A FORUM FOR SUNSCREEN DEBATING BETTER PROTECTION

Vital issues confronting the sun care market in the US will be discussed at a round table panel discussion during this month's Sunscreen Symposium by the Florida Chapter of the Society of Cosmetic Chemists.[1] It is the third time such a forum has been held during the Sunscreen Symposium chaired by Dennis Lott. The participants in this year's panel will be Dr. Reynold Tan of the US Food and Drug Administration, Dr. Robert Sayre, Dr. Nava Dayan, Joe Stanfield and myself. This forum promises to be the highlight of the symposium as it was at the past two meetings. Topics include:

- The Time and Extent Application (TEA);
- The anti-inflammatory issue of UV filters and the petition to withdraw the salicylates and benzophenones from the Category I approved list;
- Is there a need for SPFs over 50?;
- Skin damage caused by visible and UV light and
- Adequacy of sprays and its dangers.

This two-hour debate, which is guaranteed to be engaging and controversial,

Sun care is available in a range of product forms, but the number of actives is limited.

will likely draw active audience participation and will probably include debates over other vital sunscreen topics not on the agenda.

My column in the May 2013 issue of Happi (p. 50) entitled "The Archaic TEA Process Revisited" proclaimed the TEA process to be outdated and unworkable and had proposed that an "Expert Panel" be convened and sanctioned by the FDA to effectively review the proposed new ultraviolet filters. I reviewed the developments made by PASS (Public Access to SunScreens) Coalition to address the issue of implementation——one way or the other——of the TEA process by the FDA. This extremely active coalition is made up of representatives from the industry (L'Oréal, P&G and Beiersdorf), UV ingredient suppliers (BASF and Ashland), testing companies (Hilltop and Suncare Labs), most of the organizations interested in skin cancer (American Academy of Dermatology, Skin Cancer Foundation, Prevent Cancer Foundation, Melanoma Research Alliance, Cure Melanoma, Sun Safety Program) and many notable scientists and dermatologists.[2]

The PASS Coalition has an active campaign on Capitol Hill and meets regularly every other Friday morning to review progress. We have met with the staff of numerous Senators and Congressmen on both sides of the aisle. In fact, after consultation with Representative John Dingell (D-MI) on the topic, he wrote a letter to FDA Commissioner Dr. Margaret Hamburg on Feb. 14, 2013, "to better understand the status of Time and Extent applications (TEA) for over-the-counter (OTC) drugs that have been pending at the Food and Drug Administration (FDA) since 2002."

He adds, "In particular, I am concerned about the delays in consideration of TEA applications for the sunscreen in products. Skin cancer is becoming a public health epidemic in the US."[3]

Representative Dingell has requested an answer to 10 questions that he posed regarding the TEA applications, their number, their status, the number of reviewers and hours spent by the FDA and the reforms to the TEA process proposed by the FDA. On Aug. 2, 2013, Sally Howard, JD the Deputy Commissioner for Policy, Planning and Legislation at the FDA, finally answered Rep. Dingell's 10 questions in a six-page letter. The most important comment in her letter, in my opinion, is her assertion that a proposed rule addressing the first five sunscreen ingredients that were the subject of TEA's would be published by September 2013. These five ingredients are amiloxate, enzacamene, octyl triazone, bemotrizinol and bisoctrizol. Since the FDA has made similar promises before, it is highly unlikely that the FDA will meet that deadline in September, but it is possible that during the Florida Sunscreen Symposium we could be discussing the fate of those ingredients in the US sun care market!

It is a mere 11 years for a process that the FDA had indicated it would "strive to complete the TEA evaluation in 90-180 days and will implement procedures to ensure that agency resources are used appropriately and result in timely action on safety and effectiveness submissions."[4]

When I called for an "expert panel" in May 2013 to convene and assist the FDA in finalizing the status of the TEA ingredients, I was well aware of FDA's dilemma.

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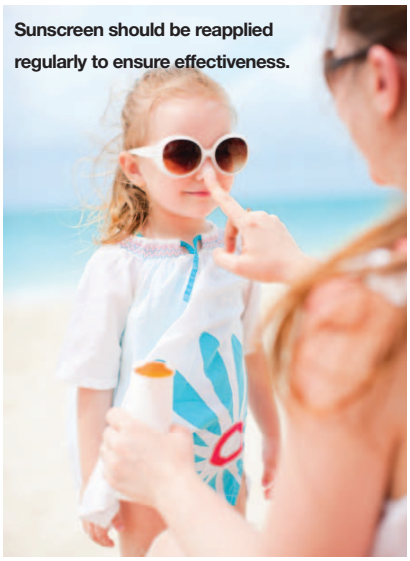

Sunscreen should be reapplied regularly to ensure effectiveness.

