

April, 2005

Mr Terry Slater
National Manager
TGA
PO Box 100
Woden, ACT 2606

Mr Slater

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 specified application rate (usually $2\text{mg}/\text{cm}^2$). 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,

Annette Callan

