C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

September 18, 2000

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Over-the-Counter Human Drugs; Labeling Requirements; Partial Extension of Compliance Dates
Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201

These comments are filed on behalf of the members of The Cosmetic, Toiletry, and Fragrance Association (CTFA) in response to the Food and Drug Administration's (FDA's) partial extension of the compliance dates for its rule that established a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products [65 *Fed. Reg.* 38191 (June 20, 2000)].

CTFA is the national trade association representing the personal care products industry. Our membership includes approximately 300 active member companies that manufacture or distribute personal care products, including a wide array of products that are both cosmetics and drugs, throughout the United States. We also represent approximately 300 additional associate members who provide goods and services to manufacturers and distributors of personal care products.

While we support FDA's action partially granting our Citizen Petition and extending the initial compliance date for the OTC Drug Labeling Regulation for one year until May 16, 2002, we maintain our position that more than one additional year is necessary to resolve all the issues related to this regulation in order to make compliance feasible, and to permit sufficient time to comply. (As the Agency noted, both CTFA and the Consumer Healthcare Products Association had requested a two-year extension of this date until May 16, 2003.) The fact that almost one year has now passed since filing of the CTFA and CHPA Citizen Petitions with little progress strengthens this position.

In several instances, CTFA has filed comments regarding the OTC labeling rule, focusing on the many unique issues facing manufacturers of cosmetic-drug products. While we support the Agency's recognition of the additional time necessary to comply with the final OTC labeling rule, we cannot in good faith state that the extension of compliance dates outlined in Table 1 of the June 20, 2000 *Federal Register* notice will be adequate for industry to comply.

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95N-0259

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C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

August 4, 2000

E. EDWARD KAVANAUGH
PRESIDENT

BY HAND DELIVERY

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

Re: Docket No. 78N-0038
Sunscreen Drug Products for Over-the-Counter Human Use

On behalf of its members, The Cosmetic, Toiletry, and Fragrance Association (CTFA), submits these comments in partial response to the Food and Drug Administration's (FDA's) reopening of the administrative record on sunscreen drug products for over-the-counter (OTC) human use. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record. 65 Fed. Reg. 36319 (June 8, 2000).

CTFA is requesting that as part of the reopening of the administrative record on sunscreens, FDA consider additional labeling issues relating to such products that are raised by FDA's general requirements for OTC drug labeling. Specifically, CTFA requests that FDA revise the final sunscreen monograph to permit modifications to certain requirements of the OTC labeling content and format rule applicable to sunscreens under 21 C.F.R. § 201.66. While CTFA will be submitting additional comments to FDA on the specific issues raised in the June 8, 2000 notice, we believe

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that now is the appropriate time and venue to make that request.[1] Taking this step will help to assure that FDA meets its goal of a comprehensive sunscreen drug product final monograph in effect on December 31, 2002.

Founded in 1894, CTFA is the national trade association representing the personal care products industry. CTFA's approximately 300 active members (who manufacture and distribute personal care products) and 300 associate members (who provide related goods and services to the industry) are responsible for providing consumers with the vast majority of personal care products sold in the United States. These products include both cosmetics and products such as sunscreens that are regulated both as cosmetics and drugs (hereafter "cosmetic-drugs.")

Included in CTFA's membership are a majority of the marketers and manufacturers of sunscreen products sold in the United States. CTFA has led a coalition of sunscreen manufacturers that has addressed and will continue to address the wide variety of important issues raised by the sunscreen monograph. CTFA has been an active participant in FDA's OTC rulemaking for sunscreens since its inception and has a long history of substantive involvement before the agency on all sunscreen related issues.

The Scope of This Document

This is a comment on changes that are necessary to change the impact of the OTC Drug Labeling Regulation (64 Fed. Reg. 13254 [March 17, 1999]) on sunscreen products. It is being filed on the public record of the Monograph for Sunscreen Drug Products for Over-the-Counter Human Use (64 Fed. Reg. 27666 [May 21, 1999]) at the

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[1] Expedited consideration of this request and a clear response regarding the degree of labeling flexibility that will be allowed by FDA will increase the chances that compliance with the OTC Labeling Regulation can be accomplished by the effective date of the Final Sunscreen Monograph (December 31, 2002). However, any significant delay in resolving these issues or failure to grant the necessary labeling flexibility will virtually guarantee that the deadline cannot be met. (Please see the discussion of time necessary to complete labeling changes at p. 28-30.)

request of FDA. The Agency believes that the appropriate way to modify the impact of the OTC Drug Labeling Regulation on any one product category is through modification of the specific regulation or monograph for that category.

This comment is not intended to change the labeling regulations already promulgated by FDA with respect to sunscreen products marketed as a lipstick and "products labeled for use only in specific small areas of the face (e.g., lips, nose, ears, and/or around eyes)" contained in 21 C.F.R. Sec. 352.52 and promulgated at 64 Fed. Reg. 27688-89 (May 21, 1999.) We believe those modifications to the OTC Drug Labeling Regulation are appropriate. This document proposes additional modifications of that rule that would establish the maximum required labeling under the OTC Drug Labeling Regulation for all other sunscreens.

This document is not CTFA's final comment on issues raised by the Final Monograph for Sunscreen Drug Products. Additional comments are being prepared by CTFA and by individual companies that will address sunscreen testing requirements, permissible claims, indications for use, directions for use, and other labeling, testing and formulation requirements. Those comments will be filed prior to the September 6, 2000 deadline established when the Agency reopened the public record of the Final Monograph for Sunscreen Drug Products for further comment.

It should be noted that the proposals in CTFA's future comments would change the content of the OTC drug label for sunscreens but would not change the required format for presenting the information in labeling if the following comments are accepted. For example, in comments to be filed at a later date, CTFA will propose additional indications for use for sunscreens which a manufacturer may choose to use in lieu of or in addition to currently allowed indications if appropriate for their particular product.

benefited consumers and should not be unnecessarily discouraged by new labeling requirements that could make it impossible to produce these products in convenient, easy-to-transport package sizes. Packaging innovations now make all of these products easy to carry and use by an increasingly mobile population. Smaller packages increase the likelihood that consumers will carry sunscreens with them and apply the product in the many different situations where they are exposed to UV radiation.

