



THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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April 16, 1999

E. EDWARD KAVANAUGH  
P R E S I D E N T

**VIA HAND DELIVERY**

Dockets Management Branch  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20857

**Request for Administrative Stay of Action and Citizen Petition  
Requesting Publication of a Comprehensive Final Monograph  
for OTC Sunscreen Drug Products**

**Re: Docket Nos. 98N-0337, 96N-0420, 95N-0259, 90P-0201, 78N-0038**

Dear Madam or Sir:

On behalf of its members, The Cosmetic, Toiletry, and Fragrance Association ("CTFA") filed the attached Request for Administrative Stay of Agency Action and Citizen Petition with the Food and Drug Administration on April 15, 1999. Please ensure that this Request for Stay and Citizen Petition is filed in the following dockets: Over-the-Counter Human Drugs; Labeling Requirements (Docket Nos. 98N-0337, 96N-0420, 95N-0259, 90P-0201) and Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph (78N-0038).

It is our understanding that the following additional information is necessary to ensure that the attached petition meets the regulatory requirements of a Citizen Petition under 21 C.F.R. § 10.30.

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WDC - 64840/1 - 0859567.01

98N-0337

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### **Environmental Impact**

The undersigned claims a categorical exclusion from filing an Environmental Assessment or Environmental Impact Statement under 21 C.F.R. §§ 25.30, 25.31.

### **Economic Impact**

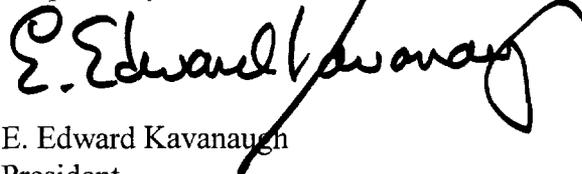
An economic impact analysis will be provided upon request.

### **Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, the attached petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Thank you for your assistance in ensuring that the attached Request for Stay of Administrative Action and Citizen Petition is filed in the appropriate dockets as of this date. If you have questions regarding this request, please do not hesitate to contact me.

Respectfully submitted,

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

E. Edward Kavanaugh  
President

Attachments



THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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Dear Madam or Sir:

On behalf of its members, The Cosmetic, Toiletry, and Fragrance Association ("CTFA") submits this Petition, under 21 C.F.R. §§ 10.30 and 10.35, requesting that the Commissioner of Food and Drugs (1) stay the effective date of the recently promulgated format and content labeling requirements for over-the-counter ("OTC") drugs as they relate to sunscreen products and (2) stay or refrain from publication of any partial final rule on this subject. This Petition also requests, under 21 C.F.R. §§ 10.25 and 10.30, that the Commissioner of Food and Drugs initiate the appropriate administrative process to publish a comprehensive Final Monograph for OTC sunscreen drug products incorporating three distinct ongoing rulemaking proceedings in this area.

These actions are necessary to prevent the harm to the public health that will result from the Agency's current rulemaking proceedings, namely reduced availability of sunscreen products and incomplete and misleading labeling on available sunscreen products. At a time when skin cancer has grown to epidemic proportions, the Food and Drug Administration ("FDA") should take all reasonable and necessary steps to ensure the wide availability and proper labeling of sunscreen products. Currently, sunscreens are widely available. Moreover, great strides have been made in the education of consumers on the importance of proper sunscreen use. As a result of industry's efforts to improve the quality and efficacy of sunscreens, as well as public information efforts by many organizations, including the American Academy of Dermatology, the American Cancer Society, the Skin Cancer Foundation, the National Institutes of Health, CTFA, the Environmental Protection Agency ("EPA") and FDA, sunscreens are widely regarded as among the most important weapons in the fight against damaging overexposure to the sun. FDA's actions that are the subject of this petition threaten to undermine the progress that has been made in this area.

## **I. Decisions Involved**

The specific administrative actions that are the subject of this Petition are:

- (1) Stay implementation of the Final Rule "OTC Human Drugs; Labeling Requirements" as it applies to sunscreen products, 64 Fed. Reg. 13254 (March 17, 1999) (the "Final OTC Drug Labeling Rule"); 21 C.F.R. § 201 et seq., until such time as FDA promulgates a comprehensive Final Monograph for OTC sunscreen drug products;

- (2) Stay and/or refrain from issuing any pending, tentative or final decision by FDA to publish a Partial Final Monograph on Sunscreen Drug Products for OTC Human Use, Docket No. 78N-0038; and
- (3) Promulgation of a comprehensive Final Monograph for OTC sunscreen drug products, Docket No. 78N-0038, that addresses all areas of OTC sunscreen drug product labeling which currently are being addressed in three separate rulemaking proceedings. This should be accomplished by prompt publication of an amended Tentative Final Monograph for OTC sunscreen drug products which would incorporate the relevant provisions of the Final OTC Drug Labeling Rule, the Agency's proposals relating to formulation, testing, and claims related to ultraviolet B ("UVB") protection, and the Agency's proposals for the formulation, testing and claims for ultraviolet A ("UVA") products.

