

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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P R E S I D E N T

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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Sunscreen Drug Products for Over-the-Counter Human Use;
Monograph; Extension of Effective Date; Reopening of Administrative
Record, FDA Docket No. 78N-0038

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These comments are filed on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA) and the Consumer Healthcare Products Association (CHPA) in response to the *Federal Register* notice of June 8, 2000. They are submitted in response to reopening of the administrative record of the Monograph on Sunscreen Drug Products to consider several critical issues affecting the marketing of these products.

CTFA has an active membership of approximately 300 companies that manufacture or distribute most of the finished personal care products marketed in the United States, and approximately 300 associate member companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories.

CHPA is the national trade association representing the manufacturers and distributors of nonprescription or over-the-counter (OTC) drug products sold in the U.S. CHPA members are responsible for 90 percent of the retail sales of OTC products in the U.S.

Together, CTFA and CHPA 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 (products that are regulated as both cosmetics and drugs). CTFA and CHPA members also export sunscreen products throughout the world, and many members have manufacturing plants located outside the U.S.

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In several instances, CTFA and CHPA have already provided the Agency with the information requested in the June 8, 2000 notice. By these comments¹, we are adding new information and resubmitting the comments and data provided in our written responses to the Agency dated January 14, 2000 (Attachment D), in addition to separate submissions to the docket and correspondence dated May 24, 2000 (Attachment B); March 6, 2000 (Attachment C); October 15, 1999 (Attachment E); September 11, 1998 (Attachment F); April 15, 1998 (Attachment G); May 12, 1994 (Attachment H); March 21, 1994 (Attachment I); and November 17, 1992 (Attachment J).

Introduction and Summary of Comments

In its Final Sunscreen Monograph, FDA has taken an extremely restrictive view of the claims that can be made about sunscreen products. The Agency has banned truthful SPF claims over 30 and required that all products that provide greater than SPF 30 protection be labeled as SPF 30+ or “plus” regardless of their true SPF value. In addition, FDA has limited statements about the documented anti-aging benefits of sunscreens to one lengthy statement and has severely limited the indications and directions for use.

We believe that in taking these steps, FDA has gone beyond the bounds of what is legally permissible, has failed to recognize the strong scientific and medical support for these claims and has denied consumers information that is critical if they are to obtain the important health benefits offered by these products. In fact, the May 1999 final monograph risks discouraging the creation of more effective sunscreens and reducing the usefulness of product labeling for communicating important information about these products.

The comments herein urge FDA to change the final monograph so as to allow consumers to continue to receive truthful information about the benefits of sun protection products through labeling. Sunscreens are important to the public health in helping to prevent not only sunburn, but also skin cancer and many other significant and detrimental effects of UV radiation. The broad goals of 1) encouraging the public to use these important products properly to obtain the appropriate level of sunscreen protection and 2) of encouraging manufacturers to continue to provide sun protection in a wide variety of products should not be sacrificed.

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

Throughout these comments we assert that resolution of several testing and labeling issues raised by the Agency is crucial for industry to continue to develop effective and appropriate sunscreens and cosmetic-sunscreen drug products for a variety of consumer use settings.

Of major significance in this debate is resolution of outstanding testing and labeling issues for high SPF products. We have previously submitted data (October 15, 1999, Attachment E and January 14, 2000, Attachment D) which confirms the ability of current methods to adequately and consistently test high SPF sunscreens. It is equally critical that the Agency remove its "SPF 30+" labeling cap for products which have proven to be safe and effective in preventing the ravages of sun exposure.

We strongly urge FDA to remove its severe restrictions on anti-aging claims and to allow a broader range of truthful statements about this important benefit.

We also urge the Agency to recognize that additional labeling indications and directions for use are required for appropriate consumer selection and use of sunscreen products. Sunscreens provide a much broader range of benefits than prevention of sunburn, which is the only indication currently permitted in the Final Sunscreen Monograph. Manufacturers must be able to communicate the other benefits of sunscreens, which have been recognized not only by public health authorities, experts and FDA's advisory panel, but also by the Agency itself.

Consumers recognize the importance of sun protection. Restrictive labeling limitations run the risk of silencing an important public health message and negating fundamental rights available to manufacturers to convey truthful information.

Lastly, we urge the Agency to move quickly to address the additional labeling comments relating to the OTC Drug Labeling Regulation submitted by CTFA under separate cover, to carefully consider and address the individual comments on UVA testing and claims submitted by our members², and to recognize that manufacturers will have a difficult, if not impossible time, meeting the rule's current proposed effective date.

²Because there was not a single consensus viewpoint on these issues, we have not addressed the issues of UVA testing and claims in this comment. These issues are addressed in other comments filed by our members.

I. Testing Issues

The Colipa Solar Simulator Specification (Spectral Power Distribution Table) Is An Appropriate Standard for Use in Evaluating the Protectiveness of Sunscreen Products and Should Be Adopted.

Sunscreens are tested for protectiveness globally, with solar simulators that are now based on virtually identical technical design. This has resulted in an improved level of harmonization of SPF testing results. However, the current description of the solar simulator spectrum in the final monograph does not contain sufficient detail and specification to assure uniformity of solar simulators in the United States.

The specification for spectral power distribution adopted by Colipa provides a more appropriate description for solar simulators used in SPF testing. We support adopting the Colipa solar simulator emission standard - with one modification to this proposed specification: for wavelengths below 290 nanometers, the energy should be limited to less than 0.1% of the total erythemal energy output of the solar simulator, instead of the "< 1% limit" proposed by Colipa³. Limiting the erythemal energy below 290 nanometers to "less than 0.1%" would reduce any contribution of "non-solar" erythemal energy to the solar simulator output and insure that it does not have a measurable impact on SPF determinations of sunscreens.

FDA has also asked for comment concerning the practicality of lowering the below-290 nanometer specification to 0.01 percent. Consistent with the comments in our January 14, 2000 letter (Attachment D) to the Agency, we do not believe it is either practical or feasible to lower the "below 290 nanometer" specification to a 0.01 percent limit. At this level of sensitivity, the specification would result more in testing the limits of the measurement spectroradiometer rather than the true output of the solar simulator. As determined above, this level of accuracy is both unnecessary and difficult to achieve using readily available measurement equipment.