Finally, during the years of the OTC Drug Review, medical and public health authorities have come to understand and emphasize the many benefits of sunscreens to protect against sunburn, skin aging and skin cancer. Many agencies and medical authorities such as the FDA, Centers for Disease Control and Prevention, American Cancer Society, American Academy of Dermatology and the Skin Cancer Foundation have stressed the importance of sun protection. This includes the use of sunscreens in reducing the threat of skin cancer and one of its most dangerous forms, malignant melanoma.

Overview of CTFA's Request and Underlying Rationale

As described in detail below, CTFA is requesting that FDA modify the labeling format and content requirements of 21 C.F.R. § 201.66 as they apply to sunscreens in a manner that will permit greater flexibility in the presentation of such information. According to FDA, the substantial labeling changes required by the Final OTC Labeling Rule are intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. CTFA continues to maintain, however, that FDA has failed to adequately articulate its basis for imposing many of the requirements of the Final OTC Labeling Rule on sunscreen and other cosmetic-drug product labels. Indeed, nowhere in the rulemaking process has FDA sufficiently considered or distinguished between OTC drug products that raise the safety and consumer confusion concerns addressed by the Final OTC Labeling Rule and cosmetic-drug products with no dosage limitations that do not raise the concerns relied upon by FDA to support the new labeling requirements.

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CTFA has previously addressed in detail FDA's failure to identify the manner in which applying the Final OTC Labeling Rule to sunscreens and other cosmetic-drugs serves the agency's goal of increasing consumer understanding about the safe and effective use of OTC drug products. CTFA has also made numerous submissions to FDA regarding the cosmetic-drug status of sunscreens and the appropriate labeling for such products. CTFA hereby incorporates by reference all of these prior comments as they relate to the requests set forth herein.[2]

Importantly, none of the modifications requested by CTFA will negatively impact the safe and effective use of sunscreens by consumers. CTFA has fashioned its requests after changes already accepted by FDA for sunscreens formulated for use as lipsticks and for use on small areas of the face. The modifications also are consistent with the format changes permitted for certain smaller packages under the Final OTC Labeling Rule.

In the Final OTC Labeling Rule, FDA described the following construct for developing appropriate OTC drug labeling:

> [w]hen developing drug labeling, the agency considers the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. The quantity and complexity of information which must be communicated to ensure appropriate product selection, convey the effectiveness of the drug, communicate risks, and provide complete directions for use, varies with the drug ingredient, the target population, the disease or symptoms the product is intended to treat or prevent, and related information about the conditions which must be provided for the safe and effective use of the drug. In some cases (e.g., lipsticks or lip balms

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[2] CTFA comments submitted to the Sunscreen TFM, Docket No. 78N-0038 (March 21, 1994); CTFA Comments submitted to the Proposed OTC Labeling Rule, Docket Nos. 96N-0420; 92N-454A; 90P-0201; and 95N-0259 (October 7, 1997); CTFA letter to Dr. Bowen on Sunscreen TFM (April 15, 1998); CTFA Citizen Petition to Stay Sunscreen Final Rule (April 15, 1999); and CTFA Citizen Petition to Stay Final OTC Labeling Rule (October 22, 1999).

containing sunscreen), minimal information is needed for the safe and effective use of the product.

64 Fed. Reg. 13270. FDA listed the typical characteristics of products requiring minimal information for their safe and effective use as follows:

- packaged in small amounts;
- having a high therapeutic index;
- carrying extremely low risk in actual consumer use situations;
- providing a favorable public health benefit;
- requiring no specified dosage limitation; and
- requiring few specific warnings (*e.g., Reyes syndrome*) and no general warnings (*e.g.*, pregnancy or overdose warnings).

Id. The agency indicated its intent to "identify products with these characteristics" and "consider appropriate exemptions in their respective monographs and drug marketing applications to the extent possible." Id. CTFA believes that sunscreens fit sufficiently within the parameters of the above criteria to justify the labeling modifications requested herein.

Sunscreens have a high therapeutic index in that their effective dose is substantially lower than the dose that would pose even a minimal risk of toxicity.

Sunscreens carry extremely low risk in actual consumer use situations. Sunscreens have a decades-long history of safe use because they have a low toxicity profile and because consumers have a clear understanding of when and how to use these products. Only minimal information is necessary to ensure the safe and effective use of sunscreens. (It is noteworthy that sunscreens are not considered drugs and are regulated as cosmetics in Europe and most other parts of the world.)

Sunscreens provide a favorable health benefit. The dangers associated with exposure to the ultraviolet rays of the sun arise under both extreme daylight conditions associated with the beach, skiing and other activities, as well as from the chronic exposure that occurs as consumers conduct daily activities outdoors. The protection from UV exposure afforded by products designed for extreme sunlight situations and by products intended for every day use, such as foundations that contain sunscreen ingredients, are both recognized as offering consumers significant health benefits. Indeed, sunscreens are one of the most important weapons in the fight against damaging overexposure to the sun.

Sunscreens require no specified dosage limitation. Concerns relating to the wrong size or frequency of dose do not exist for sunscreens. Such products may be used in unrestricted amounts on a daily, or even more frequent basis without fear of overdose. Likewise, sunscreens raise no serious concern that an improper dose may result in an adverse drug experience.

Sunscreens require few specific warnings and only one general warning. No specified warnings (*e.g.*, use during pregnancy, Reyes syndrome, etc.) apply to sunscreen products. Those warnings that are required are limited to admonitions that the product be kept out of eyes and that use of the product should be stopped if a rash or irritation develops. The one general warning that does apply to sunscreens is the warning to keep out of reach of children which would remain a part of the required labeling under CTFA's proposal. (FDA has permitted this warning to be omitted from lipsticks and to be abbreviated on products labeled for use only on small areas of the face.)