## **II. Executive Summary**

This Petition requests a stay of FDA action with respect to sunscreen products in the recently promulgated Final OTC Drug Labeling Rule, which requires major changes in the format and content of sunscreen labels. This Petition also requests that FDA stay and/or refrain from taking further action in the rulemaking that pertains only to formulation, testing standards and labeling related to UVB radiation (hereinafter referred to as the "Partial Final Monograph"). Finally, this Petition also requests that FDA publish a comprehensive Final Monograph for OTC

sunscreens. This Final Monograph would govern the formulation, testing standards and labeling related to UVA and UVB protection provided by sunscreens.

Our request, supported by interested members of Congress and members of the medical and consumer community, is that FDA stay further action on its Final OTC Drug Labeling Rule as it affects sunscreens as well as the sunscreen Partial Final Monograph until it has resolved all issues related to UVA protection and is prepared to publish one comprehensive Final Monograph. That regulation should provide a coordinated approach to all formulated, testing and labeling issues related to sunscreen products, and should be published first as an amended tentative final monograph so that all interested members of the public have an opportunity to comment.

CTFA bases its request on a strong concern that consumers seeking products that protect the skin from damage and the threat of skin cancer posed by UVA and UVB radiation will be harmed by FDA's fragmented approach to this rulemaking. While FDA is moving ahead on UVB issues, recent medical evidence has made it clear that UVA protection may be the most important factor in preventing skin cancer caused by sun exposure. In fact, the most important long-term benefits obtained from the regular use of sunscreens are protection from skin cancer and premature skin aging. These benefits are achieved by the effective filtering of damaging UVA rays. After a lengthy review process, to publish a sunscreen monograph that does not provide the necessary regulatory guidance to manufacturers on testing standards and labeling for UVA filters is not in the public interest.

OTC sunscreen products are important to the health and well-being of the American consumer. If FDA fails to take the actions we request, the unintended but certain effect will be the removal of sunscreens from products that consumers use on a daily basis to obtain sun protection. Over the last ten years, manufacturers have added sunscreen to products such as

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lipsticks, foundations, and moisturizers. As written, the Final OTC Drug Labeling regulations are inadequate to deal with labeling such products, and manufacturers will be forced to remove the sunscreen or risk having their product be deemed misbranded. The welfare of both adults and children who need these products should not be jeopardized by a rush to meet artificial regulatory deadlines. Development of a comprehensive, science-based plan for the formulation, testing and labeling of these products is in the best interest of the American public.

### **III. Action Requested**

CTFA requests three actions. First, CTFA requests that FDA promptly stay the effective date of the Final OTC Drug Labeling Rule, 64 Fed. Reg. 13254 (March 19, 1999) as it relates to OTC sunscreen drug products. This rule governs all OTC drug labeling, including sunscreens, despite a CTFA request that sunscreen products be given greater flexibility because of their important public health benefits and unique cosmetic attributes.

Second, CTFA requests that FDA stay and/or refrain from publication of a Partial Final Monograph for OTC sunscreen drug products. The Partial Final Monograph is described by Agency officials as limited to claims and standards related to protection from UVB radiation. This is a partial sunscreen monograph spawned from what was originally intended to be a comprehensive FDA monograph addressing all labeling and claim substantiation issues related to all forms of sunscreen protection (UVB and UVA). It is anticipated that this Partial Final Monograph will cause significant disruption and expense to the sunscreen industry, adversely affect consumers, and force manufacturers to eliminate sunscreen active ingredients from a wide array of daily use sunscreen products that consumers buy primarily for cosmetic purposes because the new OTC drug labeling format is not compatible with the packaging for many cosmetic-drugs that include sunscreen ingredients.

Third, CTFA requests that the Commissioner of Food and Drugs continue the development of a Final Monograph for OTC sunscreen drug products by bringing together the three distinct ongoing rulemakings related to the labeling of OTC sunscreen products. The first step in achieving this goal would be the prompt publication of an amended Tentative Final Monograph for OTC sunscreen drug products that addresses all outstanding issues. Currently, FDA's rulemaking addressing UVA protection is being indefinitely deferred. This is contrary to recent scientific findings that have confirmed that exposure to UVA radiation is linked to the alarming incidence of serious skin cancer in the United States. As FDA stated in the current sunscreen TFM issued in 1993: "[FDA] believes that consumers will benefit from labeling on OTC sunscreen drug products that clearly indicates if a drug product provides protection against UVA radiation." 58 Fed. Reg. 28194, 28232 (May 12, 1993) (the "current sunscreen TFM"). This view is shared by every relevant professional and public health group that commented on the rulemaking nearly five years ago.

CTFA requests these actions to enhance the public health, avoid potential consumer confusion, and avoid the possible loss of the wide variety of sunscreen products currently available, all of which likely will result from the current piecemeal rulemaking for sunscreens. FDA must understand the impact of its decision on the entire sunscreen category. As described herein, some of those substantive decisions will discourage manufacturers from using sunscreens in their products. Therefore, a stay would avert this potentially destructive process and allow a comprehensive sunscreen Final Monograph to be developed addressing all testing and labeling issues related to sunscreen protection.

