

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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P R E S I D E N T

COMMENTS OF
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

IN RESPONSE TO

THE FOOD AND DRUG ADMINISTRATION'S

TENTATIVE FINAL MONOGRAPH

ON OTC SUNSCREEN DRUG PRODUCTS

(58 Fed. Reg. 28195 (May 12, 1993))

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I. Introduction and Summary of Comments

The Cosmetic, Toiletry, and Fragrance Association ("CTFA") is filing these comments concerning the Tentative Final Monograph ("TFM") for OTC Sunscreen Drug Products, published on May 12, 1993 (58 Fed. Reg. 28194). Founded 100 years ago, in 1894, CTFA has an active membership of approximately 240 companies that manufacture or distribute most of the finished personal care products marketed in the United States. CTFA members market or manufacture the vast majority of sunscreen products sold in the U.S., as well as a large number of other OTC drugs and cosmetic-drugs. CTFA members also export sunscreen products throughout the world, and many members have manufacturing plants located outside the U.S. CTFA also includes approximately 280 associate member companies from related industries, such as manufacturers of raw materials and packaging materials.

CTFA has been an active participant in all aspects of FDA's review of sunscreen products. For example, CTFA and our members have been strong supporters of the Sun Protection Factor (SPF) System, which FDA and the entire scientific community now regards as the backbone of the U.S. regulatory scheme with respect to sunscreens. Several years ago, when FDA raised questions regarding the need for SPFs greater than 15, CTFA and a number of our members participated in a public hearing and justified SPFs greater than 15 on both public health and scientific grounds. More recently, at FDA's request, CTFA undertook testing to demonstrate that different laboratories can obtain valid, reproducible results when

testing high-SPF sunscreen formulations. And finally, CTFA provided FDA with the results of research demonstrating the safety of two widely-used sunscreen active ingredients -- padimate O and oxybenzone.

Twenty years ago, when FDA's review of sunscreens began, sunscreen products were available on the market but were not widely used. Today, however, as a result of industry's efforts to improve the quality and efficacy of sunscreens, as well as public information efforts by many organizations -- the American Academy of Dermatology, the American Cancer Society, the Skin Cancer Foundation, the National Institutes of Health, CTFA, and FDA itself -- sunscreens are widely regarded as the most important weapon in the fight against damaging overexposure to the sun. And, as awareness of the sun's damaging effects has increased, the public health authorities are urging consumers to use sunscreens regularly, on a daily basis, and not simply when they are at the beach.

The cosmetic industry has responded positively, by reformulating thousands of traditional daily-use skin products to include sunscreen ingredients. Unfortunately, the current FDA proposal will serve as a disincentive for greater availability of sunscreens to consumers. It overburdens these products with unnecessary and, at times, confusing labeling requirements that will not benefit consumers and will force manufacturers to reconsider the inclusion of sunscreen ingredients in traditional cosmetic products. FDA must in the final sunscreen monograph include only reasonable and necessary labeling requirements and must recognize the distinction

among the many different types of products that contain sunscreen ingredients. The TFM overburdens all products containing a sunscreen with rigid labeling requirements that penalizes the use of sunscreen ingredients. Firms would be discouraged from continuing to include these important ingredients in products in the future. This is directly contrary to a sound public health policy.

Throughout our comments,¹ CTFA requests FDA to revise the TFM to permit flexibility with respect to labeling and claims for sunscreen products. In particular, we propose that FDA should adopt flexible labeling requirements for all products containing a sunscreen, and special rules for traditional cosmetic products that contain a sunscreen (also referred to as "secondary" sunscreen products), and different rules for lipsticks containing a sunscreen. Following those comments, we address the proposed "Recommended Sunscreen Product Guide" and comment on a number of general labeling issues raised in the TFM. The comment then suggests that the maximum SPF level set in the final Sunscreen Monograph should be high enough to encompass existing sunscreen products.

CTFA's comments will then focus on FDA's proposals with respect to water-resistant sunscreen products, followed by a discussion of why the term "sunblock" should be permitted to be used on any product with an SPF of 12 or greater. The comments then address two terms that should be permitted as descriptors of sun-

¹ These comments represent a consensus developed among the Association's membership, but do not supercede or preclude comments by individual members.

induced skin damage on sunscreen products: "skin aging" and "wrinkling." Next, the comments suggest modifications with respect to FDA's proposals for a number of active ingredients reviewed in the monograph. The conclusion of the comments addresses sunscreens in hair care products and tanning products, followed by an extensive section offering technical comments on a number of testing and methodological issues raised in the TFM.

II. Products Containing Sunscreens are Important and Consumers Should Be Encouraged to Use Them on a Daily Basis

It is universally recognized that substantial exposure to the ultraviolet rays of the sun can produce a wide variety of adverse health consequences, ranging from immediate burning of the skin, to premature aging, wrinkling, and other damage to the skin, to various types of skin cancers including malignant melanoma (a very serious form of skin cancer that has increased dramatically in the past several years). For these reasons, public health authorities, leading dermatologists, and other respected health organizations have advocated the use of sunscreens on a routine, daily basis -- not only when persons are at the beach or engaging in outdoor activities. For example:

- The former president of the American Academy of Dermatology (AAD), Mark Dahl, M.D., has stated: "We strongly recommend the routine use of sunscreens as one means of protection." (Emphasis added).²
- The AAD has stated that "because the majority of the lifetime sun exposure occurs during multiple brief

² News Release, Amer. Acad. of Dermatology, December 31, 1992.

exposures not intended to produce tanning, daily sun protection should be encouraged. Some population groups, such as those who sunburn easily, have light complexions or sun sensitivity disorders, benefit greatly from a high SPF sunscreen and probably should use it every day, all year round, particularly if they live in more equatorial latitudes. . . ."

The AAD went on to recommend that "[s]unscreens should be applied once a day in the morning and reapplied after swimming and heavy exercise. It is important for consumers to remember that substantial lifetime sun exposure occurs as everyday, brief incidental exposures. Examples of this are working outdoors, participating in outdoor recreational activities, and even walking about outside at lunchtime.

"On the basis of currently available knowledge, year-round sun protection including use of a high SPF sunscreen should be recommended for all individuals, particularly those who are fair-skinned and sunburn easily, beginning in childhood."³

- The AAD has also stated that "[i]n the course of a lifetime, the majority of sun exposure occurs during multiple brief exposures not intended to produce tanning. It is important, therefore, to encourage daily sun protection. It has also been shown that the regular use of sunscreens on youngsters until the age of 18 can reduce the incidence of skin cancer by as much as 78%."⁴
- The American Medical Association's Council on Scientific Affairs has advised that "[s]unscreens should be used daily on sun-exposed skin by individuals habitually exposed to the sun. . . . Frequent use of sunscreens should become a standard procedure for children. . . ."

³ Amer. Acad. of Dermatology *Photoaging/Photodamage as a Public Health Concern*, Consensus Statement, 1988.

⁴ Adequacy of Protection from Sunglasses and Sunscreens, 102nd Cong., 2d Sess. 243 (1992).

"Use a sunscreen on cloudy, overcast, or hazy days as well as on sunny days."⁵

- Fred Urbach, M.D., a leading dermatologist, has stated that "[f]ew people spend enough time on the beach to get skin cancer and wrinkled skin. . . . You get that from gardening, running and crossing the street. These are the things that add up over the years to chronic sun damage."⁶
- The National Institutes of Health Consensus Development Conference stated that "[d]aily use [of sunscreens] is recommended during appropriate times throughout the year."⁷
- Sidney Hurwitz, M.D., Clinical Professor of Pediatrics and Dermatology at Yale University, has written that because "sun damage and skin cancer begin in childhood, we must convince medical professionals, school teachers, recreation counselors, coaches, children, and parents that protection from overexposure to the sun is an important responsibility, and that appropriate sun protection, like tooth brushing, should become an everyday habit for everyone, children and adults alike."⁸
- Health Magazine has recommended that persons "[u]se a sunscreen with an SPF of 15 whenever you're outside, especially if you're fair-skinned." (Emphasis in original)⁹
- American Pharmacy Magazine advised persons as follows: "Don't forget to use your sunscreen on overcast

⁵ JAMA. 1989;262:383.

⁶ New York Times Magazine, May 1, 1988.

⁷ National Institutes of Health Consensus Development Conference Statement, Vol. 7, Number 8, May 8-10, 1989.

⁸ J. Dermatol. Surg. Oncol. 14:6 June 1988.

⁹ Health Magazine, April 1992.

days. The sun's rays are as damaging to your skin on cloudy, hazy days as they are on sunny days.

"Individuals at high risk for skin cancer (outdoor workers, fair-skinned individuals, and persons who have already had skin cancer) should apply sunscreens daily."¹⁰

- John DiGiovanna, M.D., of the dermatology branch of the National Cancer Institute, advised persons that: "Most importantly, you should find something that feels comfortable -- a solution, lotion or cream -- and apply it daily before you go out. Many women recognize that this is the way to prevent photo-aging and they will use a sun block before they put on their makeup."¹¹
- The FDA Consumer Magazine has pointed out that "[m]any dermatologists recommend daily sunscreen use to protect against insidious sun damage."¹²
- The FDA Consumer Magazine has also advised consumers that "[r]egardless of your skin color, if you're going to be out in the sun, even for a short time, apply a sunscreen to all skin that will be exposed."¹³
- A review article published in Cutis states that "[u]se of a sunscreen as part of a daily regimen is critical. Approximately two-thirds of our lifetime sun exposure occurs during incidental exposure. The incorporation of sunscreens into daily-use moisturizers is ideal for patients who use moisturizers."¹⁴

¹⁰ American Pharmacy, Vol. NS28, No. 4, April 1988.

¹¹ FDA Consumer, May 1991.

¹² FDA Consumer, June 1989.

¹³ FDA Consumer, July-August 1993.

¹⁴ Sterling, GB, "Sunscreens: A Review," Cutis, 50, 224, 1992.

- The textbook Cancer Medicine has pointed out that "[i]f the public were aware of the irreversible damage tissue damage resulting in aging changes, precancers, and cancer caused by [ultraviolet light], they might apply sunscreens with the same enthusiasm as they do deodorants and cosmetics."¹⁵

Sunscreen products thus are different from virtually every other type of OTC drug, because public health authorities recommend that the products be used on a daily basis by persons who have no illness, as a means of preventing serious disease in the future. The same authorities have increasingly urged the personal care product industry to publicize the health importance of sunscreens and to include sunscreen ingredients not only in products whose primary purpose is to protect consumers from extreme sunlight conditions (often referred to as "beach" sunscreen products), but also in a large number of general-purpose, traditional "cosmetic" products whose principal function is not the prevention of sunburn.¹⁶ The industry

¹⁵ Holland & Frei, Cancer Medicine (2d ed., 1982), 117.