The sixth characteristic, small package size, while not satisfied by all sunscreens, is also the least substantive criteria included in FDA's list and is a characteristic of <u>many</u> daily use cosmetic products that contain sunscreen. Further, the modifications to the sunscreen labeling requirements requested by CTFA will not compromise, in any

manner, the ability of consumers to select and use sunscreens properly. The underlying records for the Final OTC Sunscreen Rule and the Final OTC Labeling Rule fully support CTFA's proposed sunscreen label and the changes requested by CTFA warrant serious consideration by FDA.

Procedural History

The Sunscreen Monograph

FDA has already published a partial final monograph addressing many of the requirements relevant to the conditions under which OTC sunscreen drug products bearing UVB claims will be generally recognized as safe and effective and not misbranded. 64 Fed. Reg. 27666 (May 21, 1999) (hereinafter the "Final OTC Sunscreen Rule"). The Final OTC Sunscreen Rule includes modifications to the general OTC drug labeling rules in 21 C.F.R. § 201.66, to accommodate sunscreen products labeled for use on small areas of the face and as lipsticks.

In response to a Request for Stay and Citizen Petition filed by CTFA on April 15, 1999, FDA stated in an October 1, 1999, decision that it would delay the effective date for the Final OTC Sunscreen Rule until December 31, 2002, while important conditions relating to both UVA and UVB radiation protection are resolved. Most recently, on June 8, 2000, FDA issued a Federal Register notice, in response to which these comments are being filed. That notice alerted the public of its decision to delay the effective date of the Final OTC Sunscreen Rule and reopening the administrative record on sunscreens to permit comment on monograph issues. (65 Fed. Reg. 36319 [June 8, 2000])

The Final OTC Labeling Rule

Prior to publishing its Final OTC Sunscreen Rule, FDA published a final rule establishing standardized content and format requirements for the labeling of all OTC drug products. 21 C.F.R. § 201.66. Over-the-Counter Human Drugs; Labeling Requirements; Final Rule. 64 Fed. Reg. 13254 (March 17, 1999) (hereinafter the "Final

OTC Labeling Rule"). The format and content regulations require, among other things, (1) use of specific headings and subheadings in a standardized order; (2) use of standardized graphical features; and (3) minimum standards for type size and spacing. These requirements are designed to enable consumers to better read and understand the information presented on OTC drug labels and to apply the information to the safe and effective use of the products. In response to this proposal, CTFA filed substantial comments questioning the legal and factual basis for applying this new format to certain cosmetic-drug products that do not bear dosage limitations. (CTFA comments to Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259 filed October 7, 1997.)

CTFA carefully analyzed the existing record for the proposal and seriously questioned whether the record contained any support whatsoever for the application of this proposed format to certain cosmetic-drug products. CTFA strongly believes that the existing labeling for these products was fully sufficient from a public health and legal standpoint. In the Final OTC Labeling Rule, FDA rejected CTFA's request that these cosmetic-drug products not be subjected to the new label format. In response to a Citizen Petition submitted by CTFA on October 22, 1999, reiterating our legal and factual concerns, FDA extended the primary implementation date for the Final OTC Labeling Rule from May 16, 2001, until May 16, 2002.

Harmonization of the OTC Sunscreen and Labeling Rules

The interplay of FDA's decisions to delay the implementation dates of the Final OTC Sunscreen Rule and the Final OTC Labeling Rule means that sunscreen products must have labeling that complies with the requirements of both sets of regulations by December 31, 2002. As FDA approaches the final stages of its rulemaking for sunscreens CTFA requests that the agency reconsider its approach to harmonizing certain of the substantive sunscreen labeling requirements with FDA's regulations standardizing the content and format requirements of the Final OTC Labeling Rule by adopting the labeling proposed by CTFA for all sunscreens. This request is consistent with the notion that having established format and content requirements generally

applicable to all OTC drug products, category-specific arguments may be addressed within the context of individual product monographs.[3] FDA officials have repeatedly advised CTFA that this is the appropriate way to address changes in the OTC Drug Labeling Regulation that are necessary for specific product categories. As described in the following section, sunscreens represent a unique OTC drug category for which the labeling modifications requested by CTFA are appropriate both as a matter of public health and law.

Flexible Labeling for Sunscreen Products is Justified

It is universally recognized that excessive exposure to the ultraviolet rays of the sun can produce a wide variety of adverse health consequences. Effects range from immediate burning of the skin, to premature aging, wrinkling, and other damage to the skin, to various types of skin cancers including malignant melanoma (a very serious form of skin cancer that has increased in the past several years). As awareness of the sun's damaging effects has increased, public health authorities (including FDA and NIH), dermatologists, and other health organizations (the American Academy of Dermatology and American Medical Association) are urging consumers to use products containing sunscreens regularly, on a daily basis, rather than only when they expect to be exposed to intense sunlight situations. See CTFA's comments to the TFM for OTC Sunscreens, Docket No. 78N-0038, at 4-5 (March 21, 1994). Thus, sunscreen products are substantially different from most other types of OTC drug products in that they are recommended for use on a daily basis for persons who have no illness, as a means of preventing serious disease in the future.

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[3] While CTFA continues to believe that many of the arguments that support the modifications proposed herein should apply across the board to all five of the personal care drug product categories identified in prior comments (i.e., antiperspirants, skin protectants, antidandruff products, and antimicrobial soaps and washes), for purposes of these comments CTFA is limiting the scope of its requests at this time to OTC sunscreen products. CTFA reserves the right to raise this issue once again or in the context of the individual monographs for the other four personal care product categories identified directly above. CTFA believes that its proposals for sunscreen products establish sound principles that should be applied to all categories meeting the appropriate criteria.