#### **IV. Statement of Grounds**

##### **A. Background**

##### **1. Nature of CTFA's Interest**

CTFA, founded in 1894, is the national trade association representing the personal care products industry. CTFA represents approximately 300 active member companies that manufacture or distribute personal care products, including a wide array of products that are both cosmetics and drugs. Our membership also includes approximately 300 associate members who provide goods and services to manufacturers and distributors of personal care products. Among the products that members rely upon CTFA to represent before the Agency are OTC sunscreens. CTFA members market or manufacture the majority of sunscreen products sold in the United States.

CTFA has actively participated in both the scientific and regulatory issues associated with FDA's review of sunscreen products. As knowledge about the damaging effect of the sun (both UVB and UVA radiation) has evolved, sunscreens have come to be widely regarded by health organizations as among the most important weapons in the fight against skin damage caused by sun overexposure. Indeed, FDA and other public health authorities now urge consumers to use sunscreens not only when sun exposure is expected to be intense such as at the beach and when engaging in outdoor activities such as skiing, but also on a daily basis to protect skin from incidental, chronic sun exposure. In response to the increase in demand for greater variety in sun protection products, industry continues to develop and expand the sunscreen market to accommodate the myriad needs and desires of consumers. Among the most significant changes in the sunscreen market over the past decade has been the development of UVA sunscreen products; the development of higher sun protection factor ("SPF") products; and the

reformulation of thousands of traditional daily use cosmetic products to include sunscreen ingredients.

## 2. FDA's Monograph for OTC Sunscreen Products

In 1993, FDA published a notice of proposed rulemaking (the current sunscreen TFM) for OTC sunscreen drug products. 58 Fed. Reg. 28194 (May 12, 1993). The TFM proposed conditions under which OTC sunscreen drug products would be generally recognized as safe and effective ("GRAS/E") and not misbranded. CTFA and many of its members submitted extensive comments on the TFM, which included substantive requests that FDA reconsider certain proposed labeling requirements such as the mandatory inclusion of the "Recommended Sunscreen Product Guide"<sup>1</sup>, the restriction on use of the term "Sunblock" to products containing titanium dioxide, and use of higher (above 30) SPF products, as well as make other revisions directed at ensuring that a wide array of sunscreen products remain on the market and be labeled in a way that would encourage, rather than confuse, consumers regarding appropriate sunscreen use. CTFA and its members also have been actively involved in the Agency's ongoing consideration of UVA radiation as it relates to the OTC sunscreen monograph and considers the resolution of UVA issues critical to all sunscreen products.

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<sup>1/</sup> A sample product label provided by FDA in the context of the Final OTC Drug Labeling Rule include a sunscreen label on which the Recommended Sunscreen Product Guide appears. While not yet confirmed, its use in that rulemaking indicates that CTFA's request that the Guide be eliminated or made optional has been rejected by FDA. See Attachment A.

### 3. FDA's Final OTC Drug Labeling Rule

FDA's Final OTC Drug Labeling Rule, 64 Fed. Reg. 13254, published in the Federal Register on March 17, 1999, establishes standardized format and standardized content requirements for the labeling of OTC drug products. Among other things, the rule requires manufacturers of OTC drug products, including sunscreen products, to substantially reformat product labels to include standardized headings and warning statements, and to use larger font and type size on the label. Because the Final OTC Drug Labeling Rule will require label changes in addition to those mandated by a Partial Final Monograph, CTFA requests that FDA stay the effective date of the rule as it relates to sunscreen products until a single, comprehensive monograph for sunscreens that resolves all of the issues relating to both UVB and UVA claims is effective.

The implementation plan set forth in the Final OTC Drug Labeling Rule provides that products for which a final monograph becomes effective on or after April 16, 1999, must comply with this rule as of the applicable implementation date for that final monograph. If FDA considers the implementation plan to be triggered by a Partial Final Monograph, a conclusion with which CTFA disagrees, issuing a sunscreen Partial Final Monograph with the standard effective date for final OTC monographs of one year from publication in the Federal Register would require sunscreens to comply with the Final OTC Drug Labeling Rule sometime during the year 2000. Thus, sunscreens would not only be forced to comply with the Final OTC Drug Labeling Rule well before products for which final monographs already exist, but sunscreens would then be forced to undergo yet another labeling change when the Agency finalizes the second part of the sunscreen monograph addressing UVA claims. See 64 Fed. Reg. 13254 (March 17, 1999); 21 C.F.R. § 201 et seq.

The implementation scheme for the Final OTC Drug Labeling Rule was expressly intended to ensure that "manufacturers would only need to make one label printing to incorporate final monograph information into the new labeling format." 62 Fed. Reg. 9024, 9042 (Feb. 27, 1997)(Proposed Rule). Requiring two labeling changes for sunscreen products would thus undermine FDA's efforts to minimize the economic impact of the Final OTC Drug Labeling Rule.

