

COMMISSION AUTHORIZED

**BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

In The Matter of)	
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Sunscreen Drug Products)	
for Over-the-Counter Human Use;)	Docket No. 78N-0038
Tentative Final Monograph)	
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Comments of the Staff of
the Bureau of Consumer Protection
of the Federal Trade Commission*

February 7, 1994

* These comments are the views of the staff of the Bureau of Consumer Protection of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Toby Levin (202-326-3156) or Susan Cohn (202-326-3053).

I. Introduction and Summary

On May 12, 1993, the Food and Drug Administration ("FDA") published its Tentative Final Monograph ("TFM") on Sunscreen Drug Products for Over-the-Counter Human Use and requested comments on aspects of it.¹ The 108-page TFM summarizes the scientific evidence about acute and long-term injuries associated with sun exposure and concludes that sunscreens may play a significant role in providing varying levels of protection from these harms. Based on our experience in analyzing the effects of information in consumer product markets and in considering regulations that address information issues, the staff of the Bureau of Consumer Protection of the Federal Trade Commission ("FTC") offers the following comments to assist FDA in its deliberations.²

The FTC enforces sections 5 and 12 of the Federal Trade Commission Act, prohibiting deceptive or unfair practices in or affecting commerce and false advertisements of drugs and cosmetics (and other items).³ One of the FTC's major responsibilities is to prevent unfair and deceptive advertising, and one important application of that responsibility has been the prevention of deceptive advertising of over-the-counter ("OTC") drug products. Advertising can effectively provide consumers with useful information, enabling them to make informed choices in purchasing and using products. The FTC has developed considerable expertise in understanding the roles of advertising

¹ 58 Fed. Reg. at 28194 (1993) (to be codified at 21 C.F.R. Parts 352, 700, and 740).

² These comments are the views of the staff of the Bureau of Consumer Protection of the Federal Trade Commission. They do not necessarily represent the views of the Commission or any individual Commissioner.

³ 15 U.S.C. §§ 45, 52. Under section 12 of the FTC Act, the Commission has jurisdiction over the advertising of food, drugs, devices, and cosmetics. The FTC also has concurrent jurisdiction with FDA over the labeling of foods, OTC drugs, devices and cosmetics. In addition, the FTC has statutory authority to enforce a number of laws that mandate disclosure, including the Federal Cigarette Labeling and Advertising Act, the Truth in Lending Act, and the Energy Policy and Conservation Act, which regulates appliance labeling, and to enforce several laws relating to standard-setting, including the Wool Products Labeling Act, and the Magnuson-Moss Warranty & FTC Improvement Act. The FTC has also promulgated disclosure rules, such as the R-Value Rule, which regulates thermal insulation labeling, the Used Car Rule, which requires warranty disclosures, and the Care Labeling Rule, which regulates clothing labeling.

and labeling in providing consumers with information⁴ and regularly considers information issues in the context of OTC drug advertising.

The FTC has had a longstanding interest in products claiming to reduce the harms associated with ultraviolet light. The FTC has entered four administrative consent orders against allegedly false and deceptive health and safety claims for artificial tanning beds, and one about sunscreen products. These orders have been directed at claims that tanning with artificial tanning beds does not contribute to the risk of developing skin cancer or other harmful side effects associated with sun exposure⁵ and that a sunscreen product blocks all of the harmful rays that cause photoaging.⁶ In addition, the Commission has issued two consumer education brochures about sunscreens, tanning, and the risks of various types of skin damage associated with exposure to ultraviolet rays.⁷ The staff of the Commission continues to monitor sunscreen advertising to ensure that consumers are not misled by deceptive claims about the protective efficacy of these products.

