

Sunscreen

Guidelines for New Efficacy Claims of Sunscreen Products

Task Force Committee for Evaluation of Sunscreen Function

1. Introduction

In 2002, the World Health Organization (WHO) published a report¹⁾ that urges people to refrain from sunbathing because the exposure of skin to ultraviolet (UV) is the leading cause of skin cancer and other skin problems. In Japan, the word “sunbathing” was deleted from the “Maternity and Child Health Notebook” in 1999; and in 2003, the Ministry of the Environment published the Guidance Manual on UV Protection (*Shigaisen Hoken Shidou Manual*), which describes in detail the harmful effects of UV on the human body and the importance of protecting yourself against it.^{2)*}

The deletion and publication were both based on the large volume of published material that delineates the harmful effects of UV on the human body. We reviewed publications that focus on the relationship between UV exposure and DNA damage and/or skin cancer, immunosuppression caused by UV exposure, and UV-induced damage to the epidermis and dermis, which is called photoaging. While plenty of research about the effects of UVB on the human body was performed before the 1990s, the focus then shifted to the effects on the human body of UVA, as well as UVA and UVB together, whose combined spectrum is closer to that of actual sunlight. The results showed that UVA itself can cause various kinds of skin damage while at the same time enhancing the harmful effects of UVB. Research has also demonstrated that cosmetics with appropriate efficacy for UV protection can help prevent the damage caused by UV exposure.

The standards of the Japan Cosmetics Industry Association (JCIA) are voluntary industry standards, and they are widely accepted in Japan for measuring sun protection factor (SPF)³⁾ and UVA protection efficacy.⁴⁾ These standards are generally applied in evaluating the UV protection claims of cosmetics. The stan-

dards were established so that consumers could choose products that best suited their specific needs. The standard should comply with the international harmonization of UV protection methodology and should include not only a UVB efficacy evaluation but also a UVA evaluation for the broader wavelength range. Regarding testing for SPF, the new International SPF Test Method⁵⁾ was adopted in 2003 in Japan after being jointly drafted by the European Cosmetic Toiletry and Perfumery Association (COLIPA), the Cosmetics Toiletry and Fragrance Association of South Africa (CTFA/SA), and the JCIA. The JCIA Standards for UV protection evaluation and labeling are cited in the Guidance Manual on UV Protection. The Guidance Manual also states that cosmetics can be used as protection against UV; indeed, it is widely recognized that cosmetics are a significant means of protecting against the harmful effects of UV rays. Since UV protection by cosmetics plays an important role in maintaining people's health and improving their quality of life (QOL), cosmetic manufacturers have been vigorously developing state-of-the-art technologies under the enactment of unified industry measurement standards. As a consequence, high-quality sunscreen products that are safe and manifest superior texture, as well as offering dependable UV protection, have been put out on the market.

Although the beneficial effects of sunscreen cosmetics had been recognized by the public with the advancement of sunscreen quality, the only efficacy claims approved by the Japanese Pharmaceutical Affairs Law were “*Hiyake wo fusegu* (prevention of sunburn)” and/or “*Hiyake ni yoru shimi sobakasu wo fusegu* (prevention of spots and freckles due to sunburn).” These expressions are just part of the efficacy that can be scientifically substantiated for sunscreen cosmetics, and consumers have not been fully informed

*(Note at translation: *Shigaisen Hoken Shidou Manual* was revised in 2006.)

of their beneficial functions. Thus, the industry requested that the situation be improved. In order to harmonize with requests from the industry, the Japanese Cosmetic Science Society (JCSS) held symposiums and seminars to discuss the issue. However, those activities did not result in the creation of a concrete strategy for improving the situation.

Subsequently, the JCSS organized the Committee for Studying Evaluation Methods for Cosmetic Functions as an ad hoc committee in 2003 in order to clarify the functions of cosmetics with special efficacy and to establish objective evaluation methods for them. Under that committee, four sub-committees were also created. Those sub-committees covered Anti-aging, Sunscreen, Skin Whitening, and Safety. The Task Force Committee for Evaluation of Sunscreen Function conducted a literature survey of publications regarding the protective efficacy of sunscreen against photoaging, for the purpose of establishing an acceptable framework for new sunscreen efficacy claims and the labeling requirements thereof.