**B. A Stay of the Sunscreen Monograph Does Not Contravene Congressional Intent behind Section 129 of the Food and Drug Modernization Act, P.L. 105-115**

FDA will not contravene Congressional intent by staying Agency action on the OTC sunscreen monograph until FDA can issue a comprehensive sunscreen monograph that addresses UVA, UVB and related labeling issues. Although Section 129 of the Food and Drug Modernization Act of 1997 ("FDAMA"), 21 U.S.C. § 393, directs FDA to issue "regulations" for OTC sunscreen products within 18 months of passage of FDAMA, Congress also recognized that there were important scientific and technical issues that had to be resolved before a comprehensive monograph could be issued. See H.R. Rep. No. 105-399 at 96 (1997).

Further, Congress stated that it did not intend that all regulation in this area be complete by a specified date. Id. Thus, Congress gave FDA the flexibility to consider the necessary scientific and technical issues on a reasonable time table. Nowhere did Congress state that a final rulemaking on any specific sunscreen issue -- UVA, UVB, or otherwise -- was required within 18 months.

This interpretation of Congressional intent was recently affirmed in a March 30, 1999 letter submitted by Senator Jack Reed, sponsor of Section 129 of FDAMA, and Senator Christopher Dodd, to Commissioner Henney. The letter states "the provision [Section 129 of

FDAMA] was intended to encourage the Agency to work toward completing its rulemaking process with regard to sunscreen products.” The Senators’ letter also states:

. . . we would also urge you to continue working toward a comprehensive sunscreen monograph that provides accurate and complete information about the full dangers of sun exposure and the benefits of sunscreen products. It is our view that publishing a final monograph at this time that does not address the full exposure from both UVA and UVB could result in sunscreen labeling that unintentionally misinforms consumers about the level and type of protection that sunscreen products provide and how best to use them.<sup>2</sup>

Thus, the key sponsor of Section 129 suggests that it was not intended to compel FDA prematurely to publish a final or partial final monograph by a date certain, but rather to work diligently toward finalizing a comprehensive consumer-oriented monograph. FDA therefore will more fully support Congressional intent by expeditiously working with industry to issue one complete, well-considered and scientifically rational sunscreen monograph.

**C. Required Elements for Granting an Administrative Stay Under  
21 C.F.R. § 10.35**

**1. CTFA’s Members Will Suffer Irreparable Injury If the Stay Is Not  
Granted**

If FDA fails to grant the stay requested in this Petition, CTFA’s members will suffer irreparable injury. FDA’s current regulatory approach, which will subject sunscreens to three separate rulemakings, will result in the loss of consumer goodwill toward many product brands marketed by CTFA members and in unjustifiable expenses related to multiple relabelings of members’ sunscreen products.

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<sup>2/</sup> Letter dated March 30, 1999, from Senators Jack Reed and Christopher J. Dodd to Commissioner Jane Henney.

First, CTFA members will suffer irreparable injury in their relationship with consumers. The industry has made significant efforts to educate consumers about sun exposure and provide a product that can protect consumers from overexposure to UV radiation from the sun. In doing so, the industry has earned significant goodwill with consumers. The reputation and good will that CTFA members have developed for sunscreen products will be damaged by the consumer confusion and, more importantly, consumer harm that will be created by two sequential but very different labels for sunscreens.

Second, publication by FDA of two sequential Partial Final Monographs will place an unreasonable and unrecoverable economic burden on the sunscreen and cosmetics industry. If the Agency issues a Partial Final Monograph that addresses standards for ingredients that provide protection against UVB radiation but not UVA radiation and does not consider the interrelationship between them, manufacturers initially will be required to conform products and product labels to the testing and labeling requirements of the Partial Final Monograph. Industry efforts to relabel sunscreens under FDA's proposed approach will be further complicated if FDA prematurely applies the Final OTC Drug Labeling Rule in conjunction with the Partial Final Monograph. Once the Agency issues a subsequent partial monograph to address UVA radiation, sunscreen manufacturers again will be required to retest and relabel their products at great time and expense to ensure that they comply with any subsequent requirements to measure and label UVA efficacy.

CTFA estimates that there are in excess of one thousand different OTC sunscreen drug product shelf-keeping units ("SKUs") that would require relabeling.<sup>3</sup> The estimated cost of redesigning and reprinting labels for OTC sunscreen drug products ranges from \$7,900 or

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<sup>3/</sup> This estimate of one thousand SKUs would be several higher if CTFA were to include each SKU for color cosmetics, such as lipsticks, which contain sunscreen.

\$11,300 per SKU. Comments of the Cosmetic, Toiletry, and Fragrance Association (October 7, 1997), Docket Nos. 96N-0420, 92N-454A, 90P-0201, 95N-0259 at 46. Accordingly, the cost of relabeling these products would range from \$7.9 million to \$11.3 million. Upon preliminary review of the requirements of the OTC drug labeling regulation as it will apply to sunscreens, CTFA believes the costs of compliance may be much higher because many products will require not just relabeling but total repackaging.