The agency is called upon to make sweeping conclusions on the safety and efficacy of not only the TEA ingredients in question but also all of the other Category I approved UV filters. Many of these ingredients are under heavy scrutiny and attack by researchers, dermatologists and consumer advocacy groups.

An expert panel that was convened at the FDA during the early 1970s managed to finalize the 21 Category I ingredients. This list of 21 ingredients has since diminished to 14 with three new ones added to this list (zinc oxide, avobenzone and ecamsule). The current list of 17 approved ingredients in the US is not sufficiently effective and, perhaps,inadequate. In fact, Dr. Robert Sayre's petition calls for the elimination of all the salicylates (homosalate, octisalate and trolamine salicylate) and the benzophenones (oxybenzone, dioxybenzone and sulisobenzone). When you combine these suspect ingredients with the questionable PABA derivatives (padimate-O, PABA and cinoxate), you would be left with the following approved UV filters:

- Octinoxate (already numerous citations in the literature question its safety);
- Octocrylene (patent restrictions);
- Meradimate and ensulizole (restrictions when used with avobenzone);
- Avobenzone (photo-unstable and requires propping up by quenchers and photostabilizers); and
- Inorganic zinc oxide and titanium dioxide.

These seven ingredients are woefully inadequate to address the desperate need for far better and superior skin cancer protection, especially if you consider that today more than 3.5 million skin cancers are diagnosed in over 2 million people in the US each year and that one in five Americans will develop skin cancer in his or her lifetime.[5] According to the National Cancer Institute, the estimated total direct cost associated with the treatment of melanoma in 2010 was $2.36 billion in the US.[6] In addition, when the Expert Panel came up with its final recommendation (the ANPR of 1978), sunscreens were used primarily on a seasonal basis to prevent sunburn among consumers with fair skin. This OTC sunscreen advisory panel anticipated that consumers would be exposed to sunscreen's active ingredients in modest amounts and for short, intermittent time periods. In fact, Dr. Robert Sayre had published data (and he carries it proudly to this date) that all that consumers need is a sunscreen product with an SPF of 2—that is two, not one hundred—and he claims that that level of protection prevents more than 90% of all potential skin cancers.

In practice, actual sunscreen usage is different than once anticipated. Focus on a sunscreen product on the US market today with an SPF of 70-110 having more than 40% UV actives (avobenzone 3%, homosalate 14%, octisalate 5%, oxybenzone 6%, octocrylene 7%, and other active UV quenchers and photostabilizers of over 5%) that the consumer is urged to use every time they are exposed to the sun, reapplying it every two hours and more often after swimming or sweating, applying each time a shot-glass full or golf ball size product. These unusually high percentages of UV filters in high SPF products if applied on the whole body by the consumer as directed——and constantly advised and reminded by health advocates——may be excessive. Habitual usage with regular reapplication among some consumers is common.

Additionally, sunscreen ingredients also were not thought to penetrate below the surface of the skin and thus any potential systemic exposure was not a concern or, as Deputy Commissioner Howard states, "was not reliably assessed using the analytical methods available at the time."[3] She adds, "Today, sunscreens are used on a routine basis by a large percentage of the population and in large amounts covering a much greater body surface area, with the result that the extent and duration of exposure to sunscreen ingredients is orders of magnitude greater than it was in the 1970s, both for individual consumers and for the public at large.

"There is also increasing evidence that some sunscreen ingredients can be absorbed through the skin, leading to systemic exposures to these agents not previously anticipated. This combination of a large and unanticipated shift in sunscreen usage, together with advances in scientific understanding and safety evaluation methods during the same period, have given rise to new questions about what information is necessary and available to support general recognition of safety and effectiveness for both currently marketed sunscreens and potential new entrants; e.g., ingredients seeking inclusion in the monograph via the TEA process."

Considering all of the above, I rest my case that the FDA is facing serious issues in supporting the potential safety of current UV filters and future inclusions in the TEA process. It needs more detailed safety information and long-term studies, active participation by the industry experts as well as concerned dermatologists and scientists to share in the responsibility of proposing effective legislation for future sunscreen ingredients and products.

The Florida Sunscreen Symposium is one forum to discuss and hash out these issues. I hope to see you there! ●

References:

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