We carefully analyzed publicized information regarding sunscreen efficacy, including scientific literature, in order to ascertain the situation in countries outside Japan and the measurement methods that had been internationally agreed upon, and we established these guidelines for new efficacy claims and the requirements for their labeling on sunscreen products. In view of the tremendous advances being made in scientific findings and measurement techniques, revision of the guidelines and the requirements for labeling new efficacy claims will be needed as and when appropriate.

In these guidelines the term "sunscreen products" covers all cosmetic products including quasi-drug cosmetic products that also have UV protection efficacy.

2. Preventive Effects of Sunscreen Products on Photoaging

The committee conducted a literature survey on the preventive effects of sunscreen products on photoaging and other forms of UV-related skin damage. Scientific and medical papers published up to 2003 were sorted according to four keywords (skin, damage, ultraviolet, and sunscreen) and then reviewed by the committee members.

2-1. Reduction of UV Damage in the Epidermis and Dermis

In a UV exposure experiment on 12 subjects that took place over six consecutive weeks (five days a week, 1 MED (Minimal Erythema Dose) of UV), Seite et al. found that the application of a broad spectrum sunscreen (SPF8, Protection Factor of UVA (PFA) 7.4) suppressed the increase of tenascin, the decrease of Type I procollagen in the dermis, and the increase of skin thickness. They also observed a reduced increase in the depth of skin surface microrelief and a reduced decrease in the density of skin surface texture. Therefore, they concluded that daily UV protection by the application of sunscreen products could diminish photo-induced skin damage.⁶⁾ Seite et al. also conducted a longer-term (13 weeks) UVA exposure experiment on human subjects. In that experiment, they found that the water content of the stratum corneum, skin elasticity, pigmentation, and the thickness of the stratum corneum were maintained at the same levels, and that tenascin expression and lysozyme deposition were effectively reduced by the application of a sunscreen product with UVA protection capacity, which eventually suppressed UV damage in the epidermis and dermis.⁷⁾

In an *in vitro* UV exposure experiment using a reconstructed three-dimensional human skin model, Bernerd et al.⁸⁾ found that the application of sunscreen products with SPF7 to the skin model resulted in the reduction of fibroblast death and alteration of the granular layer. They also reported that sunscreen products with the same SPF value but with stronger UVA protection efficacy were more effective in the reduction of skin damage.

When engineered human skin was irradiated with a solar simulator, Rouabhia et al.⁹⁾ observed that the application of sunscreen products with SPF28 suppressed destruction of the basal cell layer, separation of the epidermis and dermis, morphological changes in keratinocytes, a decrease in laminin content, and alteration of the basement membrane.

In a series of experiments that subjected hairless mice to UV irradiation, Kligman et al.¹⁰⁾⁻¹³⁾ found that the application of sunscreen products with SPF15 suppressed collagen damage and the overproduction of elastin fiber. Based on their findings, they concluded that sunscreen products with SPF15 were effective in preventing photoaging. They also reported that the ap-

plication of sunscreen products not only prevented photoaging but also protected skin that was already damaged from being further damaged due to additional exposure to UV.^{12), 13)}

2-2. Reduction of DNA Damage and the Development of Skin Cancer

In UV exposure experiments using hairless mice and three-dimensional human skin models, Gelis et al.¹⁴⁾ found that the application of sunscreen products suppressed p53 expression, the development of sunburn cells, and fibroblast death. They also reported that products with greater UVA protection showed greater effects and were concluded to be effective in the prevention of skin cancer.

In some UV irradiation experiments involving the epidermis, Al Mahroos¹⁵⁾ found that the application of sunscreen products with SPF15 suppressed thymine dimer formation; Liardet et al.¹⁶⁾ observed that sunscreen products with UVA and UVB protection capacities of SPF15 diminished DNA damage such as pyrimidine dimer formation and 8-OHdG formation; and Ling et al.¹⁷⁾ also found that sunscreen products with SPF15 inhibited thymine dimer formation. Cayrol et al.¹⁸⁾ investigated the effects of sunscreen products with different SPFs on fibroblast damage (unscheduled DNA synthesis), and they observed that the degree of reduction in unscheduled DNA synthesis became greater as the SPF value increased; they further stated that products with SPF values of less than 15 did not show any significant effects in this respect.