The costs of relabeling and repackaging double if FDA implements the sunscreen monograph sequentially, starting with a set of rules related to UVB radiation, followed several years later for a set of rules related to UVA radiation. The economic burden of multiple relabeling and retesting of cosmetics likely will cause some companies to eliminate sunscreens from their cosmetics. This will directly undermine recent public health education efforts to persuade consumers to wear sunscreens daily.

In violation of the Agency's mandate to assess the economic impact of Agency regulations, FDA has failed to address the significant economic effects that issuance of two sequential partial monographs (UVB, followed by UVA) will have on the industry and consumers. Without consideration and public comment on this issue, FDA will violate its mandate to consider the economic costs of its action to industry. Pursuant to the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612, and the Unfunded Mandate Reform Act, 2 U.S.C. § 1501 et seq. FDA is required to assess the impact that the Agency's actions will have on the affected industry. By failing to fully consider the economic impact of its actions on industry, FDA has not followed proper regulatory procedures. Moreover, Executive Order #12866 mandates that agencies should not promulgate a rule unless the benefits of the rule justify its costs.<sup>4</sup> The costs

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<sup>4/</sup> Executive Order #12866 directs agencies to assess all costs and benefit of available regulatory alternative, and when regulation is necessary, to select regulatory approaches that

to industry and the public discussed herein of proceeding with the two partial monographs far outweigh any benefits of taking that approach.

## **2. CTFA's Case Is Not Frivolous And Is Being Pursued In Good Faith**

CTFA's interest in the finalization of a comprehensive, scientifically sound sunscreen Final Monograph is a serious pursuit undertaken by the association in good faith and for legitimate public health reasons. CTFA and our members have had a long and significant role in the development and use of sunscreens. These efforts have resulted in enormous public health benefits to consumers. CTFA has been an active participant in all aspects of FDA's review of sunscreen products. For example, CTFA and its members have been strong supporters of the Sun Protection Factor ("SPF") System, which FDA and the entire scientific community now regard as the backbone of the U.S. regulatory scheme with respect to sunscreens. Several years ago, when FDA raised questions regarding the need for SPF's greater than 15, CTFA and a number of its members participated in a public hearing and justified SPF's greater than 15 on both public health and scientific grounds. Additionally, at FDA's request CTFA undertook testing to demonstrate that different laboratories can obtain valid, reproducible results when testing high-SPF sunscreen formulations. CTFA also provided FDA with the results of research demonstrating the safety of two widely-used sunscreen active ingredients -- padimate O and oxybenzone.

CTFA's concerns about the adverse impact of FDA's pursuit of three separate rulemakings for sunscreens is not frivolous. When FDA's review of sunscreens began, sunscreen products were available on the market in limited quantities but they were not widely used.

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maximize net benefits, including the potential economic, environmental, public health and safety, distributive impacts and equity.

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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, EPA and FDA itself -- sunscreens are widely regarded as among the most important weapons in the fight against damaging overexposure to the sun. As awareness of the sun's damaging effects increases, public health authorities are urging consumers to use sunscreens regularly, 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. By subjecting sunscreen products to three separate rulemakings which are likely to result in confusing and inconsistent regulations, FDA will only reduce the availability of sunscreens to consumers by forcing manufacturers to reconsider the inclusion of sunscreens in traditional cosmetic products. CTFA has a legitimate interest in preventing this from occurring.

CTFA's request for stays is being pursued in conjunction with its good faith effort to consolidate and expedite finalization of a sunscreen monograph. CTFA submitted extensive, substantive comments to both the OTC sunscreen monograph and Final OTC Drug Labeling rulemakings. Since the Agency published the sunscreen TFM, CTFA and its members diligently have pursued with FDA the promulgation of appropriate testing, compositional and labeling standards for ingredients that protect against UVA radiation in an effort to ensure that the public has access to sunscreen products that will protect against both UVA and UVB radiation. The available science demonstrates, and indeed FDA has conceded, that the public health will be best served by sunscreen products that will protect the public from harmful exposure to both UVA and UVB radiation. Regarding the new Final OTC Drug Labeling Rule, CTFA's comments submitted on the proposal addressed in detail the application of the rule to sunscreens and its potential negative effects. CTFA has been involved and consistent in its activities throughout

both rulemakings. Its comments have been thoughtful and scientifically relevant. CTFA does not seek to unnecessarily delay final Agency action on sunscreens but rather to encourage expeditious development of a single, comprehensive final sunscreen monograph that includes only reasonable and necessary labeling requirements.

