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On behalf of the 14,000 members of the American Academy of Dermatology Association, I am submitting the following comments in response to the partial delay with releasing the FDA's final monograph for over-the-counter sunscreen products. This delay is necessary for the agency to update the monograph by developing standards for the effectiveness of ultraviolet A (UVA) protection in sunscreen products. At this time, the monograph includes standards addressing active ingredients, labeling, and testing for sun protection factor (known as SPF, a biologic effect predominantly of ultraviolet B, or UVB) only. However, given the growing amount of data that links UVA radiation to photoaging and skin cancer in humans, it is essential that sunscreen products also include UVA protection. Indeed, sunscreen products with both UVA and UVB protection in them are an important part of a comprehensive sun protection regimen. The AADA, therefore, heartily approves of the agency's determination to improve the monograph by developing UVA-specific standards, and supports a delay of reasonable duration so an amendment to this effect (to 21 CFR 352) can be drafted.

**UVA Radiation and the Skin**

Available data on UVA radiation suggests that UVA exposure may have an even greater role in long-term sun damage than previously thought. This is because UVA radiation indirectly causes DNA damage, is nearly 20-fold more abundant than UVB, and it is 100 times more likely that UVA photons will reach the dermis, the site of many photoaging changes and skin cancer. Furthermore, UVA passes unfiltered through window glass, penetrates deeply into the skin, and is for the most part impervious to altitude and atmospheric conditions. That the specific UV wavelengths responsible for causing skin

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cancer and photoaging have yet to be identified does not in any way lessen the need for including UVA-specific ratings in the government's sunscreen monograph.

### **The AAD Consensus Conference on UVA Protection in Sunscreens**

The May 21, 1999 version of the sunscreen monograph (64 FR 27666) did not address UVA due to a lack of agreement over testing methods to measure the effectiveness of UVA protection in sunscreens. As advocates for skin protection and the physicians trained to furnish comprehensive care to patients with skin conditions and diseases, dermatologists were concerned about this omission in the monograph. The American Academy of Dermatology (now known as the AAD/AADA since converting in 2001 to a 501(c)(3) / 501(c)(6) organization) responded to the situation by hosting a scientific consensus conference in Washington, D.C. on February 4, 2000. Participants included a roster of those individuals and entities best qualified to address the issue of UVA measurement and labeling: (1) practicing and research dermatologists, (2) representatives from the FDA and the Environmental Protection Agency, (3) representatives from U.S., U.K, and European pharmaceutical and cosmetic industries, and (4) representatives from the photobiologic communities. The primary goals of the conference were to develop an agreement on the method(s) for determining UVA sunscreen protection, and to provide recommendations to the FDA for methods of assessment and labeling of sunscreen products for UVA protection. A summary of the proceedings and recommendations of the conference were published in the March 2001 *Journal of the American Academy of Dermatology*, which is attached for your review.

As the conference organizer, I can attest that all the program goals were met. Further, these goals answer to the priorities and concerns of the FDA with respect to UVA in sunscreens. FDA representative John Lipnicki enunciated these concerns at the conference, as follows:

“...”broad spectrum” claims should be supported by evidence of significant and meaningful absorption across the UVB/UVA spectrum, and should not mislead, confuse, or provide a false sense of security to the public. Applicable test data must be relevant to product labeling, and an indication on a sunscreen label must be clinically meaningful.”

The AADA approved an eight-point policy for UVA protection in sunscreens based on recommendations emerging from the consensus conference. It is hoped that the FDA will agree with us that this policy should serve as the basis for the UVA standards that will be added to the government's sunscreen monograph.