In UVB irradiation experiments involving human subjects, Van Praag et al.¹⁹⁾ demonstrated that sunscreen products with SPF10 were effective in preventing DNA damage since they suppressed the induction of cyclobutane-type thymine dimer formation. Bykov et al.²⁰⁾ reported that the degree of preventive effects of sunscreen products with SPF10 on the formation of cyclobutane-type thymine dimer as well as 6-4 photoproducts varied in each subject on the basis of the effectiveness of the products being used. Arase et al.²¹⁾ also reported that the ability of sunscreen products to prevent DNA damage in fibroblasts (pyrimidine dimer production) became greater as SPF value increased.

In a two-year clinical trial involving patients with actinic keratosis, Farmer et al.²²⁾ observed that sunscreen products with SPF29 reduced the emergence of newly developed actinic keratosis by 36 percent. In ex-

periments where mice were irradiated with UV, Horiki²³⁾ et al. found that sunscreen products with SPF60 were more effective than sunscreen products with SPF10 in terms of delaying the emergence of tumors and reducing the number of tumors that developed.

Guercio-Hauer et al.²⁴⁾ reported that the daily use of sunscreen products with SPF15 between infancy and adolescence reduced the lifetime incidence of non-melanoma skin cancer formation by 78 percent. In a study in which hairless mice were subjected to UV irradiation, Wulf et al.²⁵⁾ examined tumor formation and survival rates, and they observed that the application of sunscreen products delayed the emergence of skin tumors and improved the survival rates of the hairless mice.

2-3. Daily Application of Sunscreen Products

To prove the beneficial effects of daily, continuous usage of sunscreen products, some experiments involving human subjects were conducted that included “the intentional skipping of sunscreen application.” As a result of such skipping, an increase in thymine dimer formation,¹⁵⁾ an increase in sunburn cell formation, and a decrease in the number of Langerhans cells²⁶⁾ were all observed; such evidence substantiated the beneficial effects of the daily application of sunscreen products.

In view of the findings summarized above, the daily application of sunscreen products with UVA and UVB protection efficacies of at least SPF15 can prevent UV-induced photoaging of the skin and delay its progress.

3. Situation of Sunscreen Products in Japan

There are four product categories that the Japanese Pharmaceutical Affairs Law governs: drugs, medical devices, quasi-drugs, and cosmetics. Sunscreen products fall into the category of cosmetics. The only UV-related efficacy claims approved for cosmetics under the law are as follows:

- “Prevention of sunburn”
- “Prevention of spots and freckles due to sunburn.”

In the JCIA Standards (Sun Protection Factor Test Method (2003 revised version), Measurement Standards for UVA Protection Efficacy), the preventive capacities of sunscreen products against UVA and UVB, described as “PA” (Protection grade of UVA) and “SPF”, are designated as follows:^{3), 4)}

- SPF is labeled in figures up to 50 (if above 50, it is

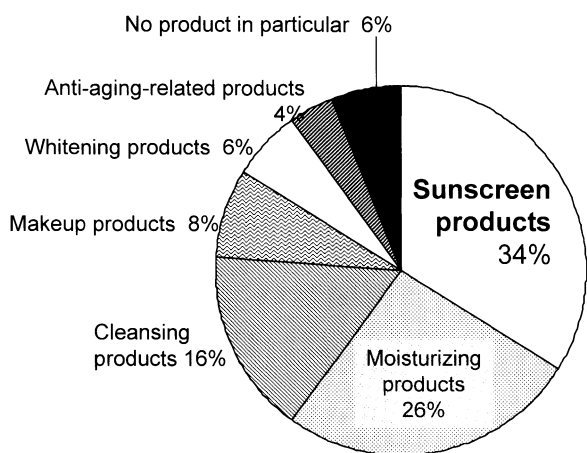


Fig. 1. Cosmetic Products that Dermatologists are Satisfied²⁷⁾

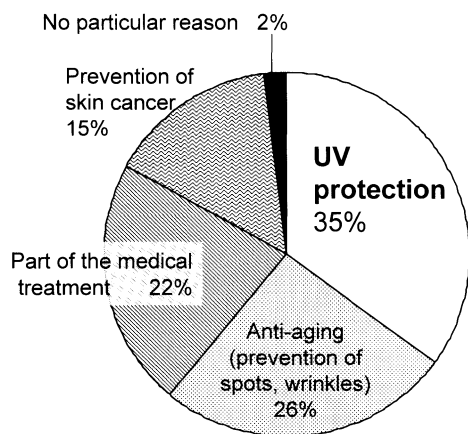


Fig. 2. Reasons for Recommendation of Sunscreen Products to Patients²⁷⁾

labeled as SPF50+)