**3. There Are Sound Public Policy Grounds For Supporting The Requested Actions**

There are sound public policy grounds for FDA to grant the stays that CTFA requests in this Petition. In particular, granting the requested stay is in the best interest of public health. A consumer that is properly educated on the dangers of overexposure to the sun is the most important weapon in the fight against skin cancer. FDA's current piecemeal approach to the regulation of sunscreens will only confuse consumers and undermine the significant education of consumers on the proper use of sunscreens that has taken place in the last decade. Granting the requested stay will allow FDA to take a unified approach to the regulation of sunscreens and provide the maximum public health benefit.

a. **A Comprehensive Monograph for UVA and UVB is Necessary to Help Reduce the Number of New Skin Cancer Cases**

Since the publication of the sunscreen TFM, FDA, medical groups, and consumer interest groups have continued to document the significance of, and expressed increasing concern about, exposure to UVA radiation. Exposure to UVA radiation has been causally linked with the high incidence of skin cancer in the United States, including basal cell carcinoma, squamous cell carcinoma, and melanoma.<sup>5</sup> According to public health experts, skin carcinoma and melanoma

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<sup>5/</sup> The effects of ultraviolet A ("UVA") light have been well-documented by medical experts and include photoaging of the skin, age spots, and skin cancer. See Kerry Hanson &

rates have reached epidemic levels in the U.S. and are expected to rise during the next century. The incidence of all skin cancers has increased between four to five percent annually to over one million cases per year. The American Cancer Society has estimated that over 900,000 new cases of basal and squamous cell carcinoma were diagnosed in 1990. In addition, an estimated 40,300 new cases of melanoma were reported in 1997 and the disease claimed the lives of 7,300 Americans in that same year. Accordingly, FDA, public interest groups, and medical groups have strongly advocated the development and marketing of products that protect against UVA light.

b. FDA Recognized the Importance of Addressing the UVA Exposure Issue in a Sunscreen Monograph

FDA has recognized the public health value of issuing a complete sunscreen Final Monograph. In the preamble to the proposed rule, FDA specifically recognized the significance and adverse effect of UVA radiation on public health and acknowledged that UVA radiation contributes to acute and chronic skin damage including erythema, melanogenesis, carcinogenesis, photoaging and morphological alterations of Langerhans cells. *Id.* at 28232 and

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John D. Simon, Epidermal trans-urogenic acid and the UV-A induced photoaging of the skin, 95 Proceedings of the National Academy of Sciences 18, 10576-10578 (1998). Whereas aging of the skin usually is characterized by the thinning of the skin and deepening of normal facial expression lines, photoaging causes coarse wrinkles, inelasticity and discoloration. The latter types of changes are considered common indications of an individual's risk for developing skin cancer. Exposure of the skin to UVA light creates oxygen radicals that prematurely photoage skin, damage DNA, may suppress the immune system and cause respiratory complications. *Id.* UVA protection, however, can prevent acute sunburn as well as other long term adverse effects of overexposure to sunlight. Accordingly, several physician groups have recommended that individuals use daily a broad spectrum sunscreen with a sun protection factor ("SPF") of at least 15 which will protect against both UVA and UVB rays.

29233. More specifically, the Agency stated that: “[FDA] believes that consumers will benefit from labeling on OTC sunscreen drug products that clearly indicates if a drug product provides protection against UVA radiation.” 58 Fed. Reg. at 28232. FDA has concluded that UVA radiation penetrates the skin more deeply than UVB and specifically stated:

that protection against UVA radiation is much more important than previously realized. The Agency believes that protection against UVA radiation may be as important to consumers’ well-being as protection against UVB radiation.

Id. Moreover, the Agency has expressed a concern that sunscreens with higher SPF levels will allow consumers to remain in the sun for long periods of time because skin that is protected by sunscreen does not burn at the same rate as skin that is not treated with a sunscreen product, thus, increasing consumers exposure to UVA radiation.

Consequently, on several occasions, the Agency has called for the development of compositional, testing, and labeling standards for OTC sunscreen product that are intended to protect consumers from UVA radiation. In fact, in 1993, the Agency expressly called for the industry to develop data and testing procedures for sunscreen products that make UVA radiation protection claims in the TFM. Id. at 28248 - 28250. In 1994, FDA again requested the industry to submit data, develop testing protocols and provide other information relating to UVA radiation for the monograph.<sup>6</sup> The industry has responded numerous times to provide the Agency with relevant information.

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<sup>6/</sup> The Agency held a public meeting to discuss testing and labeling standards for these products on May 12, 1994. See 59 Fed. Reg. 16042 (April 5, 1994). On January 27, 1999, the Agency held a public meeting with the industry to review its preliminary reactions to UVA testing methodologies submitted by the industry over the years since 1994. To date, however,

Despite the Agency's recognition of the importance of sunscreen products that protect against UVA radiation, and the significant passage of time that has occurred since FDA called for development of such testing standards and protocol, the Agency has not developed adequate protocol, testing methodologies, or labeling standards for products that are intended to protect consumers from UVA radiation. Indeed, FDA has indicated informally and publicly at official Agency meetings that the Agency intends to publish a Partial Final Monograph for sunscreens that does not include standards, testing protocols, or labeling requirements for UVA ingredients. As noted in the TFM, the Agency has advised the sunscreen industry that, once promulgated, the Partial Final Monograph will be effective twelve months from the date of publication of the Partial Final Monograph in the Federal Register. Id. at 28195. Accordingly, on or after that date, OTC drug products that are subject to the Partial Final Monograph that contain nonmonograph conditions, i.e., conditions or ingredients that are not covered by the monograph, would be considered adulterated and/or misbranded products. Id. This will leave the use of UVA claims in their present uncertain regulatory status, which will harm the public, will impede effective communication with consumers regarding the benefits of their products, and will discourage broader use of these highly necessary products.