The FDA's goal in issuing the TFM, to provide accurate, adequate information so consumers can make better-informed choices in protecting themselves against sun-induced skin damage, is important. The TFM recognizes the importance of crafting sunscreen labeling regulations that will encourage appropriate use of protective products, yet not create a false sense of security.⁸ The TFM's proposed regulations address these important goals. Some aspects of the TFM's labeling language might, however, unintentionally lead consumers to believe that

⁴ Relevant FTC staff research includes: P. Ippolito & A. Mathios, Health Claims in Advertising and Labeling: A Study of the Cereal Market (1989); M. Lynch, R. Miller, C. Plott & W. Porter, Experimental Studies of Markets With Buyers Ignorant of Quality Before Purchase: When Do 'Lemons' Drive Out High Quality Product? (1986); M. Frankena, M. Cohen, T. Daniel, L. Ehrlich, N. Greenspun & D. Keenan, Alcohol, Advertising, Consumption, and Abuse, (1985).

⁵ Sun Industries Inc., 110 F.T.C. 511 (1988); The Silver Group, 110 F.T.C. 380 (1988); An-Mar International Ltd. Inc., 112 F.T.C. 72 (1989); and Haverhills, C-3322 (Jan. 25. 1991).

⁶ Revlon Inc. and Charles Revson, Inc., Docket No. 9231, November 17, 1993.

⁷ "Sunscreens," Facts for Consumers, April 1990; "Indoor Tanning," Facts for Consumers, March 1993. FTC staff coordinated with FDA staff in the development of each of these brochures.

⁸ 58 Fed. Reg. at 28288, TFM Comment 53.

sunscreen products, particularly low SPF products, provide greater protection than may be the case. Consumers cannot judge accurately for themselves what level of protection sunscreen products provide against chronic, long-term skin injuries such as premature skin aging and skin cancer, so they must depend on the product labeling (or other sources) for information. This necessary reliance on the labeling makes it particularly important that FDA's regulations not unintentionally endorse labeling language that may confuse consumers about how much protection these products can provide.

Many of the issues addressed in this comment concern the inferences that consumers may draw from the use of particular terms. We are aware of no consumer perception studies or other consumer research that would help determine what meaning the TFM's proposed labeling terminology conveys to consumers. Because of the importance of the potential health consequences if consumers take unintended messages from sunscreen labeling claims, we suggest that the FDA consider obtaining empirical information on consumers' interpretation of the proposed terminology before issuing its final monograph. The remainder of this comment identifies proposed labeling terminology that we believe may be susceptible to unintended interpretations, which the FDA may therefore wish to consider evaluating through consumer research.

II. Sunscreen Product Guide

The TFM requires that the labeling of all sunscreen products include the following chart:⁹

⁹ TFM Comment 43, at 28217, and § 352.52(e)(4), at 28298.

**RECOMMENDED SUNSCREEN PRODUCT
GUIDE**

Sunburn and tanning history	Recommended sun protection product
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Always burns easily; rarely tans	SPF 20 to 30
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Always burns easily; tans minimally	SPF 12 to under 20
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Burns moderately; tans gradually	SPF 8 to under 12
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Burns minimally; always tans well	SPF 4 to under 8
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Rarely burns; tans profusely	SPF 2 to under 4
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The "Sunscreen Product Guide" thus identifies 5 categories of skin types, based on sunburn and tanning experience, and recommends specific SPF numbered products for each category. This guide appears to reflect an intention on the part of the FDA to provide information both to consumers who wish to use a sunscreen product to assist tanning and to consumers who wish to protect themselves from the skin injuries caused by the sun. The staff of the Commission is concerned, however, that the unintended effect of this guide may be to lead many consumers to use and rely on products with relatively low SPF numbers, believing that the products will provide a greater degree of protection than may actually be the case.

For three of the five skin types identified, the guide recommends reliance on products with SPF values of less than 12. As the TFM recognizes, the NIH Consensus Development Conference Statement and the American Association of Dermatology both have recommended that consumers, regardless of their skin type, use at least an SPF 15 product to protect themselves from the harms associated with exposure to the sun's rays.¹⁰ We are concerned,

¹⁰ See 58 Fed. Reg. at 28221, TFM Comment 45; Taylor, et al., "Photoaging/photodamage and photoprotection," Journal of the American Academy of Dermatology, Vol. 1, No. 1, Jan. 1990 at p. 10.

however, that this chart might imply to consumers that such levels of protection are unnecessary and perhaps even undesirable.¹¹ The guide's product usage recommendations will carry great weight and credibility with consumers, because they would be the mandated, standardized recommendations of the FDA, rather than promotional language devised by the products' promoters. Thus, consumers might assume that adhering to these FDA recommendations will provide the level of protection from the sun's rays believed to be appropriate by the relevant public health community. If the chart is misinterpreted to be an implicit endorsement of low SPF products, the proposed guide may give consumers an unwarranted sense of security about the level of protection low SPF products provide.

