Under the Microscope, And Under the Gun?

The Food and Drug Administration's announcement of the Final Rule in June heralded an eventful past few months in the world of sunscreens. Several very informative webinars were held including one each from Happi (which is archived on Happi.com and available for free download), Croda Inc and the Personal Care Product Council. Also, new academic findings were reported regarding UVA rays, tanning salons, caffeine and UV filters from coral for sunscreen protection. In mid-September, the Society of Cosmetic Chemists' Florida Chapter's biannual Sunscreen Symposium, not surprisingly, drew a record attendance. This is an exciting time in our industry; everyone is discussing the proposed new changes.

At the Sunscreen Symposium, a number of informative seminars were presented. The formal presentations at the Symposium are always interesting, but the informal discussions that are held in the hallways and even around the swimming pools and over dinner are absolutely invaluable. In addition, the tradition of holding a roundtable discussion continued this year as well. This year's energetic panel was extremely well organized by Dennis Lott. The panel included Dr. Reynold Tan from the FDA, Dominique Moyal from L'Oréal, Mike Brown from Boots LLC, Joe Stanfield from Suncare Labs, Olga Dueva-Koganov from Akzo, Joe Stanton from Dermatest Australia and myself. The controversial topics, each handled by two speakers, one arguing for and one against, included the following questions:

The FDA has some issues on how sun protection is applied to skin.

1. Are in vitro SPF methods viable?
2. Does a critical wavelength of 370nm or higher provide adequate UVA protection?
3. Should SPF be labeled as tested?
4. Should SPFs be limited by limiting the amount of sunscreen allowed in a product?
5. Should SPF be capped at 50?

The answers to all those questions, as well as the abstracts and bios for the speakers are available from the Florida Society of Cosmetic Chemists.[1]

Dr. Tan, the person in charge of sunscreen regulations at the FDA, participated in both the Florida Sunscreen Symposium and the Happi webinar. He and I corresponded in a series of emails and telephone conversations in which he clarified a number of issues that have emerged since the June 14, 2011 announcement of the Final Rule.

In my September column of "The Sunscreen Filter (Vol. 48, No. 9, p. 50)," Dr. Tan responded to eight questions that were posed to him. In this column, the remaining seven questions are addressed here:

Q. What about pump sprays vs. aerosols? Are pump sprays "grandfathered" since they have existed for much longer than aerosols?

A. All OTC drugs must meet standards of safety and effectiveness. Therefore, no OTC drug is exempted from meeting safety and effectiveness standards just because it was marketed a long time ago (i.e. "grandfathered"). An OTC drug is eligible for inclusion in a monograph if its conditions of use existed in the OTC drug marketplace on or before May 11, 1972. Conditions of use include active ingredient, strength, route of administration, specific OTC use or indication of the product, and dosage form (see 21 CFR 330.l4 (a)). We do not know what kinds of spray dosage forms (pump, aerosol, or other) were marketed before 1972. Our advance notice of proposed rulemaking invites submission of this information, and data and information pertinent to establishing safety and effectiveness standards for spray

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dosage forms in their various forms.