¹⁶ There are on the market a number of categories of sunscreen-containing products that are cosmetics, not drugs: hair products that contain a sunscreen to protect the hair against sun damage, nail polishes that contain a sunscreen to protect the color from fading, and tanning products that contain a sunscreen but make no claims concerning the ingredient. FDA addressed each of these categories in the TFM. However, as is discussed infra, these sunscreen-containing products are clearly cosmetics and are therefore not subject to the OTC drug review.

In addition, there may be a few cosmetic skin care products on the market that contain a sunscreen but for which no sunscreen representation is made (i.e., there is no use of the word "sunscreen," no reference to the SPF level, no reference to "sunburn," and no other representation related to these purposes). In our opinion, such a product is properly classified solely as a cosmetic. The use of a sunscreen ingredient in a traditional cosmetic skin care product and the listing of that ingredient in the statement of cosmetic ingredients – without any representation

has responded positively, by substantial public education efforts and by reformulating thousands of cosmetic products to include sunscreen ingredients. This response reflects a genuine industry interest in sound public health principles, and is motivated by a desire to accommodate these principles where that can be accomplished without detracting from the basic cosmetic purpose of the product itself.

The industry's positive response also explains why such a large number of different types of products contain sunscreen ingredients: today, there are "beach" sunscreens, moisturizers with sunscreens, lip balms with sunscreens, "sport" cream sunscreens, lotions with sunscreen, lipsticks with sunscreen, and blush with sunscreen, to name just a few of the currently-marketed products. In order to encourage continued industry efforts and the use of sunscreen ingredients wherever feasible in all types of skin care products, it is vital for FDA to provide a regulatory framework incorporating flexible labeling requirements to safeguard this progress. Overly rigorous labelling requirements may simply create a disincentive and lead to the removal of sunscreen ingredients from certain daily-use products that experts recognize as providing critical sun protection.

CTFA will now discuss the types of labeling flexibility that should be adopted by FDA in the final sunscreen monograph.

relating to sunscreen or related purposes -- does not convert the product from a cosmetic to a cosmetic-drug, because there is no drug (sunscreen) representation involved.

**III. In Light of the Wide Variety of Sunscreen Products
and the Significant Benefits They Provide,
FDA Should Adopt Flexible Labeling Requirements for the Products**

FDA and CTFA share two common goals in developing a Final Monograph for OTC sunscreen drug products: 1) to ensure the products are safe and effective, and 2) to ensure the products are properly labeled.

The OTC drug review itself is a perfect example of the enormous flexibility available to FDA to fulfill its statutory obligations. Clearly, the broadest possible use of safe, effective and properly labeled sunscreens is an enormous public health benefit. Both FDA and CTFA thus share yet another goal -- namely, the widespread use of sunscreen products in a manner that fulfills these statutory obligations. All these goals are consistent with and in furtherance of public health, as discussed above.

The following recommendations for labeling flexibility for sunscreen products further all these goals. The recommendations allow long-standing cosmetic-type products to continue to be marketed in ways the public has come to understand without misleading consumers in any way. FDA should develop final rules that do not destroy these long-established cosmetic product categories by imposing overly-restrictive drug labeling requirements that serve no real public health purpose. In our opinion, if FDA were to impose a series of "one size fits all" labeling requirements, the use of sunscreen ingredients in many important and beneficial

product categories would be greatly reduced. Such an action by FDA would be inconsistent with past OTC drug policy decisions providing labeling flexibility.

CTFA's specific proposals for labeling flexibility. CTFA offers the following specific proposals for flexible, rational labeling policies for all products intended as primary sunscreen products -- whether they are traditional "beach" sunscreens, daily moisturizers with sunscreens, sunscreen lip balms, etc. In addition, as discussed below at pages 15 - 24, we believe that products containing sunscreens only as an adjunct to their traditional cosmetic purposes -- "secondary" sunscreen products, all of whose intended uses are for traditional cosmetic purposes -- as well as lipsticks containing sunscreens, should be permitted to bear certain different labeling as long as the claims made for them are limited.

The proposals for labeling flexibility are as follows:

1. CTFA supports the goal of educating consumers to the relationship between unprotected overexposure to the sun and development of skin damage. However, we believe that flexibility should be permitted in determining how that relationship is stated. In lieu of the "Sun Alert" set forth in proposed §352.52(e)(6), alternative examples of statements pertinent to skin aging due to the sun should be permitted, provided that the effect (i.e., skin aging) and the cause (i.e., the sun or UV radiation) are clearly linked. Examples of language acceptable to FDA are set forth at 58 Fed. Reg. 28287, and are as follows:

Sunscreen may reduce the chance of skin aging caused by exposure to the sun.

While biological aging is inevitable, sunscreen may help protect skin from aging caused by exposure to ultraviolet radiation from the sun.

Skin can age prematurely from exposure to the sun. Sunscreen may help reduce the chance of this type of aging.

May help inhibit the signs of skin aging caused by exposure to ultraviolet rays from the sun.

In addition, the following statements approved in the 1978 Sunscreen Panel Report should be permitted to appear in lieu of the "Sun Alert" set forth in proposed §352.52(e)(6):

Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects.

Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer.

CTFA believes a system that permits a number of truthful (and useful) statements about skin damage due to the sun is clearly preferable to one static "Sun Alert" statement on every sunscreen product. For one thing, a static "Sun Alert" message will soon become overexposed and so familiar that it will "wear out" and no

longer be consciously perceived.¹⁷ And second, a system that permits a variety of truthful statements to appear on various products increases the likelihood that each message will be regarded as novel; each message is therefore more likely to capture a consumer's attention than fixed language that is, after passage of time, expected to appear.¹⁸

2. The requirement for the "Recommended Sunscreen Product Guide" should be eliminated. (See the discussion of the reasons why FDA should not adopt the Guide, addressed below at pages 25 - 28.)

3. CTFA agrees with FDA's position in the TFM that the SPF number should appear on the Principal Display Panel of all products intended as primary sunscreens.

4. If the sunscreen product is intended only for adult use, the following statement (or similar statement) should appear in the directions: "For adult use

¹⁷ Kaufman, Memory Without Recall, Exposure Without Perception, J. of Advertising Research (Aug. 1977). See, e.g., Craig et al., Advertising Wearout: An Experimental Analysis, J. of Marketing Research (Nov. 1976); Greenberg et al., Television Commercial Wearout, J. of Advertising Research (Oct. 1973); Appel, Advertising Wearout, J. of Advertising Research (Feb. 1971).

¹⁸ This is the well known "von Restorff effect" based on the memory research by von Restorff in the 1930's. Hundreds of studies have since replicated this effect, see, e.g., Hastie, Schematic Principles in Human Memory, in Higgins, Herman & Zanna (eds.), Social Cognition: The Ontario Symposium on Personality and Social Psychology (Erlbaum, in press); Wallace, Review of the Historical, Empirical, and Theoretical Status of the Von Restorff Phenomenon, 63 Psychological Bulletin, 410-24 (1965).

only." In such a situation, no "warning" or "cautionary" statements concerning use by children need be provided.

5. Warnings should be appropriate for the proposed use of the product and any particular warnings necessary as a result of the sunscreen active ingredient(s) contained in the product. In general, the following type of warning statements are appropriate for all sunscreen-containing products except those intended to be applied to the lips:

For external use only, not to be swallowed. Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor.

6. Use of the signal word "Indications" should be optional. Use of the word is inappropriate on a product designed to be applied on a daily basis, by a person who is not sick, as a means of preventing a disease or condition in the future. However, we agree that one or more of the "Indications" listed in proposed §352.2(b)(1) should appear on the label. In other words, a sunscreen product might bear the statement "Sunscreen to help prevent sunburn" as set forth in proposed §352.52(b)(1), or it might bear one of the other statements permitted in that section, such as the following:

(v) (Select one of the following: "Filters" or "Screens")
"out the" (select one of the following: "sun's rays," "sun's harsh rays," or "sun's harmful rays") "to help prevent
(select one or more of the following: "lip damage,"
"skin damage," "freckling," or "uneven coloration").

(vi) (Select one of the following: "Protects from" or "Shields from") (select one of the following: "the harmful rays of the sun" or "the sun") "to help prevent" (select one or more of the following: "lip damage," "skin damage," "freckling" or "uneven coloration").¹⁹

7. Use of the signal word "Directions" likewise should be made optional. However, we agree that directions or information concerning use should appear and should be appropriate for the intended use of the product. For example, for a "Daily Moisturizer with Sunscreen," an appropriate use statement might be the following: "Apply liberally as needed to face, neck and other areas for moisturization and for protection against the sun's rays." If the product should be reapplied after a certain amount of time or after a certain type of activity (e.g., swimming or excessive perspiration), then such instructions should be provided and they should be based upon a firm's substantiation with respect to the need for reapplication -- not an arbitrary time period mandated by FDA that may be totally inapplicable (and inappropriate) for a particular product.²⁰

CTFA's proposals for labeling of other sunscreen products. CTFA believes that different, more flexible, regulatory requirements should be applied to cosmetic

¹⁹ As discussed infra, we believe that "skin aging due to the sun" and "wrinkling" also should be permitted as descriptors of sun-induced skin damage.

²⁰ See the discussion of the reapplication directions in connection with water resistancy issues, infra, at pages 34 - 35.

products that contain sunscreen ingredients²¹ at relatively low levels only as an adjunct to their primary purpose. Such products are clearly secondary sunscreen products: they are traditional cosmetic products, all of whose primary intended uses are for cosmetic purposes. Where a traditional cosmetic product includes a sunscreen claim on a panel other than the PDP only to alert the consumer to this secondary purpose, in accordance with sound public health objectives, there is a strong public policy argument that substantially different regulatory requirements should be applied.

The distinction between primary and secondary sunscreens is well-recognized by the consumer and has a long marketing history throughout the world. It is an established regulatory distinction in Australia and New Zealand.²² Furthermore, FDA itself recognized the validity of this distinction in the TFM, although the agency did not carry it to its logical conclusion.

Today in the U.S., many traditional cosmetic products (products such as moisturizers and body lotions, and color products such as blushes and foundations) contain a sunscreen ingredient but make modest reference to its presence in labeling.

²¹ CTFA agrees that any product that contains a sunscreen and makes any type of sunscreen claim (e.g., it bears an SPF number, or refers to sunburn, makes a "UV protection" or related claim) is an OTC drug. However, as FDA correctly recognized in a number of instances in the TFM, sunscreen-containing OTC drugs can be subject to different regulatory requirements.

²² Australian/New Zealand Standard, "Sunscreen Products - Evaluation and Classification," Joint Standard AS/NZS 2604:1993.