As stated in our comments in 1994 (March 21, 1994, Attachment I) and most recently in our letter of January 14, 2000 (Attachment D) to the Agency, the Colipa solar simulator emission spectrum, with a modification to limit the erythemal energy below 290 nanometers to less than 0.1%, is appropriate for use in SPF testing procedures. We therefore support the solar simulator emission spectrum outlined in Table 1 of the June 8, 2000 *Federal Register* notice (65 Fed. Reg. at 36321) (2000).

³The European Cosmetic Toiletry and Perfumery Association (Colipa) Sun Protection Factor Test Method (1994).

The Longer Exposure Times Associated with Testing High SPF Sunscreen Products Do Not Produce Thermal Overloading of the Skin

Thermal overload does not occur for Colipa-compliant solar simulators operated at or below a total irradiance limit of 1500 watts/meter² (January 14, 2000 letter and data to FDA, Attachment D). Therefore, replacing the “out of band” specifications in sec. 352.71 with a limit of 1500 watts/meter² on total solar simulator irradiance for all wavelengths, in accordance with the proposed solar simulator specifications previously discussed, would be an appropriate modification of the sunscreen monograph test procedures to prevent thermal overload. This would also result in improved testing of all SPF products, as demonstrated in Attachment 1 of the January 14, 2000 letter. (Attachment D).

Additional Higher SPF “Standard” Sunscreens (i.e. Control Formulations) Are Not Necessary to Test High SPF Products

FDA has asked for comment and any supporting data concerning the need for additional “standard” sunscreens with SPF values higher than 15, as well the use of specific “standards” for specific ranges of SPF values. Consistent with the understanding that the function of the standard formulation is quality assurance for process control, rather than as a calibration standard to bracket specific SPF ranges, additional control sunscreens with SPF values higher than 15 are neither necessary nor productive.

In its June 8, 2000 notice, FDA asked whether specific “standard” sunscreens (i.e. controls) of SPF 15 or above are needed to accurately test high SPF sunscreen products. Reference is made to our comments and data submission of November 17, 1992 (Attachment J). The proposed requirement for a sunscreen control above SPF15 is impractical and unnecessary.

There appears to be some confusion regarding the purpose of a control sunscreen formulation during SPF testing. The control formulation does not function as a calibration tool, but rather as quality assurance for process control to demonstrate adequate test procedural compliance. Use of a control preparation is not a standard in the analytical sense, but rather a control on laboratory methodology.

As such, while many formulations could be suitable for use as laboratory controls (if it were demonstrated in each instance that the individual formulation could be prepared, assayed, and utilized by different laboratories), only a *single* control formulation is necessary for any individual study. Currently, there are two recognized control formulations: an 8 % homosalate preparation with an SPF value of 4 (sec. 352.70(b) of FM) and the “Formulation B” control formulation with an SPF value of 15.

We urge the Agency to allow use of either the 8% homosalate SPF 4 preparation or the "Formulation B" SPF 15 control formulation for SPF testing of sunscreen products, with the understanding that **they are methodology controls, not standards**. The choice of whether to use the SPF 4 or SPF 15 control formulation should rest with the manufacturer, based on its determination of what is appropriate in a given test situation.

The SPF 15 Control Formulation Can Be Used as a Process Control

FDA has requested data to demonstrate that multiple laboratories can prepare, assay, and utilize the CTFA "Formulation B" lotion. Data provided in Appendix A, along with other information previously provided, clearly demonstrate that multiple laboratories can manufacture and utilize the Formulation B preparation SPF 15 control. Previously CTFA submitted roundrobin collaborative SPF testing data - in which two SPF 15 control formulations were measured by several laboratories with reasonably low levels of variation (November 17, 1992 letter to FDA, Attachment J). This conclusion is also supported by the data comparison submitted with our January 14, 2000 letter (Attachment D) to the Agency.

The Agency has requested the submission of additional data necessary to document the suitability of Formulation "B" and the analytical method. On March 6, 2000 (Attachment C), CTFA on behalf of its members submitted methods validation data for both proposed control formulations (SPF 15 and SPF 4). This data submission was intended to provide the Agency with detailed methods validation information for each control formula to ensure that the proposed analytical methods work well. The Agency has received the validation package and the sample materials supporting the HPLC assay of these control formulations⁴.

High-performance Liquid Chromatography (HPLC) Assay Is a Superior Approach to Assaying the Level of Active Ingredients in a Finished Product

The use of high performance liquid chromatography (HPLC) is a superior modern approach to assaying the level of active sunscreen ingredients in a finished product because of its ability to separate the active ingredients from other components in the formulation and to provide dependable quantitative measurements. It is further enhanced when combined with UV detections systems. It can be demonstrated that the spectrophotometric assay in § 352.70(c) does not have the specificity or quantitative reliability of the HPLC assay methods. There are limited data on its use

⁴Letter from D. Cox, FDA Division of Testing and Applied Analytical Development to C. Rainey, Schering-Plough Healthcare Products, Inc. April 10, 2000.

with the SPF 15 control formulation, however, because the Agency has not published this formula as an accepted standard.

In addition to the accuracy of the HPLC assay, all of the active ingredients will also be covered by U.S. Pharmacopoeia (USP) monographs, subject to cGMP manufacturing requirements. All sunscreen active ingredients are subject to standards of identity, purity, and physical constants as specified in the USP. Therefore possible impurities associated with the active ingredients themselves will be limited per USP. In addition, gas chromatographic assays are prescribed in the USP to assure the identity and purity of the active ingredients.

FDA's Limitation of 20 to 25 Subjects in the SPF Test Is Unnecessary

In previous discussions of statistics, the Agency has stated that it believes a test sample size of 20-25 subjects is statistically sufficient for the purpose of obtaining valid data for high SPF sunscreen products. (Food and Drug Administration presentation at FDA October 26, 1999 Public Feedback Meeting).

