Finally…The Final Rule On Sunscreen Labeling

Memorial Day signals the official start of summer; it is the dawn of sunscreen season again. As in years past, annual reviews and reports purport to shed light on the newly-released products available from the industry. This year is no different in that regard. All at once, contradictory information floods the media from different directions. The experts do not agree. First, *Consumer Reports* published its annual review of the best sunscreens on the market. The Environmental Working Group's (EWG) Skin Deep Sunscreen Report was published and immediately draws condemnation from the Personal Care Product Council and the Skin Cancer Foundation.

Inevitably, the politicians toss their hats into the ring as they have done each and every year. On June 2, they renewed their call to the US Food and Drug Administration to issue the Final Regulations for sunscreens (see footnote on p. 50). The consumer, staring blindly at the upcoming season, is left holding the bag. In the end, it is left to each independent user to decipher this contradictory information to decide on crucial health concerns about protection for themselves and their families.

Then…Shazam! The FDA schedules a press conference at 10am on June 14 to announce the long awaited regulations. FDA finally announced the Final Rule for sunscreen labeling and released three additional regulatory documents:

- A Proposed Rule;
- An Advance Notice of Proposed Rulemaking (ANPR) for Dosage Forms; and
- A Draft Enforcement Guidance for Industry

It should first be noted that the announcement made is not the anticipated Final Monograph with generally regarded as safe and effective (GRASE) conditions for sunscreens. Instead, they are publishing this Final Rule that establishes proper labeling and the effective testing upon which it relies. According to FDA:

"It's in the best interest of public health to publish this Final Rule while working on remaining issues that need to be addressed in order to publish a Final Monograph."[1]

Nevertheless a Final Rule allowing companies to claim that "sunscreen reduces the risk of skin cancer and early skin aging when used as directed" is now the law of the land.

According to the Final Rule, this is accomplished when two conditions are met, namely, the product has a minimum of SPF 15 and also complies with the new testing procedures and parameters for Broad Spectrum (UVA and UVB protection) labeling. Fortunately, the four star UVA system and the extensive descriptors are gone. The in-vivo UVA testing is no longer required. Also, the complicated in-vitro UVA testing based on the Modified Diffey-Robson method has been replaced by the simpler critical wavelength spectrometer reading. This is most welcome news but not without controversy.

The Final Rule also has very important changes to sunscreen labels that manufacturers have to comply with by June 2012. These label changes "are an important part of helping consumers have the information they need so they can choose the right sun protection for themselves and their families," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research in the press conference held in Washington, DC. Other important label changes include the time (40 or 80 minutes)

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Nadim Shaath
Alpha Research & Development Ltd

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he formed a consulting company serving the cosmetic industry called ShaathMeadows Corporation (SMC) with laboratories in New York, New Jersey, Texas, Florida and Egypt. He can be reached at alpharnd@aol.com.

that the product is water resistant and that reapplication every two hours is a requirement. That last statement ensures that consumers are protected from harmful UV rays while sun bathing and by reapplication of the sunscreen every two hours to assist in minimizing the effects of photo instability inherent in the formulations due to the presence of photo-unstable ingredients. It should be noted here that the SPF testing procedure has also been modified. The number of test subjects required has been reduced to 10 instead of 20 or 25 subjects. Also, no claims are allowed concerning "sunblock," "all day protection," "waterproof" or"sweat proof."

What It Says

The other issues in this historic announcement by the FDA are addressed in the following documents:

1. The **Proposed Rule** limits the maximum SPF value on sunscreen labels to 50+. The FDA justifies this due to the fact that there is no sufficient data to show products with SPF values higher than 50 provide greater protection for users than products with an SPF of 50. The proposal creates the opportunity for the submission of data by manufacturers to support guidelines that would include higher SPF values in the Final Rule. The FDA is encouraging public comment on this document.

2. The **Advanced Notice of Proposed Rulemaking** (ANPR) allows the public a period of time to submit data addressing the effectiveness of the safety of sunscreen sprays. The FDA also requests comments on the possible warnings and directions for sprays and issues regarding dosage forms.

3. The **Draft Enforcement Guidance** for industry outlines information to assist sunscreen product manufacturers' understanding of how to label and test their products in light of the new final rule and other regulatory initiatives.

Finally, the FDA is currently re-examining the safety information available for active ingredients included in sunscreens marketed today. According to the agency, today's sunscreens have been used for many years and the FDA does not have any reason to believe these products are not safe for consumer use. Woodcock addressed specific questions concerning nanoparticles of zinc and titanium oxides, oxybenzone and retinyl palmitate that were posed by the reporters in the press conference. She revealed that the FDA has conducted its own animal testing of micronized inorganic particulates used in sunscreens and concluded that no particles penetrate the skin in agreement with the other literature studies.

As for the other ingredients, she concluded that they have been in use for years and that there are no safety alerts on any of them. Nevertheless, she repeated her earlier assertions that the ingredients' safety will be further investigated and if any adverse findings are known, they will be promptly reported and the necessary action will be taken.

No matter what the formula, no labels can contain the terms "sunblock," "all day protection," "waterproof" or "sweat proof."

It's All Good News

All in all, I am pleased with the FDA announcement despite the fact that it is incomplete and late. It removes any suspicion about the lack of regulations that advocacy groups were harping about, which caused major concerns for consumers. The simplification of all the necessary testing is most welcome. The new product labeling and improved Drug Facts Box is informative and precise. The regulations dealing with UV protection higher than SPF50, aerosol dosage and safety, ingredient safety, filter

combinations with avobenzone and other issues all require additional testing and debate. Careful and informed conclusions are needed to address those issues and should not hold the issuance of Final Rules governing sunscreens.

