JAPAN COSMETIC INDUSTRY ASSOCIATION

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September 5, 2000

The Dockets Management Branch(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852 USA

Dear Sir,

Please find the enclosed comments of Japan Cosmetic Industry Association on Sunscreen Drug Products for Over-the-Counter Human Use(Federal Register/Vol.65,No.111/Thursday, June 8, 2000/ Rules and Regulations).

Sincerely,

Minoru Fukuda

Minoru Fukuda, PhD.
Chairman
Ultra Violet Protection Task Force
Japan Cosmetic Industry Association

September 5, 2000

Comments of Japan Cosmetic Industry Association (JCIA) on Sunscreen Drug Products for Over-the-Counter Human Use

1. Comments on the High SPF Test Method

1.1 Comments on the high-SPF standard sample

P3 (3% Paramethoxy cinnamate 2-ethylhexyl, 0.50% 4-tert-butyl-4'-methoxybenzoylmethane, 2.78% 2-phenylbenzimidazole-5-sulfuric acid) that has been adopted by the JCIA and COLIPA as a standard sample should be adopted as a high-SPF standard sample. The JCIA participated in the ring test of P3 presided over by COLIPA and has collected data on its own. The JCIA firmly believes that P3 will fully serve the purpose as a standard sample based on the data indicating a mean value of 15.1 (n: 324).

1.2 Comments on the number of subjects and exposure dose

The SPF measurement test method released by the JCIA on October 1, 1999 sets the minimum number of subjects at 10 and the dose increment of UV at 10% or less at SPF30 or more. The results obtained with a

high-SPF sample by this method are shown in the table below.

	USA facility	French facility
Average SPF Value	44.07	41.23
Standard Deviation	1.73	0.87
Standard Error	6.01	2.75
No. of Test Subjects	12	10
Confidence Interval (95%)	3.82	1.97

Based on these results, the increment of 10% or less in dose and 10 subjects are considered adequate. An immoderate increase in the number of subjects will demand the cosmetic industry of unnecessary spending on product development, and the cost increases will eventually be passed along to consumers.

2. Comments on the Upper Limit of SPF

Since even Japanese may suffer sunburns at SPF30, it is necessary to develop products of higher SPF. However, products labeled unreasonably high SPF values are not desirable for the following reasons.

(1) Unreasonably high SPF values will lead consumers to expect too much effectiveness of sunscreen products. This may help increase the UV dose exposed on the skin

to an objectionable extent. (2) It is not desirable in the interest of safety that UV absorbing agents be added to cosmetic products at high concentration. (3) Labeling of high SPF values will invite excessive, meaningless competition in the industry. Based on these points, the most reasonable SPF value is considered 50+. Accordingly, the upper limit of SPF values labeled on sunscreens should be increased to 50+.

3. Comments on the End Points of UVA Protection Efficacy

From the following standpoint, the end point of UVA protection efficacy should be the persistent immediate pigment darkening reaction. (1) The 8-MOP method will present ethical problems because the subjects may be left with severe injury. (2) The immediate pigment darkening reaction fades so fast that significant errors may be committed in the determination of an accurate end point. (3) Since the method that uses delayed erythema or delayed tanning as an end point needs large amounts of energy, it is undesirable from an ethical viewpoint because it restrains the subjects for a prolonged period of time. (4) It is obvious from SPF measurements that there is no consistency between *in vitro* and *in vivo* data. There is

no reason to believe that there is consistency between *in vitro* and *in vivo* data on UVA protection efficacy alone, and there is no reports related to such consistence available.

The persistent immediate pigment darkening, on the other hand, can be considered a suitable end point for the following reasons. (1) Relatively low dose will serve the purpose. (2) The reaction is stabilized in 2 to 4 hours. (3) There is little interindividual variability of the end point by observers. (4) The subject is left with no mark of irradiation. (5) The subject receives little or no injury. (6) The experiment can be conducted with high precision.

4. Comments on the labeling of UVA Protection Efficacy

UVA protection efficacy should be labeled as grades of effectiveness.

UVA protection efficacy had better be indicated in grades than in numerical values both because UVA irradiation induces various skin reactions, such as erythema, pigment darkening, skin cancer, and photodermatitis and because some action spectra of damages has not been determined.

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