeptide) to fight wrinkles. Anti-Aging Complex (palmitoyl-

mula. It also includes Dermaxyl protective and moisturizing for

mour acts as a broad-spectrum Dermelect

SunWear offers yolomïd, a line of sunwear made with microfiber nylon and spandex treated with a proprietary pigment system that selectively transmits solar radiation. The fabric enhances light useful to the skin while protecting it from damaging rays. 866.414.7685, sunsoul.com

SunSoul therapeutic SunWear offers yolomïd, a line of sunwear made with microfiber nylon and spandex treated with a proprietary pigment system that selectively transmits solar radiation. The fabric enhances light useful to the skin while protecting it from damaging rays. 866.414.7685, sunsoul.com

Dermelect SPF 20 Facial Ar- mor acts as a broad-spectrum protective and moisturizing formula. It also includes Dermaxyl Anti-Aging Complex (palmitoyl oligopeptide) to fight wrinkles. Octyl methoxycinnamate, ethyl- hexyl salicylate, oxybenzone and titanium dioxide. 888.693.3763, dermelect.com

Surya Sunblock SPF-35 from Hale Cosmeceuticals protects and increases secretion of hGH naturally. It may be applied as a daily moisturizer alone or under makeup and is water resistant. Ethylhexyl methoxycinnamate, o- tocylene, benzophenone-3, titanium dioxide, antioxi- dants. 800.951.7005, halecosmeceuticals.com

and promoted apoptosis of DNA-damaged cells, suggesting that caffeine has the power to reduce UV absorption in the skin and to inhibit the formation of UV-induced skin cancers. A separate animal study suggests that combining caffeine and exercise may further boost its cancer-fighting protection, but hu- man studies are needed to confirm these preliminary findings.

Consumers and Compliance The most effective, most advanced sunscreen formulations available are powerless if not used properly. To date, product labeling has failed to give consumers clear and concise guidelines on how much to apply and how often to deliver optimal protection. Formulation also directly affects compliance, according to Kling. Products that lack cosmetic elegance discourage consumers from maintaining adequate coverage. “If a product is too thick or leaves a sticky white residue on the skin, consumers will use too little of the product and may not spread it evenly across the skin. If the product is too thin, there is a danger it will be spread too far and again not provide adequate UV protection. The answer is to formulate in a way that delivers ‘play time’ on the skin where the product spreads easily but has enough resistance and absorption that an adequate amount stays put on each area of the skin to deliver the expected protection,” says Kling.

There is also an increasing awareness in the industry of how critical formulation is not only from the standpoint of cosmetic elegance, but also from the standpoint of sta- bility and safety. “For example,” says Kulesza, “there is a concern that some commonly used sunscreen ingredients, namely the organic ultraviolet absorbers, can penetrate into the epidermis and become free-radical generators, potentially causing cellular damage. This is why some manufacturers recommend reapplying their products every 15 to 20 minutes, so that a new layer of sunscreen is added to ‘protect’ the previous layer which is now inside the skin...basically a sunscreen for the sunscreen!”

While combination moisturizer and sunscreen products are popular with consumers because of the 2-in-1 convenience, sunscreen manufactur- ers worry about the false sense of security they offer. Often formularia- tors add sunscreen to moisturizers only as a marketing ploy, adds Kling. “Many combination products don’t start out thinking about maximizing sun protection, but have some other cosmetic objective first and then throw in an SPF for additional label claims. The focus is only on an SPF number with no UVA protection, and the nature of the formulation encourages the consumer to spread the product too far on the skin, minimizing true protection.”

The hope from skin health experts and the cosmetic industry is that the new proposed monograph and testing methods will shift the focus away from a simplistic SPF rating system and increase the importance of measuring UVA protection as well. The newer and more stringent labeling requirements will require sunscreen manufacturers to update their packaging and litera- ture and in some cases, downgrade their claims to comply with the elevated standards. Consumers will reap the biggest benefits as they come to understand the impact of UVA rays on photoaging and skin cancer and seek out sunscreens with the best protection.

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