High grades are awarded for the current FDA effort but low grades are given for keeping us waiting for 33 years. Those three decades invited everyone—advocacy groups, scientists, media and concerned citizens alike—to have and express conflicting opinions that contributed to the chaos during this time when efforts were being made to protect individuals from skin cancer. I totally disagree with the reaction from David Andrews, Ph.D. on the EWG website stating that "FDA Sunscreen Rules are too little and very late." He further states, "Consumers will have to turn elsewhere, like EWG's online guide, to find the safest, most effective sunscreens."[2]

I hope not, and trust that the industry, the FDA and the medical, dermatology, and scientific communities can seize this opportunity to assist the consumer with the appropriate products and protocols for practicing safe and healthy exposure to the sun.

The Results Are In...

The annual reviews referred to earlier (now overshadowed by the stunning FDA announcement) include *Consumer Reports* (CR) rating products on the market.[3] CR employs outside accredited laboratory testing, declaring their intention to adhere to the scientific process. It rates the small sample of 22 creams, sprays and lotions by classifying them into three categories: SPF 30, SPF 40-50, and above SPF 50. Nine products (41%) were rated as providing excellent UVA and UVB protection. Interestingly, many of them are the ever-popular sunscreen sprays. CR always provides the cost per ounce for each product, revealing dramatic discrepancies: NO-ADD SPF 45 costs $0.59/oz. as opposed to Anthelios SPF 40 at $18.82/oz.!

This year's EWG report is basically the same as its 2010 sunscreen report, with the exception of a few more products that were reviewed.[4] They claim that one in five (20%) of these products provides safe and efficacious protection as compared to last year's findings of one in twelve (8%). Last year, I wrote about the EWG's flawed methodology in my column, and the reader is advised to consult The Sunscreen Filter (July 2010) (http://www.alpharnd.com/articles/articles/shared_files/July%20Sunscreen%20Filter%202010.pdf) when evaluating the report.

I must admit, however, that the EWG has compiled an impressive database that is practical and useful. Its ratings, however, are based on incomplete research and flawed methodology. EWG should seriously consider undertaking actual in-vivo SPF, UVA, photostability and water-resistance testing. It should also refrain from making premature concluding statements about ingredients based on incomplete and ongoing research.

Other EWG comments add to consumer confusion. I take exception to its promotion of the incorrect statement that there are two types of protection: mineral (physical) and chemical, and would prefer the more accurate classification of mineral vs. non-mineral instead. It should be clearly noted that zinc oxide and titanium dioxide are chemicals, too. The forms in which they are used in sunscreens with chemical coatings, chemical dispersants and chemical solubilizers render them just as "chemical" as octisalate, avobenzone and all the other UV absorbing molecules.[5]

Ironically, CR's top sunscreens are mostly the spray type, which, according to the EWG study, are the least desirable. The best sunscreens in the CR report are considered unsafe and ineffective in the EWG study. If consumer advocacy groups cannot provide a uniform and reliable assessment of the safety of sunscreens, should we value their findings? Should the consumer trust a biased industry or a watchdog group, their favorite blog, or a reliable and well-informed FDA?

The internet is buzzing with blogs commenting on the EWG report and the Personal Care Product Council's response, but they are overshadowed by the new FDA regulations.[6] This conflict about how best to deal with an incredibly important issue of protection from skin cancer has not assisted our efforts to provide superior, safe and effective products. The delay in establishing government-approved and up-to-date ingredient listing and uniform testing procedures has left open the door to misinformation and confusion. Hopefully this new announcement from the FDA, albeit late and incomplete, will dispel all rumors. The reality is that it will take some time to bring all parties toward a common ground. In the end, though, it is worth the time and effort if we can better protect consumers and someday eliminate all skin cancer related to direct exposure to the sun.

Footnote

Six US senators, none of whom hail from Sunbelt States, recently raised objections. Senators Jack Reed (RI), Tom Harkin (IA), Pat Healey (VT), John Kerry (MA) and the two senators from New York, Chuck Schumer and Kirstin Hilibrand, sent two letters on June 2, 2011 to Margaret Hamburg, the FDA Commissioner, and Jacob Lew, head of the Office of Management and Budget (OMB), stating that they "continue to be disappointed that the FDA has not prioritized the implementation of meaningful, enforceable standards for sunscreen protection that includes standards for both UVA and UVB protection." They are sponsoring a bill in Congress, called The Sunscreen Labeling Protection (SUN) Act, which forces the FDA to issue the final regulations in 180 days. ●

References:

1. Press release, a video and massive amounts of documentation. All can be accessed by visiting www.FDA.gov/downloads

2. http://www.ewg.org/release/fda-sunscreen-rules-too-little-and-very-late

3.http://pressroom.consumerreports.org/pressroom/2011/05/consumer-reports-health-tests-reveal-top-performing-sunscreens.html

4. http://breakingnews.ewg.org/2011sunscreen/best-sunscreens/best-beach-sport-sunscreens/

5. Chapters 13-15 in "Sunscreens: Regulations and Commercial Development," Edited by Nadim A. Shaath, Taylor and Francis, Boca Raton, FL (2005).