



## 1. SUMMARY

At 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<sup>1</sup>, to the Cosmetic, Toiletry, and Fragrance Association (CTFA), the agency identified the type of specific data and information that would be helpful for the completion of a comprehensive final monograph for OTC sunscreen drug products. The comments provided in this submission are direct responses to the questions presented in the letters of July 16, 1999 and March 20, 2000 sent by the agency to CTFA.

We support a simple threshold or pass/fail labeling system to communicate UVA sunscreen product efficacy based on a method proposed by an independent academician, Prof. Brian L. Diffey, which has been termed the critical wavelength. Our outspoken advocacy of this labeling scheme and the critical wavelength method is based on the following consideration:

### What are the needs of consumers?

We believe that consumers need:

- sun care products that protect the skin from solar ultraviolet (UV) radiation

Presently, the *in vivo* sun protection factor (SPF) test provides a measure of sun care product efficacy against erythema, a consumer meaningful benefit and a surrogate for direct DNA damage<sup>2</sup> produced by wavelengths from 290 to 340 nm. However, there is no agreed to method for measuring protection against long wavelengths of UV (i.e., > 340 nm or UVAI).

Although it is desirable to have an *in vivo* test to measure UVA protection, not one method proposed to date is adequate. The proposed *in vivo* methods modeled after the SPF test generate protection factors which are protocol-dependent and of indeterminate clinical relevance, as none of the endpoints are surrogates for long term concerns such as skin cancer or photoaging. Further, these *in vivo* tests expose humans to doses of UVA the human health consequences of which are unknown. Finally, the added costs of such testing would ultimately be passed onto consumers.

Because an *in vivo* UVA test has so many uncertainties and limitations, alternative methods have been proposed. One such test proposed by Prof. Diffey is an *in vitro* method based on substrate spectrophotometry which determines the absorption profile of a sunscreen product across all wavebands (i.e., 290-400 nm) and calculates a Critical Wavelength at which 90% absorption has been reached. The simple approach provides a measure of the breadth of protection against UV. Thus, when the *in vivo* SPF (amount of protection) is taken together with the *in vitro* critical wavelength (breadth of protection), a complete description of sunscreen product efficacy is obtained.

- a simple, meaningful and transparent label to communicate such protection

Sunscreens are recommended as part of a sun avoidance strategy to reduce the harmful skin effects from sun exposure. Public health campaigns in the US and around the world stress the benefits of sunscreen use as part of this program. The simple public health message of the American Academy of Dermatology is to wear a sunscreen with a minimum SPF of 15. This advice is clear and uncomplicated. With this in mind, a pass/fail system to communicate whether or not a sunscreen product has long wave UVA protection is strongly recommended.

The comments presented in this submission address concerns and provide data/information regarding the critical wavelength method and UVA product labeling. ***We believe with conviction and passion that the best outcome for consumers would be the adoption of a single threshold label to communicate long wave UVA protection based on products having a critical wavelength greater than or equal to 370 nm.***

<sup>1</sup> Federal Register (2000), 65 No. 111, 36319-24, References 1, 3, 6, 7, 8 and 9.

<sup>2</sup> Young, AR, Chadwick, CA, Harrison, GI, Nikaido, O, Ramsden, J, Potten, CS (1998) The similarity of action spectra for thymine dimers in human epidermis and erythema suggests that DNA is the chromophore for erythema. *J Invest Dermatol* 111:982-88.