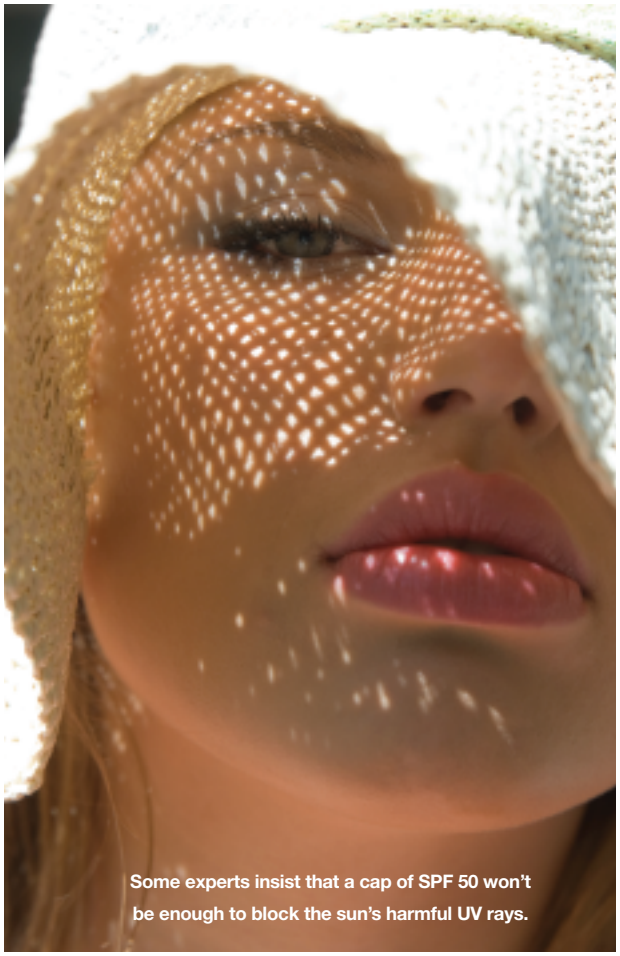
Q. What is the status of the existing inventory that may be at retail beyond 6/17/2012?

For direct selling companies, can "non-compliant products" that enter the US before June 18, 2012 be sold until expiration or only until June 2013?

A. This question should be directed to the FDA's Office of Compliance. This is a question of when a product is introduced into interstate commerce. OTC sunscreen products covered by the OTC monograph system that enter interstate commerce as of June 18, 2012 must comply with the sunscreen testing and labeling requirements in the 2011 sunscreen final rule.

Q. Are there any updates on the dosage form of "wipes" or "towelettes?"

A. We do not currently consider "wipes" or "towelettes" eligible for inclusion in the OTC sunscreen monograph. See the 2011 ANPR on dosage forms for FDA's explanation.



Some experts insist that a cap of SPF 50 won't be enough to block the sun's harmful UV rays.

Q. What is the process for a manufacturer of an ineligible dosage form that does not fall within a TEA to receive marketing authorization? Testing requirements? Approval process? (Follow-up question: What do we need to do to continue packaging SPF in a wipe form?)

A. The only recourse for these manufacturers is to submit a Time and Extent Application or a New Drug Application for their product. The manufacturer could submit a citizen petition to amend the monograph, but citizen petitions require that the amendment apply to drug conditions for drug products eligible for inclusion in an OTC monograph. Therefore, the manufacturer would have to demonstrate that its product is eligible for inclusion in the OTC sunscreen monograph.

Q. Is bar soap an eligible dosage form?

A. The only dosage forms that FDA currently considers eligible for inclusion in the OTC sunscreen monograph are oils, lotions, creams, gels, butters, pastes, ointments, sticks and sprays. In order to be eligible for inclusion in a monograph, all of the drug product's conditions of use, which include its active ingredient, strength, route of administration, specific OTC use or indication and dosage form, must have existed in the OTC drug marketplace on or before May 11, 1972.

Q. How should makeup mineral powders with SPF be treated from a regulatory testing and labeling point of view?

A. Labeling with an SPF value implies that the product is used for protection against sun-induced skin damage, particularly sunburn. Therefore, these products are regulated as drugs. Unless the product is marketed under an approved NDA/ANDA, it is covered by the regulations for OTC monograph sunscreen drug products.

Q. If TiO2 is used as a pigment/opacifier, at low concentrations (~0.1%) and not claimed as an OTC active, can it still be used in an SPF formula with avobenzone?

A. In this drug product example, the TiO2 must be considered to be an inactive ingredient in compliance with 21 CFR 330.1(e). That regulation requires that inactive ingredients must not interfere with the effectiveness of the drug product or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality and purity. The TiO2 must also not be intended to furnish a drug effect or activity, in compliance with the active ingredient definition in 21 CFR 210.3(b) (7).

