

**THE  
SKIN  
CANCER  
FOUNDATION**

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March 21, 2002

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

Dear Sirs:

In March 1994, The Skin Cancer Foundation responded to the notice published in the Federal Register on May 12, 1993, requesting comments on the Tentative Final Monograph Proposed Rules on Sunscreen Drug Products for Over-the Counter Human Use. In that response, The Skin Cancer Foundation addressed six specific issues and made some additional recommendations.

The Skin Cancer Foundation is a nationally recognized voice for consumers and physicians globally in efforts to reduce the incidence, morbidity and mortality of sun-induced malignancies.

We would now like to reiterate and add comments in the following areas concerning the Final Monograph, Partial Stay and Final Rule:

1. A proposed "cap" on Sun Protection Factor
2. Testing for UVA protection
3. Adding labeling requirements

1. **SPF "cap"**

We understand that the FDA is considering an upper limit of SPF and recommending a cap of SPF 30.

The Skin Cancer Foundation strongly believes that well formulated products with higher SPF values enable the consumer to protect his/her skin better. There can be a protective difference between SPF 30 sunscreen and one with an SPF higher than 30. It is known that consumers apply sunscreen in quantities that are less than 2mg/cm<sup>2</sup> used in SPF testing. Therefore, a high SPF sunscreen would compensate for insufficient application of sunscreen. In addition, high SPF sunscreens are useful for patients with photosensitivity disorder.

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Putting a cap on SPF also limits the research, development and growth of new products and new compounds. With such limitations, compounds that have a high protection property for UVA would not be easily available to the public. Such products also help to protect individuals from harmful effects of UVA radiation. The UVA protection issue, even though presently unresolved by the FDA, will receive a setback in the development of research and new products if UVB and UVA compounds (organic as well as inorganic) of higher SPF values are not allowed to be modified or re-formulated and sold. This technology is evolving rapidly!

With high SPF sunscreen enriched with UVB and UVA agents we can protect the pigmentary system. Until recently sunscreens were formulated primarily to minimize the sunburn reaction. Industry has achieved significant advances in this field but the problem of protecting melanocytic systems by the use of sunscreens of high SPF value or by sun blockers can be beneficial. Capping the SPF value is a step backward rather than forward, and we urge the FDA to give the UVA Protection Program top priority. If melanocytes are not activated by high SPF for sun lotions or sun blockers, the prevention of melanoma by high SPF sunscreens will be a step in the right direction. With high SPF values (>30-50) we can prevent activation and proliferation of melanocytes.

2. **UVA testing**

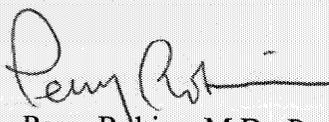
We request that the issue of UVA testing be addressed in the amended Final Monograph, indicating that it will be resolved in a scientific way acceptable to the scientific and sunscreen manufacturers community. In this area of UVA protection, The Photobiology Committee of The Skin Cancer Foundation is willing to help the FDA to better protect the consumers against the potential hazards of sunlight and recommend effective formulations acceptable to industry and the researchers in this field. We are offering our services to achieve these goals.

3. **Labeling requirements**

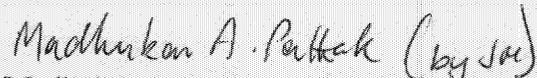
Prominent contraindications and warnings placed on the label may inhibit consumers from buying and using sunscreens to obtain adequate UV protection to prevent the induction of keratosis and skin cancer. Prominent placement of a skin types guide and warnings on the label may also lead people of certain skin types to use less effective sunscreens. The Skin Cancer Foundation advises people of all skin types to use at least an SPF 15 sunscreen. We urge the FDA not to require placement of warnings on packaging that may undermine the significant public education efforts over the last 10-15 years that have increased consumer awareness of the dangers of sun exposure and the need for sunscreen protection. We request that sunscreens of SPF 15 or greater be regarded as first line of photoprotective measures along with sun avoidance, use of protective clothing and use of broad brimmed hats and sunglasses.

We request that these constructive comments be carefully considered and incorporated into the Final Monograph for OTC Sunscreen Drug products.

Sincerely,



Perry Robins, M.D., President  
The Skin Cancer Foundation



Madhukar A. Pathak, M.B., MSc (Tech), Ph.D.,  
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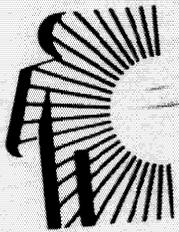
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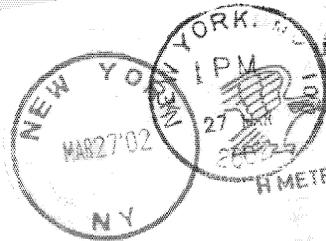
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