5849 '00 SEP -6 A8:52

1062 W. Shoal Creek Lane Tucson, AZ 85737
(888) 994-3828
FAX: (520) 323-9127
www.naatso.org email: naatso@aol.com

September 3, 2000

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

Comments on Docket 78N-0038: Sunscreen Monograph For Over-The-Counter Human Use.

Dear Madam or Sir:

The North American Alliance of Tanning Salon Owners (TSO) represents over 4000 tanning salons in the United States and hereby submits the following comments regarding the Sunscreen Monograph For Over-The-Counter Use (Docket 78N-0038) in the hope that they will help the Food and Drug Administration (FDA) reach a fair and equitable final regulation product.

1. Section 740.19 "Suntanning Preparations" May Be Arbitrary And Capricious.

   This section became effective on May 22, 2000 even though the effective date for parts 310, 352 and 700 were granted an extension until December 31, 2002. Singling out "Suntanning Preparations" to become effective earlier may constitute an "arbitrary and capricious" act and decision by FDA for the following reasons.

   a. This decision was based upon only one complaint!
   b. That complaint was filed by an individual that FDA knows, or ought to know, is "hostile" to the indoor tanning industry.
   c. The issue of the failure by manufacturers of sunscreen products to specify the correct "Application Dose" constitutes a far greater risk to the American public than does products that consumers know are designed to help develop and maintain a cosmetic tan.

   Therefore, it is hereby requested that the effective date of Section 740.19 be extended to December 31, 2002 in order to remedy this decision by FDA that TSO believes is arbitrary and capricious in nature.

2. Claims That Sunscreen Prevents Skin Cancer May Be False, Deceptive, Misleading And Unsubstantiated To The Detriment Of The American Public.

   The following information provides evidence to show that the claims being made stating that use of a sunscreen will prevent induction of skin cancer may be false, deceptive, misleading and unsubstantiated (FDMU) to the detriment of the American public. To the extent that FDA and the Federal Trade Commission (FTC) condone these practices, both organizations share responsibility with sunscreen manufacturers for this FDMU practice.

78N-0038

C 575

a. The following statement was made by Garland, et al in the publication *Epidemiology Causes and Prevention of Skin Diseases* in an article titled "Lack of Efficacy of Common Sunscreens in Melanoma prevention."

"The medical literature beginning in 1966 was searched using the Medline database (National Library of Medicine, Bethesda, MD, USA). This database includes almost all medical research studies published in the United States and most studies from other countries published since January 1, 1966, and covers virtually all of the major epidemiological, dermatological and scientific journals likely to publish articles on the epidemiology of melanoma and other skin malignancies, research on biological and clinical effects of chemical sunscreens, and spectral analyses related to ultraviolet carcinogenesis. **No epidemiological studies were identified that showed a protective effect of use of chemical sunscreen on risk of melanoma or other cutaneous malignancies in humans."**

Moreover, Garland et al stated in their summary that **"For most individuals moderate year-round exposure to UVR (ultraviolet radiation) is desirable to stimulate accommodation and protective pigmentation, as well as for adequate synthesis of vitamin D in the skin. Such moderate year-round exposures would be appropriate for all but those who cannot develop protective pigmentation or who have a history of cutaneous malignancy."**

b. The article "Sunscreens, Skin Photobiology, and Skin Cancer: The Need for UVA Protection and Evaluation of Efficacy" by Francis P. Gasparro from the March, 2000 issue of *Environmental Health Perspectives* provides additional evidence to show that these claims are FDMU.

"Although some have promoted daily use (of sunscreen) for the prevention of premature aging of the skin and the prevention of skin cancer, actual data are lacking to support these recommendations. Furthermore, the widespread implementation of such a recommendation could lead to increased chronic exposure to solar wavelengths not filtered by sunscreens."

"As counter-intuiteve as this (statement) may appear, several studies have demonstrated a correlation of skin cancer with sunscreen use."

"In fact, all a (sunscreen) label can say with any confidence is that the use of this product will prevent sunburn if used appropriately."

"Finally, the meaning of the acronym SPF should be changed from "sun protection factor" to "sunburn protection factor" to avoid giving the consumer an impression of solar invincibility and a false sense of security. SPF defined as "sun protection factor" connotes an impervious armour protecting against all assaults on skin biology. There likely never is to be any such product."

Therefore, it is hereby requested that FDA and FTC take steps to make sure manufacturers do not state or imply that use of a sunscreen will prevent the induction of skin cancer. In addition, TSO supports the recommendation by Dr. Gasparro to change the acronym "SPF" from "sun protection factor" to "sunburn protection factor" because the latter definition is more correct and descriptive of what should be expected from the use of a sunscreen product.

3. The Failure To Adequately Warn The American Public About The Perils Of Sub-Optimal Application Dose of Sunscreen Products Makes The Proper Use Of These Products Unlikely.

a. Neither the FDA nor the FDA have adequately mandated that manufacturers provide information about the perils of sub-optimal application dose of sunscreen products.

b. In the January 15, 2000 issue of the *British Medical Journal* an article by Dr. Brian Diffey titled "Has the sun protection factor had its day?" provided the following important information.