FDA's Rationales for the Final OTC Labeling Rule Do Not Apply to Sunscreens. Analysis of the rationales underlying FDA's Final OTC Labeling Rule support CTFA's claim that there is a fundamental distinction between sunscreen products and other OTC product categories. From the beginning of its rulemaking, FDA's rationale for standardizing the format and content requirements for all OTC drug products has been to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of such products. See 64 Fed. Reg. 13254. However, nowhere in the records supporting FDA's Final OTC Labeling and Sunscreen Rules is there any evidence that consumers are unable to read or understand information necessary for the safe and effective use of sunscreens as currently labeled. The concerns relied upon by FDA to support application of the Final OTC Labeling Rule requirements simply do not exist for sunscreens.

In addition to its concerns about readability and comprehension, FDA identified the following "changing patterns" of OTC drug use as among its justifications for standardizing OTC drug labeling:

- Concerns about the increased availability of more potent medicines.
- Concerns about increased consumer self-diagnosis and self-medication.
- Concerns regarding the possibility of increased or inappropriate use of OTC drug products by the elderly.
- Concerns regarding the possibility of increased adverse reactions and misuse of OTC drug products.

Over-the-Counter Human Drugs; Proposed Labeling Requirements; Proposed Rule. 62 Fed. Reg. 9024 (February 27, 1997). However, each of these justifications for imposing massive relabeling requirements are absolutely inapplicable to OTC sunscreen products.

FDA's concerns about increased consumer self-diagnosis and self-medication do not apply to sunscreen products. Sunscreens are widely used by consumers and sufficiently labeled for safe and effective use under current OTC drug and cosmetic labeling requirements. To the extent their use by consumers reflects any of the changing patterns of use identified by FDA in its proposal, such changes are precisely those that FDA and public health officials are encouraging for sunscreen use. For example, to the extent sunscreen use can be characterized as self-medication by consumers or as presenting opportunities for increased use by the elderly, a wide array of public health agencies and experts aggressively promote such uses. Indeed, in contrast to traditional OTC drug therapies, the concern with regard to sunscreens is product *under* use rather than *over* use.

FDA's concerns regarding the possibility of inappropriate use by the elderly and of increased adverse reactions and misuse of OTC drug products also do not apply to consumer use of sunscreen products. Sunscreens have an exceptional safety record and have been used by consumers of all ages for more than two decades with an extraordinary safety record. Rather than concerns about the overuse of sunscreens, the American Academy of Dermatology and other consumer groups have expressed concern (i) that consumers do not use enough sunscreen; and (ii) that many consumers do not understand the importance of protection from everyday UV exposure afforded by products such as cosmetic moisturizers containing sunscreen ingredients. In practical terms, the dangers of exceeding the "recommended dosage" associated with some categories of OTC drugs simply do not exist for sunscreens. Additionally, adverse reactions associated with sunscreen use are generally limited to mild rashes and other skin irritations, for which warning information is included in CTFA's proposed sunscreen label.

Despite the fact that the safety and consumer confusion concerns and the changing patterns of OTC drug use cited by FDA are not relevant to sunscreens, CTFA's proposed label incorporates a majority of the labeling requirements imposed under the Final OTC Labeling Rule. Consequently, CTFA believes that a good faith review of the labeling modifications it is requesting for sunscreen products, measured against the agency's rationales for standardizing the format and content of OTC drug

products, should result in the agency granting the labeling modifications CTFA is requesting for sunscreens.

Sunscreens are Fundamentally Different Than Other OTC Products. Sunscreen products are marketed for various uses. Many products are designed to protect consumers from sunlight exposure associated with prolonged outdoor activities. These products are also used by some consumers on a frequent or even daily basis. Other products incorporate sunscreen ingredients in products designed to provide cosmetic benefits for everyday use. Examples of these daily use products are moisturizers, foundations, and lipsticks. They are designed to be used during daily work and leisure activities and are attractive to consumers because they also provide cosmetic benefits that are considered important. (The best sunscreen in the world is worthless if the consumer does not use it.) Importantly, all sunscreen products offer significant health benefits to consumers.

For consumers who rely on daily use products containing sunscreens, the cosmetic attributes of such products are equally as legitimate and important, if not more so, than their drug functions. Regardless of the type of sunscreen or the particular use for which such product is purchased, all of the currently marketed products in the sunscreen category have a long history of safe and appropriate use by consumers. CTFA continues to believe in the basic premise, reiterated in numerous submissions made to the agency, that OTC drug products (1) used on a daily or more frequent basis without serious safety or efficacy concerns; and (2) for which no administrative record establishing any consumer misuse problems exists, are fundamentally different from OTC drugs purchased by consumers solely for their therapeutic purposes. Consequently, FDA rationales behind required labeling for the safe and effective use of, for example, a cough-cold product, do not necessarily transfer to sunscreen products.

Applying the modifications proposed by CTFA to sunscreen products will NOT impact the agency's continued application of the Final OTC Drug Labeling Rule to the

vast majority of OTC drug products. Rather, modifications of the nature sought by CTFA for sunscreens are specific to that monograph and rely on rationales that transfer easily only to the very small number of OTC drugs in the personal care product categories that CTFA has identified above. Moreover, CTFA has designed its proposed labeling to retain as many features of the new OTC drug label as feasible.

FDA's Proposed Sunscreen Label

Under FDA's Final OTC Sunscreen Rule, all sunscreen products (other than those intended for use on small areas of the face and as lipsticks) would be labeled in accordance with the following model:

Drug Facts	
Active ingredients	***Purpose***
Octyl methoxycinnamate (5%).....	Sunscreen
Phenylbenzimidazole sulfonic acid (4%)	
Uses • helps prevent sunburn • higher SPF gives more sunburn protection	
Warnings For external use only	
When using this product • keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if • rash or irritation develops and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • apply liberally before sun exposure and as needed • children under 6 months of age: ask a doctor	
Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palimate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soya sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.	

