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Sunscreen in the Spotlight: FDA Illuminates New Sunscreen Regulations

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On June 14, 2011 the **U.S. Food and Drug Administration (FDA)** announced new requirements for sunscreens and sunscreen-containing products currently sold over-the-counter. These changes are covered in a **Federal Register** notice to be published on June 17, 2011. The Final Rule will have a significant impact on producers of sunscreens and cosmetics and will result in changes to labeling, advertising and formulation of a vast array of products containing sunscreen and making sunscreen claims. In addition to the Final Rule, which will take effect for most producers on June 18, 2012, the FDA has also developed a Proposed Rule, an Advance Notice of Proposed Rulemaking and a Draft Guidance for Industry regarding these products.

The Final Rule imposes a number of new labeling, testing and formulation requirements on consumer products that contain sunscreen. According to Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, the FDA developed these requirements in an effort to "modernize . . . product information" about sunscreens. These changes come after over thirty years of development and delays in revising the previous requirements.

Prior rules on sunscreens focused on protection against ultraviolet B (UVB) radiation from the sun. After spending many years reviewing the science on ultraviolet A (UVA) radiation, FDA has finally established a standard broad spectrum test procedure that measures UVA radiation protection in relation to the amount of UVB radiation protection. This test procedure helps to provide a standard by which sunscreen products may be labeled as "Broad Spectrum," protecting against both UVA and UVB rays. Broad Spectrum sunscreen products with a Sun Protection Factor (SPF) of 15 or higher are also permitted to make claims regarding protection against skin cancer and early skin aging. By contrast, sunscreen products that do not meet the requirement for Broad Spectrum, or have an SPF value of less than 15, may only make claims related to the amount of protection against sunburn and must contain a warning regarding the effects of the sun on skin cancer and early skin aging.

Now that the FDA has defined the specific conditions under which statements regarding protection against skin cancer and early skin aging may be made on labeling, some sunscreen and cosmetic products may require reformulation in order to continue to use such statements. Further, advertisers of products with anti-skin aging properties based on the sunscreen content of the product will need to ensure the appropriateness of those statements or risk action by the FDA and/or the U.S. Federal Trade Commission.

FDA has also prohibited the use of claims such as “waterproof” or “sweatproof” on labeling due to the implication that such statements are misleading. Instead, products may only be labeled as “water resistant,” if they meet FDA requirements for the claim, and must bear a statement as to the length of time (either 40 minutes or 80 minutes) that the sunscreen remains effective while swimming or sweating. As with the Broad Spectrum claim, “water resistant” claims must be verified through standardized testing. Similarly, non-water resistant sunscreens must bear a warning on labeling instructing consumers to use a water resistant sunscreen if swimming or sweating.

Other claims expressly prohibited by the FDA include providing sun protection for more than two (2) hours without reapplication, providing protection immediately after application (such as “instant protection”), or identifying the product as a “sunblock.” Each of these claims are considered to overstate the effectiveness of sunscreen products that meet the Final Rule. Companies do, however, have the option of submitting data in an application to the FDA to label for the ability to provide protection for more than two (2) hours or for the ability to provide protection immediately after application.

The Final Rule may not impact all sunscreen-containing products equally. The FDA is addressing the issue of dosage forms for sunscreens in an Advance Notice of Proposed Rulemaking to be published on the same day as the Final Rule. In the Advance Notice, the FDA states that sunscreen products in “dosage forms such as wipes, towelettes, powders, body washes, and shampoos are not currently considered eligible for inclusion in the sunscreen monograph.” While the FDA considers oils, lotions, creams, gels, butters, pastes, ointments, sticks and sprays to fall within the Final Rule, the FDA plans to review the safety and effectiveness of sunscreen spray products. In particular, FDA will be considering the possibility and consequences of unintentional inhalation of spray sunscreens.

Along with the **Final Rule and Advance Notice of Proposed Rulemaking,** the FDA is issuing a Proposed Rule that, if finalized, would limit the maximum SPF value on sunscreen labels to “50 +.” The FDA explains that the Proposed Rule is necessary because it has not gathered sufficient data to demonstrate that products with SPF values higher than 50 would provide greater protection than products with SPF values of 50.

The Final Rule will take effect for most manufacturers on June 18, 2012. Companies with products with annual sales less than $25,000, however, will have extra time to prepare, as the new requirements will not take effect as to them until June 17, 2013. In the interim, the FDA has made available a draft guidance that sets out its enforcement policy with respect to sunscreen products prior to the effective date of the Final Rule. This draft guidance will be published on the same day as its other sunscreen announcements. In light of these developments, some companies have indicated that they intend to begin the process of complying with the Final Rule ahead of the official start date.

Given these sweeping changes, it is imperative that every company with products containing sunscreen review the Final and Proposed Rules carefully. To the extent that advertising, labeling and formulation of sunscreen products must change, companies should prepare action plans now to determine what changes need to be made. Additionally, to the extent that FDA’s proposals impact existing sunscreen products, companies should seriously consider engaging the FDA as the rulemaking process moves forward.

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