No one would dispute that the primary purpose of such products, as evidenced by their intended use and the claims made for them, is a cosmetic one. For example, the primary purpose of a daily moisturizer -- whether or not it contains a sunscreen -- is to moisturize the body. Likewise, the primary purpose of a blush -- again, whether or not it contains a sunscreen -- is to provide color to a woman's cheeks. The inclusion of sunscreens in these products at low SPF levels can and does provide considerable public health benefit in protecting consumers from casual UV exposure one gets from short trips out of doors, or even from sitting close to a window. As discussed above, the American Academy of Dermatology has stated that it is

important for consumers to remember that substantial lifetime sun exposure occurs as everyday, brief incidental exposures. Examples of this are working outdoors, participating in outdoor recreational activities, and even walking about outside at lunchtime.²³

From a public health standpoint, it makes no sense to force sunscreens out of such traditional cosmetic products or to prevent them from informing the public that they contain sunscreen ingredients for secondary purposes (such as incidental or casual sun exposure) as contrasted with primary purposes -- so long as consumers have accurate information about the products' use and their limitations.²⁴

²³ Amer. Acad. of Dermatology *Photoaging/Photodamage as a Public Health Concern*, Consensus Statement, 1988.

²⁴ Many currently-marketed cosmetics, which would be classified as secondary sunscreen products, are sold in containers that are quite small. Consequently, labeling space is limited. Some of this space is taken up by required elements such as the name and address of the manufacturer, the dual declaration of the net contents, the listing of the ingredients, a statement of identity, cosmetic directions for

Regulations requiring these secondary sunscreens products to be labeled like primary sunscreens would force many companies to remove the ingredient and leave the public without this accepted public health benefit. Because the main purpose of a secondary sunscreen is to function as a cosmetic, many companies would not want to convert their products to primary sunscreens; instead, they would simply remove the ingredient entirely.

CTFA believes that it is feasible and reasonable for FDA to separate these secondary sunscreen products into two distinct categories, with different regulatory requirements: 1) everyday cosmetic products (other than lipsticks) all of whose primary intended uses are for traditional cosmetic purposes, and 2) lipsticks containing a sunscreen, which women properly may rely upon as primary sunscreen products. Under our proposal, consumers and FDA could readily ascertain a product's regulatory status: if any product designed for general body use contained a reference to an SPF number or the word "sunscreen" appears on its PDP, or if any reference is made to "sunburn," or if the its labeling bears one of the "Sun Alerts" we have proposed above, or if the product is intended for general body use and its SPF is higher than 6, or if other labeling indicates that the manufacturer intends the

use, and the brand name of the product. For these reasons, in 1976 when FDA promulgated the cosmetic ingredient labeling regulations (21 C.F.R. §701, et seq.), the agency recognized the space problem and off-package ingredient labeling was allowed when the package surface area was less than 12 square inches. Moreover, as is discussed elsewhere in these comments, recent industry trends are to reduce excess packaging for environmental reasons. Specifically, blister cards and cartons (and therefore package inserts) have been eliminated by many manufacturers.

product to be used primarily as a sunscreen, then it would be a primary sunscreen product and would therefore bear one of the indications contained in proposed §352.52(b)(1), etc. On the other hand, as is discussed below, if the manufacturer intends its product primarily to be a cosmetic product, under our proposal the product labeling would be different from a primary sunscreen product. The only exception, also discussed below, would be lipsticks containing a sunscreen.

Proposals for labeling of secondary sunscreen products. We propose that flexible, rational labeling policies be adopted for secondary sunscreen products. These policies are designed to ensure that consumers will not and cannot mistake the products for ones whose primary purpose is to provide sun protection. These policies will permit a manufacturer fairly and truthfully to inform the consumer that there is a secondary sunscreen benefit, and cosmetic manufacturers would thus be encouraged to continue providing the public health benefit of protection from casual sun exposure. Our proposed requirements for secondary sunscreen products are as follows:

1. Because secondary sunscreens are intended only for incidental or casual sun exposure:

- no sunburn protection claims or other reference to sunburn would be permitted in the labeling;²⁵

²⁵ Because a secondary sunscreen product is not intended for sunburn protection, the "Recommended Sunscreen Product Guide" likewise should not be required. (See the general discussion of the reasons why FDA should not adopt the Guide, addressed below at pages 25 - 28.)

- to make certain that consumers know the intended use of the product, one of the following two statements would be made in immediate proximity to the SPF claim: "Not intended as a substitute for sunburn protection," or "Not intended for use as a primary sunscreen;"
- no reference to "sunscreen" or "SPF" would be permitted on the PDP, but both terms ("sunscreen" and "SPF") would appear elsewhere in labeling, in conjunction with each other;
- no "Sun Alert" statement as proposed above would be permitted in labeling;
- no reference to "skin cancer" or other cancers would be permitted in the labeling; and
- in order to make certain that there is no confusion in consumers' minds between the two categories of sunscreen-containing products, a product claiming an SPF greater than 6 could not be treated as a secondary sunscreen.²⁶

2. A secondary sunscreen product would still be required to list the active ingredient(s), like any OTC drug. In addition, such a product would have to comply with all cosmetic labeling regulations (e.g., full ingredient labeling, etc.).

²⁶ On the other hand, a primary sunscreen product could have an SPF higher or lower than 6. For example, a full line of "beach" sunscreens might consist of products with SPFs of 4, 8, 15, 30 and 45. Similarly, a firm that wanted to make sunburn protection claims for its product could choose to market a "sunscreen with daily moisturizer" product and subject the product to all the "primary" regulatory requirements discussed above (at pages 11 - 15). Such a product could have an SPF higher or lower than 6.

3. The claims that could be made for such a secondary product would be limited. As discussed above, no reference to "sunburn" or "skin cancer" would be permitted, use of the terms "sunscreen" or "SPF" would not be permitted on the PDP, and no "sun alert" would be permitted. However, in order to ensure that consumers fully understand that such a product is intended primarily as a cosmetic and therefore only for incidental (or casual) sun exposure, the following are examples of claims that should be permitted:²⁷

- "Helps reduce the chance of skin aging caused by incidental (or casual) exposure to the sun. SPF ____."
- "SPF ____ . Helps protect skin from aging caused by incidental (or casual) exposure to ultraviolet radiation from the sun."
- "Helps reduce premature aging from incidental (or casual) exposure to the sun. SPF ____."

4. There is a long history of safe use of these types of products, and therefore FDA should permit reduced warnings, as follows:

"For external use only, keep out of eyes. Discontinue use if signs of irritation appear."

Adoption of these proposals will ensure that consumers wanting to purchase a primary sunscreen product would not mistake a secondary sunscreen cosmetic product for one intended primarily to provide sun protection. Indeed, the labeling statements that will appear in immediate proximity to the SPF claim -- "Not intended

²⁷ As can be seen from the examples, CTFA is of the opinion that the SPF number should always accompany any sunscreen and/or sun exposure claim.

as a substitute for sunburn protection," or "Not intended for use as a primary sunscreen" -- and the lack of directions for use as a primary sunscreen, will make the intended use crystal clear to consumers, so that the products will not be relied upon for sunburn protection or as a primary sunscreen. Furthermore, these proposals will enable consumers to differentiate quickly and with certainty between the two categories of sunscreen-containing products. To ensure that consumers could still judge the level of protection offered by a secondary product, the terms "sunscreen" and the SPF number would be required to appear in conjunction with each other, but unlike a primary sunscreen product, the terms could not appear on the PDP. The fact that secondary products will have low SPFs provides additional assurance that there is no confusion in consumers' minds between primary and secondary sunscreen products.

Proposals for labeling of lipsticks containing a sunscreen. As indicated above, we also are of the opinion that one exception to these general rules should be applied to lipsticks containing a sunscreen. For one thing, these products are always of a very small size, they are always sold in small packages, and many of their containers are decorative in nature.²⁸ In addition, unlike other cosmetic products, which are often applied on top of each other (e.g., a foundation is applied on top of

²⁸ Such containers are given explicit recognition and different regulatory treatment in FDA's labeling regulations for cosmetics. 21 C.F.R. §701.13(e) provides special rules for a "cosmetic marketed in a 'boudoir-type' container, including decorative containers of the 'cartridge,' 'pill box,' 'compact,' or pencil variety, and those with a capacity of one-fourth ounce or less."

a moisturizer, with a blush then added for further coloring), the only cosmetic usually applied to the lips is lipstick. Lips are often vulnerable to sun exposure, and there is absolutely no reason why a woman at the beach should not use a high-SPF lipstick. For broad public health purposes, therefore, we believe that the following simple and straightforward rules should be made applicable for lipsticks containing a sunscreen:²⁹

- in light of their small size, reference to "sunscreen" and "SPF" would be permitted anywhere on the product, in conjunction with each other;
- no other claims relating to sun protection or skin protection would be permitted. Specifically, no "Sun Alert" statement of any kind, no reference to "skin cancer" or other cancers would be permitted, and no reference to "skin aging caused by the sun" or by "incidental exposure to the sun" would be permitted;³⁰
- because a lipstick may be used as a primary sunscreen, the product would not be limited to an SPF cap of 6. Rather, a lipstick with sunscreen would be subject to the same SPF requirements as may be imposed with respect to a "primary" sunscreen; and
- in light of the long history of safe use of the products, the following reduced warning is appropriate: "Discontinue use if signs of irritation appear."

²⁹ Of course, a lipstick containing a sunscreen would still be required to list the active ingredient(s), like any OTC drug. In addition, because the product would be a cosmetic/drug, it would also have to comply with all cosmetic labeling regulations (e.g., full ingredient labeling, etc.).

³⁰ On the other hand, a firm that wanted to make claims for its lipstick with sunscreen – e.g., claims relating to sunburn protection or protection from lip damage – could do so. In such a situation, the product would be a primary sunscreen subject to all the regulatory requirements for primary sunscreens discussed above at pages 11 - 15.

Proposals for all color products containing a sunscreen. Finally, FDA should recognize that all color products containing sunscreens (e.g., blushes, foundations and lipsticks) also raise unique manufacturing issues. Unlike noncolor products, color products must frequently be reformulated to reflect rapid changes in fashion and in the seasons. The type of process validation that FDA has described in its May 1987 guidance on "General Principles of Process Validation" could not be undertaken by a manufacturer of lipsticks with 200 separate shades, all of which contain a sunscreen ingredient. If color cosmetic manufacturers were held to overly rigid revalidation standards, very few if any would be able to keep a sunscreen ingredient in these products. For example, requiring "replicate process runs to demonstrate reproducibility" with every slight change in color for thousands of color cosmetics containing a sunscreen would be prohibitively expensive. Similarly, the new labeling controls established in 58 Fed. Reg. 41348 (Aug. 3, 1993) could not be met by these products. FDA should foster, rather than discourage or even prohibit, the use of sunscreens as secondary ingredients in color cosmetics.

All of these proposed requirements, if adopted by FDA in the final sunscreen monograph, will ensure that consumers will have adequate and correct information about secondary sunscreen products. However, the modifications we propose are flexible enough that manufacturers will not have any disincentive to remove the sunscreen ingredient from their products -- a result that would benefit no one.