While current SPF test methods are able to produce accurate and reproducible SPF values for high SPF sunscreen products, larger panel sizes could be allowed, if needed, as long as the percentage of valid results is maintained (i.e. the same ratio as 20 of 25 subjects with valid data). This was confirmed in our presentation at the October 26, 1999 Working Group Meeting with FDA and in our submission of January 14, 2000 (Attachment D).

Notwithstanding these previous discussions, the industry believes that panel sizes of 10 are adequate to provide acceptable SPF measurements. A test sample size of 10 subjects has been recognized as sufficient in Europe⁵, Japan⁶, and Australia⁷, and is currently being considered by the Union of South Africa and other developed nations.

⁵The European Cosmetic Toiletry and Perfumery Association (Colipa), Colipa Sun Protection Factor Test Method 9 (1994).

⁶Japan Cosmetic Industry Association, Standard Sun Protection Factor Test Method (1999).

⁷AS/NZS 2604:1997 app B4.2.3 (Australia)

FDA's Current Exposure Dose Format Requirement for Seven Exposure Sites Is Unnecessary

On several occasions, we have provided data to the Agency questioning the necessity of requiring seven exposure sites, two of which are smaller, halfdose increments centered around the expected SPF. (May 12, 1994 letter to FDA, Attachment H; and January 14, 2000 submission, Attachment D).

We recommend that the exposure dose format proposed by FDA in May 1999 for testing SPF values be modified. The exposure increments around the midpoint are not necessary, based on data we provided on May 12, 1994 and on discussion of the biological aspects of the test method and its endpoints (discussed at the October 26, 1999 Public Feedback meeting with FDA). The exposure increments (series of 7n with 2 half-increments) in section 352.73(c) of the SPF testing procedures in the final monograph do not add significant improvement in the precision of testing results compared to the 1978 exposure dose requirement when conducting SPF testing. Test methods with 5 exposure doses can accurately determine all SPF values, including those above 30, and the data are reproducible from test to test. We recommend dropping the two half increment exposure requirements for all SPFs, but otherwise leaving the exposure increments as proposed in the tentative final monograph (TFM) and final monograph. Furthermore, this modification would avoid unnecessary UV exposure to subjects.

Testing High SPF Sunscreens Need Not Cause Discomfort or Hardship to Subjects

FDA has asked whether there are practical human limitations to testing high SPF sunscreens. Experience has shown that the increased ultraviolet radiation exposure times required to test high SPF sunscreens can be accomplished without discomfort or hardship to subjects.

As an example, based on the data from one laboratory shown in the attached table (Appendix B), a Very Water-Resistant test on an SPF 45 to 50 product, including an SPF 15 control formulation along with the "untreated control" exposure series, would take approximately 5 hours on a fair-skinned Skin Type I-II subject using a solar simulator conforming to the Colipa specifications (used at or below 1500 w/m^2), with the seven exposure site series (including the 2 half-increment exposures around the midpoint). Of that time, one hour and 45 minutes is spent in front of the solar simulator. For subjects with darker skin types, the UV exposure times would, of course, be longer.

With the use of a series of 5 exposure sites (with no half-increment exposures), the complete test on the SPF 45-50 Very Water Resistant product (with the SPF 15 control and the untreated control exposure series) would be shorter, reducing the total time that the test subject would need to remain in front of the UV lamp. This would make high SPF tests easier to conduct (with no loss of accuracy,) and less stressful to the test subjects.

FDA Should Return to the 16-24 Hour MED Reading Time Frame

Another matter that should be reconsidered relating to the technical and human limitations of SPF testing is the current requirement to read Minimal Erythema Dose (MED) results at 22-24 hours post exposure. As has been shown in data previously submitted to the Agency, (May 12, 1994 letter, Attachment H; and October 15, 1999 letter, Attachment E) there is no scientific basis for adopting the 22-24 hour reading time requirement, based on our knowledge of the development of erythema. Reading at 16-24 hours provides the same results (as each test subject is his/her own control). Under the 22-24 hour requirement, long SPF test times may require that subjects return for MED reading at awkward or very late hours, which is difficult to ensure.

Returning to the globally accepted 16-24 hour MED reading time would make this aspect of the test easier for the test subjects, thereby increasing compliance without affecting the accuracy of the results. We strongly suggest that the Agency return to the 16-24 hour MED reading time frame.

With an understanding and recognition of the practical limitations of subjects' ability to endure long test procedures, we believe that higher SPF products can be tested in a laboratory setting along with an SPF 15 control preparation, for example, without undue difficulty.

FDA Must Establish UVA Testing Methodology for Manufacturers to Communicate UVA Protection in Labeling

While our members will respond directly to questions regarding the appropriate UVA testing methodology and claims, we urge FDA nevertheless to consider as well the importance of UVA protection and the ability of manufacturers to communicate to consumers on these issues. FDA's decision to delay implementation of a final Sunscreen Monograph until all testing and claims issues related to UVB and UVA protection are resolved was appropriate. It is very important that FDA persist in its efforts to resolve these difficult issues before any final rules are implemented. FDA has received comments from professional medical groups and U.S. agencies regarding the importance of establishing an OTC monograph that provides acceptable methods for

testing and evaluating UVA protection as well as high SPF sunscreen products.
(Appendix C)

While we do not take a position in terms of recommending testing methodology for measuring UVA protection or regulations governing claims regarding UVA protection, our members will individually address those issues in detail. We urge the Agency to ensure that standards for UVA testing are established and incorporated into the future sunscreen rulemaking. Sound methodology is critical to industry's ability to continue to develop, produce, and distribute effective products that provide protection from the effects of UVA as well as UVB exposure.

II. Labeling Issues

FDA's Restrictions On SPF Levels, Skin Aging Claims, and Indications For Use Are Unconstitutional

FDA's prohibition on the labeling of SPF products over 30, its restrictions on skin aging claims, and its limitation of the indications for use for sunscreen drug products all violate the First Amendment to the United States Constitution. The FDA, which bears the burden of establishing the need and basis for such restrictions, has no proof or data to support these restrictions. Rather, the Agency speculates that consumers cannot understand some of the labeling concepts and that the methodology to determine high SPFs may not be precise. Such speculation is ill-founded for the reasons stated herein. We do not believe there is evidence to support FDA's stated concern, but in any case, the sweeping bans on truthful labeling in the final rule go well beyond constitutionally permissible restrictions on commercial free speech.