- PA is labeled as PA+ (PFA value from 2 to less than 4), PA++ (PFA value from 4 to less than 8), or PA+++ (PFA of 8 and over)

The SPF Measurement Standards are based on the International SPF Test Method, which was published in English⁵⁾ and created through the harmonizing deliberations of the JCIA, COLIPA, and the CTFA/SA. The Measurement Standards for UVA Protection Efficacy were originally established in Japan and implemented there ahead of other countries. However, other efficacy claims such as those pertaining to the prevention of photoaging—which are gradually being put on the labels of sunscreen products in several major countries due to the growing awareness of UV protection—have not yet been approved in Japan.

On the other hand, Japanese dermatologists have

heightened expectations for sunscreen products, as illustrated in Fig. 1 and Fig. 2, which reflect the results of a questionnaire survey conducted by Matsunaga²⁷⁾ involving 618 dermatologists. According to the survey, the cosmetics item that dermatologists were most satisfied with was sunscreen products. The primary reason why they recommend sunscreen products to their patients was for “UV protection,” and the secondary reason was for “anti-aging” (the prevention of spots and wrinkles). This indicates that Japanese dermatologists recognize the UV protection effects of those products and their effectiveness in preventing photoaging.

4. Situation of Sunscreen Products in Other Countries

In most countries, sunscreen products are categorized either as drugs (OTC (over-the-counter) drugs or therapeutic goods) or as cosmetics. In those countries where sunscreen products are categorized as drugs, there are regulations in place that delineate the efficacy claims they are allowed to make. In some of those countries, if the products meet stipulated SPF values (15+, 30+, etc.) or have UVA protection efficacy (products with UVA blocking agents, Broad Spectrum Sunscreens, etc.), efficacy claims related to photoaging are also possible. On the other hand, in countries and regions where sunscreen products are categorized as cosmetics, there are no clear regulations. In the EU, for example, each manufacturer seems to take responsibility for the efficacy claims it makes on the labels of its products.** SPF values, which represent sun protection efficacy and are labeled on sunscreen products, are also measured based on the International SPF Test Method⁵⁾ in those countries.

Below is a review of the situation as of September 2005 regarding efficacy claims in the United States, Australia, and Canada, where sunscreen products are categorized as OTC drugs and/or therapeutic goods.

4-1. United States

In the United States, sunscreen products are categorized as OTC drugs and therefore do not need a prescription. However, when they are supplied in the form of lotions, creams, and the like, they come under the regulations that govern cosmetics (which require the listing of all ingredients).

** (Note at translation: The EU committee made a recommendation for claims on sunscreen products in 2006.)

The OTC Sunscreen Final Monograph issued in May 1999 listed UV protection-related efficacy claims.²⁸⁾ In describing a product, the following two claims are permitted on labels under the heading “Use”:

- “Helps prevent sunburn”
- “Higher SPF gives more sunburn protection.”

The expressions “sunblock” and/or “all-day protection” are prohibited.

The UV protection efficacy of a product is categorized into three levels and can be claimed on the PDP (Principal Display Panel) of the label under the heading “Other information”:

- “Minimal sunburn protection” (SPF2 to under 12)
- “Moderate sunburn protection” (SPF12 to under 30)
- “High sunburn protection” (SPF30 or above).

It is also recommended to make the following “sun-alert” statement under the heading “Other information”: “Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.”

When the OTC Sunscreen Final Monograph was issued by the FDA in May 1999, the protection efficacy of sunscreen products against photoaging was still under consideration. By the time the final report was released, the following efficacy claims regarding UVA protection by avobenzene²⁹⁾ and zinc oxide³⁰⁾ proposed in the OTC Sunscreen Tentative Final Monograph were allowed on labels:

- (1) “Broad spectrum sunscreen.”
- (2) “Provides (select one of the following: “UVB and UVA” or “broad spectrum”) protection.”
- (3) “Protects from UVB and UVA (select one of the following: “rays” or “radiation.”)
- (4) (Select one of the following: “Absorbs,” “Protects,” “Screens,” or “Shields”) “throughout the UVA spectrum” (when it contains avobenzene) or “within the UVA spectrum” (when it contains zinc oxide).
- (5) “Provides protection from UVA rays that may contribute to skin damage and premature aging of the skin.”