**IV. The "Recommended Sunscreen Product Guide" Is Impractical
and Unnecessary and Should be Eliminated or Made Optional**

The TFM's proposal that would require the "Recommended Sunscreen Product Guide" is both onerous and unnecessary. FDA should, in the final Monograph, eliminate the requirement that it appear in labeling, as was done in the 1978 Panel Report on sunscreens.

CTFA has no quarrel with the obvious proposition that consumers should have sufficient sunscreen label information so that they can make correct purchase and use decisions concerning the products. However, sunscreen labels should not be used to give consumers extraneous and unnecessary information. The Guide would have the effect of cluttering and obscuring important label information, and therefore would not assist consumers in making correct purchase and use decisions.

CTFA has already filed a letter, dated November 24, 1993, in which we set forth in detail the reasons why FDA should not adopt the Guide. A copy of that letter is attached as Exhibit A and is incorporated herein by reference. Briefly, the arguments against the Guide are as follows:

- The SPF system has been in place since the mid-1970's, or almost 20 years. Consumers understand it and know what level of protection they need. Perhaps the Guide could have been justified in the mid-70's, when the SPF concept was new to consumers, but it certainly cannot be justified now.
- The Guide takes a simple system -- the SPF number -- and turns it into something complex and confusing.

- It might be argued that the Guide could help a "first-time" sunscreen user who would find the information useful, but no one really is a first-time user. For example, parents routinely put sunscreens on children, so even a young person who purchases a sunscreen for the first time knows what level of protection he or she needs.
- The Guide gives too much information -- and unnecessary information -- to any particular consumer. For example, a consumer with highly sun-sensitive skin knows that he/she requires an SPF of 20 to 30 (or above), and there is no reason to give that person information about the SPF needs of an olive-skinned person.
- A drug label should not be used to give consumers extraneous information about other products that are available for purchase,³¹ i.e., sunscreen products with other SPFs. A requirement to provide information on other products is virtually unheard of; as an example, 325 mg. aspirin tablet labels are not required to contain any statements about the relative efficacy of 500 mg. aspirin tablets, or the efficacy of other pain relievers containing other ingredients (such as acetaminophen or ibuprofen). Although tampon product labels currently must make comparative statements with respect to absorbency, such regulatory requirements were mandated because of toxic shock syndrome concerns. In any event, a tampon box provides a much larger label than a sunscreen.³²

³¹ In fact, some of the disclosures might require an a firm to give information with respect to a competitor's products. For example, according to the Guide a firm that made only sunscreens with SPFs of 15 and above still would be required to provide information about the usefulness of sunscreens with SPFs below 15, or products made solely by its competitors within the industry.

³² Furthermore, an individual consumer will find the comparative information on tampons useful to her, because on any given day her menstrual flow might dictate the need for any of a number of absorbencies -- super plus, super, regular or junior. Thus, the situation with respect to labeling of tampons is much different than sunscreen labeling: in the latter situation, an individual's skin type will always be the

- It could be argued that the Guide might provide helpful information for various family members that had different skin types -- e.g., a family where one parent is olive-skinned, one child is very fair-skinned, another child tans gradually, etc. However, an OTC drug label has never been used to require that families be given information concerning the full range of products available for various family members. Again, to cite internal analgesics as an example, the label of an acetaminophen-containing product has never been required to discuss the availability and usefulness of regular strength tablets, children's strength tablets, junior strength chewable tablets, elixirs or drops -- each of which constitutes a different dosage form and strength that might be appropriate for a particular family member.

As discussed in our November 24 letter, the Guide is particularly inappropriate and unworkable for sunscreen labels, for the following reasons:

- Most sunscreens are 4 oz. or less, and the sunscreen bottles or tubes therefore are quite small. Furthermore, very useful products such as sunscreen lip balms could never fit the Guide on the label. It is very important to the goal of encouraging sunscreen use that these products be available in convenient, easily-transportable sizes.
- Many sunscreen manufacturers have discontinued use of outer cartons for environmental reasons, and therefore package inserts cannot be used. Consumers are pro-environment and they object to over-packaging. In addition, as discussed above in connection with general labeling requirements, a number of states have considered a ban on outer packages because of environmental concerns.

same.

- A great deal of label space is already taken up by required or essential information, and therefore there is only a small amount of label space available on the label for "non-essential" information. This means that the space for additional label information is at a true premium and should not be taken over by unimportant and unnecessary information.

For these reasons, as well as the others set forth in our November 24, 1993, letter, we strongly urge that the "Recommended Sunscreen Product Guide" not be required in labeling. As an alternative, FDA could make its use optional at the discretion of the sunscreen manufacturer or marketer, as was suggested in the 1978 Panel Report. On the other hand, if FDA continues to be of the opinion that the Guide should be made mandatory, firms should have the option of providing the information at point-of-purchase displays or at "shelf-talker" displays. FDA recently adopted such a procedure in regulations implementing the Nutrition Labeling Rule, where the agency permitted a variety of information to be displayed in stores.³³

**V. The Labeling Proposed in the TFM is Excessive
And, in Some Cases, Confusing**

The amount of labeling required for sunscreen products under the TFM is excessive and unnecessary. For smaller package sizes (4 oz. and less) typical of most products containing sunscreen marketed today, the amount of labeling required may

³³ See, e.g., Section 101.45 of the Nutrition Labeling Rule regulations, which state that nutrition labeling for raw fruit, vegetables and fish "should be displayed at the point of purchase by an appropriate means, including affixing it to the food, by posting a sign, or by making the information readily available in brochure, notebook, or leaflet form in close proximity to the foods."

simply be impossible to fit on the primary product container, and in the case of the smallest packages -- such as stick products for lips and other sensitive facial areas -- the required labeling may be impossible to fit on the primary product container and the secondary carton (if any is used). NDMA label readability guidelines, which are commended by the preamble section of the Sunscreen TFM, currently suggest a minimum target type size of 4.5 points for black-on-white, and a minimum type size of 6 points for reversed copy, with a minimum stroke width of 0.013 inch.

Although the preamble section of the Sunscreen TFM suggests the use of product inserts,³⁴ these are not a practical solution to the labeling dilemma. Most manufacturers have discontinued the use of product inserts and secondary cartons in response to environmental concerns over solid waste. Several states have already enacted package reduction legislation, and, in many other states, such legislation has been introduced or is being contemplated. Manufacturers have also voluntarily moved toward elimination of certain types of packaging in response to the environmental concerns of consumers.

CTFA therefore strongly disagrees with FDA's position that additional packaging should be used to accommodate the proposed labeling for sunscreen drug

³⁴ The agency states in the preamble of the TFM that "[i]n those instances where an OTC sunscreen drug product is packaged in a container that is too small or otherwise unable to include all of the required labeling, the product can be enclosed in a carton or be accompanied by a package insert that contains the information complying with the monograph." 58 Fed. Reg. 23217.

products. As responsible manufacturers of consumer goods, the consumer products industry is responding to solid waste and environmental concerns with major efforts to reduce the impact of packaging materials. This is being achieved by manufacturers and marketers reducing packaging through a combination of source reduction (including eliminating the outer cartons for some products), incorporating recycled content, providing refillable and reusable options, and designing packaging to be more easily recycled and incorporated back into new products.

This last effort has led to the development of the Preferred Packaging Guidelines by the Coalition of Northeastern Governors (CONEG) to help companies design, develop, manufacture, use, and distribute packages components while keeping packaging at a minimum. The guidelines are as follows: 1) no packaging; 2) minimal packaging; 3) returnable, reusable or refillable packaging; or 4) recycled content or recyclable packaging. While the guidelines are voluntary, approximately 30 U.S. consumer products businesses, many of which are CTFA member companies, have adopted these principles and are actively pursuing ways to reduce their use of packaging and packaging materials. The CONEG governors have suggested voluntary compliance with the Preferred Packaging Guidelines in an attempt to prevent formal legislation of packaging and packaging materials reduction. The solution suggested by the agency, which encourages the use of additional packaging to accommodate the labeling proposed in the TFM, therefore conflicts with the

programs underway by many of our member companies to reduce/eliminate their uses of packaging and packaging materials.

Furthermore, it is impractical for manufacturers to include all the labeling proposed in the TFM as well as the additional copy needed in order to sell the product. If all labeling currently proposed in the TFM were actually mandated, a sunscreen label would include the product trade name, statement of identity, logo or other distinctive graphic elements, manufacturer's name and address, net content declarations (metric and avoirdupois), SPF declaration(s) and accompanying statements (for water-resistant or very water-resistant products these would read, for example, SPF 23 before sweating or going into the water, SPF 20 after 40 minutes of sweating or activity in the water -- a point that is addressed below), indications, directions for use, warning statements, active ingredient declaration, inactive ingredient declaration, marketing copy, the manufacturer's toll-free telephone number for consumer inquiries, the "Sun Alert" statement, the "Recommended Sunscreen Product Guide" (to which CTFA objects for the reasons set forth above), and the universal product code that is necessary on all products sold in traditional retail outlets. When one examines the labeling elements that are required to be presented on the Principal Display Panel or the front panel of the package, the design problem becomes quite difficult for products packaged in 2 oz. to 4 oz. tubes, where display space is inherently limited, and it becomes particularly acute for lip products packaged in tubes which are usually 0.2 oz. or less.

In addition, FDA asked for comment on the question of requiring a product to state on the label that it "does not provide UVA protection," if that is the case. CTFA and our members object to such a proposal. If a product does provide UVA protection, it should of course be permitted to inform consumers of that fact on its label. However, a product that does not provide such protection should not be required to make a "negative" disclosure to that effect. Thousands of consumer products are marketed with limited claims of utility, and there has never been any general FDA policy requiring "negative" disclosure of broader purposes for which they are not useful. There is no reason why sunscreens should be handled differently.

Finally, a number of the indications and directions in the Sunscreen TFM are excessive in length and, in some cases, unnecessary or confusing. For example, the indication for an SPF 8-12 product, "High protection against sunburn for blondes, redheads, and fair-skinned persons" is very difficult to defend from the point of view of photobiology (because an SPF 8 product will protect a fair-skinned person whose MED will cause her to burn in 10 minutes, for only 80 minutes – which is hardly "high" protection for a person in a hot mid-day sun). Furthermore, the indication for an SPF 8-12 product is difficult for the consumer to differentiate from the indication for an SPF 20-30 product, which is described as "The most protection against sunburn for blondes, redheads, and fair-skinned persons."

In sum, FDA should rethink its overall labeling policies for sunscreen products along the line discussed in this section. The agency should bear in mind that products containing sunscreen are packaged in small containers (usually with no outer carton and therefore no package inserts), and the amount of labeling required should not be excessive.

**VI. The Maximum Level for SPF Limits Should Be Set High Enough
To Encompass Existing Sunscreen Products**

The suggested upper limit of SPF 30 is not justifiable on either a scientific or public health basis. A number of sunscreen products currently on the market are labeled with SPFs ranging from 30 to 50 and are providing the extra protection needed by some consumers. There are no inherent safety problems posed by these high SPF products; in fact, many practicing dermatologists have already written FDA in support of high SPF products and the health benefits offered to their patients.

