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FDA Issues Final Rule on Sunscreen Labeling

On June 14, 2011, the Food and Drug Administration (FDA) published a final rule regarding sunscreen labeling.¹ The final rule sets forth labeling for sun protection factor (SPF) and broad spectrum protection, establishes labeling and testing for water resistance, and addresses other elements of labeling, including directions for use and warnings. The final rule also identifies specific claims that render a covered product misbranded or would not be permissible on any over-the-counter (OTC) sunscreen product marketed without an approved application. The final rule is part of the FDA's ongoing effort to ensure that sunscreens meet modern-day standards for safety and effectiveness and help consumers have the information they need so they can choose the right sun protection for themselves and their families. The final rule takes effect for most manufacturers on June 18, 2012. Manufacturers with less than \$25,000 in annual sales will have two years to adapt to the new regulations. This summary highlights significant provisions in the final rule.

The specific requirements of the final rule include:

- Sunscreens that pass the FDA's broad spectrum test procedure, which measures a product's UVA protection relative to its UVB protection, may be labeled as "Broad Spectrum SPF [value]" on the front label.
- 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. Non-broad spectrum sunscreens and broad spectrum sunscreens with an SPF value between two and 14 can only claim to help prevent sunburn.
- Manufacturers cannot label sunscreens as "waterproof" or "sweatproof," or identify their products as "sunblocks" because these claims overstate their effectiveness. According to the FDA, sunscreens can no longer be called sunblocks because the FDA does not want to give the impression that complete protection is provided. Sunscreens also cannot claim to provide sun protection for more than two hours without reapplication or to provide protection immediately after application (e.g., "instant protection") without submitting data to support these claims and obtaining FDA approval.

¹ 76 Fed. Reg. 35,620 (June 14, 2011)

- Water resistance claims on the front label must indicate whether the sunscreen remains effective for 40 minutes or 80 minutes while swimming or sweating, based on standard testing. Sunscreens that are not water resistant must include a direction instructing consumers to use a water resistant sunscreen if swimming or sweating.
- All sunscreens must include standard “drug facts” information on the back and/or side of the container.

With respect to broad spectrum testing, the final rule includes an *in vitro* broad spectrum test procedure for assessing protection across both UVA and UVB regions of the UV spectrum. Certain elements of labeling in the final rule apply only to products that are determined to be “broad spectrum” in accordance with the test procedure. Note that the FDA is aware that not all sunscreen active ingredients provide substantial protection UVA wavelengths, and that OTC sunscreen products that do not contain certain ingredients are not likely to pass the broad spectrum test criteria. Further, the FDA is no longer requiring a four-star rating or descriptors to indicate the level of UVA. In 2007, the FDA proposed a rating system for UVA products designed to help consumers identify the level of UVA protection offered by a product. Specifically, one star would represent low UVA protection; two stars would represent medium protection; three stars would represent high protection, and four stars would represent the highest UVA protection available in an OTC sunscreen product. Under the final rule, the FDA establishes a pass/fail broad spectrum test and a broad spectrum labeling statement to indicate the level of UVA and UVB protection.

In addition to the sunscreen labeling final rule, the FDA also published three additional regulatory documents, a proposed rule, an Advance Notice of Proposed Rulemaking (ANPR) for Dosage Forms and a Draft Enforcement Guidance for Industry (Draft Guidance).

- **Proposed Rule:** The proposed rule would limit the maximum SPF value on sunscreen labels to “50+” because, according to the FDA, 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. If the proposal is finalized, an OTC sunscreen product marketed without an approved application and labeled with a specific SPF value higher than 50 would be subject to regulatory action. The FDA is requesting comments to the proposed rule by September 15, 2011.
- **ANPR:** In the ANPR, the FDA listed those dosage forms of OTC sunscreen products that the FDA currently considers potentially eligible for inclusion in the OTC sunscreen monograph (i.e., oils, lotions, creams, gels, butters, pastes, ointments, sticks and sprays). For sprays, the FDA requested additional data to address remaining questions about effectiveness and safety. The FDA also invited comment on potential labeling and testing conditions for sunscreens in spray dosage forms, contingent on receiving additional data that would be needed to allow their classification as generally recognized as safe and effective. The FDA also identified certain dosage forms that we do not consider currently eligible for review for potential inclusion in the OTC sunscreen monograph (i.e., wipes, towelettes, powders, body washes and shampoos). Data and information must be submitted to the FDA by September 15, 2011.

- **Draft Guidance:** The Draft Guidance outlines information to help sunscreen product manufacturers understand how to label and test their products in light of the new final rule and other regulatory initiatives. The Draft Guidance is available by clicking [here](#).² Comments on the Draft Guidance are due by August 16, 2011.

² <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf>