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T A N N I N G  
R E S E A R C H  
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October 14, 2003

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

**Citizens Petition** (Docket No. 78N-0038)

Dear Sir/Madam:

The undersigned submits this petition under 21 CFR 10.25 and 10.30. This petition requests the Commissioner of Food and Drugs to amend 21 CFR Part 352 Sunscreen Drug Products For Over-The-Counter Human Use. Specifically this petition requests that SPF's should not be capped, and if capped not at SPF 30 +.

**A. Action Requested**

This petition requests that 21 CFR Part 352 be amended to delete sections concerning the SPF 30 + cap. It is recommended that there should not be a cap, and certainly not a cap at such a low level of protection.

**B. Statement of Grounds.**

The petition herein is very simple and one that echoes previous petitions and/or comments from most world organizations: do not cap SPF's. The only difference in this request is that it is based on desires voiced by millions of consumers through their buying patterns. Now is a time that sunscreen sales data becomes available in the US that essentially captures the present year's activity. In reviewing the 2003 data it occurred to the undersigned that perhaps the agency is not aware of suncare sales patterns in food, drug and mass retail outlets. The 2003 suncare season was perhaps the worst suncare sales season on record as compared to data from the previous year. Much of the nation experienced abnormally wet and cool spring and summer weather resulting in suncare sales being down over 7% in dollars and over 8% in units. Despite these conditions, sales of sunscreen products having an



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SPF over 30 increased by 8.3% from the previous year. In the 2003 season there were over 300 products having an SPF over 30 on the market, accounting for about 22% of sales. New products of SPF 30 or higher introduced in 2003 more than doubled (in dollar volume) the new products introduced in 2002 having an SPF over 30. For clarification, it should be noted that the over SPF 30 products are almost always significantly over SPF 30. There are remarkably few SPF products between SPF 30 and SPF 45. Therefore, with few exceptions over SPF 30 products are in reality SPF 45 and higher. The American consumer clearly is demanding higher SPF products.

Why is the consumer demanding higher SPF sunscreens? I believe that much of the public's practical experience has shown that they are not adequately protected with SPF's 30 or lower. Many studies show that sunscreens do not prevent sunburn and in some cases people that use sunscreen receive more sunburn than people who do not<sup>1,2,3</sup>. The reasons they need more protection are quite simple; (1) they do not use enough sunscreen to provide the labeled SPF<sup>4,5</sup>, and (2) consumers prolong their exposure beyond the protective quality of the formulas available. There is only one logical way to solve this problem; build broadspectrum, photostable products that will provide all day protection from one application. This most likely will not be done if the SPF is capped at 30 +.

A 30 + cap will more than likely produce less choices on the shelf for the consumer. Cost competition will probably dictate that manufacturers place the least amount of sunscreen actives possible to obtain the 30 + category. The market may merely become a commodity market with no incentive for research that would lead to more effective products. Ultimately this could result in less sunscreen being used and will not be in the best interest of the consumer. The economic impact if sunbathers sunburn and miss work as a direct result is already significant<sup>2</sup>. Making less protective products is clearly not the answer for this problem.

Protection should be broadspectrum, and photostable. If only products are allowed to be sold that meet those requirements, then there is no logical reason to limit protection. Therefore, by copy of this letter, I am repeating a previous petition requesting that there should be no SPF limitation, citing consumer needs and habits as an additional justification.



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Although most organizations including industry representatives, the American Academy of Dermatology and the Skin Cancer Foundation have opposed the cap in comments after the 1999 printing of the Sunscreen Monograph, there does exist a contingent that states that an SPF 30 should afford most individuals adequate protection. The agency in the comment section of the 1999 Sunscreen Monograph succinctly stated the most common arguments in favor of a cap:

- 1) An SPF 30 absorbs most erythemal light and the advantage of subjecting users to more potentially irritating chemical sunscreens for ever decreasing absorption increases is unwarranted.
- 2) Higher SPFs may encourage users to stay in the sun longer and receive excessive non-erythemal rays.

The undersigned do not believe these arguments are valid. The industry continues to do research resulting in higher SPFs with less sunscreen actives. If higher SPFs can be obtained with less chemicals, this is not a valid justification for limiting.

The theory behind higher SPF encouraging longer sunbathing thus encouraging the user to receive more non erythemic UV rays, is also not valid if high SPF sunscreen products are required to have significant UVA protection and are photostable. This would allow the user to have a better chance of being fully protected, reducing exposure across the entire spectra. If a strategy to cap SPF in order to drive the consumer out of the sun quicker is valid, then why would a 30 cap be chosen? Why not a 15, or 8? Surely any lower SPF would allow the user to sunburn quicker, stay outside less and thus ultimately receive less UV. The undersigned believe this is not a logical strategy. Consumers by their buying patterns described herein have shown that they want more protection, not less.

### C. Environmental Impact

This proposed amendment should have no environmental impact.





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**D. Economic Impact**

Previous FDA considerations under the Unfunded Mandates Reform Act and Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612) should be valid for actions per this petition. The only additional economic burden that would be placed on Marketers and ultimately consumers would occur if insufficient reaction time is allowed from the final monograph printing to the monograph effective date. As has been described in previous comments to the agency, the suncare development cycle is quite long. Work has already begun for the 2005 suncare season. A monograph issued around the end of 2003 should have an effective date based on these considerations, and should not be effective until the 2006 suncare season. Shipments for the 2006 season would normally start around December 2005.

**E. Certification**

The undersigned believe this petition has been a fair representation of pros and cons concerning the subject petition.

Sincerely,

Signature)	
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3. Wulf, HC, Stender, IM, Lock-Anderson, J. Sunscreens used at the beach do not protect against erythema: a new definition of SPF is proposed. Photodermatology, Photoimmunology and Photomedicine.
4. Hart, G, Wright, A, Cameron, R,. An Assessment of the Adequacy of Sunscreen Usage. Radiation Protection Dosimetry, Vol. 91, nos. 1-3, pp. 275-278, 2000.
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The sales data cited herein was provided based on permission by A. C. Nielsen. The data was based on sales from Food, Drug, and Mass, excluding Wal Mart.

