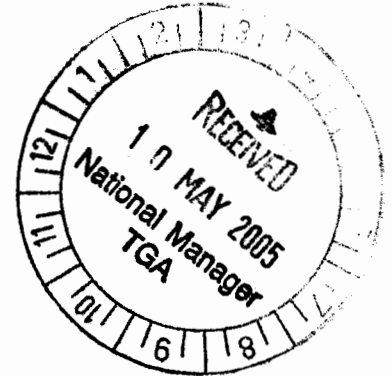


WHM:SLADMINMAY04-05

4th May 2005

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



Dear Mr Slater,

RE : AUSTRALIAN REVIEW OF POLICY FRAMEWORK FOR REGULATING PRODUCTS AT THE COSMETIC/THERAPUTIC INTERFACE SPECIFICALLY SUNSCREEN PRODUCTS

I write to strongly oppose the suggestion that secondary sunscreens with a SPF of no more than 20 will be deregulated.

Such an action will be deleterious to the health of many Australians and specifically is likely to lead to increases in the incidence of melanoma and skin cancer. To allow cosmetic companies to provide products without specific SPF testing in Australia and no measurement of UVA efficiency is to allow onto the market, inferior products for which there is no guarantee of quality or efficiency.

Furthermore, without stability testing these products will sit on people's shelves until they are out of date and therefore useless.

SPF is dependent on quality manufacturing methods, stability of the formulation and use before proven expiry date. There must be adequate control by the TGA of these aspects.

The TGA should require all sunscreen products to be registered on the Australian Register of Therapeutic goods to ensure compliance with appropriate test methods, quality standards, stability tests, goods manufacturing policy and the Australian Standard.

Without such regulation consumers and medical professionals will have no confidence that the products are beneficial in the prevention of melanoma and skin cancer. Anything less than adequate regulation is a compromise of public health.

It would be of great concern if a product sold as a cosmetic, without this level of control by the TGA, were to make claims for sun protection or SPF without the rigorous testing

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that is now necessary to ensure that sunscreen products provide the level of protection claimed by the SPF shown on the label.

Yours sincerely,



W.H. McCarthy, AM., M.ED, FRACS,
Professor of Surgery (Melanoma & Skin Oncology)
The University of Sydney