Placing an upper limit of 30 on SPF claims would inhibit current and future scientific efforts to develop products that provide legitimate benefits to consumers. A prohibition on SPF claims over 30 would inappropriately stifle perfectly legitimate innovations in this field. Any limitations on labeling claims must provide for current products with an SPF of 50.

**VII. A Number of FDA's Proposals with respect to Water-Resistant
Sunscreen Products Should be Modified**

CTFA disagrees with a number of the changes proposed in the TFM with respect to "water-resistant" sunscreen products.

First of all, CTFA strongly objects to FDA's proposal (contained in proposed 21 C.F.R. §§352.50(b)(2) and (c)(2)) to require two SPF values on water-resistant and very water-resistant sunscreen products. We do not believe that the use of two numbers will be of benefit to consumers. Rather, we believe that there should continue to be one SPF value and that said value should be the SPF of a product after water immersion. Consumers have had approximately 15 years of experience with sunscreen products that have been labeled with one SPF value. The SPF value would be assumed to be the static SPF unless a product makes water-resistant/proof claims. Consumers will know if they need to purchase a sunscreen product that provides protection after exposure to water and/or excessive sweating. They will intentionally look for the indication of water resistance/proof on a product label and assume that the stated SPF is the value after exposure to water and/or excessive sweating.

Second, the directions in proposed 21 C.F.R. §352.52(d)(2) would require a sunscreen product label to state how often the product should be reapplied in order to maintain its stated SPF value. The incorporation of two SPF values would result in confusion concerning the value that is achieved after reapplication. If a label is

required to state that the product should be reapplied after water exposure and/or excessive sweating, the additional SPF value provides no useful information to the consumer.

Third, as discussed above (see page 15) in connection with other overly-restrictive requirements concerning "Directions," CTFA believes that FDA should permit firms to provide truthful reapplication instructions based on the substantiation the firm possesses -- not on arbitrary time periods selected by the agency.³⁵ If a firm possesses adequate substantiation that its product does not need to be reapplied as frequently as the reapplication periods selected by FDA, then it should not be strait-jacketed by the agency's time periods. A firm that manufactures a longer-lasting product that does not need to be reapplied as frequently as its competitors' should be able to make a truthful claim to that effect. Any other result would create a disincentive for firms to develop innovative, long-lasting formulations.

Finally, CTFA urges FDA to reconsider its proposal to describe sunscreens as "very water-resistant." Consumers are already familiar with the term "waterproof," which has been used for many years, and substitution of the term "very water-resistant" creates additional confusion and uncertainty.

³⁵ 21 C.F.R. §352.52(d)(2) of the TFM, for example, would require water-resistant products to state that they should be reapplied after 40 minutes of swimming, etc., and it would require very water-resistant products to state that they should be reapplied after 80 minutes of swimming, etc.

VIII. The Term "Sunblock" Should Not Be Restricted to Products Containing Titanium Dioxide; Rather, the Term Should be Permitted For Any Product with an SPF of 12 or Greater

The TFM states that the term "sunblock" should be reserved exclusively for sunscreen drug products containing opaque ingredients, specifically those which are SPF 12 or higher and contain the ingredient titanium dioxide. This is based on the assumption that titanium dioxide "reflects the burning rays of the sun." However, we submit that the use of the term "sunblock" should not depend on the mechanism of action or the specific active ingredient, but rather on the end result -- namely, protection from sun damage.

Any sunscreen product that stops ultraviolet radiation from reaching the skin "blocks" the UV. This is not only a function of what might be labeled "physical sunscreen" agents, but is also true of "organic sunscreen" agents. The method by which the product stops the UV from entering and burning the skin is irrelevant to the effectiveness of its performance, which is expressed as its SPF.

An SPF 12 product blocks 90% of the sun's burning rays regardless of the composition of its active ingredients, and an SPF 15 product blocks 93% of those rays -- again, regardless of its active ingredients. A consumer is interested in how well the product works, not the specific ingredient(s) that provides protection or the specific mechanism of protection. In a combination product, a minimum amount of titanium dioxide can be used in combination with other active ingredients to achieve the product's SPF. Calling an SPF 12 product that contains 2% titanium dioxide, octyl

methoxycinnamate and oxybenzone a "sunblock," while calling an SPF 30 product that contains octyl methoxycinnamate, oxybenzone and octyl salicylate only a "sunscreen" is misleading and confusing to consumers trying to choose a sunscreen product providing the highest level of protection. The SPF 15 product is blocking significantly less damaging UV than the SPF 30, but according to the TFM it could be labeled "sunblock." This distinction in the description of performance is inappropriate from both the scientific and the consumer perspective. For many years, use of the term "sunblock" has been based on a product's high level of protection from damage, and not on its mechanism of action.

It is a disservice to the consumer to reserve the term "sunblock" for certain products that might be selected based on erroneous assumptions of efficacy. All sunscreen products with SPFs of 12 or above should be allowed to use the term "sunblock," since all such products by definition block in excess of 90% of the sun's harmful rays. It is the percentage of the damage blocked that should constitute the definition of a "sunblock," not the composition of active ingredients chosen.

IX. The Terms "Skin Aging" and "Wrinkling" Should be Permitted as Descriptors and/or Indications for Sunscreen Products

CTFA proposes that use of the term "skin aging" should be permitted as a descriptor of sun-induced skin damage, on the ground that the term "skin damage" (proposed by the agency) is not sufficiently precise so as to convey to a consumer the specific type of skin damage that sunscreens can protect against. Skin aging, on the

other hand, is well-known to consumers as a particular type of skin damage. In addition, CTFA believes that the term "wrinkling" should be permitted to be used in one of the approved "Indications," along with approved terms such as "freckling" and/or "uneven coloration. Our rationale is as follows:

"Skin Aging." Consumers understand the term "skin aging" and associate it with the damaging effects of the sun. A 1993 consumer perception study³⁶ showed that consumers associate "premature aging" with skin looking older, more wrinkled than expected for chronological age. Further, consumers believe "premature aging" is caused by sun-exposure and life-style.

During the past several years there have been numerous articles concerning the hazards of sun exposure. The major theme of the articles is that there are two major types of sun damage -- cancer and skin aging. The articles have definitely succeeded in educating the public about the adverse effects of sun exposure. As a result of these efforts, today's consumer is more knowledgeable and very definitely associates sun exposure with skin cancer and skin aging.

³⁶ "Consumer Skin Aging Perception Study." Procter & Gamble Company, Cincinnati, Ohio (August 1993).

A study conducted by the American Academy of Dermatology³⁷ illustrates this point. The AAD study, which surveyed fashion leaders regarding consumer trends and attitudes towards tanning and sun bathing, revealed that a deep tan and prolonged sun bathing habits are rapidly declining. The main reason for this is fear of premature aging of the skin and knowledge about skin cancer. Two notable quotes from two fashion leaders illustrate this point succinctly: Shirley Lord of Vogue stated: "women are very aware that the sun causes premature aging--photodamage. There definitely is a trend away from deep sun tanning." And Linda Wells of the New York Times Magazine suggested that women are learning from past mistakes: "The effects of the sun are now visible on a whole generation of women who sat in the sun. The results are aged, leathery-looking skin. People are starting to take care of themselves and cover up and use a sunscreen."

The AAD study clearly illustrates that the media's efforts have been successful. Consumers are already familiar with the concept of sun-induced skin aging and cancer. The term "skin damage" is not adequate by itself; rather, "skin aging" is more readily recognized and is better associated with the hazards of sun exposure. It is more consistent with the terminology currently being used by the media, which has the effect of aiding consumer understanding.

³⁷ "Fashion Leaders Say The Tan Is Fading," American Academy of Dermatology Survey, American Academy of Dermatology and the Avon Foundation (1988).

Furthermore, "skin aging" is consistent with the terminology used as examples of alternative, approved claims set forth in the TFM. (See 58 Fed. Reg. 28287. The list of approved claims is reproduced above, at page 12.) All these claims refer to "skin aging" rather than "skin damage." The agency makes several references in the TFM linking premature aging of the skin as a harmful effect of sun exposure, as follows:

- The agency believes that consumers equate the term "sunscreens" or similar terms with the mitigation of the harmful effects of the sun, such as sunburn, premature aging of the skin (or skin aging due to the sun), and skin cancer. 58 Fed. Reg. 28204.
- Any variation of the statements in proposed §352.52(e)(6) (the "Sun Alert") that does not relate skin aging or skin cancer as being "due to the sun" will cause the product to be misbranded under the section 502 of the Federal Food, Drug, and Cosmetic Act. 58 Fed. Reg. 28298.

For all the above reasons, the term "skin aging" due to sun exposure appears to be a term more frequently associated -- and more accurately associated -- with sun exposure than "skin damage."

Wrinkling. CTFA likewise believes that the term should be authorized to be used in one of the "Indications" set forth in proposed §§352.50(b)(1)(iv) and (b)(1)(v). In those sections, FDA has proposed that the terms "freckling" and/or "uneven coloration" may be used to describe a product's intended function. CTFA believes that the term "wrinkling" should be added as one of the approved terms,

because wrinkling -- like freckling and uneven coloration -- is one aspect of the signs of sun-induced skin damage.

It is important to describe skin damage or aging in terms with which consumers can readily identify and associate. "Wrinkling" is extremely important to consumers, and the term is easily understood. Furthermore, wrinkling has a strong psychological impact on how consumers view their appearance. Consumers strongly associate wrinkling with skin aging and their desire to avoid an "aged look" causes them to seek protection. Hence, use of this term to describe sun-induced skin aging is a powerful way to motivate consumers to seek sun protection.

The following studies illustrate that skin cancer and wrinkling are widely identified as the most undesirable consequences of sun exposure. A national survey³⁸ on the attitudes of 502 women on the aspects of skin aging revealed:

- 86% believed that unwrinkled skin is an important attribute.
- After skin cancer, wrinkling and age spots were the most frequently mentioned dangers of the sun exposure.

In addition, the 1993 Consumer Study of 252 women on the aspects of Skin Aging revealed:

³⁸ "A National Survey on Women's Attitudes Toward Appearance." Avon Beauty and Skin Care Report, Avon Products, Inc. and the University of Pennsylvania Center For Human Appearance (1990).

- 87% of all consumers cited wrinkles/lines as the most obvious signs of aging.
- 64% of the respondents thought wrinkling was caused by sun exposure. Consumers readily associated sun exposure with wrinkles.
- Consumers were almost equally concerned with Wrinkling as Skin Cancer.

A survey by the American Academy of Dermatology and Self magazine on the attitudes and sun practices of 500 women³⁹ revealed:

- After skin cancer, 50% of the women getting less sun exposure than 10 years ago cited fear of wrinkling as the reason.