Dr. Tan's answers to the questions are most helpful. Unfortunately, they address only a limited amount of the many inquiries that have surfaced since their announcement of the Final Rule. There has been a range of responses to the FDA's Final Ruling. Already, several sunscreen manufacturers have expressed displeasure over the FDA's proposed limitation of the SPF to 50+ that is in line with most other international regulations. Johnson & Johnson, Energizer Personal Care and others have submitted public comments in opposition to this rule. J&J said in its comments filed last month, "By capping the SPF at 50, many consumers will no longer have the choice to use higher protection levels that they currently find suitable for their individual needs. Higher SPF sunscreens are safe, effective and are an essential cornerstone of helping to keep the public protected from the damaging effects of ultraviolet radiation."[2]

Members of the Personal Care Product

Council (The Council), however, seem to be divided on this issue. Farah Ahmed from The Council indicated that many companies represented in her trade organization are neutral on this issue. The Environmental Working Group (EWG) has formally responded to the FDA's Final Rule announcement by supporting the government's position on capping the SPF at 50+. EWG, however, criticized the Final Rule for not being comprehensive.[3] With postponements of the comment period and with this heated debate still brewing, the finalization of the Proposed Final Rule (capping of the SPF) and the ANPR (decision on the spray products) will probably be delayed allowing both sides of these issues to submit their data and supporting material.

Some observers remain wary. Senator Jack Reed (D-RI), who had previously proposed legislation in Congress that would require the FDA to finalize the sunscreen regulations (including the SPF proposal) within 180 days, has issued a statement through his press secretary, Chip Unruh, in which he states, "We're watching it closely and don't want this process dragged on any further than it has."[4]

New advances in our understanding of sun protection also surfaced during the past few months. A number of reports were published in professional journals, trade magazines and on the internet, including a study from Kings College London led by Antony Young. He found that UVA rays are more carcinogenic than previously realized. Dr. Young wrote, "The damage seemed to increase as it went through the epidermis, and we think that it is due to a form of backscatter. In other words, the damage goes through and it is somehow reflected back."[5]

They also found that sunlight streaming through windows may increase the risk of skin cancer. Windows filter out the sunburn-causing UVB rays, yet allows 100% of the UVA radiation through. The research also highlights the dangers of using a sun tanning bed, which emits mostly UVA radiation. In October, the Governor of California, Jerry Brown, signed into legislation a new law that prevents minors under the age of 18 from using tanning beds.[6]

Recently, researchers at Rutgers University and Washington University published their findings in the *Proceedings of the National Academy of Sciences* that suggest that topical caffeine may help lower the risk of UV-induced skin cancer. They found that caffeine inhibits a protein enzyme found in skin, thereby protecting against skin cancers. The study suggests that caffeine would be beneficial in sunscreen formulations to increase skin protection against UV-induced skin cancers.[7]

Another study by researchers from

King's College London, in collaboration with the Australian Institute of Marine Science and the University of Maine, discovered a natural compound produced by coral that could be suitable for use in sunscreens.

Dr. Paul Long from King's College stated, "We already knew that coral and some algae can protect themselves from the harsh UV rays in tropical climates by producing their own sunscreens but, until now, we did not know how."[8]

Coral is generally found in shallow waters and therefore naturally produces a type of UV filter for protection from the sun's UV rays. It is this natural sunscreen that scientists hope to synthetically re-create for human use. Other noteworthy topics that appeared recently included an article entitled "FDA Rule for broad spectrum labeling: Key substrate findings" by Heliosun Labs[9] and another entitled "Antioxidants in sunscreens for improved ROS protection," jointly authored by the researchers at the University of California-Riverside and Merck Consumer Care.[10]

During the past few months, interested parties came to the table to discuss the current and future state of sunscreens. The debates are far from over, however, a constructive dialogue has begun. Our industry has the infrastructure to present, discuss and act upon the best proposed changes. FDA, The Society of Cosmetic Chemists, academic investigations and consumer watch groups have had numerous opportunities to add perspective to a heated debate. ●

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