

APPENDIX I
STUDY PROTOCOL

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A CONSUMER'S EVALUATION OF UVA LABELING

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A CONSUMER'S EVALUATION OF UVA LABELING

Introduction:

In 1978, the US Food and Drug Administration (FDA) proposed to establish a monograph for OTC sunscreen products. Years later, a tentative final monograph was published in the Federal Register of May 12, 1993. Up to that point, the proceedings at the FDA included only sunscreens containing ultraviolet B which was linked to burning and skin cancer.¹ In the Federal Register of April 5, 1994, the FDA reopened the administrative record and announced a public meeting to discuss ultraviolet A (UVA) radiation protection claims and testing procedures. Reported information suggests that UVA is associated with skin aging and, to a lesser degree, skin cancer.² On September 16, 1996, the FDA amended the proposed rule and included avobenzone (Parsol 1789) alone and avobenzone in certain combinations as allowable UVA sunscreens. Additional submissions were made to the sunscreen monograph in 1997-1998 on UVA testing methodology. Earlier in 1999, during a public feedback meeting, UVA testing procedures and labeling claims were discussed. On May 21, 1999, the FDA issued its final monograph regulating over-the-counter (OTC) sunscreen products. In this document, permission was given for the use of avobenzone alone and for the use of avobenzone in combination as UVA blocking sunscreens in addition to zinc oxide. The mandated labeling included the wording "*Broad spectrum UVA and UVB protection*". This labeling allows manufacturers with UVA sunscreen products to make UVA protection claims even if these products protect against the smallest amounts of UVA.³ Sheldon Pinnell, a prominent author in the Dermatology community, has been quoted to say that "*There's a lot more ultraviolet A light than there is ultraviolet B. It's present with us pretty much throughout the year, as opposed to UVB, which tends to be predominately out in the summertime*".⁴

The maximum protection (against UVB) possible and permitted by the FDA has risen steadily since the original call for an OTC sunscreen monograph in 1978. The use of new active UVB sun block materials as single ingredients and the use of these new materials in combination with existing materials have improved formulations to allow maximum levels of protection to rise from 15 to 30 to 45+. [The labeling claim for maximum level of protection permitted by the FDA will be SPF 30, effective May 21, 2001].

Recently, the American Academy of Dermatology (AAD) Task Force issued their Draft Report recommending a certain *in vitro* UVA measuring method (critical wave length) be used to

¹ US Food & Drug Administration: *Proposal of Rulemaking for Sunscreen Products*, Federal Register, August 25, 1978.

² US Food & Drug Administration: *Request for Information on UVA*, Federal Register, April 5, 1994.

³ US Food & Drug Administration: *Final Monograph for Regulation of Over-the-counter Sunscreen Products*, Federal Register, May 21, 1999.

⁴ McPherson, H.C.: *Does Sunscreen Really Protect Against Skin Cancer?* Health.com, August 10, 1998.

support a "Broad spectrum" claim for UVA protection with *a minimum protection value of 4*. The reason for the Academy's recommendation to use this "threshold" pass/fail labeling system was *"to avoid confusing consumers"*. The AAD also opined that *"While the deleterious effects of UVB radiation exposure are well known, the complete action spectrum for photocarcinogenesis and photoaging, particularly the efficacy of ultraviolet A (UVA) in humans remains to be elucidated"*. Apparently, the ambiguous approach of the AAD is based on a belief that not enough information is available to associate UVA with deleterious effects on the skin which accelerate aging. In fact, there are numerous published articles that clearly establish the link of UVA exposure to premature aging of the skin.^{5 6 7 8 9}

Today, companies with advanced research and state-of-the-art technology, such as L'Oreal, can deliver formulations with UVA protection as high as UVA Protection Factor 12. Products containing UVA protection available on the market with the permitted labeling claim contain merely a UVA Protection Factor of 4 or less. The current labeling system for UVA containing sunscreens does not allow for the flexibility of adding on a level of protection, for offering consumers higher levels of UVA protection, or for permitting consumers to make a choice.