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### **The AADA Policy for UVA Protection of Sunscreens**

- Sunscreen UVB protection, as reflected by SPF, should be the primary consideration for sunscreen potency.
- The in vitro critical wavelength method is a criterion for a broad-spectrum claim. The threshold for this claim should be 370 nanometers (nm).
- The critical wavelength method must be combined with an in vivo method; the latter could be either persistent pigment darkening (PPD) or protection factor in the UVA (PFA). A minimum of a 4-fold increase in PPD or PFA value in the presence of sunscreen is recommended.
- Only sunscreens that fulfill the above in vitro and in vivo criteria can be labeled as "broad spectrum."
- No sunscreen that has only UVA protection may claim to be a "broad-spectrum" sunscreen.
- An increase in the SPF must be accompanied with a proportional increase in the UVA protection value. It is recommended that these "proportional" values be determined jointly by the FDA and the industry.
- A threshold pass/fail labeling for broad-spectrum UVA protection is recommended. Therefore, sunscreens fulfilling the above criteria would be labeled simply as "broad spectrum." This would minimize confusion to consumers. The specifics of the threshold (critical wavelength, PPD/PFA value, and the UVA/UVB proportionality) could be displayed in fine print on the back of the container.
- More funding should be provided for radiation biology research to help elucidate UVA mechanisms of injury.

### **UVA Protection Determination Methods**

The AADA urges the FDA to require that sunscreen manufacturers subject their products to both in vivo and in vitro critical wavelength testing if they wish to brand their products as "broad spectrum" sunscreens. A product that has been subjected to a single form of UVA testing does not qualify as one that provides broad-spectrum protection. A sunscreen that has only UVA protection in it likewise does not qualify as one that provides broad-spectrum protection.

Both the PPD and PFA tests (the in vivo methods) are widely recognized and easily duplicated means of assessing the amplitude or depth of UVA protection in a sunscreen. We recommend at least a 4-fold increase in PPD or PFA value in sunscreen products, recognizing that many products may have PPD/PFA values of greater than 4. The critical wavelength test (an in vitro method) measures the breadth or width of UV protection in sunscreen. The AADA strongly recommend that the FDA uses a critical wavelength of 370 nm as threshold. In combination, these



two testing methods are the most reliable and scientifically sound ways available of assessing the UVA protection in sunscreen products. For this reason, these methods should be included in the monograph.

Sunscreens with higher SPF values must include a proportionate increase in the UVA protection value as well. Raising the UVA protection value in high-SPF sunscreen products will guarantee that the breadth of overall UV protection is not “cancelled out” by SPF increases. This is an important consideration that must be addressed in the monograph so that sunscreens will in fact provide reliable, broad-spectrum protection. The AADA recommends that the proportional values for SPF and UVA filtering in sunscreens be determined together by the FDA and the sunscreen industry.

The AADA chose not to adopt the immediate pigment darkening (IPD) method as part of its policy. This *in vivo* test requires a brief dose of UVA exposure after which skin coloration should be immediately assessed. However, the brown-gray skin coloration that fades within minutes of UVA irradiation provides only a brief “marker” that can easily pass unnoticed or be misinterpreted if not immediately observed, making the IPD method less practical than the PPD and PFA methods.

### **UVA Protection Labeling**

A key goal of the sunscreen monograph is to establish product labeling that imparts essential information to consumers and their health care providers that, while being functional and straightforward, will also raise confidence in the effectiveness of the sunscreens used by Americans. In short, consumers need to know in “plain English” that the sunscreen they use offers trustworthy sun protection.

The testing methods supported by the AADA are the first step toward guaranteeing the overall quality of sunscreens in general, and specifically the effectiveness of UVA protection. Practical labeling builds upon the testing standards and is necessary to improve the likelihood that consumers will use sunscreens. Accordingly, we strongly recommend that a “pass/fail” approach be adopted for determining whether “broad-spectrum” protection is included on sunscreen product labels. Simply put, sunscreens meeting the abovementioned UVA testing criteria would be designated as providing “broad-spectrum” protection under this pass/fail system. The general public easily understands the pass/fail concept. For clinicians and other individuals who might require more detailed information, we further recommend that the specifics of the pass/fail parameters (e.g., PPD/PFA value, critical wavelength, and the UVA/UVB proportionality) be displayed in fine print on the back of the sunscreen container. This two-pronged approach to sunscreen



labeling has the additional merit of not being likely to require much space on the label itself.