The guide's SPF-level recommendations are apparently based on the likelihood of experiencing sunburn. Protection against sunburn is clearly important to consumers; however, it is our understanding that protection against sunburn may not necessarily be correlated with protection against the longer term chronic harms of sun exposure, such as skin cancer and premature skin aging.¹² Staff is concerned that, by focussing on sunburn and protection from sunburn, the guide may unintentionally contribute to a consumer misperception that exposure to the sun is risk free as long as sunburn is avoided. Thus, the guide may imply that use of the recommended sunscreens renders suntanning safe, an implication that could encourage those who would like to tan to believe that they can do so without risk of more serious skin damage.

One aspect of the proposed labeling, the "sun alert" that would be required on package labels, is intended to counter some of the risks described here. This required language is:

SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin

¹¹ Indeed, consumers might misconstrue the recommendations to discourage them from using products with SPF values higher than the upper end of the range correlated with their skin type. For instance, consumers who believe they burn minimally and always tan well may infer, incorrectly, from the chart's advice to use sunscreen products with SPF values of 4 to under 8, that products with SPF values of 8 or higher are not recommended.

¹² See 58 Fed. Reg. at 28232, 28288; see also Donawho & Wolf, J. Natl' Cancer Inst. (Jan. 19, 1994) (study of effectiveness of sunscreen in preventing tumors in sunscreen-protected mice).

aging, some types of skin cancer, and other harmful effects due to the sun.¹³

If the FDA undertakes any consumer research about the language that the TFM requires or authorizes, this "sun alert" should be included to determine what messages or warnings consumers understand from it. The FDA may also wish to consider the scientific community's recommendation that consumers use at least an SPF 15 product for protection.¹⁴

III. Permitted Indications

The TFM authorizes some indication statements that may convey protection claims that are more absolute than the FDA may intend to allow. The TFM's discussion of labeling references to skin cancer and premature skin aging makes clear that unqualified sunscreen product claims regarding protection against these harms would be deemed unacceptable. For instance, in explaining why claims such as "[p]revent (or reduce) skin aging caused by exposure to ultraviolet rays" would be objectionable, the TFM states that "[t]he agency objects to the absolute term 'Prevent (or reduce)' used in this claim The agency concludes that a qualified statement is appropriate, and that the use of absolute terms such as 'prevent' is not justified in the labeling of sunscreen drug products."¹⁵ The TFM also provides examples of claims regarding protection against premature aging that the FDA would deem acceptable. Each of these examples explicitly includes the word "may" to qualify the protective benefits of sunscreens:

- (1) Sunscreen may reduce the chance of skin aging caused by exposure to the sun.
- (2) While biological aging is inevitable, sunscreen may help protect skin from aging caused by exposure to ultraviolet radiation from the sun.
- (3) Skin can age prematurely from exposure to the sun. Sunscreen may help reduce the chance of this type of aging.
- (4) May help inhibit the signs of skin aging caused by exposure to ultraviolet rays from the sun.¹⁶

(emphasis added).

¹³ 58 Fed. Reg. at 28286, TFM Comment 51 and § 352.52(e)(6) at 28298.

¹⁴ See n. 10, supra.

¹⁵ 58 Fed. Reg. at 28287-88, TFM Comment 52.

¹⁶ 58 Fed. Reg. at 28287, TFM Comment 52.