c. Medical Experts Recognize the Importance of a Comprehensive Monograph on UVA and UVB Issues

Experts in the field also recognize the importance of a complete sunscreen Final Monograph to public health. As noted by several interested parties, including medical professional groups, skin cancer experts, dermatologists, pediatric specialists, the Federal Trade

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the Agency has failed to make any recommendations with regard to standards for products intended to protect against UVA radiation.

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Commission ("FTC"), and the EPA (see Attachment B) publication of a monograph that only addresses UVB radiation will confuse and misinform consumers about the need for sun protection. In the absence of a label that addresses both UVA and UVB radiation, consumers will mistakenly assume that sunscreen products are effective equally against both. Further, a sunscreen regulation that does not address UVA radiation, instructs consumers to consider their tanning history in choosing an appropriate SPF number, and only recommends that children be covered with a minimum of SPF 4 likely will discourage consumers from properly using sunscreens on themselves and their children. Likewise, the use of sunscreens that focus on exposure to UVB radiation rather than UVA radiation will give consumers a false sense of security and may encourage them and their children to remain in the sun for longer, more dangerous periods of time. This may increase their exposure to harmful UVA radiation and, thus, exacerbate the skin cancer epidemic.

The publication of a Partial Final Monograph also undermines the successful ongoing program by health educators to encourage consumers to take adequate sun protection measures. Through the educational efforts of the sunscreen industry, health care professionals, and consumer interest groups, the public has begun to take protective measures against harmful ultraviolet A and B rays. Indeed, several surveys, including a study by the American Academy of Dermatology, have reported an increased awareness among adults of the need for sun protectants to guard against skin cancer and premature photoaging of the skin. See Mortality and Morbidity Weekly Report, June 19, 1998. In reviewing these and related consumer research surveys regarding adult awareness of the effects of sunlight exposure, health educators have credited the clarity and consistency of current health education about sun protection as a major factor in the public's modification of behavior. As suggested by comments from the EPA, a UVB-only monograph will represent a lost opportunity to apprise consumers of the critical

importance of preventing UVA exposure. In order to prevent this, the Agency should issue a single, comprehensive, final monograph that addresses both UVA and UVB radiation and other labeling issues, thus avoiding confusing consumers and discouraging the proper use of sunscreens.

In sum, the public health will be adversely affected if FDA publishes a Partial Final Monograph for sunscreen products that this change may have already been made includes compositional, testing, and labeling criteria for UVB radiation but does not include similar criteria for UVA radiation. Products that are designed to comply with the Partial Final Monograph will not protect consumers against UVA radiation and more importantly, will mislead consumers to believe that they are protected and can stay in the sun for longer, more dangerous periods of time. As a result this labeling likely will not assist the consumer to reduce the incidence of skin carcinoma and melanomas and, therefore, will undermine public health.<sup>7</sup>

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<sup>7/</sup> Moreover, the Agency's actions fail to take into consideration the time required to test and label sunscreen products. As a general rule, because of the seasonal nature of the primary sunscreen market, companies test and design labels for sunscreen products at least two years before the product line is marketed. In order to comply with publication of the partial final monograph and subsequent publication of a second sunscreen monograph, therefore, the industry will be required to test, retest, label, and relabel sunscreen product at least two years before introducing products to the market that comply with the monograph. Therefore, the publication of two consecutive partial monographs will result in multiple years of disruption to the sunscreen market, potentially interfering with consumer access to properly labeled sunscreens.

**4. Any Delay Is Far Outweighed By The Substantial Public Health Benefit To Be Derived From Publication Of A Comprehensive Sunscreen Final Rule**

The publication of a Partial Final Monograph for sunscreens that fails to address all of the labeling concerns relevant to the product category will further delay resolution of outstanding issues, contrary to the best interests of the Agency, consumers, and industry. For example, a sunscreen rule that does not address UVA radiation will confuse the public about the protective efficacy of sunscreen products and thus, may discourage certain consumers from properly using sunscreen effectively on themselves and their children. Secondly, the use of sunscreens that protect against exposure to UVB radiation but not to UVA radiation will encourage consumers and their children to remain in the sun for longer periods of time, increasing the exposure to harmful UVA radiation. A confusing series of relabeled products may also disrupt increasing consumer knowledge and sensitivity to the need for sun protection. Accordingly, the publication of a Partial Final Monograph for sunscreens will harm rather than protect public health. Alternatively, there is no evidence that a delay in the final monograph for sunscreens will have an adverse effect on public health. Therefore, the benefits of a single, comprehensive monograph clearly outweigh any delay.