### **High SPF Sunscreen Products**

The AADA reiterates its long-standing recommendation that sunscreens with an SPF factor higher than 30 list the specific SPF value on the label and packaging. At present, the monograph requires that sunscreen be rated according to performance categories, with “30+” or “30 plus” being the maximum SPF allowed to indicate high sunburn protection. Essential information about the protective value of high SPF sunscreen vanishes as a result of this ratings system. The AADA strongly recommends that this “cap” be lifted, or set to a higher value. There are two compelling reasons to do so. The SPF testing requires that sunscreen products be applied a 2mg/cm<sup>2</sup>, which translates to about 1 oz. of sunscreen to cover the entire skin surface. Studies have shown that in actual use, consumers apply a quantity of sunscreen that is much less than the 2mg/cm<sup>2</sup> used in SPF testing; therefore, the SPF in a real use situation is significantly less than the SPF on the label. Further, persons with photosensitivity skin disorders, undergoing medical treatments that render them more sensitive to the sun, with the fairest skins, and children, among others, require the highest possible SPF protection in sunscreens. The incidence of skin cancer is also rising at an alarming pace, with a lifetime risk of invasive melanoma – the most deadly form of skin cancer – now at least 1 in 74. Thus, using a sunscreen with an SPF value of 50 instead of 35, for example, is a significant health matter for all persons wanting to maximize sun protection for themselves. As physicians and health care advocates, dermatologists are very concerned that Americans will be denied this critical information and therefore unable to employ the best possible sun protection as part of their sun protection regimen.

Truncated labeling, if left unchanged, is likely to affect the health of Americans in another harmful way, too. The incentive for sunscreen manufacturers to develop, produce, and market products with high SPF values will evaporate if improvements in sunscreen formulation cannot be recognized by the listing of specific SPF values on labels and packaging.

For these reasons, the AADA strongly urges the FDA to change its policy on high SPF sunscreen labeling as part of the delay with implementation of the monograph.

### **Effective Date of Monograph**

Lastly, the AADA asks that the FDA move up the anticipated date for implementation of the monograph’s OTC sunscreen standards so that these standards take effect before 2005. The monograph has been under development for more than two



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decades; Americans have waited long enough for the standardization of sunscreen formulation, testing, and labeling to ensure the availability of dependable, high quality products. At present, the United States is one of the very few industrialized countries that have a lack of clarity on this issue. As dermatologists concerned about sun protection, we advocate the use of sunscreen for the promotion of healthy skin habits, and therefore are extremely hopeful that this delay will not be of much longer duration. In this vein, the proceedings of the UVA consensus conference, summarized in the AADA policy, represent a body of immediately accessible knowledge that should be tapped by the agency as it drafts the monograph amendment. The availability of this data from the relevant stakeholders, it is hoped, would substantially shorten the amount of time needed to draft the monograph amendment.

**Conclusion**

Thank you for considering our recommendations for the content and effective date of the sunscreen monograph amendment. Please contact Laura Saul Edwards in our Washington, D.C. office at 202/842-3555 or [ledwards@aad.org](mailto:ledwards@aad.org) if I can respond to questions or concerns the FDA has regarding our policy or recommendations.

Sincerely,

Henry W. Lim, M.D.  
Chair, AADA Environment Committee

HWL/lse  
Enclosure

CC: Fred F. Castrow, II, M.D, President  
AADA Environment Committee Members  
Tom Conway, Executive Director  
John Barnes, Associate Executive Director, Government Affairs & Health Policy

## American Academy of Dermatology Consensus Conference on UVA protection of sunscreens: Summary and recommendations

Washington, DC, Feb 4, 2000

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Kevin Cooper, MD,<sup>e</sup> Warwick Morison, MD,<sup>f</sup> Vincent A. DeLeo, MD,<sup>g</sup> and  
Lubomira Scherschun, MD<sup>a</sup> *Detroit, Michigan; Oklahoma City, Oklahoma; Vienna, Austria;*  
*Boston, Massachusetts; Cleveland, Ohio; Baltimore, Maryland; and New York, New York*

**T**he incidence and mortality from skin cancer increase yearly. Of paramount concern is the high incidence rate of cutaneous malignant melanoma. Currently, the efficacy of sunscreens is assessed by sun protection factor (SPF) measurement, which quantifies protection against erythemogenic wavelengths, predominantly in the ultraviolet B (UVB) spectrum (290-320 nm). Although 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.