NOTE: This sample is intended to provide a "picture" of the new label and does not necessarily reflect type size, leading or other technical format requirements. No attempt has been made to distinguish between the thickness of barlines and hairlines. Additional or alternate language for indications and directions for use will be recommended by separate comment on the Final Sunscreen Monograph.

CTFA's Proposed Sunscreen Label

Consistent with the justifications and rationales detailed below, CTFA requests that FDA adopt the following label model for all sunscreen products:[4]

Active ingredients.....Octyl methoxycinnamate (5%)
Phenylbenzimidazole sulfonic acid (4%)
Use helps prevent sunburn
Warnings
• Keep out of eyes.
• Stop use if skin rash occurs.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions • apply liberally before sun exposure and as needed
• children under 6 months of age: ask a doctor

↓
Inactive ingredients. Optional disclosure provided at other location on label or in labeling accompanying the product as follows:

Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palmitate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soy sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.

Comments on Changes

- Drug Facts title deleted. Inappropriate and unnecessary for sunscreens
- Omit "Purpose" as repetitive of the statement of identity on the PDP and "Use" information
- Omit "higher SPF" except as proposed by CTFA products with SPF over 30.
- Omit "For External Use Only"/Self evident for product
- Omit subheadings and condense information
- Omit barlines, hairlines and box enclosure
- Option of listing inactive ingredients in different location or in accompanying labeling provided

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[4] The label proposed above is intended to provide a simple "picture" of a proposed label that would apply to all sunscreen products regardless of package size. (Of course, any exemptions provided by FDA for smaller packages would still be available for such products.) The proposed sunscreen product label incorporates the modified format provisions that allow for the elimination of the box enclosure as well as for other modifications cited in 21 C.F.R. § 201.66(d)(10). There has been no attempt to fulfill the type size requirements in this illustration. The labeling language used above is for demonstration purposes only. To the extent the Final Monograph for Sunscreen products permits the use of different statements or claims, this proposed label is not intended to limit such options. Similarly, the above proposal does not include other optional statements that may be permitted, nor have statements required for water resistant products been incorporated into the above proposal.

Side-By-Side of the FDA and CTFA Proposals

Drug Facts	
Active ingredients	*Purpose*
Octyl methoxycinnamate (5%)	Sunscreen
Phenylbenzimidazole sulfonic acid (4%)	
Uses • helps prevent sunburn • higher SPF gives more sunburn protection	
Warnings For external use only	
When using this product • keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if • rash or irritation develops and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions • apply liberally before sun exposure and as needed. • children under 6 months of age: ask a doctor	
Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palimate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soya sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.	

Active ingredients.....Octyl methoxycinnamate (5%)
Phenylbenzimidazole sulfonic acid (4%)

Use helps prevent sunburn

Warnings

- Keep out of eyes.
- Stop use if skin rash occurs.

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

Directions • apply liberally before sun exposure and as needed
• children under 6 months of age: ask a doctor

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Inactive ingredients. Optional disclosure provided at other location on label or in labeling accompanying the product as follows:

Inactive ingredients water, isohexadecane, glycerin, butylene glycol, triethanolamine, stearic acid, cetyl alcohol, cetyl palmitate, DEA-cetyl phosphate, aluminum starch octenyl succinate, titanium dioxide, imidazolidinyl urea, methylparaben, propylparaben, carbomer, acrylates/c10-30 alkyl acrylate crosspolymer, PEG-10 soy sterol, disodium EDTA, castor oil, fragrance, red 4, yellow 5.

CTFA's Proposed Sunscreen Label Ensures Proper Consumer Information In A Form Consistent with FDA's Standardized Labeling Format

As is evident from the above copy, the sunscreen label proposed by CTFA is consistent with the important elements of the Final OTC Sunscreen Rule and the Final OTC Drug Labeling Rule:

- Active ingredient information and concentrations are provided;
- Use information as it relates to the primary use of the product mirrors that required by FDA (additional or alternative indications for use will be proposed by CTFA);
- Warnings title is preserved as a separate heading;
- Keep out of reach of children and poison control statements are identical to information currently required;
- Direction information is identical to that currently required (additional or alternative directions for use will be proposed by CTFA); and
- All headings and information:
  - are presented in the required order;
  - would use the required type size;
  - use the proper letter case;
  - are left justified; are presented in bold and italic print as required; and
  - use bullets appropriately.

The changes presented by CTFA's proposed sunscreen label are limited to the following:

- Elimination of the Drug Facts title;
- Elimination of information provided under the Purpose heading;
- Elimination of the statement under "Use" that "higher SPF gives more sunburn protection," except as proposed by CTFA for products with SPF over 30;
- Elimination of the "For External Use Only" statement;
- Condensing of the warning subheading and information;
- Elimination of the box enclosure, barlines and hairlines; and
- Moving list of inactive ingredients to other location on the product label or to labeling accompanying product.

CTFA used two mechanisms to develop its proposed sunscreen label: (1) application of the modifications developed by FDA in the Final OTC Sunscreen Rule for certain small sunscreen packages including content changes (reductions in

unnecessary required wording); and (2) modifications permitted for small packages under the Final OTC Drug Labeling Rule (format changes). Both of these mechanisms may legitimately be applied to all types of OTC sunscreen products. As detailed below, FDA's Final OTC Sunscreen Rule provides for modifications to sunscreens formulated as lipsticks and for small areas of the face. CTFA strongly supports the modifications permitted by FDA under those circumstances. Because, however, all sunscreens are personal health care products that are critical to preventing serious medical conditions, have become well known to consumers over several decades of use, and have no record regarding either consumer confusion or safety problems, CTFA believes that many of the modifications sanctioned by FDA for lipsticks and products labeled for use only on small areas of the face should apply to all sunscreen products.

