

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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

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

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CITIZEN PETITION: DOCKET 78N-0038

Dear Sir or Madam:

This Citizen Petition is submitted under 21 CFR Sec. 10.30 on behalf of The Cosmetic, Toiletry, and Fragrance Association¹ and The Consumer Healthcare Products Association² ("Petitioner"). This Citizen Petition requests the Commissioner of Food and Drugs to take the following action with respect to the Final Monograph for Over-the-Counter Sunscreen Drug Products, 21 CFR Part 352, Subparts C and D ("Final Monograph").

ACTION REQUESTED

The Petitioner requests the Commissioner to reopen the administrative record of the Final Monograph for the purpose of considering this information when developing the proposed amendments to the Final Monograph.

¹ CTFA is the national trade association representing the personal care products industry. It has an active membership of almost 600 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States, as well as a large number of OTC drug products and products that are both drugs and cosmetics. CTFA also includes associate member companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories.

² CHPA is the national trade association representing the manufacturers and distributors of nonprescription or over-the-counter (OTC) medications. Members of CHPA are responsible for over 90 percent of the retail sales of OTC drugs in the United States. In addition, CHPA members manufacture and distribute some products that are both drugs and cosmetics.

STATEMENT OF GROUNDS

Consideration of this petition

The Agency's regulations recognize that the administrative record of a final monograph may be reopened to consider new data and information, see 21 CFR 330.10 (a)(12)(i), and that the Commissioner may publish a proposed amendment if the Commissioner finds general recognition of safety, effectiveness and labeling under 21 CFR 330.10 (a)(4). In fact, FDA has already indicated its intention to do so in this rulemaking.³ On May 21, 1999 FDA published a final rule for OTC sunscreen drug products in Part 352 intended to provide UVB radiation protection, however, the Final Monograph did not address active ingredients, labeling, and test methods for products intended to provide UVA protection.⁴ In addition, CTFA and CHPA petitioned FDA to reconsider a number of decisions regarding Sun Protection Factor ("SPF") claims, anti-aging claims, uses and directions, and labeling to be required under the OTC Drug Labeling Regulation. Accordingly in the Federal Register of June 8, 2000 FDA extended the effective date for all OTC sunscreen drug products in order for the Agency to develop a comprehensive sunscreen Final Monograph that addresses the formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352.

Petitioner filed extensive comments on specific information the Agency requested when it reopened the administrative record in the June 8 notice. As part of our September 2000 submission, we resubmitted data that confirms the ability of current methods to adequately and consistently test high SPF sunscreen products and urged FDA to remove its "SPF 30+" labeling cap for products that are proven to be safe and effective. This petition provides further scientific rationale that FDA should not restrict the truthful labeling of high SPF sunscreen products that meet the testing requirements in the Final Monograph.

Publication of test results for high SPF formulations

A lack of data demonstrating the ability of widely used SPF test methods to produce accurate and reproducible SPF values for sunscreen products with SPFs above 30 was one reason that the Food and Drug Administration (FDA) had recommended that the SPF value on sunscreen product labels be limited to "30+" in its 1999 Final Monograph.

³66 Fed. Reg. 67485 (December 31, 2001).

⁴64 Fed. Reg. 27666 (May 21, 1999).

The goals of the enclosed published study⁵ were to assess whether the existing SPF test methodologies as defined by the FDA sunscreen monographs could produce accurate and reproducible results for high SPF formulations and to provide insight on the number of test subjects needed, the variability of the data, and the appropriate exposure increments for testing high SPF formulations.

Because equipment, techniques, and subject populations may vary somewhat even between laboratories following the same testing protocol, there have been few comparisons of SPF data obtained from multiple testing sites. In the enclosed study, the authors report the results of repeated testing of three high SPF formulations within one laboratory, and also the results of testing one formulation at four independent SPF testing laboratories in the United States. The results demonstrate that current test methodologies are suitable for determining high SPFs, and that the variability of the data both within one laboratory and among different US laboratory sites is acceptable.

The SPF testing methodology included in the 1999 Final Monograph was fundamentally unchanged from the method described by FDA in the 1993 Tentative Final Monograph.⁶ Three high SPF formulations were tested according to the 1993 Tentative Final Monograph "very water-resistant" test method and/or the 1978 Proposed Monograph "waterproof" test method⁷, within one laboratory. Both methods include 80 minutes of water immersion after product application, followed by a series of UV (ultraviolet) exposures from a solar simulator. In the 1993/1999 test method, the UV exposure increments are determined by the expected SPF of the formulation. For these studies, a series of seven exposures (5 exposures at 15% increments, plus two half-increment exposures around the mid-point) was utilized.