"Why do people who use high factor sunscreens still get sunburnt" The protection offered by a sunscreen – defined by its sun protection factor – is assesses after it is phototested in vivo at an internationally agreed application thickness of 2 mg/cm^2. Yet an number of studies have shown that consumers apply much less than this, typically between 0.5 and 1.3 mg/cm^2. Application thickness has a significant effect on protection, with most users probably achieving a mean value of 20-50% of that expected from the product label as a result of common application thicknesses. So the likely explanation for people getting sunburnt despite using high factor sunscreens is that inadequate amounts of sunscreen were applied or areas of the body were missed, or both, coupled with overexposure to the sun in the belief that they were protected."

c. The aforementioned article by Dr. Gasparro substantiates Dr. Diffey's premise.

"In mid-1999, no sunscreen product provided exact instructions on the amount of product to be applied to skin. This is important because studies have shown that much less than half the effective SPF amount is typically applied by the user. The reason for under application of sunscreens is clear. Although the FDA-approved testing method requires the application of 2 mg/cm^2 to obtain the SPF claimed, nowhere on any sunscreen product are users advised the quantity of sunscreen that should be applied to protect their skin."

"Hence, applying half the recommended amount of an SPF product would reduce the efficacy not by approximately 2-fold but by something closer to approximately 4-fold."

It should be mentioned that other authors state that the efficacy is reduced by the application dose factor. Therefore, if one-half of the recommended dose is applied (1.0 mg/cm^2 instead of 2.0 mg/cm^2) of an SPF 8 sunscreen, the effective protection would be approximately equal to an SPF 4 product.

It should also be noted that 2.0 mg/cm2 can be translated into a dose of 40 cc's (cubic centimeters) or 1.25 ounces of lotion for an adult full-body application of sunscreen. This means that an 8 ounce bottle will provide approximately sis (6) adult full-body applications of sunscreen. For a family of four on a beach vacation, a single 8 ounce bottle would provide only a single day's supply. Therefore, if the family vacation was for one week, they would need to purchase six or more bottles of sunscreen in order to be adequately protected. FTC and FDA must pay particular attention to Dr. Gasparro's statement that "In mid-1999 no sunscreen product provided exact instructions on the amount of product to be applied to skin" as it moves to remedy this FDMU situation.

d. An article titled "Sunscreen Application and Its Importance for the Sun Protction Factor" by Stenberg, et al, was published in the *Archives of Dermatology* in November, 1985. This means that the followilng information has been available to FDA, FTC, the sunscreen industry and the dermatology community for over 15 years.

"To achieve a good sun protection, a layer thickness of 2 mg/cm^2 is recommended. Fifty individuals were asked to apply five different sunscreens ad libitum. Ten percent dihydroxyacetone was added to the sunscreens in order to make them fluoresce when irradiated with Wood's light. The layer thickness was calculated by dividing the amount applied by the area. The thickness of the sunscreen layers varied little between different parts of the body and brands; in general, it was close to 1.0 mg/cm^2. The corresponding protection factor was measured for two sunscreens on 20 persons. The results indicate that the sun protection factor under ad libitum conditions is only 50% of what would be achieved using a layer thickness of 2 mg/cm^2."

Therefore, it is hereby requested that FDA and FTC take steps to make sure that all sunscreen product manufacturers provide accurate and appropriate instructions about application dose. Moreover, TSO believes that a "warning" should be affixed to all sunscreen products that will inform the American public of the sunburning dangers involved when a sub-optimal application dose of sunscreen is applied.

4. The Failure To Instruct The American Public About How Their Constitutive Pigmentation Provides Natural Protection From UVR Results In The Dissemination Of False, Deceptive, Misleading And Unsubstantiated Information.

   a. The message that is given the American public regarding the use of sunscreen products implies that all skin types (subtypes) have the same tolerance to ultraviolet radiation. This message is obviously designed to make a larger proportion of the public believe that they must use a high SPF sunscreen every day of the year which means that this message is marketing driven rather than scientific evidence based.

   b. Constitutive pigmentation (our natural skin color) is photoprotective with the darker skin types having the most tolerance to UVR. The fact of the matter is that the message delivered to the American public today is correct for only skin type 1 individuals who are genetically incapable of developing a tan and for skin type 2 and 3 individuals who do not develop and maintain a cosmetic tan year-round.

Therefore, it is hereby requested that FDA and FTC take steps to make sure that sunscreen manufacturers provide information regarding the natural photoprotection that is enjoyed by individuals with darker natural skin color. Moreover, it should be made clear that these individual may not require application of a sunscreen product every day of the year, no matter the season or their location.

5. The Failure To Instruct The American Public About The Ultraviolet Index Results In The Dissemination Of False, Deceptive, Misleading and Unsubstantiated Information.

   a. Nowhere on any bottle of sunscreen product is there an explanation of how the use of the Ultraviolet Index (UVI) can be used by the American public to determine their relative risk of sunburning.

   b. Most newspapers and the National Weather Service website contains a UVI forecast and this information can be used (in conjuction with knowledge about their skin type) to help predict the sunburning potential in their area.