FDA Should Not Restrict the Truthful Labeling of High SPF Sunscreens

We urge the Agency to allow for labeling of SPF claims over 30, because they are truthful claims that can be substantiated. Restricting the labeling of all sunscreen products over SPF 30 to SPF 30 "plus" or "+" may actually mislead a consumer into thinking that all such products provide the same protection. Many products are currently truthfully labeled as SPF 45, SPF 50, etc. These are essential products for many consumers for whom lower SPF levels are not sufficient. Consumers are familiar with these products and know the level of protection they need. Physicians want products with this information to advise their patients who need high SPF protection. In addition, products with an SPF over 30 will continue to be available and labeled as such in other countries, placing U.S. consumers at a disadvantage in obtaining the optimal level of sun protection.

Many prominent medical authorities such as the American Academy of Dermatology (AAD) and The Skin Cancer Foundation have consistently maintained that high SPF products should be allowed, based on the very real need for them. It is well established that there are several groups of high risk individuals who must have high SPF products. These groups include individuals with actinic keratoses or skin cancer, individuals at high risk for melanoma, and individuals with outdoor occupations. Furthermore, there are multiples of individuals who seek to minimize photoaging. In addition, many individuals occasionally need higher SPF protection in specific seasons or when visiting certain geographical locations.

The incentive for industry to provide a full range of sunscreen products with higher levels of protection will be lost if the products cannot be distinguished. Manufacturers will no longer have an incentive to fund research for better sunscreen products that provide greater UV protection, if they cannot communicate the level of sunscreen protection and benefits which these products provide. Products that protect at the higher SPFs, such as 45 or 50, or even higher, may be reformulated to reduce active ingredient(s), and hence cost, if FDA insists that only SPF 30+ can be claimed on the label.

Dr. Mark Naylor, speaking on behalf of the AAD at a July 22, 1999 FDA public meeting, explained in his presentation that actual MED exposures in several cities in the United States are considerably higher than had been previously recognized in the context of chronic sun exposure. Individuals with a high risk for skin cancer are extremely vulnerable without adequate sunscreen protection. For people living in these and other parts of the country, high SPF products are a very real necessity. While erythema prevention is important, there is increasing recognition that sunscreens must be used for protection against photosensitivity and photodamage, as well as prevention of certain forms of skin cancer and genetic damage. (Mark Naylor, remarks at the FDA Public Feedback Meeting, "High SPF Sunscreens: A Dermatologist's Viewpoint" July, 22 1999, Attachment K). Many of these biological effects occur with sub-erythral doses of UV exposure.

Consumers Do Not Prolong Sun Exposure When Using High SPF Sunscreens

In meetings and in correspondence, FDA has raised concerns about consumer perception, understanding, and use of high SPF sunscreen products. While the SPF system has been explained (based on the labeling in the proposed 1978 monograph) as allowing one to stay in the sun [SPF value]-times longer than without sunscreen, there is no clear evidence to support a conclusion that consumers are therefore extending their time in the sun.

The “Compensation Hypothesis”

It has been suggested that the use of products containing sunscreens may encourage longer exposure to sunlight which, in turn, may lead to an increased risk of skin cancer. This concern, named the “compensation hypothesis” by Weinstock⁸, has at least two components: (i.) that sunscreen use *per se* prolongs exposure to sunlight compared to non-sunscreen use; and (ii.) higher Sun Protection Factor (SPF) products encourage longer exposure to sunlight than products with lower SPF. Careful review of the data suggests the “compensation hypothesis” is incorrect.

The “compensation hypothesis” has been addressed in epidemiology and behavioral or consumer-type studies. These studies have compared sunlight exposure in groups using sunscreen to those who are not. The relationship between SPF and time spent in the sun has not been studied as frequently. The data either support or refute such a relationship although the definitive study remains to be conducted.

Two recently reported prospective epidemiology studies⁹, do not support the “compensation hypothesis”. In the study by Green *et al.*, there was no measurable increase in sun exposure among the group of adults applying sunscreen daily for 4.5 years compared to the control group (i.e., *ad lib.* sunscreen use). Similarly, Gallagher *et al.* found in a 3 year study that daily application of sunscreen did not affect total sunlight exposure in a group of children compared to the control group. These population based studies do not support the “compensation hypothesis”. What is important in both studies was that daily use of sunscreens reduced the risk of skin cancer, which suggests that the change in the sunlight spectrum through a sunscreen has a positive benefit.

Behavioral studies where exposure to sunlight has been determined in sunscreen and non-sunscreen groups do not support the “compensation hypothesis”. For example, in a survey of 808 sunbathing Danes, Stender *et al.*¹⁰ found the sun exposure time was not different in a group of subjects using sunscreens compared to subjects not using sunscreen. Similarly, Zitser *et al.*¹¹ found no statistically significant difference in the intended beach stay between those persons who used sunscreen and those who did

⁸ Weinstock, MA (1999) Do Sunscreens Increase or Decrease Melanoma Risk: An Epidemiologic Evaluation. *J Invest Dermatol Sym Proceedings* 4:97-100.

⁹ Green, A. *et al.* (1999) Daily sunscreen application and betacarotone supplementation in prevention of basal-cell and squamous-cell carcinomas of the skin: a randomized control trial. *Lancet* 354:723-29; Gallagher, RP *et al.* (2000) Broad-Spectrum Sunscreen Use and the Development of New Nevi in White Children. *JAMA* 283:2955-60.

¹⁰ Stender I-M., *et al.* (1996) Sun Exposure and Sunscreen Use among Sunbathers in Demark. *Acta Dermatol. Venereol.* 76:31-3.

