

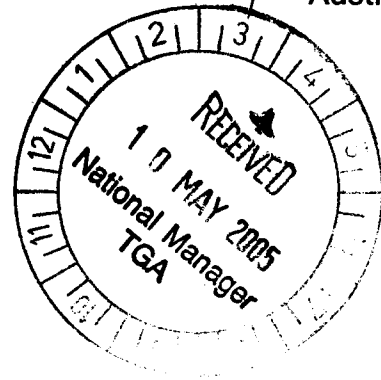
Mr Lesar  
cc to ballala

From the desk of  
**Professor Alan Coates AM**  
Chief Executive Officer  
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**The Cancer Council**  
Australia

**May 5, 2005**

Mr Terry Slater  
National Manager  
Therapeutic Goods Administration  
PO Box 100  
Woden, ACT 2606



Dear Mr Slater,

***"Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods" (The Newgreen Report)***

The Cancer Council Australia strongly supports the current status quo in relation to the classification of moisturisers with sunscreen.

The recommendation of allowing moisturisers to promote up to a SPF 20 raises a number of key concerns for the reasons detailed below.

The (SPF) rating indicates the level of protection provided by a sunscreen against UV radiation. Therefore specifying a number makes an implicit therapeutic claim of a certain level of skin protection from UV radiation.

The report tables the points of difference between moisturisers and sunscreens, in particular, that moisturisers are used "sparingly" whereas sunscreens are "liberally" applied. If the product is being purchased and is used (sparingly) as a moisturiser, then it cannot deliver on the promise of sun protection as stated by the SPF level indicated. To avoid consumer confusion, and avoid implicitly false claims, cosmetic products should not be permitted to carry an SPF level, unless they go through the current TGA approved testing procedures.

Skin cancer control public awareness campaigns delivered over the past 25 years have promoted the use of sunscreens with at least SPF 15+, and more recently SPF 30+ for excellent skin protection from UV radiation. Allowing cosmetic product to carry a label indicating up to SFP 20+ creates the perception that it has excellent sun protection qualities when the reality will be completely different in general use application. Of great concern is that manufacturers will be able to state SPF claims without first undergoing TGA scrutiny.

The report states that *'the Cancer Council Australia is satisfied with the current regulatory arrangements but expressed concern that if*

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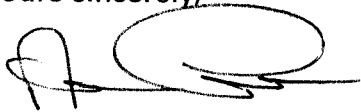
*moisturisers with secondary sunscreens were treated as cosmetics, there was the possibility of diminution of standards.* The expectation on page 65 of the review, that *'any moisturisers with sunscreen that were made under questionable conditions or whose labelling was deficient or whose claims were beyond those permitted, would be quickly examined and tested by competitors and complaints made to the authorities'*, is not sufficient to assuage the Cancer Council's concern. Clear guidance regarding effective labelling is preferable as compared to relying on competitors to conduct tests (which would be at significant cost) and lodge complaints about products. At this point it is already too late and customers have already been misled.

The statement on page 65 that *'The SPF is a statement of fact determined from standardized tests conducted by a laboratory on the particular formulation. It does not, in itself, promise any therapeutic benefit.'* We suggest that, again, due to the extensive public awareness campaigns featuring SPF, the general public would in fact expect a therapeutic benefit, given the term's long term association with sun protection. There is well-published data showing regular use of sunscreen reduces the risk of solar keratoses, a precursor to skin cancer<sup>1</sup>.

The suggested use of wording such as *'use as a sunscreen for prolonged exposure to sunlight'* and *'use a primary sunscreen when in direct sunlight'* are not, in our opinion, sufficiently clear messages to add to reinforce to the consumer that the product is primarily a moisturiser. These statements will not limit the creativity of manufactures who could exploit any changes to the current arrangements to reduce testing costs and potentially mislead the consumer with quasi looking 'primary sunscreens' that are in effect only moisturisers with sunscreen. The Cancer Council recommends personal sun protection, which includes sunscreen of SPF 30+ when the UV Index is 3 (moderate) or higher, irrespective of whether a person is in direct sunlight or not. Also, 'prolonged' is not a sufficient descriptor, as it is not quantified, so not particularly useful as it can take as little as 15 minutes for sunburn to occur on a clear January day.

To this end, any change to lessen the regulatory requirements of manufacturers will in our mind only lead to customer confusion, but worse still potentially negative health outcomes in the long term.

Yours sincerely,



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**Clinical Professor**  
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**The University of Sydney**

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<sup>1</sup> Thompson SC, Jolley D, Marks R. Reduction of solar keratoses by regular sunscreen use. N Engl J Med. 1993 Oct 14;329(16):1147-51.