Things are Heating Up In the Sunscreen Category

Happy New Year! This issue marks the first anniversary of my column. The positive reactions I have received to *The Sunscreen Filter* attest to its timeliness; an informational filter is sorely needed to keep pace with rapid sunscreen developments. In recent years, the sunscreen industry has witnessed explosive growth, yet the U.S. continues to operate without final and definitive regulations. Unfortunately, our regulating institutions have remained stagnant and have not kept pace with the industry's growth.

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For example, what is the status of the Final Rules for Sunscreens as determined by the Food and Drug Administration? Despite many petitions, remarks, meetings and even action by attorneys general, congressmen and senators, we still do not have final regulations. Cosmetic companies are in a flux as they try to operate under the directives of The Tentative Final Monograph of May 21, 1999 and under the shadow of the Final Proposed Rules of Aug. 27, 2007.

Recent Events

Recently, concerned industry and government representatives met to discuss the problem. On Dec. 12, 2008, a meeting was held in Bethesda, MD at the campus of the National Institute of Health (NIH). It was organized by the Personal Care Product Council (The Council) and attended by representatives of the cosmetics industry, members of the American Academy of Dermatologists (AAD) and the FDA, including FDA Team Leader Matthew Holman. In his opening statement, Mr. Holman made it clear that the FDA is working diligently on the monograph but cannot give a date for the release of the Final Rule. Speakers from The Council reiterated the industry position submitted to the FDA a year ago. The two different industry positions on the UVA in-vitro method of testing were presented by Jean Grieve (Position A advocated by Johnson and Johnson, L'Oréal, Schering-Plough and others) and by J. Frank Nash (Position B advocated by Procter & Gamble, Unilever and Ciba).

UVA Method Discussed

At the meeting, it appeared as if the UVA method was the only controversial topic among the industry representatives. Position B supports the FDA's highest UVA classification with the "ideal flat spectrum" whereas Position A advocates the "critical wavelength" procedure and opposes a flat spectrum as the ideal, on the basis that UVB is more harmful than UVA. It seems that all the parties were satisfied with the fruitful exchange of opinions, and much of the earlier controversy was diffused. One lingering issue, the Time and Extent Application (TEA) for the seven ingredients that are awaiting approval as UV filters by the FDA, remains unresolved. Apparently, the five years that have passed weren't sufficient to make that determination, and their final status is still under consideration.

Citizen's Petition Filed

On Nov. 20, 2008, eight scientists and dermatologists, including Dr. Sandra Read from The Citizen's for Sun Protection and Catherine Ehrenberger from Ciba, filed a Citizens Petition to Commissioner Andrew von Eschenbach of the FDA requesting the Commissioner to do the following:

1. Prioritize this health issue as economically critical and act immediately.

2. Expedite the now stagnant review of sunscreen filters under the TEA Process.

3. Issue an Enforcement Action so that the State of the Science Broad-Spectrum UVB/UVA sunscreen actives can be incorporated into products for the U.S. population without further delay.

A panel of leading medical and consumer experts held a press conference at the National Press Club in Washington, D.C. on November 20, 2008 with a keynote address by Congresswoman Nita Lowey (D-NY, Westchester). Rep. Lowey, who had introduced "The Sunscreen Consumer Right-to-Know Act" in Congress last year, said in the video-taped press conference, "The FDA has been drag-

ging its feet on finalizing a rule that was initially proposed more than a year and a half ago and as a result is putting the health of every American in jeopardy. It is unacceptable." In her reference to the inadequate sunblock protection in the U.S., she added, "The only thing being blocked is the truth."

Deadlines Loom

Good luck to the FDA! It must act expeditiously to issue the Final Rule. Pending legislation in Congress by Senators Christopher Dodd (D-CT) and Jack Reed (D-RI) is demanding that the FDA finalize its sunscreen rules within 180 days. Lurking in the shadows is the recent Citizens Petition supported by Rep. Nita Lowey. Connecticut's Attorney General, Richard Blumenthal, has asked the FDA to act immediately to implement rules that would prevent misleading claims in sunscreen advertising and labeling. The Council's comments to the FDA a year ago, including the yet unresolved two industry positions on the UVA testing method, have not been fully addressed. The litigation in California filed against the five major sunscreen companies may need to be factored in by the FDA. Also to be considered is the unrest and dissatisfaction among the consumers in the USA who look to the FDA to insure their protection from the harmful ultraviolet rays by products that may or may not be in compliance. We need to be constantly reminded that every year over a million people in the U.S. are diagnosed with skin cancer, the most common form of cancer. More malignant melanomas are detected each year and one American dies every hour from melanoma. Ironically, skin cancer is largely preventable and can be reduced significantly by avoiding the sun during peak hours of the day and incorporating effective sunscreen use into one's daily routine. It is critical that consumers have the information they need to choose sunscreens that will adequately protect their skin.