Growing indirect evidence suggests a relatively greater role for UVA in long-term sun damage than in acute effects such as sunburn, tanning, and vitamin D synthesis, all of which are overwhelmingly attributable to UVB. UVA has several unique characteristics compatible with such a role: (1) it constitutes about 5.0% of the terrestrial profile of sunlight, whereas UVB only makes up 0.5%; (2) it is not filtered by win-

### *Abbreviations used:*

AAD: American Academy of Dermatology  
FDA: Food and Drug Administration  
IPD: immediate pigment darkening  
PFA: protection factor in UVA  
PPD: persistent pigment darkening  
SPF: sun protection factor

dow glass; (3) it has little temporal flux attenuation; (4) it is relatively unaffected by altitude and atmospheric conditions; and (5) it has deep cutaneous penetration. Therefore in sunlight reaching the surface of the earth, UVA is almost 20-fold more abundant on average compared with UVB. UVA is present all day and throughout the year (although there is variation in the irradiance throughout the day and the season of the year) and reaches skin through windows. The probability that each incident photon will reach the dermis is 5 times greater for UVA, so that  $5 \times 20 = 100$  times more UVA than UVB photons reach the dermis, the site of many photoaging changes. In addition, it has been shown that UVA radiation causes oxidative damage to guanine bases in DNA indirectly, through a free radical-mediated mechanism.

In May 1999 the Food and Drug Administration (FDA) published a sunscreen monograph, but because of the lack of agreed-upon methods of measurements, UVA protection by sunscreens was not addressed in the monograph. Because of the concerns of the American Academy of Dermatology (AAD) on this issue, a UVA Sunscreen Working Group was created by Darrell Rigel, MD, then President of the AAD. This working group (chair: Henry W. Lim, MD; members: Kevin Cooper, MD,

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Vincent DeLeo, MD, Barbara Gilchrest, MD, Herbert Höningmann, MD, Warwick Morison, MD, and Mark Naylor, MD) first convened in New York City on July 29, 1999 to review the available *in vivo* and *in vitro* methods of UVA protection. After this meeting and subsequent telephone conference, the task force recommended that an AAD-sponsored consensus conference be held to provide a forum for discussion on this topic.

The above recommendation was approved by the AAD, and a full-day consensus conference was held in Washington, DC, on Feb 4, 2000. Meeting participants included members of the AAD, federal agencies (FDA, Environmental Protection Agency), representatives from the United States, United Kingdom, and European cosmetic and pharmaceutical industries, and representatives from the photobiologic communities (American Society for Photobiology, Photomedicine Society, and The Skin Cancer Foundation).

#### CONFERENCE GOALS

Five goals provided a discussion framework for the conference participants:

1. To create an open dialogue among members of the medical and scientific communities, federal agency representatives, and industry leaders
2. To present and discuss the available *in vitro* and *in vivo* methods of UVA sunscreen protection determination
3. To develop a consensus on the method(s) of determining UVA sunscreen protection
4. To develop a consensus on consumer labeling of UVA sunscreen protection
5. To provide recommendations to the FDA regarding methods of assessment and labeling of sunscreen products regarding UVA protection

#### CONFERENCE PROCEEDINGS

The conference commenced with a welcome and opening remarks from Darrell S. Rigel, MD (New York City), who stated that the lifetime risk of invasive melanoma in the United States has gone from 1 in 1500 in 1935 to 1 in 250 in 1980, and it has now reached 1 in 74 in 2000. The AAD has advocated the use of sunscreens as a component of the total sun protection measures. Although there is an effective way of measuring protection from UVB, there is not a standardized method to measure the efficacy of UVA blocking.

