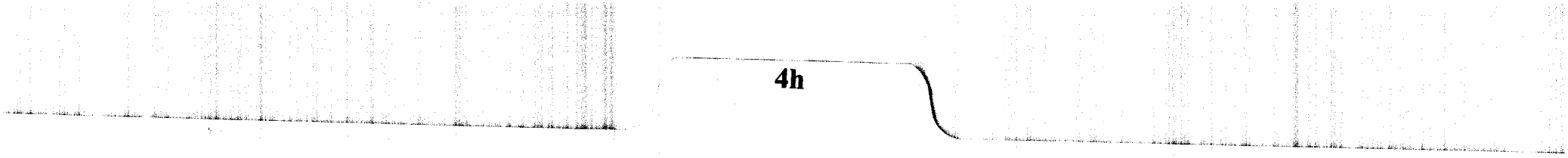
4h

h) Provide feedback regarding appropriate label claims.

Comment

The single most important decision regarding UVA protection will be how to communicate the information to consumers. Based on our studies presented below, we recommend products with critical wavelengths greater than or equal to 370 nm be labeled as "Broad-Spectrum". The reasons for this pass/fail designation are:

- it provides consumers with clear, simple and relevant information which does not interfere with or otherwise complicate the existing SPF number, which would remain the primary criteria for selection of a sunscreen product;
- using critical wavelength to classify products ensures the level of UVA protection is commensurate with SPF;
- manufacturers can provide consumers with broad-spectrum products without compromising product aesthetics or incurring excessive costs, which ultimately would be passed onto consumers; which may affect the amount of product applied and as a consequence go against the purpose of promoting sunscreen use;
- it results in a seamless, transparent public health message, i.e., as part of a sun avoidance strategy, wear an SPF 15 broad-spectrum sunscreen.

It is with thoughtfulness and conviction that we recommend the pass/fail labeling option as the optimal labeling system for communicating UVA efficacy. To this end, a product achieving a critical wavelength equal to or greater than 370 nm would be designated as broad-spectrum.

Background

Presently, all sunscreen products are labeled with an SPF number and from our studies[7] and those of others[21], the vast majority also indicate some UVA protection. In this regard, the present system is not optimal since there is no agreed to method for evaluating UVA protection. To more fully understand the suncare market and the ability of the critical wavelength method to characterize products, we evaluated 59 commercial sunscreens[8], and found:

- only 10% of products achieved a critical wavelength ≥ 370nm
  - ⇒ all products with a critical wavelength ≥ 370nm contained a UVA-I active
  - ⇒ a UVA-I active (i.e., avobenzone, titanium or zinc oxide) is necessary, but not sufficient to achieve a critical wavelength ≥ 370nm since 27% contained a UVA-I active but only 10% achieved a critical wavelength ≥ 370nm

Consumer Labeling Study: How Best to Communicate UVA Protection?

This summarizes the results of two identical, independent, studies to evaluate three methods of sunscreen UVA efficacy communication. These studies, US990979 and US994964, were conducted in the late spring and early fall of 1999, respectively, among representative male and female consumers age 18+. The goal of these studies

[21] Rosenstein BS, Weinstock MA, Habib R (1999) Transmittance spectra and theorectical sun protection factors for a series of sunscreen-containing sun care products. *Photodermatol Photoimmunol Photomed* **15**:75-80.

was to identify the option that represents the clearest and easiest UVA communication and best allows the consumer to make a safe and effective product choice.

Objectives

The objectives of the studies were

1. to evaluate three sunscreen product labeling schemes, SPF and UVA efficacy, among representative male and female consumers, and
2. to identify the best means to communicate a product's UVA efficacy / lack of efficacy to consumers while maintaining the importance of SPF protection.

Test Design

This methodology was designed to closely imitate a representative male or female consumer's experience of selecting a sunscreen product from a typical store shelf. Each labeling option (i.e. "store shelf representation) was depicted visually on an 8.5 x 11" sheet of paper (called the "product cell"), and is presented in **Appendix II.**

Each respondent received one product cell and was instructed to examine the cell as if they were at the store shelf with the intent to purchase a sunscreen product. Then, the panelist completed a questionnaire which gathered information regarding the choice of a product appropriate for their needs, ease of selection, why the specific product was chosen, current SPF product purchase habits and key demographic information.

