Update on Sunscreen Labeling and Regulation

Simpler, clearer labeling and packaging may likely lead to better understandings of how proper sunscreen use can help prevent skin cancer.

BY TED PIGEON, SENIOR ASSOCIATE EDITOR

Take a stroll down the aisle of your local pharmacy and you may notice that products in each medicine section—e.g., nausea relief, headache and pain relief, antihistamines, etc.—have nearly identically designed labels on the front and back of their packaging. That’s because the US Food and Drug Administration (FDA) closely regulates approved uses, safety labels, and even marketing claims of all pharmaceutical agents on the market—OTC and prescription only—to ensure their safety and efficacy. And yet, at least one section of the medicine aisle has bucked labeling uniformity for several years, with products donning a range of claims, wordings, and catch phrases: sunscreens.

Historically, sunscreens have not been subject to the same rigorous review process as have a bevy of other agents and products. Indeed, the only official measurement of a sunscreen’s ability to protect against UV light, the Sun Protection Factor (SPF) has been the lone measurement standard for nearly 50 years. During that time, new terms and catchphrases crept their way onto sunscreen bottles and have since entered the sunscreen lexicon: “waterproof,” “sweatproof,” and perhaps most controversial, “Broad Spectrum.”

This is all about to change, however, as sunscreen manufacturers will roll out new labeling for their products this summer. The labeling will be in accordance with new FDA regulations aimed to draw a clearer warning regarding the dangers of UV light and the benefits of sunscreen. Of equal importance but perhaps less noticeable to consumers, the new labeling also limits the claims that sunscreen manufacturers can make about their products.

How the impending labeling requirements will affect consumers’ choices regarding the use of sunscreen remains to be seen. Moreover, as manufacturers face greater scrutiny regarding the specific verbiage on their products, many questions remain as to how these latest developments will shape the future of sun protection practices and awareness.

THE FINAL RULE

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take home tips

In June 2011, FDA unveiled the long-awaited final rule (not to be confused with “final monograph”) on sunscreen regulations. It clarifies claims on use, water resistance, and the “Broad Spectrum” designation for sunscreens that provide adequate UVA and UVB protection. SPF continues to be a somewhat controversial issue, and changes may still be on the horizon for it. The FDA identified other areas for which they requested industry comment. One of these is information concerning dosage forms, which has become a more significant issue with the continued prominence of sunscreen sprays.
(not to be confused with “final monograph”) on sunscreen regulations. (You can view the final rule here: http://1.usa.gov/JX8n5s.) The rule addresses a number of areas that dermatologists and sunscreen experts have deemed problematic regarding the marketing claims and labeling of sunscreens. Among its requirements are clarifications about claims on use, water resistance, and the “Broad Spectrum” designation for sunscreens that provide adequate UVA and UVB protection.

**Use.** According to the FDA, “Only Broad Spectrum sunscreens with an SPF value of 15 or higher can claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures.” Moreover, the rule stipulates that any sunscreen with an SPF value between 2 and 14 can only claim to help prevent sunburn.

**Claims.** In recent years, controversy arose over the claims some sunscreen manufacturers used to market their products, including terms like “waterproof” and “sweat-proof.” The veracity of these claims was not substantiated, thus FDA now explicitly notes that manufacturers cannot label sunscreens as “waterproof” or “sweat-proof,” or even identify their products as “sunblocks,” as these claims overstate their effectiveness.

In addition, according to the FDA, manufacturers must also make an explicit note of the duration of protection, or else they must include something about reapplication. “Sunscreens also cannot claim to provide sun protection for more than two hours without reapplication or to provide protection immediately after application without submitting data to support these claims and obtaining FDA approval.”

Another area that the FDA has clarified is water resistance claims. Water resistance claims on the front label must now indicate whether the sunscreen remains effective for 40 minutes or 80 minutes while swimming or sweating, based on standard testing. In addition, sunscreens that are not water resistant must include a direction instructing consumers to use a water resistant sunscreen if swimming or sweating.

