

Johnson & Johnson
CONSUMER COMPANIES, INC.

VIA FEDERAL EXPRESS

August 31, 2000

Dockets Management Branch (HFA 305)
Docket No. 78N-0038
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

9236 00 SEP-1 10:19

Dear Sir or Madam:

The following submission contains comments filed by Johnson & Johnson Consumer Products Company to Docket No. 78N-0038.

These comments are in response to the notice published in the Federal Register, Volume 65, No 111 Thursday, June 8, 2000 regarding Sunscreen Drug Products for Over-the-Counter Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record

J & J Consumer Products urges the Agency to accept the proposals regarding UVA test methodology and labeling made herein. We also support the comments filed by CTFA and its member companies: Schering-Plough, Estee Lauder, L'Oreal, Bath & Body Works and our affiliate company, Neutrogena.

We believe that adoption of these proposals will expedite the finalization of a comprehensive Sunscreen Final Monograph

Sincerely,



Marjorie B. McTernan
Director, Regulatory Affairs
J & J Consumer Products Worldwide

Attachments
Submitted in triplicate

Johnson & Johnson
CONSUMER COMPANIES, INC.

August 31, 2000

Document Management Branch, Docket No. 78N-0038 (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, Maryland 20857

Re: Recommendations for Sunscreen Test Methodology and Labeling for UVA Protection

Dear Sirs:

JOHNSON & JOHNSON and its affiliated Consumer Franchise Companies currently markets a variety of topical products containing sunscreen actives, including products intended for use at the beach, outdoor sport activities, as well as daily moisturizer products with SPFs intended for protection from incidental sun exposure. We, with other members of our industry have worked in affiliation with the professional health care community to promote education of the public on the dangers of sun exposure. We have stressed the need to protect against both UVB and UVA damaging rays contained in sunlight throughout the calendar year. The points addressed in this recommendation letter are intended to help provide further information on testing methodologies and labeling that we believe will provide the consumer and the professional health care provider with information necessary for an informed decision on the most appropriate suncare protection product.

We believe the following points are necessary for product choice by the consumer:

Objectives:

1. SPF must be the pre-eminent factor for the choice of protection level - with UVA protection a secondary consideration.
2. Higher SPF must contain proportional UVA protection to provide adequate protection from sun damage
3. There must be a means for consumers and the professional health care provider to differentiate between products that provide no meaningful UVA protection, a basic level of UVA protection, or those that offer substantial additional UVA protection.
4. The test methods for UVA claims must be validated to provide information data on both the magnitude and broadness of the protection provided.
5. Labeling of the UVA protection must be simple and clear and not detract from choice of the appropriate SPF level for the product primary usage.

Proposal:

We would propose the following elements for testing and labeling of products containing sunscreen active ingredients:

1. **Assuring the choice of product by SPF:** The SPF determination of the product must be displayed on the Principle Display Panel of the product label. We propose that any reference to UVA protection must be restricted to the labeling described below.
2. **Proportionality of UVA protection:** A constant ratio of UVA protection to SPF protection should be maintained to assure balance of protection across the spectrum with increased SPF. This UVA protection level should be determined using one of two validated *in vivo* UVA test methods - the "Protection Factor A" (PFA)^{1,2,3} or the "Persistent Pigment Darkening" (PPD)^{4,5} test methods. The measure of spectral broadness should be determined *in vitro* using an appropriate spectroradiometric or spectrophotometric technique. The "critical wavelength" test method is appropriate for this measure

Criteria for making UVA Claims for Sunscreen Containing Products

Claim	Proportionality PFA or PPD : SPF	Absorbance Measure
"with UVA protection"	≥ 1:5	≥ 360nm
"with extra UVA protection"	≥ 1:4	≥ 360nm

We recognize that the proportionality ratios outlined above may not be optimal and would theoretically be more equal to yield more balanced protection. However, given the limited number of Category I UVA absorbers, their limited potency, the limitations of concentrations and allowed combinations, more equal ratios would require UVA protection levels beyond what can be achieved with today's technologies.

3. **Providing information for product choice for UVA protection:** By providing two categories of protection, the consumers and health care professional will be able to distinguish between and choose products that provide more than the basic level of UVA protection. This also provides an incentive for industry to formulate products with higher than basic UVA protection as they can be distinguished in the marketplace. Such labeling should be permitted on the Principle Display Panel in conjunction with the SPF rating of the product, as well as on the rear panel with further details.
4. **Measurement Methods for UVA protection:** JOHNSON & JOHNSON, along with several other sunscreen manufacturers, is concerned that relying solely on an *in vitro* test method may be inappropriate to assess UVA protection. Until the time when an *in vitro* test can be validated against an *in vivo* human test, and shown to be free from inherent errors, we feel it is essential to rely on human testing methods, similar in concept and technique to the accepted SPF test to provide meaningful evaluation of the UVA protectiveness of sunscreen preparations. Additionally, we are unaware today of validated *in vitro* test methods that can measure the water resistance properties of sunscreen products. With other industry partners we have submitted additional comments supplying data from round-robin testing showing the lack of correlation of test results comparing "critical wavelength" testing with actual protection levels. While "critical wavelength" tests would indicate "broad-spectrum" protection as defined by a sunscreen absorbance >370nm, the actual biological protection as demonstrated by a PFA or PPD test method can be very low (approximately 2). Labeling such a product with "broad spectrum" or "UVA" protection labeling may mislead consumers to believe they have substantial UVA protection when in fact they are minimally protected

against UVA. Thus, it is our position that use of an *in vitro* "critical wavelength" test alone is insufficient for determination of UVA labeling purposes. When used in conjunction with an *in vivo* test which determines the magnitude of the protection, the "critical wavelength" test can provide additional information on the nature of the protection provided.