The conference organizer, Henry W. Lim, MD (Detroit, Mich), outlined the genesis and the purpose of the consensus conference. He indicated that the conference was organized to facilitate a discussion among members of the AAD, industry, and the photobiology community, with the aim of generating a con-

sensus and providing a recommendation to the FDA. He was followed by Barbara A. Gilchrest, MD (Boston, Mass), who reviewed the biologic effects of UVA radiation. She emphasized that rational testing and labeling for UVA sunscreen protection is made difficult by the present lack of information regarding the action spectra for the most significant forms of photodamage for normal skin; that is, the UV wavelengths principally responsible for melanoma and photoaging are unknown. In humans, the efficacy of UV in causing sunburn has been determined experimentally; it decreases exponentially with wavelengths from 300 to 400 nm. Formation of DNA photoproducts, such as thymine dimers, also determined in human volunteers, has an identical action spectrum. In combination with available epidemiologic and animal data and with the well-established role of photoproducts in DNA mutations and subsequent malignancy, this action spectrum strongly implicates UVB wavelengths in photocarcinogenesis, at least in development of squamous cell carcinomas, and suggests that UVA plays a relatively insignificant role. However, the lack of a direct linear correlation between sun exposure and melanoma risk, the recognized ability of UVA to cause at least some oxidative DNA damage through generation of free radicals, the lack of identified "UVB signature mutations" in melanomas (perhaps because of present ignorance of the critical genes mutated during development of melanoma), and experiments in one species of fish and in opossums have led some authorities to hypothesize a disproportionately large role for UVA in melanoma than in other forms of skin cancer. Only new insights into melanoma pathogenesis will resolve this important question.

The situation is equally problematic for photoaging, in that experiments in imperfect animal models have yielded conflicting data regarding the relative ability of UVA and UVB to cause "aging," and there are no established short-term biomarkers for either dermal or epidermal photoaging changes that might permit experimental determination of an action spectrum in humans. In contrast to the above questions, however, many idiopathic photodermatoses and drug-induced photosensitivities have well-studied action spectra, in many instances peaking in the UVA1 (340-400 nm) range. Persons with these disorders, however, constitute only a small portion of sunscreen users.

John Lipnicki, a representative from the FDA (Rockville, Md), briefed the attendees about the government's priorities and concerns. Specifically, the FDA requested that "broad spectrum" claims should be supported by evidence of significant and meaningful absorption across the UVB/UVA spectrum, and should not mislead, confuse, or provide a false sense of security to the public. Applicable test data must be

relevant to product labeling, and an indication on a sunscreen label must be clinically meaningful.

The next section of the conference focused on the available in vivo and in vitro methods of testing UVA protection. In vivo methods discussed were immediate pigment darkening (IPD), persistent pigment darkening (PPD), and protection factor in the UVA (PFA or APF) determination, whereas the in vitro method was the critical wavelength ( $\lambda_c$ ) determination.

Christopher Irwin from Procter & Gamble (Cincinnati, Ohio) explained the IPD method of UVA assessment.<sup>1</sup> This in vivo response is a transient brown-gray skin coloration that occurs and fades within minutes of UVA exposure. Fitzpatrick skin types III, IV, and V are used for this test; dose requirement ranges from 1 to 5 J/cm<sup>2</sup>. It requires a single visit and a short irradiation time; however, its major limitation is the transient nature of the end point, which requires an immediate reading.

Dominique Moyal, PhD, from L'Oreal Research (Clichy, France) presented the PPD method.<sup>2,3</sup> This technique measures melanin photo-oxidation after UVA exposure. This technique is also valid for the assessment of photostability. Subjects with skin types II, III, and IV can be used for this testing. The end point of pigment darkening is stable between 2 and 24 hours after irradiation. UVA dose needs ranges from 8 to 25 J/cm<sup>2</sup> for pigment darkening; as such, it requires a high-intensity light source and up to 1 hour of irradiation of sunscreen-protected skin.