**Broad Spectrum Designation.** One of the most significant markers of the final rule is the update on the “Broad Spectrum” term and the inclusion of a defined standard with which manufacturers must comply in order to use the term. According to the FDA, “Sunscreens that pass FDA’s Broad Spectrum test procedure, which measures a product’s ultraviolet A (UVA) protection relative to its ultraviolet B (UVB) protection, may be labeled as ‘Broad Spectrum SPF [value]’ on the front label.”

The rule contains more specific directives as to the placement and location of drug facts and various other items, but these categories above constitute the areas of greatest emphasis and shift from previous rulings.

**WHAT CAN LABELS SAY?**

- “Only Broad Spectrum sunscreens with an SPF value of 15 or higher can claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures.”
- Any sunscreen with an SPF value between 2 and 14 can only claim to help prevent sunburn.
- “Sunscreens also cannot claim to provide sun protection for more than two hours without reapplication or to provide protection immediately after application without submitting data to support these claims and obtaining FDA approval.”

**COMMENTARY**

The FDA final rule constitutes the most sweeping change made to the sunscreen market in considerable time. It takes effect next month (June 18, exactly), at which point all sunscreens marketed in the US must comply with the rule. However, according to one leading sunscreen expert, some companies have already begun rolling out new packaging in advance of the deadline. “Some companies have taken the rule as an opportunity to devise a new look for their sunscreens altogether, with new package and artwork, in addition to new labeling,” notes Patricia Agin, PhD, Scientific Affairs Leader in Merck Consumer
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Care’s Global Division. Though the final rule posed unique challenges for sunscreen manufacturers, particularly those with smaller packages, Dr. Agin notes that the rule has largely been met with enthusiasm. “Apart from necessitating the tasks of retesting and relabeling products, the FDA final rule has spurred quite a bit of interest in discovering ways to rethink the packaging and promotion of sunscreens,” observes Dr. Agin.

Given that the ruling provided the sunscreen manufacturing companies an opportunity to evaluate how they communicate on the front label and format their art and verbiage, Dr. Agin believes that consumers will be better informed as a result. “I personally feel that the new labels are much easier for consumers to read, since the majority of important information regarding key claims is right there on the front,” says Dr. Agin. For example, while consumers are not likely to understand how the products are tested for terms like “waterproof” or “Broad Spectrum,” they will more easily learn of the differences between products, as some sunscreens will bear these phrases and others will not.

Nevertheless, predicting consumer response to the new changes in labeling is difficult, particularly since it will have been more than a full year since the changes were announced to when they were implemented. Despite the recent shifting state of sunscreen labeling, Martin A. Weinstock, MD, PhD, Professor of Dermatology at Brown University, is hopeful that—at some point in the future the rule has indeed made a determination on whether or not SPF should be capped. Were it to decide on a cap, Dr. Agin observes that at some point in the future the rule will make a determination on whether or not SPF should be capped. Were it to decide on a cap, Dr. Agin notes that such a move would be consistent with a global trend. “If you look on a global basis, SPF 50 is the highest level allowed in several regions and countries, such as the European Union, Japan, and Australia,” Dr. Agin says. “With the number of factors that contribute to sunscreen formulation, there are other, more important things than achieving the highest SPF level,” Dr. Weinstock continues.

As SPF continues to be a somewhat controversial issue, Dr. Agin points out that changes may still be on the horizon for it. “When the FDA revealed its final rule on sunscreens, it had proposed additional ideas and asked for industry comment. One of these was a cap on SPF,” explains Dr. Agin. “The FDA had asked for a demonstration of the clinical benefit of an SPF, and companies were granted a 90-day period to comment,” she continues. While it is not certain when, Dr. Agin observes that at some point in the future the FDA will indeed make a determination on whether or not SPF should be capped. Were it to decide on a cap, Dr. Agin notes that such a move would be consistent with a global trend. “If you look on a global basis, SPF 50 is the highest level allowed in several regions and countries, such as the European Union, Japan, and Australia,” Dr. Agin says. “With the number of factors that contribute to sunscreen formulation, there are other, more important things than achieving the highest SPF level,” Dr. Weinstock continues.