¹¹ Zitser BS *et al.* (1996) A Survey of Sunbathing Practices on Three Connecticut State Beaches. *Connecticut Med.* 60:591-4.

not. As well, there was no difference in the duration of time spent in the sun between subjects using sunscreen with SPF less than 15 and those using products with SPF greater than 14. Finally, a study by Wulf *et al.*¹² found that sun exposure time and dose were almost identical among sunscreen users and non-users. Collectively, these data suggest that the use of sunscreen products does not encourage consumers to prolong exposure to sunlight and, as such, do not support the “compensation hypothesis”.

The study by Autier *et al.*¹³ reported that use of higher SPF sunscreen products increased the duration of recreational sun exposure in a group of 18-24 year old Europeans. While these findings appear to support the “compensation hypothesis”, there are numerous concerns regarding the interpretation of these data – the most notable being that the cohort used were sun seekers, which is the most likely explanation for their prolonged time spent in the sun. Specifically, it has been reported in previous studies that subjects in the age group of the Autier *et al.* study, spend more time in the sun¹⁴. As such, the study of Autier *et al.* is confounded by the design and, as such, should be cautiously interpreted. On balance there is little evidence to support the “compensation hypothesis” of sunscreen use.

Industry Has Proposed Labeling for High SPF Products

With abundant caution in response to the Agency’s concerns to ensure that there is no risk, we submitted additional labeling information about the proper use of high SPF sunscreen products on May 24, 2000 (Attachment B), by proposing a mandatory indication for all sunscreen products with an SPF above 30:

[bullet] higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.

We urge FDA to restore the ability to truthfully label the actual SPF for products with an SPF over 30. We know that consumers benefit from the availability of sun protection in a wide variety of products and recognize that a manufacturer’s ability to convey truthful information about sunscreen protection on product labels is paramount to ensure that consumers select and use these products appropriately.

¹² Wulf H-C *et al.* (1997) Sunscreens used at the beach do not protect against erythema: a new definition of SPF is proposed. *Photodermatol. Photoimmunol. Photomed.* 13:129-32.

¹³ Autier P *et al.* (1999) Sunscreen Use and Duration of Sun Exposure: a Double-Blind, Randomized Trial. *J Natl. Cancer Inst.* 91:1304-9.

¹⁴ Johnson EY, Lookingbill DP (1984) Sunscreen Use and Sun Exposure. *Arch Dermatol.* 120:727-31. Banks *et al.* (1992) Attitudes of Teenagers Toward Sun Exposure and Sunscreen Use. *Ped.* 89:40-2. Reynolds *et al.* (1996) Predictors of Sun Exposure in Adolescents in a Southern U.S. Population. *J Adol Med.* 19:409-15.

Professional Labeling of Sunscreen Products is Not Necessary

FDA should not require professional labeling of sunscreens. The proposed labeling of sunscreen products - with the labeling recommendations outlined in this submission and our comments of August 4, 2000 (Attachment A) - are more than adequate for professional use. Complete and accurate product labeling should be available to all consumers, not just their health care providers. FDA itself recognizes the growing trend of self-care decisions.¹⁵

Given their important public health benefits, sunscreens should be labeled to provide adequate information for consumers to use in selecting the appropriate product, rather than relying on the advice of their physician.

In its June 8, 2000 *Federal Register* notice the Agency wrote, "Sunscreens are part of a sun protection program in which it is clear that the goal is to limit sun exposure even with the use of a sunscreen. Without adequate labeling, high SPF numbers may dilute the desired public health message," (65 FR 36319 at 36323). It is our position that without language that indicates the actual level of SPF protection, consumers *cannot know what level of protection* they are in fact using. An SPF labeling cap of 30 plus impedes the consumer's ability to compare and select appropriate products. The mandatory indication for sunscreen drug products over 30 which we have proposed is a far better solution consistent with public health needs than an SPF labeling cap of 30 "plus" or "+."

In addition, the industry has worked diligently to create consumer-friendly materials to educate consumers on the role of sun exposure habits and practices. Industry has partnered with the AAD, the Skin Cancer Foundation, and other organizations, both in the US and other countries, to communicate the importance of minimizing exposure to harmful UV. These campaigns provide consumers with a better understanding of the problems associated with increased sun exposure and encourage safe-sun practices, resulting in an increased awareness of the dangers of sun exposure in the general population. Copies of these materials have been submitted to the Agency on several occasions - most recently in 1999.

¹⁵CDER "News Along the Pike" July 2000 issue, "'Health care in the United States is changing with more products being marketed directly to consumers,' said Robert DeLap, M.D., Director of the Office of Drug Evaluation V, who served as chairperson of the [June 28-29, 2000 OTC] hearing. He said FDA expects the trend to continue. 'We are open to the possibility of having more and different kinds of medicines available to consumers,' he said." www.fda.gov/cder/pike/july2000.htm, Sherunda Lister, Issue 7, "Center Opens Reexamination of OTC Drugs"

FDA Should Allow Additional Indications for Sunscreen Drug Products to Encourage Their Use For Sun Protection

Sunscreens are recognized as critical to protecting the public from chronic sun exposure on a day-to-day basis by several organizations including the AAD, the American Cancer Society, the Skin Cancer Foundation, the National Institutes of Health, the Environmental Protection Agency¹⁶ and the FDA itself.

Sunscreens are one of those rare therapeutic products that can actually prevent very serious disease conditions. When used effectively, as part of a sun protection program, they can attack the condition at its source. Instead of trying to treat sunburn, the ravages of photo-aging, or the effects of DNA damage and immune system suppression, sunscreens can help prevent these situations from occurring. The biological effects of UV radiation, and the risks of incremental exposure on the population as a whole, can be easily calculated and are significant. As previously discussed, this is particularly true for the susceptible segments of the population, for whom even small amounts of UV exposure pose an unacceptable risk, or who might be in environments where the UV exposure is exceptionally great, and for children.¹⁷

Key to sunscreens' ability to protect is their appropriate use. For sunscreens to reach their potential as an important public health tool, consumers must understand why they should be used, when they should be used, and how they should be used. The importance of complete and accurate labeling for sunscreens should not be underestimated.

