

Ask the Ingredient Expert



by
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Q IS IT TRUE THE FDA RECENTLY proclaimed sunblocks illegal? How could they do such a thing? Don't they know people need these products?

A: Yes, in a way, it's true. As it stands now, as of May 21, 2001, the term "sunblock" will not appear anywhere on a sunscreen label in the United States. If a product features this statement, it shall be considered a non-monograph sunscreen and will require special approval by the FDA before it can be sold.

This new ruling is part of the Final Monograph for over-the-counter (OTC) sunscreens – a document detailing the regulations governing the manufacture and sale of sunscreens published this past May by the FDA. According to the Final Monograph, the term "sunblock" is "unclear and may mislead and confuse consumers into thinking that the product blocks all of the sun, when in fact it does not... No product available totally blocks sun damage." Until this past May, FDA allowed the term because it described the method of protection used in the sunscreen. "Sunblocks" were defined by FDA as products which derived at least 12 SPF points from titanium dioxide. But consumers, and most professionals advising consumers of sunscreen use, were not aware of this definition. Instead, they came to think of sunblocks as offering total sun protection. So when sunburn occurred, people started to wonder if sunscreens worked at all. They were also more inclined to purchase an SPF 15 sunblock over a more effective SPF 30 sunscreen offering broad spectrum protection, simply because they thought the first product would block all of the sun's rays. While we may not like the "sunblock" ban, it's hard to argue with the FDA's reasoning.

There are other surprises in store for sunscreen retailers come the 2001 deadline. Here's a few changes you'll see, unless petitioners wishing to amend the Final Monograph have their way:

- The claim "PABA-Free" must be elongated to "aminobenzoic acid (PABA)-free" if it appears in any area of the sunscreen label or on point-of-purchase advertising.
- The phrases "skin aging", "wrinkling", "premature skin aging" and "photoaging" will not be permitted on sunscreen labels, which includes

documents such as brochures, ads and training materials that describe specific sunscreen products. This means a manufacturer or retailer cannot state their sunscreen slows "skin aging", prevents "wrinkling", or retards "premature skin aging" or "photoaging". According to FDA comments, a sunscreen's label

should only describe its use in preventing sunburn. The agency believes indicating other uses, including preventing photoaging or skin cancer, is misleading to consumers, since no product can offer complete prevention in these areas. However, in the optional area described as "Sun Alert", FDA has provided language that will allow consumers to learn about the role sunscreens play in reducing skin aging, in a context the FDA believes is not misleading. The alert, printed on sunscreen labels at the manufacturer's discretion and if space allows, would read "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." It may also appear on point-of-purchase sales aids, brochures and other materials designed for educating consumers about the dangers of sunlight. One saving-grace: FDA may allow sunscreens containing avobenzone (Parsol 1789) or zinc oxide to feature a statement about protection against photoaging, but the decision to do so has not been made at time of this writing.

- Sunscreens offering protection higher than SPF 30 will be lumped into one category labeled "SPF30+". This means that products offering distinctly different levels of protection, such as SPF 31 and SPF 45, will feature the same SPF designation. While the increased protection offered by SPF's in the upper 40s is only slightly greater than that offered by those in the lower 30s, it can make a big difference to people who suffer from UVA-aggravated disorders such as lupus and photoallergies, people who take photoreactive medications like those used to treat diabetes or high blood pressure, or people who wish to have more thorough protection than

columnist ingredients

an SPF 30 provides themselves or their children. Sunscreen makers are already contacting FDA regarding the new ruling. If they're successful, SPF 30+ will not be an issue in 2001.

Q: What is a "filler ingredient"?

A: Good question! The term has never made sense to me. Used by journalists and cosmetic "experts" to attack products they either don't approve of or are selling against, the phrase "filler ingredients" seems to imply that a cosmetic company puts ingredients in a product that are not necessary or don't perform a function. Having been on the

formulation side of the cosmetic industry for 25 years, I can tell you that every ingredient in a product must pull its own weight or it is out, simply because of cost. Every ingredient, even water, costs something. So why would a cosmetic company include an ingredient that would eat into its profit structure if the ingredient weren't deemed necessary in some way? I've heard a variety of ingredients labeled as "fillers", from preservatives to emulsifiers to colorants and fragrance. But all of these ingredients are required to produce a safe, stable and attractive product.

The only ingredients I can think of which don't do much for the skin, and aren't required for the safety or stability of the product, are the very ingredients consumers often believe are delivering results. Vitamins A, C or E can be wasted in a product if they aren't treated with care by the formulator or protected by packaging that seals out light and air. And, while chamomile, calendula, lavender and other plants may seem like a patch of friendliness inside an otherwise unfriendly field of chemicals, all too often the plant extracts used in cosmetic formulas lack the very phytochemicals that did so much good for past generations, who processed the plants according to traditions that supposedly preserved chemical activity.

A good marketer will tell you, though, that even unstable vitamins and "hollow" plant extracts have their place in a formula: they cause the product to move from the store shelf to the bathroom shelf, where the ingredients many consumers think of as "fillers" can do their job cleaning, softening or moisturizing the skin. ■

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