CTFA's Proposed Content Changes

As discussed above, sunscreen drug products present virtually none of the concerns that formed the basis for the Final OTC Labeling Rule. Moreover, FDA has already adopted many of CTFA's proposed changes for lipsticks and sunscreen products labeled for use only on small areas of the face. Thus, with respect to those changes, FDA has already concluded that there is no underlying public health risk to CTFA's proposed label as applied to sunscreen products. CTFA's proposed sunscreen label would provide a consistent format for all products in this particular category and would include only modest revisions from the requirements imposed on all other OTC drug product labels.

Among FDA's motivations in establishing standardized content requirements for all OTC drug product labels is to enable consumers to better read and understand important drug information to ensure the safe and effective use of such product. CTFA's proposed modifications to the content requirements set forth at 21 C.F.R. § 201.66(c) and at 21 C.F.R. § 352.52, designed to apply to all OTC sunscreen products, will not compromise that goal.

Elimination of the "Drug Facts" Heading

The requirement that the title "Drug Facts" appear at the top of the information panel should be eliminated for all OTC sunscreen products because it is unnecessary and reduces the space available for important label information, both required and discretionary. The "Drug Facts" title is unnecessary for sunscreens given the nature of sunscreens generally (e.g., high therapeutic index and extremely low risk) combined with the fact that the resulting label will still preserve the essential elements of the new OTC label format. The title is inappropriate, particularly for those products which provide important cosmetic benefits, because it unnecessarily narrows the product label. In addition, we do not believe the absence of the Drug Facts title detracts from the power of the format or substantive content required by the Final OTC Labeling Rule.

CTFA's request to eliminate the "Drug Facts" title is consistent with FDA's decision in the Sunscreen Final Monograph to exempt from that requirement products labeled for use only on "specific small areas of the face." However, there is no reason that this flexibility should not be extended to all sunscreens. All sunscreens meet the criteria specified by FDA for products that should qualify for more flexible labeling treatment. (See 64 Fed. Reg. At 13270) Sunscreens require minimal information for their safe and effective use. They have high therapeutic indices, are extremely low risk, provide a favorable public benefit, require no specified dose limitations and require few specific warnings and only one general warning. Accordingly, making the requested minor modifications to the label, such as removing the "Drug Facts" title but retaining other critical elements such as warnings and directions is entirely appropriate. As the Agency stated, this was the reasoning on which FDA based its decision to require abbreviated labeling for sunscreen products intended for small areas of the face. That proposed labeling distilled the labeling requirements to their essential elements. The rationales on which FDA based its decisions for products used on small areas of the face are no less relevant in the context of all sunscreen products.

FDA noted in the preamble to the final rule on the OTC label format that, in one of the labeling studies that FDA conducted in conjunction with the OTC label format rule, "Evaluation of Revised Formats for Over-the-Counter (OTC) Drugs" ("Study B"), indicated that in consumer preference tests, consumers preferred OTC labels that contained a title. Of course, a consumer preference does not mean a title is essential to accomplishing FDA's stated goals of ensuring full consumer understanding of product information. Based on the long history of safe use of sunscreens, we believe consumers already fully understand how to use such products safely and effectively and that including a title for the required information is unnecessary.

In addition to being unnecessary, the "Drug Facts" title is inappropriate on sunscreen products that also provide cosmetic benefits. Besides their drug purposes, such products also have legitimate, beneficial cosmetic purposes which are equally recognized under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §§ 321 et seq. "Drug Facts" inappropriately denotes a single purpose to a product that provides a dual benefit. Removing the "Drug Facts" title is a reasonable accommodation to address the issue, particularly in light of the fact that it does not undermine the agency's labeling goals. By simply removing the "Drug Facts" title, the critical information that must be contained in a sunscreen label will continue to clearly and legibly appear.

Eliminate Purpose Heading and Associated Information

CTFA's proposed sunscreen label does not include a "Purpose" heading or the "sunscreen" statement that would accompany that heading. CTFA believes that requiring such information is unnecessary in that it is duplicative of both the statement of identity requirement for the principal display panel of sunscreen products and of the "Use" statement immediately proceeding the listing of active ingredient information. FDA has already recognized that reiterating the purpose information in the required format is not necessary for sunscreen drug products in smaller packages and intended for use on small areas of the face and as lipsticks. 21 C.F.R. § 352.52(f)(1). Similar

accommodation for all sunscreen products, regardless of intended use or package size, does not adversely impact the ability of consumers to understand the purpose for which sunscreen products are designed or to apply that understanding to their safe and effective use of such products.

Eliminate the "Use" Statement Relating to Higher SPFs

We believe that consumers are already educated to understand that higher SPF numbers give greater protection. Under separate cover, CTFA has proposed that for products labeled over SPF 30 FDA require a label statement advising the consumer that "higher SPF products give more sun protection, but are not intended to extend the time spent in the sun." We believe this is the only specific indication for use that is necessary for high-SPF products, and that this indication is appropriate only for products labeled with SPFs over 30.

Omit "For External Use Only" Statement

CTFA's proposed sunscreen label omits the "For external use only" warning. Such warning is unnecessary based on widespread consumer knowledge regarding the appropriate use of sunscreen products. CTFA is not aware of any adverse event data suggesting that consumers inappropriately apply sunscreen products. FDA has already adopted this modification for sunscreen labeled for use on small areas of the face and as lipsticks, 21 C.F.R. § 352.52(f)(1)(iii), and should apply it to all sunscreen products.

Eliminate Subheading Information for Warnings by Condensing Language

CTFA's proposed sunscreen label modifies the content of certain of the required warning statements by presenting information that would be presented as subheadings into the text of the warning. Thus, for example, CTFA recommends that the statements:

> **When using this product**
> • keep out of eyes. Rinse with water to remove.
> **Stop use and ask a doctor if**
> • rash or irritation develops and lasts

be presented as follows:

> Keep out of eyes.
> Stop use if skin rash occurs.