A survey of the knowledge about sunscreens and sun hazards among 489 outpatients in a dermatology/internal medicine clinic⁴⁰ demonstrated that:

- 73% believed sun exposure causes wrinkling of the skin and 69% believed it causes skin cancer.

And finally, a magazine survey of 6,000 readers⁴¹ showed:

- 57% stated they spend less time in the sun for fear of wrinkles.

³⁹ "Women and the Sun." Self Magazine Survey of Women, Self Magazine and the American Academy of Dermatology (1989).

⁴⁰ "Sunscreen Use and Sun Exposure". Johnson E.Y. and Lookingbill D.P., Arch. Dermatol., 120, 727-731 (1984).

⁴¹ "Good-Bye Summer Tan", Glamour Magazine Survey of 6000 Women, Glamour Magazine Inc., May 1993 Issue. (1993).

These five studies, taken together, clearly illustrate that the term "wrinkling" is in the consumer's vocabulary, and that after skin cancer, "wrinkling" is recognized as the primary concern of sun exposure.

Each year the public reads numerous articles on the hazards of sun exposure and safe sunning. Due to those tremendous educational efforts, consumers are aware and do understand the reasons for sun protection. However, despite these efforts, many consumers do not routinely use sunscreen for all conditions of sun exposure. This point was demonstrated in the hospital/clinic survey discussed above, which showed that

[t]here was a notable disparity between [the health care provider's] ability to educate patients in terms of knowledge concerning SPF and sun exposure risks, and [their] ability to change behavior. There is clearly a need to motivate consumers to more actively use sunscreens.

A recent Consensus Conference on Photoaging/Photodamage⁴² addressed the issue of motivating consumers to protect themselves from the sun. The Conference stated as follows:

Overwhelming epidemiologic and laboratory data indicate that sun exposure and other sources of ultraviolet play the major role in causing the undesirable skin changes commonly perceived by the public as aging. No scientific evidence contradicts this relationship.

⁴² "Photoaging/Photodamage and Photoprotection". Taylor, C.R. et al., 4, American Academy Dermatology Vol. 22, No. 1. 1- 15 (1990).

Photoaging is the term used to describe those changes in the appearance and function of the skin due to sun exposure rather than to the passage of time alone.

Communication of this relationship to the public is extremely important in that it is likely that this, more than awareness of the casual relationship between sun exposure and non-melanoma skin cancer, may motivate the public to practice sun protection.

The Consensus Conference went on to state that "The most urgent need is for improved strategies to convince the public to minimize hazardous sun exposure."

Thus, there is an important need to motivate consumers to protect against sun damage. CTFA believes use of the term "wrinkling" (as well as the term "skin aging") is very understandable to consumers. "Wrinkling" is a term consumers know and it is a powerful way to attract and motivate them to seek protection. Both terms are totally consistent with the terminology being used by the media in articles about the hazards of the sun.

Therefore, we are proposing that "Indications" be expanded to include "skin aging" and "wrinkling" as descriptors of sun-induced skin damage. In short, we propose that proposed 21 C.F.R. §§352.52(b)(1)(v) and (vi) be revised slightly to read as follows (*italicized* words are new):

(v) (Select one of the following: "Filters" or "Screens")
"out the" (select one of the following: "sun's rays," "sun's
harsh rays," or "sun's harmful rays") "to help prevent"
(select one or more of the following: "lip damage," "skin
damage," "*skin aging due to the sun*," "freckling,"
"*wrinkling*" or "uneven coloration").

(vi) (Select one of the following: "Protects from" or "Shields from") (select one of the following: "the harmful rays of the sun" or "the sun") "to help prevent" (select one or more of the following: "lip damage," "skin damage," "*skin aging due to the sun*," "freckling," "*wrinkling*" or "uneven coloration").

These proposals, if adopted, will help consumers more readily to recognize why sunscreens should be used and motivate them to modify their behavior seek sun protection. More specific reference to "skin aging" as a form of sun induced skin damage and use of the descriptor "wrinkling" in referring to skin aging is not misleading. Furthermore, it strengthens consumers' motivation to use sunscreens on a regular basis.

**X. A Number of The TFM's Proposals with respect to
Sunscreen Active Ingredients Should Be Modified**

In general, CTFA agrees with FDA's discussion and categorization of various sunscreen active ingredients. However, CTFA has the following suggested modifications:

Titanium dioxide. CTFA is aware that a number of firms have made submissions to maintain Category I status for titanium dioxide. CTFA agrees with those submissions and believes that the ingredient should be placed in Category I in the final monograph.

In addition, we believe that products containing titanium dioxide as their sole active ingredient should not be required to contain an ocular irritancy warning. The

determination of ocular irritancy should be based on total product formulation, not on the presence of titanium dioxide or its possible interaction with another ingredient. In other words, if the product causes eye irritancy, then a warning should be required.

Titanium dioxide is an inert inorganic oxide and is thereby chemically distinct from all other Category I sunscreen actives, which are organic compounds. Titanium dioxide also has a toxicologic profile markedly different from other sunscreen actives. With respect to ocular irritancy, for example, titanium dioxide is a color additive approved by the Food & Drug Administration as exempt from certification procedures. (See approvals of the ingredient found in 21 C.F.R. §73.575 (food), 21 C.F.R. §73.1575 (drugs) and 21 C.F.R. §73.272575 (cosmetics). The approved drug and cosmetic uses contain the provision for the safe use of this material for the eye area. Furthermore, extensive documentation is available to support the safe use of this material in the eye area. This includes animal and human ocular safety testing.

Based on the foregoing, CTFA requests that the eye irritancy warning proposed in the TFM should not be required simply because a sunscreen contains titanium dioxide as its sole active ingredient.

Zinc oxide. Zinc oxide was not considered as a sunscreen active ingredient by the Panel in its 1978 report, and it has been placed in Category III in the TFM.

However, CTFA is aware that a number of firms are providing data to support its placement in Category I, and CTFA strongly supports those efforts.

Padimate O. In the TFM the agency included for comment a proposal that sunscreen products must contain less than 500 ppb NMPABAO. CTFA strongly opposes this requirement on a number of grounds.

First, toxicological studies indicate that NMPABAO does not have mutagenic or suspected carcinogenic potential,⁴³ and therefore there is no scientific basis for establishing a level above which a product would be considered contaminated. Indeed, FDA acknowledged in the TFM that the risk associated with NMPABAO contamination of Padimate O containing sunscreen products is very low. Furthermore, NMPABAO is unstable in the presence of UV radiation which further renders human exposure to this contaminant -- found in only a few products in the parts-per-billion range -- to insignificant levels under normal conditions of use.

In addition, CTFA is unaware of any data or other information that indicate that NMPABAO contamination is present at levels greater than 500 ppb in sunscreen products in the absence of known nitrosating agents, e.g., the nitrite releasing preservative, 2-bromo-2-nitro-1,3-propanediol (BNPD). Finally, it can be

⁴³ Dunkel, V.C., San, R.H.C., Harbell, J.W., Seifried, H.E., and Cameron, T.P. (1992) Environmental and Molecular Mutagenesis 20: 188-198.

demonstrated that Padimate O can be used in sunscreen formulations without any detectable levels of NMPABAO contamination.

FDA itself has concluded in the TFM that if products are formulated without nitrosating agents there would be no nitrosamine contamination, and CTFA agrees with the agency's conclusion. Industry is aware of the known nitrosation potential of certain ingredients and has recommended that such ingredients not be used in the presence of amines in order to avoid nitrosamine contamination of its products.⁴⁴

In summary, CTFA believes that any requirement that each batch of sunscreen product be analyzed for NMPABAO is not justified on the basis of product safety or any widespread contamination. The high costs associated with nitrosamine analyses, the expensive and specialized equipment needed, and highly trained chemists required to perform the analyses would be prohibitive. The net effect of such an unjustified and costly requirement would be that this safe and effective sunscreen discontinued from use in sunscreens without any identifiable hazard to the public or benefit to consumers.

Ingredient nomenclature. In the TFM, the Agency clarified the nomenclature of specific Sunscreen ingredients and the need to for simpler, more "user-friendly"

⁴⁴ See, e.g. papers published by the Cosmetic Ingredient Review: (1980) J. Environmental Pathology and Toxicology 4, 47 - 62 and (1984) J. American College of Toxicology 3, 139 - 156.

names. CTFA members fully agree with FDA's simplification of the following names:

Octocrylene *instead of* 2-ethylhexyl-2-cyano-3, 3,-
diphenylacrylate
Octyl methoxycinnamate *instead of* Ethylhexyl-p-
methoxycinnamate
Octyl salicylate *instead of* 2-Ethylhexyl salicylate
Trolamine salicylate *instead of* Triethanolamine salicylate

However, the simplification process should extend to the following names as well:

Ethyl 4[bis(hydroxypropyl)] aminobenzoate
Glyceryl aminobenzoate
Diethanolamine methoxycinnamate
Phenylbenzimidazol sulfonic acid

With respect to the first two active ingredients listed above, USAN has already adopted and suggested names -- Roxadimate and Lisadimate, respectively. For the third compound USAN has designated the name Diolamine methoxycinnamate, thereby making the ingredient's name parallel to the name Trolamine salicylate. We suggest that a preferable alternative would be to permit use of the acronyms used in the CTFA Dictionary for Triethanolamine and Diethanolamine -- namely, "TEA" and "DEA," respectively. These acronyms are already widely accepted and understood by consumers, and CTFA members urge the Agency to consider them when preparing the final monograph.⁴⁵

⁴⁵ No USAN name has been assigned for Phenylbenzimidazol sulfonic acid, but if this should happen prior to publication of the Final Monograph, CTFA would also ask the Agency to use this name in the Final Monograph.

Finally, CTFA feels compelled to comment again on the nomenclature of Aminobenzoic acid. While we acknowledge that Aminobenzoic acid is the official name for this compound, FDA should recognize that over the years (indeed, since before publication of the Panel Report in 1978) consumers have learned to recognize this ingredient on the label as "PABA." In order to permit continued use of this acronym we propose either to allow listing of the compound as PABA or, if that is not acceptable, we respectfully urge that the ingredient be permitted to be listed as "PABA (aminobenzoic acid)."

Combinations of ingredients. CTFA believes that FDA's proposed minimum levels of active ingredients that should be permitted to be used in sunscreens containing a combination of actives are too high. CTFA and our members are currently undertaking testing in an effort to demonstrate that levels below the concentration specified in the TFM are, in fact, efficacious. It is anticipated that these new data will be submitted to the agency in accordance with the May 1994 date for acceptance of new data.

XI. Skin Care Products that Contain a Sunscreen but Make No Reference Concerning It Are Not Drugs and Are Outside the Purview of the OTC Drug Review Process

In the TFM, FDA has addressed a number of categories of products that contain sunscreens but that cannot be classified as drugs. One such type of product is a daily-use skin product that contains a sunscreen ingredient but for which no sunscreen representation is made (i.e., there is no use of the word "sunscreen," no

reference to the SPF level, no reference to "sunburn," no other representation related to these purposes, and no listing of the sunscreen as an active ingredient). Such a product is not a drug and is therefore not within the purview of the OTC drug review.