In the USA, requests for the final report on measurement procedures and efficacy claims regarding UVA

have been made since the last publication of the OTC Sunscreen Final Monograph in May 1999. However, as of September 26, 2005, when this manuscript was being written, the new OTC final monograph³¹⁾ had not been published yet.***

4-2. Activities of the Skin Cancer Foundation

The Skin Cancer Foundation, a private sector organization in the United States, provides the “Seal of Recommendation” to sunscreen products which meet the following criteria:³²⁾

- A sun protection factor (SPF) of 15 or greater
- Validation of the SPF number by testing on 20 people
- Acceptable test results for phototoxic reactions and contact irritation
- Substantiation for any claims that a sunscreen is water- or sweat-resistant.

The application of the seal is now extended to sunglasses, window glass film, umbrellas, clothing, and other items as well.

4-3. Australia

In Australia, sunscreen products are categorized as “therapeutic goods.” In 2002, the Therapeutic Goods Regulations³³⁾ were amended and the following efficacy claims regarding UV protection are now described in the Australian regulatory guidelines for OTC medicines.³⁴⁾

If a sunscreen product meets the criteria for a Broad Spectrum Sunscreen, its label is permitted to claim that it can “aid in the prevention of premature skin aging” (or words to that effect). If a sunscreen product meets the criteria for a both Broad Spectrum Sunscreen and has SPF30+, and if phrases such as “avoidance of long-term sun exposure” and “importance of wearing protective clothing, a hat, and eyewear” are emphasized and labeled together, that product is permitted to claim that it:

- “May assist in preventing some skin cancers”
- “May reduce the risk of some skin cancers.”

For the evaluation of a Broad Spectrum Sunscreen with UVA protection efficacy, three measurement procedures using UVA absorption as a standard are established (liquid procedure, thin film procedure, and plate procedure). If a product meets either of the following

***(Note at translation: FDA proposed the amendment of final monograph in August, 2007.)

criteria, it is certified and labeled as a Broad Spectrum Sunscreen.³⁵⁾

- When the product is applied as a membrane at 8 μm thickness, the absorption in the 320–360 nm range should be less than 10 percent.
- When the product is applied as a membrane at 20 μm thickness, the absorption in the 320–360 nm range should be less than 1 percent.

4-4. Canada

Sunscreen products are categorized as “therapeutic products” in Canada. In the Therapeutic Products Directorate revised in 2002,³⁶⁾ the following efficacy claims can be put on the label in addition to the SPF value:

- Sunburn protectant, sunscreen, or sunblock
- Helps prevent, or protects, from sunburn
- Blocks, filters, or screens certain of the sun’s harmful Ultraviolet or UV rays to help prevent sunburn
- For sun-sensitive or fair-skinned persons, to prevent sunburn
- For skin where exposure to Ultraviolet (or UV) light is contraindicated (only applicable for products of SPF greater than 15)
- Provides X times your natural protection against sunburn
- Gives sunburn protection
- The liberal and regular use of this product over the years may help reduce the chance of premature aging of the skin
- UVA/UVB sunburn protection, UVA/UVB protection
- Broad spectrum UVA/UVB protection, broad spectrum protection against UVA/UVB rays
- Absorbs throughout the UVA/UVB spectrum to provide sunburn protection
- Protects against UVA/UVB rays.

If a sunscreen product meets the definition of a Broad Spectrum Sunscreen and has SPF15 and over, the following statement is permitted on the label: “The sun may cause sunburn, premature aging of the skin and skin cancer. Avoiding the sun, wearing protective clothing and the regular use of sunscreen over the years may reduce the chance of these harmful effects.”

5. Efficacy Claims

The committee proposes that the following efficacy

claim should go on the labels of sunscreen products in Japan that manifest the appropriate UV protection efficacy: “Daily use of sunscreen products can prevent the development of wrinkles and spots (photoaging) caused by the long-term exposure to UV.”

