Changes in Sun Protection Call for a New Column

In today's environment of rapid sunscreen developments, an information filter is sorely needed. This issue marks the first in a bimonthly column primed to filter through the latest news and views in sunscreens, ultraviolet filters and their regulations, considering both commercial and technical developments. In preparation for the writing, I debated possible titles for this endeavor. The staff in my office took great pleasure in suggesting snappy column titles such as "UV and Me," "UV View," "Sun Scream," "Made in the Shade," "Don't Get Burned," "Sun Thing to Talk About" and many others that are not fit to print! We also avoided simple but imprecise titles such as "Sunscreens" or "UV Filters." I settled on a title that reflects my strengths to filter information about the recent developments in sunscreens and UV filters. Let's get right to it:

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The sunscreen industry is in flux!

• The field has expanded in dramatic fashion. You have likely witnessed the explosive growth of the sunscreen industry from its infancy to one that will reach $7.6 billion worldwide by 2011 (Euromonitor International, Happi webinar, August 23, 2007). Formal regulations in the U.S. have set parameters for this growth. Market demands have fueled advances in the industry as people clamor for coverage and novel applications. Improvements in scientific and technical techniques have also directed the evolution of sunscreens. Until now, these factors have shaped the state-of-the industry, understanding their influence can help us predict future progress.

• This is an industry structured by formal regulatory changes. We observed the formation of the sunscreen OTC (Over-The-Counter) panel culminating in our first monograph, the Advanced Notice of Proposed Rulemaking (ANPRM) on August 25, 1978 (FedReg 43: 38206-269). We patiently waited through the delay and inaction of the FDA until May 21, 1999 when the Tentative Final Monograph (TFM) (FedReg 64: 27,666-693) was published. For almost 30 years, no new developments in UV filter technology were permitted in U.S. sun care aside from a few exceptions, namely, the approval of avobenzone on Sept. 16, 1996, zinc oxide on Oct. 22, 1998 and Mexoryl SX on July 24, 2006. Currently, we seem to be poised, at last, to see the Final Proposed Rules come to light (FedReg 49070-49182 on Aug. 27, 2007).

• From a commercial development perspective, the sun care industry has been transformed from its early beginnings evoking the iconic image of the Coppertone baby with her bare, untanned bottom and the "glistening bodies" of Hawaiian Tropic, to this multibillion dollar industry that increasingly provides daily wear protection, tanning and pre-tanners, after-sun products and even clothing with UV filter protection along side products for recreational use. The shift in the consumer consciousness about skin health has been met with innovation and variation.

From a technical perspective, ultraviolet filters have been transformed from low molecular weight, narrow band spectrum filters (predominantly PABA and its esters, cinnamates, benzophenones and salicylates) to filters designed according to the Dalton 500 rule with multiple chromophores offering both broad-spectrum as well as UVA and UVB protection. Extinction coefficients of UV filters have increased from 4000 to over 100,000. New, elegant and complex micronized forms of titanium and zinc oxides were introduced. Testing has improved dramatically with modified in-vivo and in-vitro procedures practiced. SPF boosters, quenchers of photo-unstable filters, antioxidants, anti-aging ingredients and other technical developments proliferated.

Issues to be Considered

In addition to the factors mentioned above, there are many issues that need addressing and we can do that here. Certain topics call for discussion within an open and unrestricted forum for the benefit of the scientist, the consumer and the profit maker, such as:

• Skin cancer's meteoric rise and the lack of a definitive biological and genetic mechanism about why sunlight over-exposure contributes to this cancer.

• Cosmetic formulations and filter innovations.

• In-vivo, in-vitro, photostability and other analytical testing procedures.

• Regulations, patentability and uniform registration of products worldwide.

• Investigating the new buzzwords including "broad spectrum," "UVA protection," "apply repeatedly," "practice safe-sun," " no tan is a safe-tan," to new issues surfacing such as "photostability," "photo reactivity," "endocrine disrupters," "nanotechnology," "triplet-triplet quenchers," "SPF boosters," "antioxidants," "anti-aging ingredients and claims," "bad press" and more.

The Final Monograph

For our first episode, let us begin to tackle an issue that is primarily of interest in the U.S., one that also has major ramifications worldwide and will undoubtedly have the most impact on the future of UV protection and the U.S. sun care industry: The Final Monograph!

On Aug. 27, 2007 The FDA published the Final Proposed Rules for sunscreens (www.fda.gov/OHRMS/Dockets/98fr/07-4131.pdf).

Here are some of the highlights:

1. Ingredients: The combination of avobenzone (up to 3%) with both zinc oxide (up to 25%) and ensulizole (up to 4%) is now allowed. The combination of avobenzone with titanium dioxide is still not permitted.

2. SPF: The SPF will now be an acronym for "Sunburn Protection Factor" (formerly Sun Protection Factor). It will be capped at 50+ as opposed to the current 30+. The SPF is solely described as "UVB." Adjustments were also made to the sunscreen SPF testing.