FDA's narrow approach in the sunscreen final monograph to providing consumer information, however, would reverse the significant gains which public health authorities have worked to establish in the past two decades, based on sound science and prevention strategies now available. As the only indication currently allowed in the monograph is protection against sunburn, it incorrectly suggests that the only benefit of sunscreens is the protection against sunburn. If the consumer believes that the only benefit these products provide is protection against sunburn, these products will not be used by the very populations that are just now beginning to consider the effects of chronic or daily sun exposure in terms of premature aging and wrinkling, in addition to sun-sensitive individuals. Consumers will not purchase and use these products for

¹⁶ EPA's web site urges consumers, especially children, to "always use sunscreens" "Overexposure to ultraviolet (UV) radiation in sunlight can result in a painful sunburn. It can also lead to more serious health effects, including skin cancer, premature aging of the skin, and other skin disorders;" <http://www.epa.gov/sunwise/index>

¹⁷ Regular use of sunscreens of SPF 15 or higher during the first 18 years of life can lower the risk of certain types of skin cancer up to 78 percent. (Stern, RS, et al.: 1986 Risk Reductions for Nonmelanoma Skin Cancer With Childhood Sunscreen Use. *Arch. Dermatol.* 1986; 122:537-545.)

protection against the incidental exposures that they know from experience do not result in sunburn.

In addition, there is a significant risk that many cosmetic-drug products with sunscreens would be reformulated in order to remove the need for expensive sunscreen ingredients, the need to manufacture under drug CGMPs, and the need to conduct (or repeat) additional SPF and/or UVA testing prior to marketing, if the only allowed indication for those products is protection against sunburn. The United States would take a step backward on public health at the expense of the consumer.

As the Agency itself has recognized, a wide variety of products are now marketed for sun protection use, many of which include cosmetic benefits and other attributes of importance to the consumer. (64 Fed. Reg. Sunscreen Drug Products for Over-the-Counter Human Use; Final rule, at 27673) (1999). Given the expanding conditions of use of sunscreen drug products (to the recognized health benefit of all), it is imperative, that these products be labeled appropriately for their use. Consumers use sunscreen products for more than just prevention of sunburn. The Agency has acknowledged this fact as well:

Consumers' increased awareness of the need to protect themselves against the harmful effects of both UVA (320 to 400 nanometers) and UVB (290 to 320 nanometers) radiation has created a demand for sunscreen products with higher SPF's and better broad-spectrum (290 to 400 nanometers) protection of longer duration. Manufacturers have responded by creating products with higher SPF's that claim to provide protection against both UVA and UVB radiation.¹⁸

FDA's effective ban on anti-aging claims associated with sunscreen use is an arbitrary and inappropriate restriction of language used to communicate a truthful claim. While the etiology of skin cancer and of photoaging is not fully understood, it is recognized that the contribution of suberythemal doses of UV is a factor. Sun-induced skin damage that may contribute to the eventual development of skin cancer or photoaging likely occurs well before the appearance of sunburn. The Agency has recognized this fact in the final sunscreen monograph which allows for the optional use of the "Sun Alert" statement ("Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun."), but arbitrarily limits claims about the anti-aging benefits of sunscreens to the use of that precise language. That restriction on truthful claims should be eliminated.

¹⁸61 Fed. Reg. 42398 at 42399, August 15 (1996).

It is also critical that manufacturers be permitted to use additional truthful indications in the labeling of sunscreen drug products. We strongly urge the Agency to include the following additional indications for all sunscreen products, to be used individually or in any combination:

- Helps protect against harmful effects of the sun
- Helps protect against (casual) (incidental) (intermittent) (daily) sun exposure
- Helps protect against skin damage caused by the sun
- Helps protect against skin aging caused by the sun
- Regular use helps protect against certain forms of skin cancer caused by the sun

In the TFM, the Agency not only recognized but also insisted on maintaining the strong association of skin aging with exposure to the sun by stating that any variation in the "Sun Alert" statement "that does not relate skin aging or skin cancer as being 'due to the sun' will cause the product to be misbranded under section 502 of the act." Section 352.52(e)(7) Anti-aging claims are truthful claims. Most UV-induced skin damage results from sun exposure as a child or during early to mid adulthood. Photoaging, which is manifested primarily by wrinkles and discoloration of the skin, is far more prevalent in the adult population than the effects of chronological aging, which do not occur until late adulthood.

Furthermore, avoiding or minimizing the effects of skin aging due to sun exposure are major incentives for consumers to use sunscreens. Research has shown that consumers are motivated to apply a sunscreen when they make the association that the sun can cause wrinkling and extensive damage over time. Dermatologists also recognize this use pattern. (Dr. Vincent DeLeo, Remarks at July 22, 1999 FDA Public Feedback Meeting) The final rule's prohibition of anti-aging claims except through verbatim use of the "Sun Alert" statement eliminates a potent and effective inducement to avoid sun damage. As the Agency itself has stated most recently, "...if you use enough, it [sunscreen] helps prevent your skin from taking on that wrinkled, leathery look of photo-aged skin. Best of all, it protects you from the harmful ultraviolet rays that cause skin cancer."¹⁹

¹⁹ Larry Thompson, *Trying to Look Sunsational ? Complexity Persists in Using Sunscreen*, 34 July-August 2000 FDA Consumer, 2000 p.15 -21

It is unreasonable to require manufacturers to limit discussion of the anti-aging attributes of their products to the prescribed language of the "Sun Alert" statement. Sunscreen products do help prevent premature aging, sun damage, and skin cancer, as well as prevent sunburn.

As we stated in comments of March 21, 1994 (Attachment I), 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. 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 is.²⁰

Manufacturers are entitled to make these truthful claims, and consumers should know about these additional indications when selecting a sunscreen drug product.

