

FDA TALK PAPER

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SUNSCREEN REGULATIONS FINALIZED

The Food and Drug Administration today finalized its regulations for over-the-counter (OTC) sunscreen drug products. The regulations (referred to as a "final monograph") list the sunscreen active ingredients that can be used in these products as well as labeling and testing requirements. The regulations provide for uniform, streamlined labeling for all OTC products intended for use as sunscreens to assist consumers in making decisions on sun protection.

FDA has been involved with the development of regulations for OTC drug products since 1972, and sunscreens is just one of many categories of OTC drug products for which "monographs" have been finalized.

Highlights of the new regulations include the following:

- Similar labeling requirements for all OTC products intended for use as sunscreens (including sunscreen-cosmetic combinations such as makeup products carrying sun protection claims) to provide good, useful information to consumers.
- Uniform, streamlined labeling for all sunscreens. Accommodations in labeling will be made for sunscreens that are labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes).

- A list of 16 allowed sunscreen active ingredients, with zinc oxide and avobenzone being the two most recent additions.
- Both required and optional label claims, warnings, and directions.
- Required sun protection factor (SPF) testing. The higher the SPF the more sunburn protection.
- A new SPF category of "30" plus (or "30+") for SPF values above 30.
- Simplification of the previously proposed five product sun protection categories to "minimum," "moderate," or "high," plus optional claims to help consumers with selection of sunscreen products.
- A "Sun Alert" statement that reflects the important role sunscreens play in a total program to reduce the harmful effects of the sun (i.e., "Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.")
- Cessation of unsupported, absolute, and/or misleading and confusing terms such as "sunblock," "waterproof," "all-day protection," and "visible and/or infrared light protection".
- In addition to these changes new cosmetic regulations developed during the sunscreen rulemaking require tanning preparations that do not contain a sunscreen ingredient to display the following warning:

"Warning--this product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn."

Because of the testing requirements for and seasonal nature of sunscreen products, manufacturers of sunscreens will have 24 months to comply with the new requirements. Manufacturers of cosmetic tanning preparations that do not contain a sunscreen will have 12 months to include the required warning statement on their products. However, all manufacturers are encouraged to provide the new labeling as soon as possible.

Claims concerning ultraviolet A (UVA) protection will continue as previously proposed until the agency further evaluates this issue.

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