

Procter & Gamble

The Procter & Gamble Company
Sharon Woods Technical Center
11511 Reed Hartman Highway, Cincinnati, Ohio 45241-9973

00 SEP -7 P1 45

September 5, 2000

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

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

Dear Sir/Madam:

This provides three (3) copies of comments to the administrative record of the Sunscreen Drug Products for Over-the Counter Human Use, Final Rule, which was reopened on June 8, 2000.

The Procter & Gamble Company is a manufacturer of products containing ultraviolet (UV) filters including Oil of Olay and Cover Girl. We have had a long standing interest in the sunscreen monograph and on several occasions have submitted technical comments to assist in making purposeful, data-based regulatory decisions regarding sunscreen drug products. To this end, we are responding to the agency's request for information/data arising from public meetings on January 27, July 22, and October 26, 1999, and in letters of July 16 and September 2, 1999, and March 20, 2000. The comments presented in this submission specifically address questions raised by the agency regarding the Critical Wavelength method for evaluation of UVA efficacy.

To facilitate the presentation of our comments, we have selected the question format from page 2 of the March 20, 2000 letter from Dr. Linda Katz, Deputy Director Division of Over-the-Counter Drug Products, to Mr. Thomas Donegan, Vice President-Legal & General Counsel of the Cosmetics, Toiletries and Fragrances Association (CTFA). In this letter, it is stated "The following outstanding data and information requested by the agency at the above mentioned meetings [January 27, July 22 and October 26, 1999] concerning the OTC sunscreen drug product rulemaking remain. . .". As such, we have categorically responded to each question.

The Procter & Gamble Company believes the interests of consumers come first. From this perspective, we strongly recommend the agency adopt a simple label to communicate the presence or absence of sunscreen product UVA efficacy. We believe the threshold criteria used to label a sunscreen product as "broad spectrum" should be based on products having a Critical Wavelength greater than or equal to 370 nm. It is our considered view that the combination of SPF and Critical Wavelength provide a complete description of UV efficacy of sunscreen products and communicate an uncomplicated message to consumers thereby preserving and advancing public health campaigns advocating the routine use and appropriate application of sunscreen products as part of a strategy to reduce skin damage produced by sun exposure.

Respectfully,
The Procter & Gamble Company


J Frank Nash, Ph.D.
Senior Scientist

C-581

78N-0038

TABLE OF CONTENTS

PAGE

1. Summary..... 2

2. Overview of Principles..... 3

3. Information regarding your “critical wavelength” method submission (from the above mentioned July 16th letter)..... 6

 a) It was stated that “a region of the substrate at least 1 cm² in area will be measured (spectrometer); or “5 individual regions of the substrate at least 0.25 cm² in area will be measured (spectroradiometer).” Explain why the difference in instrumentation choice would influence the number of measurements taken or the size of the area measured..... 6

 b) Explain how the use of the quartz backing plate alleviates the incompatibility of the Transpore™ tape with certain vehicle ingredients and sunscreen application technique..... 7

 c) Explain whether the minimal erythema dose (MED) of 1 J/cm² is intended to be a weighted or unweighted dose, or how this value (1 J/cm²) was determined..... 8

4. Information concerning ultraviolet A (UVA) radiation testing and labeling of OTC sunscreen drug products (from the above mentioned January 27th and October 26th meetings and July 16th letter)..... 9

 a) Explain the rationale concerning the selection of the “critical wavelength” method over other in vitro UVA test methods (including the Diffey “ratio” method)..... 9

 b) Address the observation that products with significantly different absorption spectra can have similar “critical wavelength” values..... 12

 c) Submit sunscreen product absorbency/transmission data requested for “ratio method” calculations..... 15

 d) Provide data relative to the determination of the “pre-irradiation” dose concerning the photostability modification to the “critical wavelength” method..... 17

 e) Provide data relative to the differential “wash-off” of ingredients during water immersion or sweating (i.e., differential changes to UVB and/or UVA absorption)... 19

 f) Submit data/information relative to the “diffuse reflectance” method, including an assessment and comparison with the “Diffey methods”..... 21

 g) Provide information concerning the appropriate proportionality between UVB (relative to the SPF) and UVA absorption in sunscreen products..... 22

 h) Provide feedback regarding appropriate label claims..... 27

5. UVA Labeling and Test Method Recommendation..... 31

APPENDIX I (Volume 1)

APPENDIX II (Volume 1)

FOOTNOTE REFERENCES (Volume 2)