UNRESOLVED AND ONGOING ISSUES
Apart from SPF, other areas will likely call attention in coming months and years. According to Dr. Agin, the FDA identified other areas for which they requested industry comment. One of these is information concerning dosage forms, which has become a more significant issue with the continued promi-
nence of sunscreen sprays. “We hope they are going to find that sprays are appropriate and safe and continue to be a recognized dosage form,” observes Dr. Agin.

Another development track concerns Time and Extent Applications (TEA), which, according to Dr. Agin, concern the addition of new ingredients to the monograph. In recent years, sunscreen manufacturers have incorporated a bevy of new ingredients—such as antioxidants—into their products. (For more on this, see the feature article on page 31.) “Sunscreens have evolved to encompass benefits beyond the prevention of sunburn,” notes Dr. Agin. “Many of the ingredients in newer sunscreens play a role in maintaining skin health while also protecting against UV light,” she continues. TEAs would expedite the approval process for products containing proven ingredients.

While the FDA’s “Final” monograph on sunscreens may still be many years away, Dr. Agin is hopeful that the FDA will act on the areas of TEAs and dosage forms. Indeed, much work remains, but these issues remind that the realm of sunscreens is continually evolving. Moreover, new advancements in formulation, delivery, and packaging will continue to drive developments and shifts in the manufacturing and regulation of sunscreens.

MOVING FORWARD
The ongoing dialogue regarding SPF, dosage forms, and new ingredients may continue to shine a light on the work that lies ahead on the regulatory horizon, but Dr. Agin and Dr. Weinstock agree that the final rule on sunscreens represents an important step in the right direction. Simpler, clearer labeling and packaging may likely lead to better understandings of how proper sunscreen use can help prevent skin cancer, according to Dr. Agin. Moreover, the new labeling should help consumers understand that UV protection goes beyond sunscreens. It is more nuanced, and Dr. Agin believes that new and forthcoming products address the varying needs of consumers. “Sunscreens are not just to be applied on vacation or at the pool,” Dr. Agin notes. “In fact, many more usage occasions are emerging, and people are becoming aware of incremental levels of protection that help to reduce exposure,” says Dr. Agin. “The focus of technology is on delivering products that deliver protection beyond SPF, are more aesthetically pleasing, and offer differentiated performance benefits,” explains Dr. Agin. Products for every occasion and with multiple built-in benefits are filling the market, a trend that Dr. Agin expects should continue.

In the broader scope of UV protection, sunscreens represent one of several integral components in skin health. “Sunscreens should be incorporated as part of a daily program consisting of various avenues of sun protection,”

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—Dr. Weinstock notes Dr. Agin. “One alone is not enough,” she continues. According to Dr. Weinstock, it is important for consumers to know that sun protection encompasses elements such as protective clothing, as well as a general mindfulness of factors such as time of day and duration of exposure. Several campaigns and organizations, such as the Skin Cancer Foundation, work to bolster awareness and inform consumers regarding the importance of an all-encompassing approach to UV protection, as Dr. Weinstock and Dr. Agin advocate. These efforts have been countered by the lobbying interests of the tanning industry, which has resisted regulation. As the FDA conjugates about the regulation of indoor tanning, Dr. Weinstock notes that the evidence suggests that artificial UV light may play a role in the incidence in melanomas, particularly those diagnosed early in life. However, on the positive side, the overwhelming evidence about the dangers of UV light and artificial UV light appear to have contributed to recent legislation enacted in California to ban those under the age of 18 from indoor tanning as positive steps. (For more on this, see our March issue, featuring an interview with California State Senator Ted Lieu, who sponsored the legislation.)

Despite the range of activity regarding UV protection in various arenas, the future is not certain. Although sunscreens are not the only tools for fostering better habits of sun protection, their role in this effort is integral. Thus, while the FDA operates independent of advocacy campaigns and the like, its updated rule to require greater clarity in sunscreen labeling is a critical development in the broader shift toward greater awareness of the importance of preserving and maintaining skin health.