FDA Should Permit Alternative Directions for Sunscreen Drug Products

The monograph directions, as written, are not flexible enough to allow proper cosmetic application. Current sunscreen regulations require as part of approved directions the following language:

"apply "(select one or more of the following, as applicable: "liberally," "generously," "smoothly," or "evenly") "(insert appropriate time interval, if a waiting period is needed) before sun exposure and as needed". Sec. 352.52 (d)(1)

At the July 22, 1999 Feedback Meeting with the Agency, we raised the issue of the need for alternative directions for products such as make-up with sunscreen. The Agency has recognized in sec. 352.52(d) that some sunscreen products, such as makeup products with sunscreen, may be applied in a variety of ways, using fingertips, sponges or brushes ("More detailed directions applicable to a particular product formulation (e.g. cream, gel, lotion, oil, spray, etc.) may also be included.") We propose that the Agency recognize the following alternative directions for products such as make-up with sunscreen products:

apply "smoothly" or "evenly" "before sun exposure" and/or "as needed"

Another direction is needed because make-up products contain sunscreens as an added benefit. FDA has previously recognized that directions for an OTC drug product

²⁰CTFA comments filed on March 21, 1994 p.12-13 (Attachment I)

must be flexible to accommodate the variety of product applications.²¹ The requirement to use the expression “before sun exposure” may not always be appropriate, as these products are not exclusively or even primarily used for protection against sun exposure. For example, consumers do not choose make-up products primarily for sun protection. The main purpose of these products is to provide color to the skin. The product formulations, including cosmetic ingredients, is important to product selection.

FDA Must Preserve the Lawful Marketing of Combination Sunscreen/Skin Protectant Products

In the Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule, FDA recognized that a product containing a combination of certain Category I sunscreens and skin protectant ingredients lawfully may be marketed. See proposed 21 C.F.R. §352.10(b), 58 Fed. Reg. 28194, 28296, (May 12, 1993). Such products have been lawfully marketed consistent with this proposed rule and FDA Compliance Guide Section 450.300 OTC Drugs - General Provisions and Administrative Procedures for Marketing Combination Products (CPG 7132b.16). In the sunscreen final rule, FDA failed to finalize this portion of 21 C.F.R. §352.10. In the preamble to that same final rule, however, FDA recognized the continued lawful marketing of such products when it acknowledged that it would address sunscreen-containing lip balm product labeling issues in a manner consistent with how it had just addressed sunscreen-containing lipstick products in this final rule. Further, the Agency stated that it would address these labeling issues for sunscreen-containing lip balm products in the final monograph on OTC skin protectant drug products²².

We request that FDA make clear, through the skin protectant drug final monograph or the sunscreen drug final monograph or both, that such combination products, which clearly provide a public health benefit, lawfully may be marketed under such final monographs.

III. Compliance Issues

FDA Must Provide Sufficient Time to Comply with Monograph Requirements

There are many issues to be resolved as a result of reopening the record of the

²¹ “The directions described in paragraph (d)(1) and (d)(2) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks may be applied and removed and *should have appropriate directions* (emphasis added).” 21 C.F.R. 333.350(d)(2) Topical Acne Drug Products for Over-the-Counter Human Use; Final Monograph; Rule August 16, 1991

²²64 Fed. Reg. 27666 at 27682 (1999).

sunscreen monograph. Some involve test methods to substantiate claims; others involve permissible label claims relating to UVA protection, SPF, and anti-aging, and indications and directions for use that could require design of entirely new labeling; some are likely to require product reformulation and testing; still others will affect the format and amount of information on the labeling that could require new labeling or even new packaging because of space limitations. Moreover, because a significant portion of the industry sells product in a seasonal market, the industry has unique timing issues associated with product testing, development and sales to the retail trade, as discussed below. Therefore, it is very important that FDA provide sufficient time for industry to take the steps necessary to begin manufacturing and marketing product under the new regulatory scheme.

FDA has granted an extension of time until December 31, 2002 to comply with the final monograph. That step was very necessary in allowing time to resolve several important scientific issues still outstanding at the time of FDA's publication of the partial final monograph on May 21, 1999. However, in granting more time, the Agency also has established an ambitious schedule for considering the important issues that remain to be resolved regarding sunscreens. These issues are all in addition to the issues relating to the OTC Drug Labeling Regulation and its impact on sunscreen products which CTFA addressed in its comments of August 4, 2000 (Attachment A).

As FDA moves to address the issues raised by this and other comments filed during the reopening of the public record in the sunscreen rulemaking, we urge the Agency to take into account the time for compliance and to address the additional time that will be necessary to comply when it publishes a proposed rule. We believe that an additional 18 months will be necessary to ensure that all products, including seasonal products, can comply with the final rule FDA intends to issue by December 2001.

Time to Comply with Labeling and/or Packaging Changes, Retesting, and Reformulation

Although the time requirements can vary from company to company because of variations in product mix, sales and distribution systems, and many other factors, the sunscreen industry will require as much as an additional 18 months from December 2002 to engineer an efficient program to test, relabel and, if necessary, to reformulate sunscreen products.

This additional time for relabeling and product development takes into account a variety of necessary actions, including assessing changes necessary on existing labeling; evaluating products by final testing methods; preparing of art and print work and review of regulatory compliance; printing and delivery of new labeling; and, where necessary, complete redesign and execution of new product packaging systems, which are consistent with consumer needs, retail space requirements, and maintenance of the brand image and identity.

Time Required for Testing and Reformulation

Most currently marketed products were tested for SPF according to the 1978 proposed monograph or the 1993 TFM. While we submit that there is no public health risk or difference in the SPF determination under either of these methods, we understand that many products will need to be retested once the final rule is published in December 2001. Consequently, additional time will be necessary to arrange for and conduct this testing at the limited number of qualified testing facilities. Completion of the testing will be necessary in some circumstances before labeling changes can be finalized.

Furthermore, existing products formulated to provide UVA as well as UVB protection may need to be retested, relabeled and possibly reformulated depending on the UVA testing methodology and UVA labeling ultimately approved and recognized by the Agency. Again, this will not be known by industry until December 2001, and it may not be possible to test and relabel all products for UVA efficacy in less than one year.