Measurement of the protection level of a product in the UVA (magnitude):

JOHNSON & JOHNSON has previously filed documents with the Agency in 1991 in support of inclusion of zinc oxide as a category I sunscreen agent. As part of the submission, we provided information on a new UVA test method that we described as a "PFA" test method demonstrating the efficacy of zinc oxide in the UVA range. The Agency replied to this submission indicating in the Federal Register Vol. 63, 1998, No 204, Pg 56587 "the Agency considers testing procedures similar to the UVA protection factor method described (Comments No. RPT5 and CR7, Docket No. 78N-0038, Dockets Management Branch) *as adequate for determining the UVA protection potential of a finished OTC sunscreen drug product*".

This test method has been the subject of two additional round-robin tests for determination of validity, reproducibility, and feasibility in multiple testing facilities. The outcome of the first study³ confirmed the sensitivity of the method solely to UVA absorbers protection, demonstrated dose-response of the protection level, reproducibility of the results across testing facilities, and feasibility of the testing in commercial testing centers.

The second round-robin test was conducted earlier this year under the auspices of the CTFA. The details of this test are being submitted to the Agency via this Docket, by a group of industry companies, including JOHNSON & JOHNSON. Results of this test confirmed the ability of the test method to distinguish varying levels of UVA protection in products containing both organic and inorganic UVA. Moreover, the test results confirmed that the "PFA" test protocol that we have submitted for consideration yields data consistent with, and virtually identical to those determined using the "PPD" test method submitted by L'Oréal^{4,5}. We consider both methods to be valid, equivalent, and acceptable for testing of the absolute measure of UVA protection of sunscreen products. Either test protocol should be permitted for determination of product UVA protection.

Either of these two *in vivo* human test methods can be utilized in conjunction with the well established procedures for determination of the water resistance properties of sunscreen products as outlined in the Sunscreen Final Monograph.

Measurement of the broadness of UVA protectiveness of a sunscreen product : In our proposal for testing and labeling UVA protection claims, we are addressing the proportionality of protection via use of the *in vivo* PFA or PPD test methods and the ratio of PFA : SPF outlined above. The determination of the broadness of UVA protection can then be determined using an *in vitro* spectrophotometric or spectroradiometric measurement that measures the broadness of protection. The *in vitro* "critical wavelength" test is adequate for this determination. We would propose to maintain the established 360nm benchmark wavelength as a requirement for UVA claims.

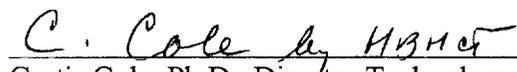
Combining the *in vivo* PFA or PPD test method with the *in vitro* test procedure provides a meaningful and rigorous test of both the magnitude of the biological protection provided by sunscreen products as well as the broadness of the protection. We would strongly recommend that the Agency include this combination of tests as measurement criteria for UVA product claims.

5. **Simplicity of Claims Structure:**

As marketers of a wide variety of product types, with a wide variety of product claims are well acquainted with the necessity of providing meaningful and concise product claims. From consumer studies evaluating the ability of various UVA claims to be understood by consumers conducted by the CTFA member companies as well as some individual consumer companies, it is our understanding from the data that a simple phrase describing the UVA protection is the most meaningful and impactful communication device. Use of symbols or numerical scores, in conjunction with SPF only tend to confuse the importance of each. In keeping with our effort to maintain SPF as the primary determinant of product choice, we recommend the phrases "with UVA protection" and "with extra UVA protection" be the extent of labeling to distinguish the two categories of products containing UVA absorbers meeting the criteria described above.

In conclusion, we support the comments endorsed by our affiliate company, Neutrogena, as well as our industry associates Schering-Plough, Estee Lauder, L'Oreal, Bath & Body Works regarding UVA testing and labeling, as well as the comments filed by our industry manufacturer's association, the CTFA. We urge the Agency to adopt our recommendations in order to achieve a timely conclusion and publication of the comprehensive Sunscreen Final Monograph.

 8/31/00
Marjorie McTernan, Director Regulatory Affairs

 8/31/00
Curtis Cole, Ph.D. Director Technology Development

References

1. Cole, C.A. Van Fossen, R. (1992) Measurement of sunscreen UVA protection: An unsensitized human model. *J. Amer. Acad. Dermatol.* 26:178-184.
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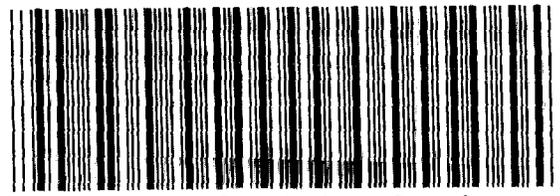
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