The TFM's discussion of claims regarding skin cancer protection is similar. The two examples of skin cancer related claims that are considered acceptable both include the qualifying word "may":

- (1) May reduce the chance of some kinds of skin cancers caused by exposure to the sun that would otherwise appear 20 years from now.
- (2) Regular, everyday use of this product from childhood on, may reduce the chance of some types of skin cancers caused by exposure to the sun."¹⁷

(emphasis added). The FDA states,

Because of the seriousness of skin cancer, the agency believes that sunscreen drug product labeling related to skin cancer should be especially limited and carefully stated. It is very important that the labeling of sunscreen drug products not include any phrases or terms that may induce a false sense of security in sunscreen users.¹⁸

Thus, with respect to claims that specifically mention protection against skin cancer or premature skin aging, the FDA has clearly indicated that lack of explicit qualification will render labeling unacceptable.

The staff of the Commission concurs with the FDA's conclusion that claims that are not appropriately qualified may induce in consumers a false sense of security. Some of the indications specifically permitted in the TFM may, however, inadvertently allow such unqualified claims. For instance, the TFM would allow any product containing approved sunscreen ingredients to bear a claim that it "shields from," or "protects from," or "filters," or "screens out" the "sun's rays," or the "sun's harsh rays," or the "sun's harmful rays" to "help prevent skin damage."¹⁹ These phrases are not required to be qualified. Such language may convey to many consumers a message that is considerably less qualified than FDA may intend. The effect would depend in part on the context in which a phrase is used. For example, the phrase "shields from," in the context of "the harmful rays of the sun," may evoke an image of complete

¹⁷ 58 Fed. Reg. at 28288, TFM Comment 53.

¹⁸ Id.

¹⁹ 58 Fed. Reg. at 28296 (§ 352.52(b)(v) and (vi)). Such claims would be allowed even for a product with an SPF as low as 2.

protection, implying to consumers that use of the product will provide complete protection from the sun's harmful rays.²⁰

Although these approved indications do not specifically refer to skin cancer or premature skin aging, they do permit reference to the more general term "skin damage." Since "skin damage" is broad enough to include all skin injuries associated with exposure to the sun's "harmful rays," some consumers might interpret it to encompass both skin cancer and premature skin aging (as well as sunburn, the more immediate and temporary effect of sun exposure). Thus, the staff of the Commission is concerned that these approved indications may convey to consumers just the type of unqualified messages that FDA seeks to avoid -- that use of sunscreen products will prevent skin aging or skin cancer caused by exposure to the sun. We therefore recommend that FDA examine carefully whether the use, without qualification, of such terms as "shields from," "protects from," "filters out," and "screens out" with reference to the sun's rays might convey an overstated message to consumers.

The TFM would also permit sunscreen labeling to state that the product "[a]llows you to stay in the sun up to (insert SPF of product up to 30) times longer than without sunscreen protection."²¹ While it appears that the intent of this indication is to inform consumers how much sun exposure they can incur before they will suffer a sunburn,²² it may convey a much more expansive meaning. Specifically, it may imply to consumers that they can safely stay in the sun for the specified period of time without risking any sun-induced skin injury. Consumers may be led to believe that use of the product will prevent, for that period of time, not only sunburn, but also any increased risk of other sun-induced chronic, long-term skin damage, such as premature skin aging and skin cancer. The FDA may therefore wish to consider modifying this indication along the following lines: "Allows you to stay in the sun without burning up to (insert SPF of product up to 30) times longer than without sunscreen protection."

²⁰ Similarly, claims that a product "filters" or "screens" out, or "protects from" the sun's rays may convey to consumers a greater sense of safety than FDA intends.

²¹ 58 Fed. Reg. at 28296 (§ 352.52(b)(1)(iii)).

²² The two approved indications preceding this one ("Sunscreen to help prevent sunburn;" and "Filters" or "screens out the sun's burning" or "harsh and often harmful rays" "to prevent sunburn") and the one following it ("Provides up to (insert SPF of product up to 30) times your natural protection from sunburn") are all specifically linked solely with protection from sunburn. 58 Fed. Reg. at 28296 (§ 352.52(b)(1)(i), (ii), and (iv)).