When sunscreen products are used, of course, certain problems can occur such as the unintentional skipping of an application, the removal by bathing, rubbing or wiping, or the application of a sunscreen product with an inappropriate UV protection efficacy given the prevailing environmental conditions. In light of this, and because photoaging results from long-term exposure of skin to UV radiation, we have prepared several candidate cautionary statements pertaining to UV protection as part of our efforts to enlighten consumers. Any cautionary statement chosen would appear on the label together with the efficacy claim. We offer the following suggestions:

- “Take everyday measures against the harmful effects of UV.”
- “Apply sunscreen products every 2–3 hours.”
- “Apply sunscreen products again after you have wiped your skin with a towel or a cloth.”
- “Protect your body from UV by wearing a broad-rimmed hat, using an umbrella, and/or wearing long-sleeved garments.”
- “Try to limit the time you spend outside during those hours UV from the sun is at its strongest (10 am to 2 pm).”

6. Requirements for the Efficacy Claim

The SPF measurement procedure mentioned in these guidelines is the international standard that has been in use for several years; the measurement procedure for PA was established in Japan, ahead of the rest of the world. Since both measurements have been followed and widely used in Japan, the efficacy claim proposed by the committee should be applied and labeled together with SPF and PA values, following the conditions mentioned below.

6-1. Recommended SPF and PA Values

The efficacy claim proposed by the committee should be put on the labels of sunscreen products that meet UV protective efficacies of at least SPF15 and PA+. The requirement of SPF15 or above was established based on the survey of the scientific reports mentioned previously, and it is considered to be appropriate

protection against UVB in daily life. On the other hand, while the need for UVA protection is fully recognized, there is not sufficient scientific evidence to establish the relationship between the level of the PA value and the prevention of photoaging. Therefore, PA+ or above (PFA2 or above) was established as the minimum level required for UVA protection. In the future, revisions should be considered when the need to revise these requirements arises as new scientific research data become available.

The measurements of SPF and PA should be conducted in compliance with the voluntary industry standards at a third-party organization. The manufacturer or distributor of sunscreen products should keep an official report about the results of the measurements at least as long as the product is on the market. The measurement standards for SPF and PA, in particular those for the former, have been revised with advances in technology, and measurements must be conducted in compliance with the new standards once they become effective. As of October 2006, the 2003 revised version³⁾ of the JCIA's SPF measurement standard was still in force, and the 2006 version is already scheduled.*****

6-2. Target Cosmetic Items

The efficacy claim proposed by the committee covers all sunscreen products that meet the UV protection efficacy of SPF15 and PA+ or over. However, sunscreen products that are not specifically for skin care purposes, including hair care products, eyelash products, and others, are not included, even though they have sufficient UV protection effects.

At present, most products classified as makeup (lipstick, eye shadow, eye liner, cheek blush, etc.) are considered to be items for the purpose of "beautifying, promoting attractiveness, and improving appearance" under the definition of cosmetics in the Pharmaceutical Affairs Law, so they are not formulated and produced to have UV protection effects. There are no makeup products that currently meet the above standards for UV protection effects. However, it is possible that some makeup products will manifest sufficient UV protection effects in the future and be launched in the market on that basis. But because the UV protection effects of such makeup products would be limited to specific skin regions, the combined application with products that

cover the larger skin region would be necessary. In this respect, cautionary statements of some sort will be required with those products so that consumers understand the importance of the combined application of appropriate sunscreen products in order to prevent photoaging.

The efficacy claim proposed by the committee covers sunscreen products that provide UV protection effects through the absorption, scattering, and screening of UV radiation on the skin surface. If new sunscreen products are developed that achieve prevention effects in the skin after the UV has penetrated into the epidermis, then a new efficacy claim and new labeling requirements should be separately discussed and determined in conjunction with the appropriate safety considerations.

6-3. Safety Requirements

In compliance with the safety evaluation guidelines issued by the JCSS's Task Force Committee for the Evaluation of Safety, sunscreen products that claim efficacy should go through the appropriate safety evaluations.

7. Proposal for the Labeling of Efficacy Claims

It will be difficult for consumers to fully understand the efficacy claim proposed by the committee and to enjoy the benefits thereof if manufacturers do no more than merely stamp the claim on the labels of their products. However, by conducting further activities together with dermatologists and other medical professionals, companies can go a long way in helping to inform consumers of the importance of preventing photoaging as well as the appropriate preventive measures that must be taken to achieve that.

Also, sunscreen products that plan to put the efficacy claim proposed by the committee on their labels should follow and meet the requirements mentioned previously, and the establishment of a unified check-up system controlled by a third party to ensure the results of the measurements for SPF and PA as evidenced in reports is anticipated to prove and state the products' efficacy.

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***** (Note at translation: JCIA's new SPF measurement standard has taken effect in July 2007.)

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