Curtis Cole, PhD, from Johnson and Johnson (Skillman, NJ) explained the method of determination of protection factor in the UVA (PFA).<sup>4</sup> Similar to the PPD method, reading is done at 24 hours. The end point is either erythema or tanning; as such, subjects with skin phototypes I-IV can be used.

In vitro critical wavelength ( $\lambda_c$ ) determination method was discussed by Brian Diffey, PhD (Newcastle, UK). Critical wavelength is defined as the wavelength below which 90% of sunscreen's UV absorbance occurs.<sup>5,6</sup> In this method, sunscreen is applied on a substrate, and UV absorbance is then measured from 290 to 400 nm. Therefore this is a measurement of the breadth or the width of UV protection, whereas in vivo measurement such as SPF is a reflection of the amplitude or the depth of protection. For a given sunscreen preparation, an increase in the SPF would result in an increase in absorbance at the UVB range, hence a decrease in the critical wavelength value; therefore, to maintain the same critical wavelength value, a more efficient UVA filter must be added into the preparation.

Patricia Agin, PhD, from Schering-Plough (Memphis, Tenn), and J. Frank Nash, PhD, from Procter & Gamble

(Cincinnati, Ohio), discussed several options in communicating the efficacy of UVA protection of products to consumers. These include UVA protection factor (which would be a number), qualitative measures (minimal, moderate, and maximal protection), or a pass/fail system (a threshold that all products must pass to make the "broad spectrum" claim).

International experience with sunscreen testing methods and labeling procedures was the topic of the subsequent section of the conference. James Ferguson, MD (Dundee, Scotland, UK), explained the Boots UVA Star System used in the United Kingdom since 1992. This is an in vitro measurement of the ratio of the product's UVA (320-400 nm) absorbance over its UVB (290-320 nm) absorbance. The UVA star labeling is placed in the back of the container. Herbert Hönigsmann, MD (Vienna, Austria), indicated that both SPF and PPD numbers are used in products sold in Austria. Robin Marks, MD (Melbourne, Australia), described the Australian/New Zealand Standard, which has been in use since 1983.<sup>7,8</sup> This Standard, based on in vitro testing, specifies that a "broad spectrum" claim can be made if the product fulfills either one of the following criteria: (1) an 8- $\mu$ m layer of the product does not transmit more than 10% of radiation between 320 and 360 nm or (2) a 20- $\mu$ m layer of the product does not transmit more than 1% of radiation between 320 and 360 nm. In addition, all broad-spectrum products must have an SPF of not less than 4. This is accompanied by a widespread effort of public education. Heiner Gers-Barlag, PhD, from Beiersdorf AG (Hamburg, Germany) explained that the Australian Standard is currently used in Germany.

After the above presentation, the approximately 80 participants were assigned to 1 of 3 discussion break-out groups. Each group was asked to specifically address questions regarding UVA sunscreen protection determination method(s) and labeling. Three group leaders, Kevin Cooper, MD, Vincent DeLeo, MD, and Mark Naylor, MD, directed the discussion groups.

The recommendations from the discussion groups were further discussed by the AAD UVA Sunscreen Working Group after the conference. The following are the AAD's final recommendations for UVA protection of sunscreens:

1. Sunscreen UVB protection, as reflected by SPF, should be the primary consideration for sunscreen potency.
2. The in vitro critical wavelength ( $\lambda_c$ ) method is a criterion for broad-spectrum claim. The threshold for this claim should be 370 nm.
3. The critical wavelength method must be combined with an in vivo method; the latter could be

either PPD or PFA. A minimum of a 4-fold increase in PPD or PFA value in the presence of sunscreen is recommended.