IV. UVA Protection Claims

The TFM does not include approved indications for protection against UVA radiation, because the FDA has determined that there is inadequate information for FDA to propose a method of determining a sunscreen product's ability to protect against it.²³ The TFM discusses the subject and requests comment on proposed labeling. The proposal would apply if (1) the ingredient absorbs ultraviolet radiation up to 360nm²⁴ or above and (2) the product containing the ingredient demonstrates UVA protection using testing procedures that the FDA proposes be developed.²⁵ Under this proposed labeling, products that satisfy these criteria would be allowed to use the following indications: "Protects against," or "Absorbs," or "Screens out," or "Shields from" "UVA rays" or "UVA radiation."

The same concern described in § III of this comment would apply here. These broad safety-related terms such as "shields from" may convey to consumers that the product provides complete protection from UVA radiation, so that if they use the product they need not be concerned about incurring any UVA-related skin damage. Unless the products to which such claims are affixed can in fact prevent any significant amount of potentially harmful UVA rays from penetrating the user's skin, such unqualified claims may well induce in consumers a false sense of security.²⁶

²³ 58 Fed. Reg. at 28233 and 28250, TFM Comments 53 and 73.

²⁴ Ultraviolet radiation from approximately 320 nanometers to 400 nanometers comprises the UVA range, while the lower range of 290 to 320 nanometers comprises the UVB range. 58 Fed. Reg. at 28233, TFM Comment 53.

²⁵ In the interim, until the final UVA testing and labeling regulation is issued and effective, products may bear UVA protection claims provided (1) they absorb UVA and (2) they meet the agency's enforcement policy which allows claims that appeared in labeling prior to the beginning of the OTC drug review process. 58 Fed. Reg. at 28233, TFM Comment 53.

²⁶ It is not clear from the FDA's proposal what percentage of the specified UVA spectrum (to 360nm or above) an ingredient must be able to absorb in order to satisfy the criteria for UVA protection labeling. It is not clear whether an ability to absorb 5 or 10 or 20 percent of this range would qualify an ingredient as an effective UVA protectant, or whether it must absorb close to 100 percent of the UVA spectrum up to 360nm in order to bear UVA protection labeling. If a relatively low threshold would qualify, then our concern would be particularly pertinent.

V. The PCDs

The TFM authorizes the use of a series of "Product Category Designations" or "PCDs"²⁷: "Minimal Sun Protection Product" for products with an SPF of 2 to under 4; "Moderate Sun Protection Product" for products with an SPF of 4 to under 8; "High Sun Protection Product" for products with an SPF of 8 to under 12; "Very High Sun Protection Product" for products with an SPF of 12 to under 20; and "Ultra High Sun Protection Product" for products with an SPF of 20 to 30. The FDA may want to consider whether the multiple superlative terms "high," "very high," and "ultra high" may be confusing to consumers. These multiple superlatives may unintentionally foster consumer confusion about the level of protection each SPF provides. In spite of its limitations²⁸, the SPF rating system has provided consumers with a clear basis for comparing different products' levels of protection. If the FDA concludes that additional verbal descriptors are nonetheless desirable, staff suggests that the proposed descriptor scheme be simplified so as not to include duplicative superlatives or terms potentially subject to misinterpretation. Because the SPF number is already available to help consumers compare products, staff suggests that the FDA be cautious about authorizing additional comparisons that may overstate the protection provided.

IV. Conclusion

Based on the Commission's extensive experience in analyzing advertising claims the the likely implicit messages they may convey, the staff of the Commission believes that the FDA's proposal includes terms and phrases for labels that may, unintentionally, misinform consumers about the level or type of protection that sunscreen products provide. The FDA may wish to conduct consumer research to learn how consumers interpret the proposed language and to test whether modified language might inform consumers more effectively and accurately. Many consumers are very interested in protecting their skin from sun damage, as evidenced by the tremendous increase in sales of sunscreens and the proliferation of products containing sunscreens. It is thus very important that the labeling information about the relative protection provided by available OTC sunscreen products not be deceptive or misleading. We appreciate the opportunity to provide these comments and hope they help the FDA in providing consumers with accurate and meaningful labeling information.

²⁷ 58 Fed. Reg. at 28221, TFM Comment 44; and § 352.52(e), at 28297.

²⁸ The SPF value is based only on a measure of protection from sunburn caused by UVB radiation.