The data illustrate that either the 1978 Proposed Monograph test method or the 1993 Tentative Final Monograph method can provide accurate and reproducible results for high SPF formulations. Further, these results can be achieved with panels of 20-25 subjects without an unacceptable level of variability. Where higher variability exists (such as within the four laboratory comparison data, Table 4), the 1993 statistical treatment of the data can appropriately control the "final" SPF value derived from the test panel.

The data also illustrate that formulations tested under the 1978 Proposed Monograph and labeled with SPF values according to that test method were determined to provide a level of protection not significantly different than the SPF level obtained using the Tentative Final Monograph method. Marketed products tested by the 1978 proposed

⁵ Agin, Patricia A. and Edmonds, Susan. H. Testing high SPF sunscreens: a demonstration of the accuracy and reproducibility of the results of testing high SPF formulations by two methods and at different testing sites. *Photodermatol Photoimmunol Photomed* 2002; 18:169-174.

⁶ 58 Fed. Reg. 28194 (May 12, 1993).

⁷ 43 Fed. Reg. 38206 (August 25, 1978).

method, therefore, would not pose a public health threat or a safety hazard based on the data shown; the necessity to retest these products is therefore called into question-- as long as full panels of data meeting the appropriate statistical parameters exist to support their efficacy and labeling.

Based on the results shown in this study, the current methods for testing sunscreen formulations have been shown to be appropriate for testing formulations with SPF's above 30. Either the 1978 proposed method (series of 5 exposures at 25% increments) or the 1993 TFM /1999 Final Rule method (series of 7 exposures, including 2 half-increment exposures, at 15% increments) can provide satisfactory data to determine a valid product SPF. We would recommend that the graduated series of exposure increments for different SPF categories designated in the 1993/1999 monographs be used, but without the two "half-increment" exposures, to reduce unnecessary subject exposure to UV radiation. The half-increment exposures do not appear to add to the accuracy of the test panel outcome.

Furthermore, the data illustrate that despite operational differences between laboratories, if the solar simulator light sources meet the FDA Final Monograph and current COLIPA⁸ requirements, and identical protocols are used, it is reasonable to expect that test results for well-formulated products will be consistent.

FDA's prohibition against disclosure of SPF values over 30 on sunscreen formulations suppresses truthful commercial speech in violation of the First Amendment. As the data in the enclosed publication demonstrates, there is no technical reason for retaining the concept of a cap on SPF at 30+. The data clearly show that higher SPF formulations can be accurately tested with the current SPF testing methodology. We urge FDA to reconsider the cap on SPF in light of these data and restore the ability to truthfully label the actual SPF for products with an SPF over 30.

The purpose of this petition is to provide updated scientific data, and to enable the Agency to decide this issue with information that is directly relevant and essential for the Agency to consider in drafting its proposed amendment to the Final Monograph. In particular, it would be inappropriate for FDA to restrict the truthful labeling of SPF products over 30 without consideration of current data that provides accurate and reproducible SPF values for sunscreen products with SPF's above 30. We are asking the Agency to consider this material as providing new support for actions requested of FDA, namely the ability of current SPF testing methods to accurately measure sunscreen protection provided by formulations with high SPF's.

⁸COLIPA. COLIPA Sun Protection Factor Test Method, The European Cosmetic, Toiletry and Perfumery Association, 1994.

In sum, the data is directly relevant to the proposed conditions under which sunscreen products may be tested and marketed. Good cause exists for the Commissioner to consider this material because it provides further scientific data and rationale for the need to permit truthful labeling of high SPF sunscreen products at a time when the Agency has raised such questions specifically in the Final Monograph and invited comment in the context of the First Amendment.

ENVIRONMENTAL IMPACT

According to 21 CFR 25.31(c), this petition qualifies for a categorical exclusion from the requirement that an environmental assessment be submitted.

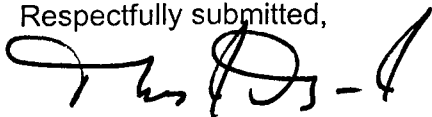
ECONOMIC IMPACT

According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this petition.

CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data known to the Petitioner which are unfavorable to the petition.

Respectfully submitted,



Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance
Association



Eve E. Bachrach
Senior Vice President, General Counsel
and Secretary
Consumer Healthcare Products
Association

cc: Charles J. Ganley, M.D. (HFD-560)
Matthew R. Holman (HFD-560)

Attachments