Time for Proper Marketing and Distribution

Another unique feature of sunscreen marketing is that, although the industry encourages year-round sunscreen use, a significant segment of sunscreen products are considered seasonal products, and are sold and used principally in the spring and summer months (May to August). This unique aspect of sunscreen retail sales increases the complexity and time necessary for compliance with a new monograph. Typically, retailers return unsold seasonal products to manufacturers at the end of the season (from September to December). (Based on one company's estimates, this can constitute approximately 20-25% of the product originally sold and can represent a value of as much as \$175 million or more.) These products are then stored and redistributed prior to the beginning of the next season (January to April).

Thus, manufacturers with seasonal products supply and sell their inventory in two marketing cycles over a period of 18 months. This cycle is further lengthened and complicated if the manufacturer is also relabeling and reformulating product (which may take as long as 12 to 15 months). Thus, it is our current judgment that if FDA adheres to its proposed schedule, sunscreen manufacturers will need an additional 18 months (until June 30, 2004) to accomplish these changes without significant injury and product disruption for consumers.

Although the nature of additional testing and labeling requirements still to be finally decided by FDA could have an impact on how much additional time will be necessary to comply, most outcomes will require at least this much additional time. Of course, any delay in FDA's planned schedule for issuing a final regulation will further extend the time required.

Conclusion

In conclusion, there is ample scientific support for the need to provide consumers with the highest level sunscreen protection available to provide critical protection from exposure to the sun. As we have stressed, SPF products above 30 can be safely tested with accuracy and the assurance that they provide their labeled protection.

All sunscreen products, including SPF products above 30, may be safely and consistently tested on solar simulators whose specifications are appropriate for use in SPF testing procedures. Testing high SPF sunscreens need not cause discomfort or hardship to subjects. The longer exposure times associated with testing high SPF sunscreen products do not produce thermal overloading of the skin. Furthermore, with the readily acknowledged and acceptable modifications to the current exposure dose format requirement, as well as the Agency's return to the 16-24 hour MED reading time frame, testing of all sunscreen products, including SPF products above 30, will be easier to conduct and more comfortable for test subjects. Multiple laboratories can prepare, assay, and utilize the two control formulations. With the additional indications which we have proposed, consumers can continue to use these products as they are meant to be used. High SPF sunscreens exist today, and consumers rely on them.

The restrictions of anti-aging claims to a verbatim repetition of the "Sun Alert" statement should be eliminated. All truthful statements regarding the benefits of sunscreens to reduce photoaging should be permitted.

It is imperative that the Agency permit the use of other appropriate labeling indications and directions which are of critical importance in the effective selection and use of sunscreen drug products. We consider the final rule's limitation to two indication statements, both of which refer only to sunburn, to be illogical and a disservice to consumers, especially as they are likely to incur sun-induced skin damage prior to the onset of erythema. Indeed, consumers may well consider *foregoing* the use of sunscreen products if they believe they will not be exposing themselves for a long enough time to induce a sunburn.

Finally, it is critical that Agency provide sufficient time for industry to be able to conform to the final monograph. By doing so, FDA will allow the industry to comply in the most comprehensive and economical manner to the benefit of consumers.

Our members develop, manufacture, and market products that have already made a significant impact on the very real and continuing public health threat of excess UV exposure. We ask that the Agency promulgate responsive regulations, recognizing that to do so will allow continued innovation in the development and marketing of safe and effective products that meet the needs of the American public for sunscreen protection.

Respectfully submitted,

A handwritten signature in black ink that reads "E. Edward Kavanaugh". The signature is written in a cursive style with a large, sweeping flourish at the end.

E. Edward Kavanaugh
President

Attachments

cc: Robert J. DeLap, M.D.
Charles J. Ganley, M.D.
Linda M. Katz, M.D.
John D. Lipnicki

Attachments [in Chronological Order - Most Recent First]

- A. CTFA comments filed in response to Sunscreen Drug Products for Over-the-Counter Human Use: Final Monograph, Dockets Management Branch, Food and Drug Administration (HFA-305) (August 4, 2000).
- B. CTFA/CHPA letter from Thomas J. Donegan, Jr., Vice President- Legal & General Counsel, CTFA to Charles J. Ganley, M.D., Director, Division of OTC Drug Products (HFD-560), Food and Drug Administration (May 24, 2000).
- C. CTFA submission on Methods Validation from Thomas J. Donegan, Jr., Vice President -Legal & General Counsel, CTFA to Charles M. Ganley, M.D., Director, Division of OTC Drug Products (HFD-560), Food and Drug Administration (March 6, 2000).
- D. CTFA/CHPA letter from Thomas J. Donegan, Jr., Vice President - Legal & General Counsel, CTFA to Charles J. Ganley, M.D., Director, Division of OTC Drug Products (HFD-560), Food and Drug Administration (January 14, 2000)
- E. CTFA letter from Thomas J. Donegan, Jr. Vice President -Legal & General Counsel, CTFA to Charles J. Ganley, M.D., Director, Division of OTC Drug Products (HFD-560), Food and Drug Administration (October 15, 1999).
- F. CTFA/NDMA letter from Thomas J. Donegan, Jr., Vice President - Legal & General Counsel, CTFA to Debra L. Bowen, M.D., Deputy Director, Office of Drug Evaluation V (HFD-560), Food and Drug Administration (September 11, 1998).
- G. CTFA/NDMA letter from ThomasJ. Donegan, Jr., Vice President - Legal & General Counsel, CTFA to Debra L. Bowen, M.D., Director, Division of OTC Drug Evaluation (HFD-560), Food and Drug Administration modifying comments filed March 21, 1994 (April 15, 1998).
- H. CTFA letter from James H. Skiles, Associate General Counsel, CTFA, to Dockets Management Branch (HFA-305), Food and Drug Administration (May 12, 1994).
- I. CTFA comments filed in response to OTC Sunscreen Drug Products Tentative Final Monograph, Dockets Management Branch (HFA-305), Food and Drug Administration, (March 21, 1994).

- J. CTFA letter from E. Edward Kavanaugh, President, CTFA to William E. Gilbertson, Pharm.D., Director, Monograph Review Staff, Food and Drug Administration (November 17, 1992).
- K. Mark Naylor, M.D., presentation at the FDA Public Feedback Meeting, "High SPF Sunscreens: A Dermatologist's Viewpoint" (July 22, 1999).

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