

# Procter & Gamble

The Procter & Gamble Company  
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May 2, 2000

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Docket Management Branch, Docket No. 78N-0038 (HFA-305)  
Food and Drug Administration, Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20857

**Re: Technical Concerns and Comments Regarding the March 3, 2000 Submission to Docket No. 78N-0038 Sunscreen Drug Products for Over-the-Counter Human Use by L'Oréal Research/Cosmair Cosmetic Corp.**

Dear Sirs:

The purpose of this letter is twofold: first, to make you aware of serious misrepresentations of the Critical Wavelength presented in the letter and report submitted March 3, 2000 by L'Oréal Research/Cosmair Cosmetics Corp.; and, second, to present our general concerns about current *in vivo* UVA test methods with specific technical remarks regarding the "L'Oréal method" Persistent Pigment Darkening (PPD).

The purpose of the Procter & Gamble Company is to provide products of superior quality and value that improve the lives of consumers. To this end, we have recognized for several years that consumers need sun care products which protect against all wavelengths of solar ultraviolet (UV) radiation, i.e., 290 - 400 nm. Whereas the Sun Protection Factor (SPF) provides an *in vivo* measure of sunscreen protection against short wavelengths of UV, i.e., < 340 nm, based on erythema, this test provides little information regarding protection against long wave UV, commonly referred to as UVAI (340 - 400 nm). In this regard, we have submitted previously data to the Agency supportive of an *in vitro* method, termed "modified-Diffey" and its summary statistic, the Critical Wavelength, which provides a simple, reliable, and sensitive measure of the breadth of UV protection. Importantly, the Critical Wavelength is independent of SPF yet ensures UVA protection commensurate with SPF so that as the SPF increases, so too must the UVA protection to maintain the same Critical Wavelength. Thus, when used together, the Critical Wavelength and SPF completely describe sunscreen product efficacy.

It is our view that the Critical Wavelength has been distorted and misrepresented as "inadequate" based on a flawed technical analysis presented in submissions to the Docket on May 15, 1998 and again March 3, 2000 by L'Oréal Research/Cosmair Cosmetics Corp. We believe the intent of this effort is:

- (1) to obfuscate the value and widespread utilization of *in vitro* substrate spectrophotometry and calculation of the Critical Wavelength as a simple, reproducible method for determining the effectiveness of sunscreen products against longwave UVA; and
- (2) to advance an *in vivo* UVA method, designed and developed by L'Oréal Research/Cosmair Cosmetics Corp., with the intent of generating a UVA Protection Factor (UVA-PF) that could be used to devise a numerical or categorical label for sunscreen products.

In this regard, we believe the use of a UVA-PF to communicate sunscreen product efficacy would be deceptive and confusing to consumers. Moreover, given the thoughtful concerns expressed by the Agency and other independent academicians/clinicians that the SPF "number" may be misleading, we maintain that the generation of another protection factor, namely the UVA-PF, or multiple categories of UVA protection based on this UVA-PF, would be an unfortunate and misguided public health policy decision.

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Given the complexity of the issues we are addressing, this submission has been divided into 2 sections. In **Section I**, we provide the technical basis for our view that the Critical Wavelength has been misrepresented. **Section II** provides general comments and concerns regarding current *in vivo* UVA tests and a detailed critique of the "L'Oréal method" PPD. In this regard, we have limited our comments to the most obvious and disturbing concerns with the "L'Oréal method". It is our view that any one of the concerns are sufficient to question the widespread implementation of such an approach, which would be used for sunscreen product efficacy and labeling decisions.

Although we trust the Agency recognizes the technical misrepresentations and shortcomings of the May 15, 1998 and March 3, 2000 L'Oréal Research/Cosmair Cosmetics Corp. submissions, this presents the technical basis of our comments to allow a more purposeful consideration of this measure of sunscreen product long-wave UVA effectiveness. We would be happy to address any questions regarding the contents of this submission.

Respectfully,  
THE PROCTER & GAMBLE COMPANY



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