The distinction between a cosmetic and a drug depends upon the claims or representations made for the product -- not on its formulation or the ingredient(s) contained in it. The definitional difference between a cosmetic and a drug under Sections 201(g) and (i) of the FD&C Act rest upon the "intended" use of the article. The legislative history makes clear that it is the "representations" that are made for the article that will determine the proper regulatory classification:

The use to which the product is to be put will determine the category into which it will fall. * * * The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935). In cases in which the distinction between a cosmetic and a drug was in contention, the courts have uniformly looked to the labeling and advertising of a product to determine the "intended" use. United States v. An Article . . . Sudden Change, 409 F.2d 734, 739-742 (2d Cir. 1969); United States v. An Article . . . "Line Away", 415 F.2d 369, 371-372 (3rd Cir.). In National Nutritional Foods Association v. Mathews, 557 F.2d 325, 333-336 (2d Cir. 1977), the court held that FDA could not subject dietary supplements containing high levels of vitamin A and D to regulation as drugs, merely because those high levels

have a "drug" effect, unless it could also identify labeling claims or other evidence to show that these products were "intended" to function as drugs. Similarly, in Action on Smoking & Health (ASH) v. FDA, 655 F.2d 236, 239-241 (D.C. Cir. 1980), the court held that cigarettes were not drugs simply because they affect the structure or function of the body, unless there was evidence that the products were "intended" to be used for this purpose.

FDA has uniformly followed this approach in distinguishing between a cosmetic and a drug. In defining "intended uses" in 21 C.F.R. § 201.128, for example, FDA has stated that "intended use" refers:

. . . to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

At no point in the regulation does FDA state that the "intended use" may be shown by the intrinsic nature of the article itself or the ingredient that is included in the product. Rather, objective intent is shown by the claims and representations.

This is consistent with the position that FDA has taken throughout the OTC drug review. For example, in discussing the regulation of debriding agents in the TFM for health care OTC drug products, FDA stated that ingredients recognized in

an OTC drug monograph need not comply with the terms of the monograph if only cosmetic claims are made for the product. 53 Fed. Reg. 2436, 2446 (January 27, 1988) ("Products marketed only as cosmetics are not subject to this rulemaking."). Similar statements by FDA may be found in a number of other TFMs, e.g., 48 Fed. Reg. 6820, 6822 (February 15, 1983) (skin protectants) and 47 Fed. Reg. 39108, 39114 (September 3, 1982) (skin bleaching agents).

In the Sunscreen TFM, it appears that FDA correctly regards skin care products containing a sunscreen -- with no representations concerning the ingredient(s) or its sunscreen benefits -- as cosmetics. CTFA agrees with this interpretation. We should also point out that, as cosmetics, they are outside the purview of the OTC drug review process.

**XII. Tanning Products that Make No Reference to Sunburn Protection
Are Not Drugs And Are Not Subject to the Purview
of the OTC Drug Review**

In the TFM, FDA addressed two types of tanning products: first, in the preamble, the agency states that a tanning product that contains a sunscreen should be reclassified as a drug because it prevents sunburn and affects melanogenesis; and second, FDA states that it is proposing to amend the cosmetic regulations by adding a new section that would require suntan preparations that do not contain a sunscreen to display a warning stating that it "does not contain a sunscreen and does not protect against sunburn." We believe the TFM is incorrect in both instances.

With respect to the first category -- i.e., tanning products that contain a sunscreen -- we agree that any form of sunscreen or related claim made for the products would render them a cosmetic-drug. But since 1940 FDA has taken the consistent administrative position that products offered for the purpose of acquiring an even tan are solely cosmetics, and become drugs only when represented to prevent or treat sunburn. There is no basis for overturning this interpretation of the FD&C Act, which was contemporaneous with its enactment and has been uniformly adhered to by FDA since then. Nor would this represent wise public policy. The sole effect would be to drive sunscreen ingredients out of suntan products, thus exposing consumers to even higher levels of harmful ultraviolet rays. Accordingly, CTFA urges that FDA continue its longstanding policy that products represented only for purposes of tanning may contain sunscreen ingredients without being converted to drugs so long as no sunscreen or related claims are made.

Likewise, the second category of tanning products -- i.e., tanning product that do not contain a sunscreen -- are most definitely cosmetics and not drugs. As is also discussed above, the products are thus outside the purview of the OTC drug review process. For this reason, CTFA objects to any warning statements being placed on tanning products.⁴⁶

⁴⁶ FDA states that it "tentatively finds that the majority of consumers expect sunburn protection from suntanning products, whether the product contains a sunscreen ingredient or not." (58 Fed. Reg. 28207). However, the agency has provided no basis for its assumption.

**XIII. Hair Care Products and Nail Products That Contain a Sunscreen
Are Cosmetics and Therefore Are Outside the Purview
of the OTC Drug Review Process**

In the TFM, FDA also addressed two other cosmetic products that contain sunscreens: hair products that contain a sunscreen to protect the hair from sun damage, and nail polishes that contain a sunscreen to prevent the color from fading. These products are solely cosmetics (as FDA correctly recognizes), and therefore are not within the purview of the OTC drug review. CTFA objects to FDA's intent to use the OTC drug review as a means of amending the cosmetic regulations to address these products.

We also have substantive disagreement with the agency's proposals as to how the products should be regulated as cosmetics. FDA proposes that all cosmetic products using the term "sunscreen" must also declare the cosmetic benefit of the sunscreen in labeling. In our view, however, sunscreen-containing products used for purely cosmetic applications should not be required to be labeled any differently from other non-sunscreen-containing cosmetics.

Cosmetic labeling regulations require that the principal display panel of a cosmetic bear a statement of identity of the common or usual name of the cosmetic. Thus, the common names for cosmetics containing sunscreen ingredients are prominently and clearly stated on the front panel of the cosmetic label (i.e., "nail polish," "hairspray, or "hair conditioner"), and we do not believe that consumers

possibly could confuse the use of these products with sunscreen-containing drug products. We do not agree with the agency's contention that

[i]t would be misleading to consumers to only use the term "contains a sunscreen"...without clarifying the purpose of the ingredient. Without such qualification, consumers might believe the product offered skin protection. (58 Fed. Reg. 28205).

We think it is implausible that any reasonable consumer would ever think that a nail polish with sunscreen or a hairspray with sunscreen protects the skin.

If, however, FDA disagrees with our positions and decides to implement a regulation for cosmetics containing a sunscreen, we do not agree with the TFM that the following statement should appear in direct conjunction with the term "sunscreen" each time the term appears on the labeling:

This product contains a sunscreen that assists in protecting the hair from damage by the sun.

We suggest that if FDA decides to promulgate a regulation for these cosmetic products, it should permit the term "sunscreen" to appear anywhere on the label with the purpose of the sunscreen also permitted to be explained anywhere on the label. Such a result could be achieved by revising proposed 21 C.F.R. §700.35(b) to read as follows:

Any information describing the purpose of the sunscreen in a cosmetic shall appear once on the label.

**XIV. FDA Should Either Exempt Currently Marketed Sunscreens
From the Requirement of Re-testing for SPF or Provide
An "Interstate Commerce" Effective Date of 24 Months
After Publication of the Final Monograph**

The TFM leaves unresolved a number of important issues pertaining to labeling, testing and formulation of sunscreens. The resolution of many of these issues will not be known and cannot be predicted before publication of the final monograph. Industry cannot take steps now to change practices that are still subject to agency data-gathering or otherwise under active consideration. This further foreshortens the period of time available for industry adjustment to the new requirements. Therefore, to address these concerns, CTFA presents the following two alternative proposals:

The first alternative -- and the preferred one -- is to "grandfather" currently marketed sunscreens from the requirement of re-determining the SPF. This makes sense because many of these formulations have been on the market for quite some time and therefore users of the products have become accustomed to them, they are familiar with the products' efficacy, and they would be confused if their well-known products were suddenly marketed with a slightly different SPF -- a difference that, in all likelihood, is caused by test variability rather than any true difference in efficacy. In addition, as one CTFA member will demonstrate in its comments to FDA, the economic impact of retesting and reformulation would be significant and on an industry-wide basis could easily reach over \$35 million or more without adding any value for the consumer.

Alternatively, CTFA requests that FDA establish an "interstate commerce" effective date that provides at least 24 months after publication of the final monograph for compliance. FDA typically sets a 12-month effective date for final monographs and other OTC drug requirements, whereby affected products initially introduced or initially delivered for introduction into interstate commerce are required to be in compliance twelve months after the publication date. See e.g., Final Monograph for Topical Antimicrobial Drug Products for OTC Use; 52 Fed. Reg. 47312 (Dec. 11, 1987): interstate commerce effective December 12, 1988. However, in two recent similar situations FDA recognized that a 24-month period was necessary under certain circumstances (see the Rule concerning Imprinting of Solid Oral Dosage Forms, 58 Fed. Reg. 47948 (Sept. 13, 1993), and Proposed Rule concerning Tamper-Evident Packaging Requirements for OTC Human Drug Products, 59 Fed. Reg. 2542 (Jan. 18, 1994)). We believe that a similar time period should be granted when the Sunscreen final monograph is promulgated.

Under ordinary circumstances, a 12-month effective date provides adequate time for industry to alter labeling and/or to make necessary formulation changes. The Sunscreen TFM, however, contemplates wholesale changes that would affect virtually the entire sunscreen market subject to the OTC drug review. The far-reaching nature of the TFM is attested to by the sheer volume of the publication itself: at over 100 pages of Federal Register text, the Sunscreen TFM dwarfs all OTC drug review publications in recent memory.

The proposed new testing method to evaluate SPF values, if required for all sunscreens, will mean nearly every marketed sunscreen product will have to undergo new testing, which in some cases may lead to formulation changes and further testing. Testing, of course, is a prerequisite to development of accurate labeling and to manufacturing. Without an interstate commerce effective date of 24 months, the limited number of testing laboratories may be unable to accommodate the significantly increased volume of product testing in a timely fashion, thereby disrupting manufacturing schedules that coincide with the seasonal nature of the sunscreen market.

If either of the above requests is not granted, the net result would be an interruption of adequate supplies of sunscreen products to consumers. Surely the agency does not intend such an outcome. There is no public health or safety reason for not granting one of the above proposed alternatives: currently marketed sunscreen products are safe and effective and bear informative and truthful labeling that is familiar to consumers based on well over a decade of use. Exempting existing sunscreen formulations from SPF re-testing or providing a 24-month effective date for compliance with the final monograph will help ensure uninterrupted consumer supplies of these important products during an orderly industry transition to the new requirements.

Accordingly, CTFA requests that the agency grant one of the above proposed alternatives.