Therefore, it is hereby requested that FDA and FTC take steps to make sure that sunscreen manufacturers provide information to the American public that will help them to understand and use the UVI to determine their sunburning risk.

6. The Failure To Instruct The American Public About The Photoprotective Properties Of Facultative Pigmentation Results In The Dissemination Of False, Deceptive, Misleading and Unsubstantiated Information.

a. In an article by Barbara A. Gilchrest, MD and Mark S. Eller, MD, of the Department of Dermatology at the Boston University School of Medicine that was published in the September, 1999 issue of the *Journal of Investigative Dermatology* the authors stated the following:

"Life on earth evolved in the presence of ultraviolet (UV) irradiation from terrestrial sunlight, and essentially all organisms developed photoprotective mechanisms to limit the resulting damage. Melanin pigmentation, both constitutive (baseline) and facultative (inducible), is the major recognized form of protection against UV-induced damage. Photoprotection is attributable to the fact that the melanin polymer can directly absorb UV photons, dissipating the otherwise injurious energy as heat, and can further absorb free radical species generated by the interaction of UV photons with cellular lipids and other molecules that otherwise cause oxidative damage. Scattering and reflection of UV photons by proteins in the stratum corneum is believed to be a second, albeit minor, mechanism of photoprotection, and the stratum corneum is known to thicken following UV irradiation, particularly in poorly melanized skin."

"Mammalian skin responds to UV irradiation by increased production of the pigment melanin in melanocytes, with subsequent distribution to surrounding keratinocytes in a manner shown to be photoprotective. Also, recent data indicate that mammalian cells, like bacterial cells, have a UV-inducible DNA repair capacity that further protects the tissue from subsequent UV exposure. The combined effect of UV-induced melanogenesis (tanning) and enhanced DNA repair capacity, as well as possibly other as yet poorly elucidated inducible responses, is to render the skin far more resistant to subsequent UV injury. **Such responses can reasonably be presumed important in protecting skin from acute and chronic UV damage, including the development of skin cancer."**

"Sun (UVR) induced tanning is known to be photoprotective, with a sun protection factor (SPF) of approximately 3 – 5, depending on the individuals genetically determined ability to tan."

Therefore, it is hereby requested that FDA and FTC take steps to make sure that sunscreen manufacturers provide information to the American public that will help them to understand that their facultative pigmentation (an adaptive tan) will provide significant protection (approximately 3 – 5 times) from ultraviolet radiation, including the development of skin cancer.

Taken together, the North American Alliance of Tanning Salon Owners believes that the suggestions and recommendations contained herein will help FDA produce a better and more comprehensive Sunscreen Monograph that will provide meaningful information for the American public.

Sincerely,

Donald L. Smith

Donald L. Smith
Executive Director / North American Alliance of Tanning Salon Owners

Express®

FedEx. PRIORITY OVERNIGHT WED

emp# 019434 05SEP00

TRK# 8202 9856 0166 FORM 0215

Deliver By: 06SEP00 AA

20857 -MD-US IAD XA GAIA

36

52

FedEx USA Airbill FedEx Tracking Number 8202 9856 0166

0215 Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 11/5/00 FedEx Tracking Number 820298560166

Sender's Name D. L. Smith Phone 888 594-3828

Company NAATSO

Address 1062 W SHOAL CREEK LN

Dept./Floor/Suite/Room

City TUCSON State AZ ZIP 85737

2 Your Internal Billing Reference

3 To

Recipient's Name Dan [illegible] Phone 301 [illegible]

Company Food & Drug Administration (HFA-305)

Address 5630 Fishers Lane / Room 1061

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

City Rockville State MD ZIP 20857

8202 9856 0166

0139867044

4a Express Package Service — *Packages up to 150 lbs.* Delivery commitment may be later in some areas.

- [x] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day* — Second business day
- [ ] FedEx Express Saver* — Third business day

* FedEx Envelope/Letter Rate not available. Minimum charge: One-pound rate

4b Express Freight Service — *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging * Declared value limit $500

- [x] FedEx Envelope/Letter*
- [ ] FedEx Pak*
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling Include FedEx address in Section 3.

- [ ] SATURDAY Delivery — Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] SUNDAY Delivery — Available for FedEx Priority Overnight to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available with FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [x] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods cannot be shipped in FedEx packaging.

- [ ] Cargo Aircraft Only

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below.

- [x] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check
- [ ] Obtain Recip. Acct. No.

Total Packages | Total Weight | Total Charges | Credit Card Auth.

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Call 1-800-Go-FedEx® (800-463-3339)

Visit our Web site at www.fedex.com

SRP 0300 • Rev. Date 8/99 • Part #154813 • © 1994-99 FedEx • PRINTED IN U.S.A.

359

Time®

DOCKET NUMBER 78N-0038

DOCKET #: 78N-0038