The three label options are described verbally as "Pass/Fail System," "3-Tiered Scale: Verbal Descriptor" and "3-Tiered Scale: Graphonumerical". Examples of each are included in **Appendix II.**

Labeling Information

- All products in cells were labeled as "XYZ Sunscreen - SPF A", where A = either 4, 8, 15 or 30.
- The following table outlines how UVA efficacy was communicated on the products within each option's cell:

Pass/Fail System	3 Tiered Scale-Verbal Descriptor[1]	3 Tiered Scale - Graphonumerical[2]
Blank Bottle (i.e. no UVA protection claimed)	Blank Bottle (i.e. no UVA protection claimed)	Bar graph with level 4 "UVA Protection"
"Broad Spectrum UVA and UVB Protection"	"UVA and UVB Protection"	Bar graph with level 8 "UVA Protection"
	"UVB Plus Extended UVA Protection"	Bar graph with level 12 "UVA Protection"

[1]taken from 1995 submission by Schering-Plough to Docket 78-0038N
[2]taken from 1997 submission by Cosmair Corp. to Docket 78-0038N

Summary of Results:

A thorough analysis of the data from both studies resulted in the following conclusions and key findings. Detailed data tables of the combined representative male and female populations are included in **Appendix II**.

- A total of 2238 individuals completed questionnaires (1082 in the spring and 1156 in the fall).

- The data from both tests indicate that the "Pass/Fail System" approach allowed consumers to most easily choose the sunscreen product appropriate for their personal use. "Ease of Choice" for the "Pass/Fail" leg was significantly higher vs. both 3-Tiered Scale approaches among representative males and females in both studies. Specific target groups within the tests' populations, such as SPF product purchasers and those consumers with a history of skin cancer, also indicated it was significantly easier to select their product from the "Pass/Fail" group in both studies. Additionally, consumers in the "Pass/Fail" group selected the maximum amount of UVA protection significantly more often than the Tiered groups without sacrificing or reducing the level of SPF.

- The Graphonumerical approach had significantly fewer panelists indicating their selection was "easy" and significantly less choosing the maximum UVA level versus the Pass/Fail. This option appears to place an undue emphasis on UVA efficacy features and diminishes the UVB focus. This is supported by the inflated number of "want highest level of UVA" voluntary comments as a reason for product choice. Additionally, the number of "UVB protection" comments as the reason for product choice is consistently lower across both studies versus the Pass/Fail and Verbal Descriptor options.

- The Verbal Descriptor option's ease of selection was the lowest of the three options. Additionally, it also had the lowest percentage of panelists selecting maximum UVA vs. both the Pass/Fail and Graphonumerical approaches. Of equal importance, this system may mislead consumers into thinking that "extended" protection translates to staying in the sun longer than normal and could potentially misguide those seeking maximum UVA/UVB combination protection. This is supported by inflated voluntary comments for "extended protection from sun/UV/UVB rays" and "extended/longer UVA protection" for this option which suggests that consumers are inferring an extended "time" element. Clearly, this confusion leads to the potential for long and short term adverse health effects (sunburn, skin cancer) to the consumer and should be avoided.

- The SPF levels chosen were consistent among the three labeling options. The majority of panelists chose products with either SPF 15 or 30. A small percentage in each of the three options selected low SPF products. Reasons for selection of low SPF products appeared to be based on personal preference, e.g. "wanted low level of SPF to achieve a suntan."

Conclusion:

This test design represents a valid method to realistically imitate a consumers' experience of purchasing a sunscreen product from a store shelf. This is supported by 1) the SPF levels selected by the panelist via the test cells were consistent with the SPF levels that the panelists are currently purchasing for facial moisturizers and/or

recreational beach sunscreens and 2) the conclusion and findings were consistent between both tests.

Based on these independent studies evaluating UVA label options, the pass/fail label was significantly superior to the other labels with respect to ease of product selection, selection of the higher level of protection, and SPF remained the primary indicator of sunscreen product efficacy.

We recommend that the pass/fail label be used as the means of communicating UVA efficacy of sunscreen products.