**XV. Technical Comments on a Number of Testing Issues
Raised in the TFM**

CTFA has a number of comments on technical issues raised in the TFM. Broadly, our comments fall into three general categories: first, comments concerning the subjects involved in SPF testing; second, comments on control standards used in SPF testing; and third, comments concerning light sources (solar simulators) used in sunscreen SPF testing. A discussion of each of these areas follows.

Comments with respect to subjects involved in SPF Testing.

Number of subjects to be used. Proposed 21 C.F.R. §352.72(g) states that the number of subjects to be used shall be "fixed in advance by the Investigator." We suggest that the language be deleted and in its place the following be added:

A test panel shall consist of not more than 25 subjects.
From this panel, at least 20 subjects must produce valid
data for analysis.

Our rationale is as follows: In the event that the first 20 subjects yield valid data, no further subjects need be impaneled. The risk to human subjects and the expense to the tester can therefore be curtailed. If the Investigator must specify in advance that 25 subjects will be impaneled in order to guard against the possibility that up to 5 additional subjects may be necessary, then in hundreds of cases annually the irradiation of human subjects and the expense to the sponsor will be needlessly incurred.

Furthermore, it is a valid expectation that all subjects initially impaneled will not produce valid data, in some cases due to failure to accurately estimate the SPF "anchor," to return for final MED grading, technical error in application of the product or of irradiation by the solar simulator. These subjects should be considered replaceable subjects, and should not be included in the count of "up to 25 allowable subjects."

Definition of Minimal Erythema Dose. Proposed 21 C.F.R. §352.72 states that "the smallest dose of energy that produces redness reaching the borders of the exposure site" shall determine the minimal erythemal dose (MED). In proposed 21 C.F.R. §352.73, it is stated that the MED is the "lowest dose of radiation that produces uniform redness reaching the borders of the exposure site." We encourage FDA to consider the definition of MED proposed by COLIPA for the inclusion in the final monograph, which states that MED is "the quantity of radiant energy required to produce the first perceptible, unambiguous, redness reaction with clearly defined borders."⁴⁷

Our suggestion is based on the fact that not all exposure series are achieved using a template with apertures for each exposure site. Several solar simulator configurations known to CTFA do not employ or require templates to cover the entire site of product application. The use of a template in these circumstances is

⁴⁷ COLIPA SPF Test Method (Draft): The Recommendations of the COLIPA Task Force on Sun Protection Measurement. December, 1992.

unnecessary and complicates the test procedure. While UV exposures from these instruments produce an erythematous response which is distinct, uniform and clearly defined, it does not spread to "reach the borders" because of the absence of the template. In the interest of describing the MED in a manner that applies to reading the erythema produced by a variety of solar simulator configurations, we submit that "reaching the borders" is not a necessary part of an accurately defined and consistently determined MED.

Furthermore, in the interest of international harmonization, we believe that the COLIPA definition more closely fits the understanding of MED being used throughout the world today and is more descriptive than either the definition included in the TFM or than some of the definitions currently in use in other countries. For instance, the recent Australian/New Zealand standard defines the MED as "the first subsite in the exposure series to show minimal redness perceptible to the eye. . . ."48 The Japanese definition of MED is "the minimal UV dose that produces minimally perceptible erythema throughout most [$>2/3$] of the radiation field."⁴⁹

Randomization and Blinding. Proposed 21 C.F.R. §352.70 states that

the test products and the standard sunscreen, as specified in §352.70 should be applied in a blinded,

⁴⁸ Australian/New Zealand Standard AS/NZS 2604:1993.

⁴⁹ Standard SPF Test Method. J. Soc. Cosmet. Chem. Japan 26, 207-214, 1992.

randomized manner. If only one sunscreen drug product is being tested, the testing subsites should be exposed to the varying doses of UV radiation in a randomized manner.

We recommend that the paragraph be changed to read as follows:

the test products and the standard sunscreen, as specified in §352.70, should be applied in a blinded manner. Test areas for each material should be randomly assigned for various and appropriate areas of the back. It is not recommended that UV exposures be randomized within a given test area. If only one sunscreen drug product is being tested, the testing area should also be randomly placed in a variety of appropriate areas on the back.

Furthermore, in order to approximate true blindedness, we recommend that the individual who grades erythematous responses and records these results, be different from the clinician who applied the test materials at the beginning of the test.

There are two issues that deserve comment -- randomization of sites and blinding. It is entirely reasonable that different test materials be randomly assigned to different areas of the back during testing. It is not reasonable, however, to randomly irradiate test sites with varying doses of UV from a solar simulator within the space designated for a given product. In sunscreen testing, each material is subjected to increasing doses of UV in a given test product area. It is, in part, the performance of the product in relation to increasing amounts of UV that indicates to the clinician that in fact both the test and the product are working correctly.

If the procedure is followed exactly as described in the TFM on page 28300, then it is unlikely that there will be a dose response pattern in any of the test sites. This could pose a difficulty for the clinician in evaluating the validity of the test.

In terms of blindedness, it is important to note that in practice it is highly unlikely that the individual applying a given material will be truly "blinded." This is due to the fact that test products are distinct and easily distinguished on the basis of film forming properties, viscosity or other physical characteristics. In addition, it is also likely that a distinction will be observed between that test material and the homosalate standard. We therefore recommend that the individual who reads the responses on the back of each panelist and records the results be different from the individual who applies the test material at the beginning of the test. In this way an approximation of true blindedness can be achieved.

Number of Irradiation Subsites and Exposure Increments. The TFM recommends changing from five exposure sites at equally spaced 25% dose increments to the use of seven exposure sites, two of which are smaller, half-dose increments centered around the expected SPF in order to provide "more precise" SPF values. The exact increments vary with SPF levels. CTFA is currently generating data (which will be submitted to FDA on or before May 12, 1994) that preliminarily demonstrates that the MED's vary by about 10% between initial and repeat sites on a subject. Requiring increments lower than 25% will not give "more precise" SPF numbers. In addition, by using the same products with both dosing regimens (five

sites, equal increments and seven sites, including half-dose increments centered around the expected SPF), it was found that mean SPFs did not differ statistically. Therefore, we do not support the use of 7 exposure sites and a change in the increments because it does increase the risk but not the precision of the test.

Determination of MED at 16-24 Hour Versus 22-24 Hour. Proposed 21 C.F.R. §352.72(h) states that MEDs should be read at 22-24 hour post-exposure rather than the 16-24 hour allowed previously. However, the time period of 16-24 hour post-exposure is the universally accepted time frame for reading erythema in the European Union, Australia and Japan. FDA should, in the interest of international harmonization, adopt the 16-24 hour time period.⁵⁰

Because the control and the test product exposures are given during the same visit to the laboratory for testing, their ratio at any time after erythema has developed should be constant. Both sites will develop an erythematous response which is composed of both UVB and UVA components.

Because SPF testing takes place in the laboratory throughout the day, subjects return to the laboratory the next day for the reading of results. It is often difficult to control precisely the return of subjects within a 2-hour period due to work

⁵⁰ See COLIPA SPF Test Method (Draft): The Recommendations of the COLIPA Task Force on Sun Protection Measurement. December, 1992; Australian/New Zealand Standard AS/NZS 2604:1993; and Standard SPF Test Method. J. Soc. Cosmet. Chem. Japan 26, 207-214, 1992.

schedules, etc. For practical purposes, the 16-24 hour interval is more acceptable for most subjects and most laboratories, assuming that equivalent results would be obtained. For many laboratories, the 22-24 hour requirement would pose a hardship by limiting the times of day when SPF testing could be done so that subjects could easily return exactly 22-24 hours later. It is also possible that a test of several products on one subject could take longer than 2 hours for the administration of all exposures. The control exposure would then fall outside the two-hour "window" proposed in the TFM.

The agency also expressed concern that immediate pigment darkening (IPD) could interfere with MED reading at 16 hours. In industry's experience, IPD from solar simulator exposures is a transient phenomenon, rapidly fading within an hour after irradiation.⁵¹ Sites which have developed delayed tanning in Skin Types III or IV at 16 or 24 hours are not graded as erythema. Subjects chosen for testing higher SPF products are generally the more sensitive Skin Types I and II, who have little to no IPD response and rarely exhibit delayed tanning within 24 hours. Therefore, there is no reason to delay reading to 22 hours, since IPD is not a confounding event at 16 hours and has not been found to be a practical problem in MED reading.

⁵¹ Agin PP, Desrochers DL, Sayre RM. The relationship of immediate pigment darkening to minimal erythema dose, skin type and eye color. *Photodermatol.* 2:228-294, 1985.

To demonstrate that the product SPF determined on a panel of subjects is not different whether read at 16 or at 24 hours, the following data will be obtained. A high SPF and a low SPF sunscreen formulation will be tested on a sufficient number of subjects to provide statistical power. Each subject will return for the reading of control and product protected MEDs at 16 and at 24 hours post-exposure. The SPF for each subject and the mean for the entire panel will be determined. These data will be submitted before the May 12 deadline for new data.

Comments on Control Standards Used in SPF Testing.

Use of the COLIPA control standard for SPF testing. CTFA urges that the COLIPA "European low SPF Standard Code Number COL 492/1 (formerly the DIN standard),"⁵² as well as 8% homosalate, be listed as approved control standards, and that each be permitted to be used at the option of the investigator. The addition of the European low SPF Standard will serve to permit a sunscreen product tested with either control to be marketed internationally. Such a result would eliminate the expense of duplicative testing and it would also eliminate the risks to an additional 20 human subjects.

⁵² SPF TEST METHOD (Draft), The Recommendations of the COLIPA Task Force "Sun Protection Measurement," December 1992, page 5.

In support of this additional control standard, CTFA is submitting as Exhibit B validating data from four independent testing laboratories. The COLIPA control standard was validated as achieving the stated "SPF range of 3.4 to 4.8."⁵³

Alternate assay method for 8.0% Homomenthyl Salicylate. CTFA proposes that in the final monograph FDA should adopt an alternate HPLC assay method for 8.0% Homomenthyl Salicylate. The procedure to be used is set forth in Exhibit C.

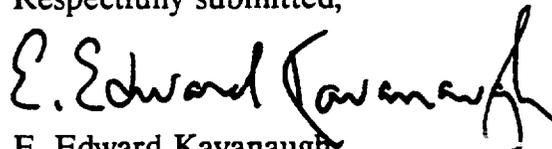
Comment on Light Sources (Solar Simulators) for Sunscreen SPF Testing.

In proposed 21 C.F.R. §352.71, FDA proposes to redefine the specifications for solar simulators used to determine sunscreen SPFs. CTFA is also desirous to assure that the specifications for solar simulators are appropriate and realistic. Proposed modifications to §352.71, and our rationale for such modifications, are set forth in Exhibit D.

* * *

CTFA appreciates the opportunity to comment on the important issues raised in the Sunscreen TFM. Please do not hesitate to contact us if you have questions concerning our comments or if we can provide additional assistance.

Respectfully submitted,



E. Edward Kavanaugh
President

⁵³ Id.