CTFA believes that the currently required subheading information and warning language is not necessary for full consumer understanding of the warning information, or for the otherwise safe and effective use of sunscreen products. The warning information relayed by CTFA's proposed sunscreen label, which compresses four lines into two, is substantively the same as that provided by the separate subheadings and retains the hierarchy of FDA's preferred format. Moreover, FDA's modifications for sunscreen products labeled for use on small areas of the face adopt the identical format and content for presenting the warning information. 21 C.F.R. § 352.52(f)(1)(iv). Presumably in allowing such modification FDA felt comfortable that necessary warning information was adequately conveyed. CTFA believes that similar modifications should apply to all sunscreen drug products.

Move Listing of Inactive Ingredients to Labeling at Point of Sale

In addition to the substantive content changes suggested above, CTFA proposes to allow, as an option, the relocation of inactive ingredient information from the label, to labeling at the point of sale. CTFA previously has proposed that FDA provide the same flexibility to OTC drug products currently afforded to cosmetic products, by allowing ingredient information to be included in labeling "accompanying the product" if the package has a total surface area of less than 12 square inches and is not enclosed in an outer container. See 21 C.F.R. § 701.3(i).

CTFA believes that FDA has the authority to provide similar flexibility to OTC drug products under section 412(c) of the FDA Modernization Act of 1997 (FDAMA). Section 412 amended the misbranding provisions of the FD&C Act to require that a drug will be misbranded unless its label bears, among other things, "the established name of

each inactive ingredient listed in alphabetical order on the outside container of the retail package. . . ." FD&C Act § 502(e)(1)(iii). This provision applies to OTC drugs and was incorporated into the final rule establishing a standard format for the labeling of such products. 64 Fed. Reg. 13254 (1999). However, section 502(e), as amended by FDAMA, did not alter the section of the misbranding provision that states, in pertinent part, "to the extent that compliance with the requirements of subclause . . . (iii) . . . is impracticable, exemptions shall be established by regulations promulgated by the Secretary." Thus, FDA retains the authority to grant relief from the inactive ingredient listing requirement.

In February 4, 2000 correspondence to CTFA, FDA stated that it declined to include in the OTC Format Labeling Rule the provision from its cosmetic regulations that allows for the use of an off-label declaration of ingredients under certain circumstances because "it conflicts with section 502(e) of the Act, which provides that a drug is misbranded if its label does not bear inactive ingredient information on the outside container of the retail package." As described above, however, that response does not recognize the statutory authority granted to FDA to establish exemptions from the ingredient labeling requirements by regulation. Thus, CTFA believes that no legal impediment to the action we have requested exists. Accordingly, our proposed sunscreen label reflects the removal of inactive ingredients that would be listed on labeling accompanying the product.

Proposed Format Changes

In the course of its rulemaking to standardize the content and format requirements for all OTC drug products, FDA included the following among its objectives regarding a standard format:

> [A] standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information.

> This final rule provides a format for presenting information that will allow consumers to readily distinguish among seemingly similar products and to readily access important drug information.

64 Fed. Reg. 13254 and 13270. More recently, FDA summarized the benefits of the required format as follows:

> The new format establishes a clear, easy-to-read presentation that lists the required information in a logical hierarchy, with simple headings and subheadings to introduce major sections of the labeling. The format also includes minimum type size and graphical standards, to help ensure that consumers are able to read the required labeling comfortably, from beginning to end. And, the format is designed to allow consumers to compare similar products side-by-side, to help them recognize the differences among products, and to help them select the best product to meet their needs.

Letter from William K. Hubbard to E. Edward Kavanaugh of CTFA (February 4, 2000).

CTFA's proposed sunscreen label in no way diminishes the power of the format devised by FDA. Indeed, the vast majority of the standard format requirements set forth in 21 C.F.R. § 201.66(d) are preserved in CTFA's proposed sunscreen label. As noted above, CTFA's proposed sunscreen label would not change any of the following format-related requirements:

- Use of upper and lower case letters;
- Left justification of information;
- Type size;
- Use of bold and italic type; and
- Use of bullets.

Of the format changes that CTFA is suggesting, most have already been adopted by FDA for some OTC drug product labels. Extending those modifications more broadly across the entire sunscreen product category will not compromise FDA's goal of presenting the information consumers need in an easy to understand and identifiable manner.

Eliminate the Requirement that Information be Surrounded by a Box Enclosure

For many of the same reasons that support the elimination of the Drug Facts title from the sunscreen label, discussed above, under proposed content changes, the requirement for a box enclosure around the OTC label format information should be eliminated for sunscreen products as well. In light of the nature of sunscreens generally (e.g., high therapeutic index and extremely low risk) and the fact that the label CTFA is proposing will still preserve the essential elements of the new OTC label format, the requirement for a box enclosure is unnecessary. Eliminating the requirement for a box enclosure is a reasonable accommodation: it preserves the essential elements of the label while allowing sunscreen manufacturers to market all aspects of their products.

As the agency is aware, the requirement for such a box was eliminated for small packages under the Final OTC Labeling Rule. However, the regulation still requires that the information be set off from the rest of the labeling on small packages by use of color contrast. 21 C.F.R. § 201.66(d)(10)(v). As noted above, as consumers become more and more familiar with the OTC label format, they automatically will look for the substantive information they need on the product label. Elements such as the box enclosure will become less important. Indeed, FDA recognized the non-essential nature of the box enclosure when it eliminated that requirement for sunscreens for small areas of the face. See 21 C.F.R. § 352.52(f)(2).

Even if the box enclosure requirement for sunscreens is eliminated, consumers will still be able to easily locate the OTC label format information on the product label. This is because the label will still contain the same information in the same order as other OTC drug products. Moreover, this information will be easily located on the label because it still will be set off from the rest of the text by use of contrasting color.

As discussed in greater detail above, the nature of sunscreens are such that "minimal information is needed for the safe and effective use of the product." 64 Fed.

