

**DR. ANTHONY HALL**

M.B.B.S., F.A.C.D., DERMATOLOGIST  
Provider No. 049 912 EH  
A.B.N. 56 052 145 365

May 12, 2005

Mr Terry Slater  
National Manager  
TGA  
PO Box 100  
WODEN ACT 2606



Dear Mr Slater,

**AUSTRALIAN REVIEW OF POLICY FRAMEWORK FOR REGULATING PRODUCTS AT THE COSMETIC/THERAPEUTIC INTERFACE SPECIFICALLY SUNSCREEN PRODUCTS.**

I strongly oppose the suggestion to deregulate secondary sunscreens with an SPF of no more than 20.

Sun protection is vital and certainly products with an SPF on the label are seen as providing an important therapeutic benefit.

The mention of the SPF on the label is itself a claim for efficacy of the product, for prevention of sunburn and skin cancer. The SPF is obtained by measurement at a specific application rate (usually 2mg/cm<sup>2</sup>). It is important that label instructions advise how to apply the product to achieve the SPF.

The SPF is also dependent on quality manufacturing methods, stability of the formulation and use before a proven expiry date. There must continue to be controls by the TGA over all these aspects.

The TGA should require all sunscreen products to be listed on the Australian Register of Therapeutic Goods to ensure compliance with appropriate test method, quality standards, stability tests, Good Manufacturing Practice and the Australian Standard.

I believe that consumers and their pharmacy and medical professionals need the confidence that this system provides. Anything less is a compromise of public health.

I would be most concerned if any product that makes any claim for sun protection or SPF could be sold as a cosmetic without this level of control by the TGA.

Yours sincerely

A handwritten signature in black ink, appearing to read "Anthony Hall". The signature is written over a large, stylized flourish that extends across the page.

Anthony Hall, MBBS, FACD  
ah:so

This letter is intended for the person to which it is addressed and may contain information that by law is privileged or confidential. If the reader of this letter is not the intended recipient you are hereby notified that any disclosure, distribution or copying of this letter is prohibited by law.

If you have received this letter in error, kindly notify us immediately on (03) 52 215 203

**McCOLL O'BRIEN P/L**  
A.B.N. 20 480 887 567

D