To better serve the American public, L'Oreal's objectives are: 1) to raise consumer awareness of UVA adverse effects on skin aging, 2) to provide our consumers with education on the availability of products with higher levels of UVA protection, and 3) to offer our consumers choices of UVA protection levels in its wide range of sunscreen products. This consumer survey is conducted to ascertain which labeling system best shows the level of UVA protection as preferred by the American consumers.

Objective:

This study is conducted to ascertain the understanding and the preference of American consumers on sunscreen product labeling.

⁵ Oikarinen, A., Peltonen, J., Kalliainen, M.: Ultraviolet Radiation in Skin Aging and Carcinogenesis: The Role of Retinoids for Treatment and Prevention, *Ann. of Med.*, 23 (5): 497-505, 1991.

⁶ Matsui, M.S., DeLeo, V.: Longwave Ultraviolet Radiation and Promotion of Skin Cancer, *Can. Cells*, 3(1): 8-12, 1991.

⁷ Farmer, K., Naylor, M.F.: Sun Exposure, Sunscreens, and Skin Cancer prevention: A Year-round Concern, *Ann. of Pharma.*, 30 (6): 662-673, 1996.

⁸ Bernerd, F., Asselineau, D.: UVA Exposure of Human Skin Reconstructed in vitro Induces Apoptosis of Dermal Fibroblasts: Subsequent Connective Tissue Repair and Implications in Photoaging, Cell Death and Differentiation, 5 (9): 762-802, 1998.

⁹ Berneburg, M., Grether-Beck, S., Kurten, V., et al.: Singlet Oxygen Mediates the UVA-induced generation of the Photoaging-associated Mitochondrial Common Deletion, *Journ. of Biol. Chem.*, 274 (22) 15345-15349, 1999.

Study Design:

A close-ended questionnaire is utilized in the study conducted in twenty (20) locations across the United States (see Appendix 1).

Study Population:

Respondents who are purchasers/users of sunscreen products are screened according to the inclusion criteria listed in the screener (see Appendix 2). Only respondents who meet these inclusion criteria are enrolled into this study. The respondents are recruited on site, in person.¹⁰ The study population is made up of balanced groups of men and women reflecting approximately 72% Caucasian, 13% Blacks, 11% Hispanic, and 4% Asian.¹¹ Respondents are also selected to obtain a mix of education levels from high school or less to graduate school level. These respondents are recruited from twenty (20) urban and suburban locations throughout the United States and these study sites are selected for their diversity in geographic locality and demographic make-up. Geographic regions are represented by the Northeast (New England and Middle Atlantic area), the Midwest (East North and West North Central areas), the South (South Atlantic, East South and West South Central areas), and the West (Mountain and Pacific areas). Population constitution (based on population, education level, and median household income) of multiple locations is further reflected in the selection of these urban and suburban cities.¹² These cities include: Ft. Smith, Arkansas; Downey, California; Aurora, Colorado; Boynton Beach, Florida; Atlanta, Georgia; North Riverside, Illinois; Indianapolis, Indiana; West Des Moines, Iowa; Boston, Massachusetts; Minnetonka, Minnesota; Jackson, Mississippi; Nashua, New Hampshire; Wayne, New Jersey; Albuquerque, New Mexico; New York, New York; Cleveland, Ohio; Memphis, Tennessee; Houston, Texas; Vancouver, Washington; and Charleston, West Virginia.

1) **Sample Size:** Two thousand (2,000) respondents

2) **Inclusion Criteria:**

- Participants who are eighteen (18) years of age or older
- Participants who are purchasers and/or users of sunscreen products, especially during the summer time.
- Participants must be primary purchase decision-makers for health care or skin care products such as sunscreens, moisturizers (if female); primary or joint purchase decision-makers for health care or skin care products (if male).

