

## **FDA Announces New Rules About Sunscreen Labeling**

### ***Pharmaceutical Law Update***

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On June 14, 2011, the Food and Drug Administration (FDA) issued new rules regulating sunscreen labeling. The rules standardize the testing that manufacturers must conduct, provide guidelines for labeling in connection with which sunscreens provide protection against cancer and eliminate claims that any sunscreen is waterproof. Although the rules become effective next year (except for manufacturers with annual sales of less than \$25,000, which have two years to comply), some of the language used by the FDA gives rise to a more immediate concern over potential false advertising and unfair competition litigation by plaintiffs' attorneys against companies that manufacture or market sunscreens. There has been litigation over sunscreen marketing claims.

### **Rulemaking History**

The FDA has been evaluating sunscreen labeling for 33 years. It first issued proposed rules for over-the-counter (OTC) sunscreen products in 1993. Those rules addressed labeling and sun protection factor (SPF) testing to prevent sunburn, which is primarily caused by ultraviolet B (UVB) radiation. Before those rules became effective, Congress passed the Food and Drug Administration Modernization Act of 1997, which required regulations for OTC products for the prevention of sunburn. In 1999, new rules were proposed governing UVB labeling, but were stayed to add ultraviolet A (UVA) testing and labeling requirements. Both UVA and UVB radiation contribute to skin cancer. In 2007, revised proposed rules were issued, but never adopted.

The new rules just issued, which are effective June 18, 2012, address labeling and the effectiveness testing on which labeling is based. The new rules do not address what active ingredients are generally recognized as safe and effective, a subject that is currently under review. Additional review also is being conducted on the safety and effectiveness of sunscreen products in the form of sprays.

### **Key Points of the New Rules**

- Manufacturers are banned from labeling sunscreens as "waterproof" or "sweatproof" or identifying them as "sunblocks." According to the FDA press release, "these claims overstate their effectiveness." Water resistance claims are limited to whether the sunscreen is effective for 40 or 80 minutes while swimming or sweating based on standardized testing.
- The breadth of a grand jury's subpoena power, however, is oftentimes at odds with the safeguards that are meant to be created by the entrance of a valid and agreed-upon protective order. By way of example, a company may produce certain documents during the civil discovery process because they believe the documents will be safeguarded from further distribution through the execution of an appropriate protective order, including documents generally outside the reach of a grand jury's subpoena power such as foreign documents, or deposition testimony originating outside of the United States. Should a grand jury be able to obtain that discovery by serving a subpoena on the party who received the discovery during

civil litigation, even though the grand jury would not ordinarily have access to some of those materials through the use of a direct subpoena to the producing party? As another example, a person who is hesitant to provide deposition testimony for the fear that he or she might potentially incriminate himself or herself criminally may provide that testimony under the safeguards of a protective order, rather than seek the protections of the Fifth Amendment's privilege against self-incrimination. Should a grand jury be able to obtain that deposition transcript through the use of a subpoena even though that deponent may have otherwise sought the protections of the Fifth Amendment privilege against self-incrimination during a criminal proceeding?

- Sunscreens that pass a broad spectrum test procedure that measures UVA protection in relation to UVB protection are allowed to be labeled as "Broad Spectrum." In other words, the UVA protection must be equivalent to the UVB protection to achieve the coveted Broad Spectrum label.
- Only Broad Spectrum sunscreens with an SPF of 15 or higher are allowed to claim that they reduce the risks of skin cancer and early skin aging.
- Non-Broad Spectrum sunscreens and Broad Spectrum sunscreens with an SPF between 2 and 14 must carry a warning that they have not been shown to prevent skin cancer or early skin aging. They can only claim to help protect against sunburn.

Although not a final rule as those above, the FDA has proposed a rule that would limit SPF values to no more than 50. According to the FDA press release, "there is not sufficient data to show that products with SPF values higher than 50 provide greater protection for users than products with SPF values of 50."

While the rules note product liability claims are not preempted, the rules recognize the provisions governing express preemption under section 751(a) of the Food Drug and Cosmetics Act.

## **Conclusion**

The intention of the new regulations is to help consumers decide how to buy and use sunscreen, as well as allow them to better protect themselves from skin cancer, early skin aging and sunburn. According to the Environmental Working Group, an environmental consumer advocacy organization, the rules don't go far enough and are weaker than the rules proposed in 2007, which included a prohibition on labeling sunscreens with values higher than "SPF 50+." Nevertheless, the new rules may have the unintended consequence of inspiring plaintiffs' lawyers to renew their efforts pursuing false advertising and unfair competition claims against sunscreen manufacturers and marketers.

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