During the New York Society of Cosmetic Chemists meeting December 11-12, 2008, 28 scientific papers were podium presented with only one presentation dealing with sunscreens (Dr. Zoe Draelos did, however, discuss melanogenesis—a related topic). That lone exception was an excellent presentation delivered by Dr. Olga Dueva-Koganov from Ciba Corporation entitled "Complying with New FDA Guidelines for In-vitro Evaluation of UVA Protection."

> **"The only thing being blocked is the truth."**
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> ***—U.S. Representative Nita Lowey (D-NY)***

Her procedure was in general compliance with the requirements published in the new FDA guidelines of August 2007. The main exception was the substitution of Vitro Skin N-19 in place of the roughened quartz plates recommended by the FDA procedure. Her rationale was that Vitro Skin works well with the application dose recommended by the FDA, and the spot-to-spot variability in the substrate's own transmittance is low.

Dr. Dueva-Koganov noted that there is no commercial source currently for "roughened" quartz plates with standardized roughness. The degree of roughness in the quartz plates is not specified by the FDA guidelines. Another minor exception was increasing the application time from the 10 seconds parameter recommended by the FDA protocol to 30 seconds. The lower application time, she argued, was not enough to achieve uniform distribution over the substrate on a relatively large application area, especially if the material to be tested contains particulates.

Using these optional test conditions, which closely follow the requirements published in the new FDA guidelines for the in-vitro evaluation of UVA ratings, Dr. Dueva-Koganov successfully evaluated several commercial and experimental sunscreen formulations. She demonstrated that it is possible to meet the highest UVA rating of four stars and a UVA1/UV ratio of over 0.95 by optimizing the composition of sunscreen actives and assuring the photostability of the product.

The Technology Showcase at the the annual meeting of the Society of Cosmetic Chemists featured 103 posters for new cosmetic ingredients and applications. Conspicuously missing were new and novel introductions of UV filters, boosters, quenchers and ingredients to enhance the performance of sunscreens. In fact, only five posters dealt with that subject, a mere 4.85% of all posters presented, unlike past meetings where sunscreen related posters generally represented at least 25% of those displayed. Is the lack of novel ingredients and original scientific presentations on sunscreens a sign of hesitation by scientists and suppliers, a fear of the unknown, or an omen of things to come?

Sunscreen Posters

The five posters included Ciba's two new UVA absorbers (Tinosorb S and M) and the FDA-UVA in-vitro protocol that Dr. Dueva-Koganov reported on; BASF's Ethyl Hexyl Triazone (a highly efficient UVB filter that is still awaiting FDA approval through the TEA process) and a skin penetration

study of both microfine TiO2 (T-Lite) and ZnO (Z-Cote) by Zaheera Hussein from BASF; and EMD's Oxynex ST liquid, an antioxidant that also assists in the photostability of avobenzone. None of the above ingredients are new developments in the sunscreen market. The two other posters dealt with non-nano-sized inorganic filters. Presumably the nanoparticle scare has induced suppliers of inorganic filters to focus on the increased particle size. Kobo Products, Inc. has developed a zinc oxide where all the primary particles are greater than 100nm. The other is Zinclear IM from Dow/Amerchol, a ZnO filter with an average particle size of >1 micron (1000 nm). Dow/Amerchol also introduced Sol Terra Boost, a new ingredient designed to increase the SPF performance of mineral filter systems. When this water dispersible powder is used at 2%, it presumably doubles the efficiency of ZnO-containing sunscreens, with minimal impact on the aesthetics and rheology. In all fairness, Sol Terra Boost was the only novel ingredient related to sunscreens that was introduced at the SCC meeting this year.

The Dangers of Salons

Originally, this month's column was going to focus on tanning booths and salons. This controversial practice has become a five billion dollar industry in the U.S., a five-fold increase since 1992. On an average day in the U.S., more than one million people "catch some rays" in tanning salons. Nearly 70% of the patrons are females between the ages of 16 and 29. According to recent statistics, 30 million people tan indoors annually!

The U.S. Department of Health and Human Services has declared UV radiation from the sun and artificial sources, such as tanning beds and sunlamps, as a known carcinogen (cancer-causing substance).

Advocates for tanning salons, on the other hand, argue that the more controlled exposure to UV light minimizes the dangers of tanning beds, which makes them safer than sun tanning. These advocates also point to the fact that the majority of Americans are Vitamin D deficient and would benefit from moderate and controlled UV exposure that is found in their tanning salons. In today's economy, consumers are even more sensitive about "getting burned," especially when it comes to spending their money on tanning. My next column, will present scientific research related to tanning booths and tanning beds and attempt to separate fact from fiction generated by bloggers on the internet. I welcome your comments on the use and misuse of tanning booths and salons.