4. Only sunscreens that fulfill the above in vitro and in vivo criteria can be labeled as "broad spectrum."
5. No sunscreen that has only UVA protection may claim to be a "broad-spectrum" sunscreen.
6. An increase in the SPF must be accompanied with a proportional increase in the UVA protection value. It is recommended that these "proportional" values be determined jointly by the FDA and the industry.
7. A threshold pass/fail labeling for broad-spectrum/UVA protection is recommended. Therefore sunscreens fulfilling the above criteria would be labeled simply as "broad spectrum." This would minimize confusion to consumers. The specifics of the threshold (critical wavelength, PPD/PFA value, and the UVA/UVB proportionality) could be displayed in fine print on the back of the container.
8. More funding should be provided for radiation biology research to help elucidate UVA mechanisms of injury.

In summary, the AAD recommends use of a sunscreen with SPF 15 or higher that meets the UVA protection criteria described above.

## CONCLUSIONS

The AAD consensus conference concerning UVA protection of sunscreens provided a setting for interaction among members of the AAD, industry, government agencies, and the photobiology community. It is hoped that the recommendations developed at the conference will assist the FDA in completing the final sunscreen monograph. The goal of these recommendations is to establish standardized, effective, yet practical UVA sunscreen testing methods and provide labeling that is understandable to consumers. Ultimately, public education on sun avoidance, the use of protective clothing and hats, and the use of broad-spectrum sunscreens with an SPF of at

least 15 should reduce the incidence of skin cancer in the United States.

The time and effort of the speakers who participated at the conference are gratefully acknowledged: Patricia Agin, PhD (Memphis, Tenn); Curtis Cole, PhD (Skillman, NJ); Kevin Cooper, MD (Cleveland, Ohio); Vincent A. DeLeo, MD (New York, NY); Brian Diffey, PhD (Newcastle, UK); James Ferguson, MD (Dundee, Scotland, UK); Heiner Gers-Barlag, PhD (Hamburg, Germany); Barbara A. Gilchrest, MD (Boston, Mass); Herbert Hönigsmann, MD (Vienna, Austria); Christopher Irwin (Cincinnati, Ohio); Henry W. Lim, MD (Detroit, Mich); John Lipnicki, MD (Rockville, Md); Robin Marks, MD (Victoria, Australia); Dominique Moyal, PhD (Clichy, France); J. Frank Nash, PhD (Cincinnati, Ohio); Mark Naylor, MD (Oklahoma City, Okla); and Darrell Rigel, MD (New York, NY).

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## REFERENCES

1. Kaidbey KH, Barnes A. Determination of UVA protection factors by means of immediate pigment darkening in normal skin. *J Am Acad Dermatol* 1991;25:262-6.
2. Chardon A, Moyal D, Hourseau C. Persistent pigment darkening response as a method of evaluation of ultraviolet A protection assays. In: Lowe NJ, Shaath NA, Pathak MA, editors. *Sunscreens: development, evaluation and regulatory aspects*. 2nd ed. New York: Marcel Dekker; 1997. p. 559-82.
3. Stanfield JW, Edmonds SH, Agin PP. An evaluation of methods for measuring sunscreen UVA protection factors. In: Lowe NJ, Shaath NA, Pathak MA, editors. *Sunscreens: development, evaluation and regulatory aspects*. 2nd ed. New York: Marcel Dekker; 1997. p. 537-58.
4. Cole C. Multicenter evaluation of sunscreen UVA protectiveness with the protection factor test method. *J Am Acad Dermatol* 1994;30:729-36.
5. Diffey BL. A method for broad spectrum classification of sunscreens. *Int J Cosmet Sci* 1994;16:47-52.
6. Diffey BL, Tanner PR, Matts PJ, Nash JF. In vitro assessment of the broad-spectrum ultraviolet protection of sunscreen products. *J Am Acad Dermatol* 2000;43:1024-35.
7. *Sunscreen products—evaluation and classification*. Australian/New Zealand Standard. AS/NZ 2604-1997. Sydney: Standards Australia/Standards New Zealand; 1997.
8. Marks R. Summer in Australia: skin cancer and the great SPF debate. *Arch Dermatol* 1995;131:462-4.