3. UVA Testing: The FDA has finally addressed UVA testing and labeling. Two methods were proposed: An in-vivo Persistent Pigment Darkening (PPD) test and an in-vitro test that is a modification of the Boots adaptation of the Diffey-Robson method. This method measures the ratio of UVA I to the total UV spectrum. The in-vitro method is a measure of the breadth of the absorbance while the in-vivo method is a measure of the magnitude (height) of the absorbance. The lower of the two results is recorded. The proposed in-vitro test stipulates the use of "roughened quartz" plates with application quantities of 2 mg/cm^2.

4. UVA labeling: Four stars awarded to the highest, three stars for high, two stars for medium, one star for low and no stars for the absence of UVA protection.

5. Indications: The current statement "helps prevent sunburn" will be amended to "low UVB sunburn protection," "medium," "high" and "highest UVB sunburn protection."

6. Warnings: On the drug fact box the following "Sun Alert" statement must appear on all OTC sunscreen drug products except for lip 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."

7. Directions: It is required that the manufacturers insert a new direction "apply and reapply as directed to avoid lowering protection."

8. Implementation: It is proposed that this Final Rule take effect 18 months after its date of publication. A 3-month comment period ending in November 26, 2007 was extended by one month to Dec. 26, 2007. Many requests have been received by the FDA for at least a 9-month extension to complete more tests and evaluations. No further extensions have been approved to date.

Other issues such as photostability, UVA water resistant testing, nanotechnology, sunscreens containing AHA's, the avoidance of terms such as "sunblock" and "waterproof," and economic impact have also been addressed.

Will industry be able to live with the final rules as stated?

Why the FM Needs Changes

The FDA is to be commended for its thorough review of all the issues pertaining to sunscreen regulations, but will we be able to live with the Proposed Final rules as stated? Without modifications, the real answer is probably not! Here are a few reasons:

1. The new proposed in-vitro test is not in harmony with internationally recognized in-vitro testing conditions. The Personal Care Products Council (formerly The Cosmetic, Toiletry and Fragrance Association), The American Academy of Dermatology, the Skin Cancer Foundation and other groups are calling for the alternative "Critical Wavelength" in-vitro determination. Outside the U.S., including the German Society for Scientific and Applied Cosmetics and the Japan Cosmetic Industry Association, and companies such as Procter & Gamble, Unilever and Ciba are suggesting only minor changes to the FDA's proposed protocol. The calculation method and the reading levels used to determine the labeling for UVA protection must be modified. Also more details regarding substrate, application amount and irradiation dose is required. It is quite difficult to achieve the in-vitro reading of 0.95 (four-star rating) in the U.S. except for the lowest of the SPF protection products. The use of the ratio

UVAI /UV may force manufacturers to lower the UVB protection of their products at the cost of designing increased UVA I (340-400nm) protection. Currently only large particle size titanium dioxide is capable of protection at the 380nm level.

2. The proposed labeling maybe confusing to the consumer. A consumer comprehension study to understand its impact would be advisable.

3. The 17 approved ingredients in the U.S. are woefully inadequate in addressing the multitude of issues for protecting the consumer. The alarming increase of skin cancer and the rise in negative consumer perception towards the use of suncare products for protection needs to be addressed. The first line of defense in any sunscreen product is its ultraviolet filter. Currently, there are six new European UV filters awaiting approval by the FDA through the Time and Extent Application (TEA) process. (For a review consult N. Shaath, "Encyclopedia of Ultraviolet Filters", Allured Publishing, March 2007). Also several more UV filters that are photostable and provide broad UVA/UVB spectrum protection, remain locked up in the research laboratories. More importantly, a faster, less expensive procedure to allow for approvals of innovations in the field of filters and suncare ingredients, other than the costly NDA (New Drug Application), is perhaps required to address this epidemic rise of skin cancers. Finally, the status of SPF boosters, photostabilizers and quenchers, as well as antioxidants and anti-aging ingredients in sun care formulations needs to be reviewed and clarified.

4. Other controversial issues that are in the Proposed Rules include the technically incorrect designation that sunburn protection factors (SPF) are attributed to the UVB rays solely. The UVA contributes significantly to the SPF and in fact no product with an SPF of about 10 can be increased without a UVA filter.

At a time when new regulations are being finalized, it is extremely important that we have an open forum to discuss these tough issues, address them head-on and find a consensus common ground that would primarily benefit the consumer. The terrifying increase in skin cancer despite the proliferation of available sunscreens prods us more urgently to resolve any delays. As the AAD recently stated "The American consumer has waited 29 years for this directive from the FDA, but skin cancer has not!"

I plan to present the different views on the Proposed Rules in my April column and would welcome your comments on this topic as well as your suggestions for future topics. Email me at alpharnd@aol.com