**V. Conclusion**

CTFA believes that the actions requested herein are in the best interest of public health. Such actions, if promptly implemented, will assure the continued availability of the widest array of sunscreen products for consumer use, accompanied by labeling that fully and accurately

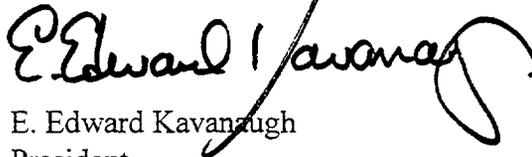
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conveys the necessary public health information. CTFA strongly urges that this comprehensive action be undertaken expeditiously so as to ensure the greatest public health protection.

Respectfully submitted,

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

E. Edward Kavanaugh  
President

Attachments

**ATTACHMENT A**

# Coppertone Kids Sunscreen

Product Using Section 201.66(d)(10) Modified Format\*  
 [Immediate Container Label, No Outer Carton]

**Drug Facts**

Active Ingredients	Purpose
Methoxycinnamate 7%	Sunscreen
2-Ethylhexyl Salicylate 7%	
Oxybenzone 7%	
Homosalate 7%	

**Use** to help prevent sunburn

**Warnings**

For external use only

When using this product do not use in or near the eyes  
 if product gets into eyes, rinse thoroughly with water

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, contact a Poison Control Center or get medical help right away

**Directions** children under 2 years of age should use sunscreen products with a minimum SPF of 4  
 adults and children 6 months and over: apply liberally 15 minutes before sun or water exposure; reapply after 80 minutes of swimming or excessive sweating or anytime after towel drying  
 children under 6 months: ask a doctor

**Other Information** Recommended Sunscreen Product Guide

Sunburn and tanning history	Recommended sun protection product
Always burns easily; rarely tans	SPF 20 to 30
Always burns easily; tans minimally	SPF 12 to under 20
Burns moderately; tans gradually	SPF 8 to under 12
Burns minimally; always tans well	SPF 4 to under 8
Rarely burns; tans profusely	SPF 2 to under 4

grey line is actual size of product

**Sun alert:** The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun

**Inactive ingredients** water, sorbitan isostearate, sorbitol, polyglyceryl-3 distearate, octadecene MA, copolymer, triethanolamine, stearic acid, barium sulfate, benzyl alcohol, fragrance, dimethicone, aloe extract, jojoba oil, methylparaben, tocopherol (vitamin E), propylparaben, carbomer, disodium EDTA, imidazolidinyl urea

- \* Note: 9 point Helvetica Narrow Bold Italic Title
- 8 point Helvetica Narrow Bold Italic Headings
- 6 point Helvetica Narrow Bold Subheadings
- 6 point Helvetica Narrow Text
- 6 point Leading

**ATTACHMENT B**

Excerpts of Comments Submitted by  
Professional Medical Groups and United States Agencies  
Regarding the Need for UVA OTC Sunscreen Monograph

**The American Academy of Dermatology**

- In comments submitted to the Agency in 1993, the AAD stated that:

The specific UV effect that is to be blocked must be considered when describing the efficacy of a particular sunscreen, whether this be UVA erythema, UVA induced drug photosensitivity, immediate pigment darkening, delayed tanning or other effects of photodamage.

See Letter submitted by Dr. Mark Dahl, the American Academy of Dermatology, to the Food and Drug Administration, Docket No. 78N-0038, November 8, 1993.

- In further comments submitted to the Agency in 1994, the AAD stated that UVA radiation is carcinogenic alone and may be additive to UVB carcinogenesis.
- The AAD further noted that a greater amount of UVA reaches the earth's surface, is more constant throughout the year, and thus urged the FDA to act with haste in developing a consensus for acceptable methodologies to be used for evaluation of UVA protection sunscreens. See Letter submitted by Dr. Peyton E. Weary, the American Academy of Dermatology, to the Food and Drug Administration, docket No. 78N-0038, March 18, 1994.

**The Skin Cancer Foundation**

- In 1994, the Skin Cancer Foundation also urged the FDA to establish a standardized scientific testing and certification method for UVA protection. See Letter submitted by Dr. Perry Robins, the Skin Cancer Foundation, to the Food and Drug Administration, Docket No. 78N-0038, March 25, 1994.

**The United States Environmental Protection Agency**

- In 1994, the Environmental Protection Agency ("EPA") called for FDA to address UVA radiation in the sunscreen monograph, stating that "since natural sunlight emits both UVA and UVB, and since the . . . UV index includes a portion of UVA in the forecast, consumers will need to know that they are receiving full UV spectrum protection from a sunscreen product." See Letter submitted by the Environmental Protection Agency to the Food and Drug Administration, Docket No. 78N-0038, May 11, 1994.

## The Federal Trade Commission

- The Federal Trade Commission commented that a sunscreen monograph that does not address UVA radiation may harm public health because consumers will be led to believe that sunscreens will provide protection against UVA radiation. See Letter submitted by the Federal Trade Commission, to the Food and Drug Administration, Docket No. 78N-0038, February 7, 1994.