¹⁰ These practices of recruitment are customary for the Consumer Research industry. Personal Communications, H. Lipstein (Goldfarb Consultants), K. Lethbridge (Focus on Fifth), C. Capello (Moskowitz & Jacobs), A. Sen (Marketing Decisions Group), and W. Feinberg (LA Focus).

¹¹ U.S. Census Bureau, Population Division, Population Estimates Program, Washington DC, 20233, (<http://www.census.gov/populationestimates/nation/intfile3-1.txt>), Internet Release Date: April 11, 2000.

¹² U.S. Department of Commerce, Bureau of Census, County & City Data Book: Table C. Cities --Education & Money Income, Table D. Places--Population & Money Income, 1994.

- Participants who take part in outdoor activities (picnics, parks, outdoor sports and games, beach [a requirement for coastal areas]...)
- Participants who are men or women
- Participants must be able to read, understand, and follow the written instructions presented in the Questionnaire (see Appendix 3).

3) Exclusion Criteria:

- Participants (or their family members) who work for an Advertising Agency, Marketing Firm, Public Relations Firm, Market Research Firm, or a Manufacturer or a Distributor of Healthcare, Skincare, Beauty or Cosmetic products
- Participants who have taken part in any Marketing Research survey or discussion within the past six (6) months
- Participants who are infrequent users (less than once every four [4] weeks) of sunscreen products
- Participants who are **not** primary purchase decision-makers for health care or skin care products such as sunscreens, moisturizers (if female), or primary or joint purchase decision-makers for health care or skin care products (if male).

Methodology:

1) Materials:

- Educational materials: general information on UVA, UVB rays, and Sun Protection Factor (SPF) is presented to respondents in two (2) forms: visual aids (at the study site) and attachments to the individual questionnaire (see Appendix 4).
- Examples of labels are also presented to respondents in two (2) forms: visual aids (at the study site) and attachments to the individual questionnaire (see Appendix 4).

2) **Method:** Four (4) labeling systems are evaluated by the respondents. To eliminate biases on the order of presentation, each of the four (4) labeling systems is presented first, second, third, and fourth in equal frequencies. The twenty-four (24) combinations are randomly assigned to respondents according to a randomization list (see Appendix 5). At each study site, respondents are asked to read the Educational material prior to reading the questionnaire. Interviewers read the first question to respondents to ensure understanding on the part of respondents. The respondents then complete the questionnaire on their own. Data obtained from the questionnaire are tabulated and analyzed as outlined in the Data Analysis Section.

- 3) **Data Collection:** The results of the study are assessed in the form of the close-ended questionnaire. The questionnaire consists of six (6) multiple-choice questions. Questions 1 and 2 allow one (1) answer; Questions 3, 5, and 6 allow multiple answers; Question 4 allows filling in the blanks.

Logistics:

The study is coordinated by Goldfarb Consultants, Inc., a leading Market Research Firm. Goldfarb's representatives are responsible for the pre-testing and placement of the study throughout the United States, the recruitment of respondents, and the collection, data entry and data processing of the completed questionnaire in accordance with the protocol. L'Oreal's representatives are responsible for monitoring the study, the data analysis, and writing the final study report. Six (6) of the twenty (20) sites selected for monitoring are: Aurora, Colorado; North Riverside, Illinois; Indianapolis, Indiana; Wayne, New Jersey; New York, New York; and Vancouver, Washington. Instructions to the Field Staff are included in Appendix 6.

Statistical Consideration:

Ranking scores are compared using ANOVA with the Student-Newman-Keuls multiple comparison procedure as a follow-up test. The Chi-square test is applied to compare the percentages of the "most preferred" among the four (4) test labels. For a detailed Statistical Plan, see Appendix 7.

Data Analysis:

Demographics variables (age, gender, educational background, and location) are collected and tabulated. Statistical tests are used to analyze the data including ANOVA, Student-Newman-Keuls, and Chi-square.