Reg. at 13270. Sunscreens have high therapeutic indices, are extremely low risk, provide a favorable public benefit, require no specified dose limitations and require few specific warnings and only one general warning. Even in light of the low risk nature of the product, elimination of the requirement for a box enclosure in no way reduces the amount of information available to the consumer. Accordingly, given the nature of sunscreen products combined with the fact that the box enclosure is not essential and its elimination will in no way reduce the amount of information available to consumers, CTFA requests that it be eliminated for all OTC sunscreen products.

Eliminate the Requirement for Barlines and Hairlines

For the many of the same reasons that the requirement for a box should be eliminated, we also believe that the use of barlines and hairlines as part of the OTC label format should not be required for any sunscreen product. FDA already has recognized that these may be eliminated for lipsticks and sunscreen products labeled for use only on small areas of the face. For the flexible labeling that we also believe to be appropriate for all sunscreens, we do not believe that the barlines or hairlines are necessary to make the required information understandable by the consumer. Moreover, this requirement would add significantly to the space required for the label and would reduce the options available for smaller, more portable package sizes for these products.

Eliminate the Heading and Information Related to the "Purpose" of the Product

Although addressed more fully above as a proposed content change, CTFA's decision to eliminate the "Purpose" heading on sunscreen labeling does include a format component in that the heading and accompanying information would not be aligned to the right of the list of sunscreen active ingredients as required by 21 C.F.R. § 201.66(d)(6). Since, however, the Final OTC Drug Labeling Rule requires the purpose information to be included within the same horizontal barlines as the active ingredient information, the elimination of the heading in this manner would have only a minimal impact on the format of sunscreen labels. The hierarchy of information and

graphical images would not be changed in any manner. Recognition that this proposed modification to the format does not defeat the FDA's intent in standardizing the presentation of information is further supported by FDA's own decision to permit the purpose heading and accompanying information to be omitted from sunscreen products designed for use on small areas of the face and as lipsticks. 21 C.F.R. § 352.52(f)(1). No basis exists for refusing to extend that accommodation to all sunscreen products.

FDA Must Consider the Need for Industry to Have Sufficient Time to Design and Implement Labeling Changes

The process of reformatting and redesigning labels to implement the requirements of the OTC Drug Labeling Regulation will be a lengthy undertaking. Although the proposals made in this document will simplify the requirements and reduce the time and resource requirements for implementing the rule, extensive time will still be required.

In addition, if appropriate relief to reduce the labeling requirements for sunscreens is not provided by FDA, many existing products will be required to be repackaged or discontinued. Designing an entirely new package will require additional time well beyond that which is required for changing the labeling. In addition, in many if not most cases, consumer displays and other in-store promotional materials will have to redesigned to accommodate and be consistent in design with new packaging. For this reason as well, CTFA urges FDA to give serious consideration to these proposals to reduce the number of products that must be repackaged (or discontinued).

Although requirements can vary from company to company because of variations in product mix, sales and distribution systems, and many other factors, 18 months is generally the minimum requirement to engineer an efficient effort to change the labels for sunscreen products that are marketed throughout the year. (See the following discussion for additional requirements for seasonal products.) This time would run from

the initial date that the final requirements for labeling are known to the time the product is ready to be placed in the distribution chain, and takes into account the following activities:

- Understanding the new labeling regulations and assessing changes on existing labels
- Preparation of art and print work and review for regulatory compliance
- Printing and delivery of new labels

This time frame does not take into account the time that would be necessary if existing products also must be repackaged. Under the current FDA OTC Drug Labeling Regulation, many products would require new packages or would have to be discontinued. The design of entirely new packaging systems will add at least one year to the process. This process is even more challenging than designing new labels, and sufficient time must be allowed for the following requirements:

- Develop proposals that are consistent with consumer needs, retail space requirements and maintenance of the brand image and identity
- New Package Design
- Safety and Environmental Compliance Review
- Consumer Testing
- Execution of New Package Design

A unique feature of sunscreen marketing adds to the need for an expedited FDA decision on final labeling requirements for sunscreens. Typically, retailers return unsold "beach sunscreens" or seasonal products to manufacturers at the end of the season. These products are then redistributed at the beginning of the next season. Because relabeling existing product is frequently not a practical alternative, manufacturers need additional time to comply to minimize the need to destroy product that does not have compliant labeling (instead of being recycled to retailers during the following season.)

Because of the many obstacles that must be overcome before product with revised labeling can be made available in the marketplace, we strongly urge FDA to resolve these labeling issues and communicate their final proposals to the public before the end of 2000. Any longer delay places FDA's goal of a December 31, 2002 compliance date for a revised sunscreen monograph in jeopardy.

The foregoing discussion assumes that it is possible for sunscreen manufacturers to comply with revised labeling requirements by designing new labels for existing packages. If FDA's final decision requires the development of entirely new packaging to accommodate the revised labeling, it is already doubtful that compliance would be possible by a December 31, 2002 date. In addition, the requirement for new packaging could lead to decisions to discontinue many current products, a result that would not be in the best interests of consumers. We therefore urge FDA to seriously consider the reduced labeling requirements proposed in this document as a means to increase the feasibility of meeting the requirements of the OTC Drug Labeling Regulation for this important product category.

Conclusion

We urge FDA to adopt the CTFA proposals for more flexible labeling for all sunscreen products. Recognition of the unique characteristics of this product category and the wide variety of forms of sunscreen products that are available in the marketplace will greatly benefit consumers. Medical and public health authorities, including the FDA itself, have long recognized the importance of these products and their benefit to consumers in reducing the risk of skin cancer.

It is simply contrary to the public interest to impose unreasonable labeling requirements on sunscreens when there is no demonstrated problem with existing labeling. Ironically, the current regulations also will reduce the incentives to make sunscreen protection in a number of convenient, easy-to-use forms.

By granting CTFA's proposals to modify the labeling requirements, FDA can still gain the benefits of its new labeling format while preserving availability of products that benefit consumers and public health.

Respectfully Submitted,

E. Edward Kavanauch
President