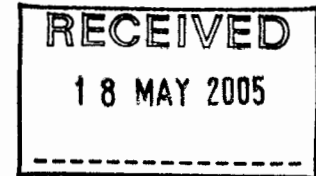


4 Khartoum Road, North Ryde, NSW 2113
P.O. Box 139, North Ryde, NSW 1670
Telephone (02) 9888 0977
Fax (02) 9887 3487

Monday, 16 May 2005

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606



Attention: Mr. Pio Cessarini
Director – Non-prescription Medicines Branch

Dear Mr. Cessarini

**Company Response –
The NICNAS/TGA Review of Policy Framework for Regulating Products
at the Cosmetics/Therapeutic Interface (the “Newgreen Review”)**

Beiersdorf Australia Ltd participates both as a sponsor of therapeutic goods and as a introducer of chemicals, predominantly through cosmetic products in both the Australian and New Zealand markets. We have had a long history in these markets with well recognised global brands, amongst which include Nivea and Elastoplast.

We refer to the TGA’s and NICNAS’s open letter of 3 May 2004. We very much appreciate the opportunity to provide comment on the review of the policy framework for regulating products at the cosmetic / therapeutic interface that is being conducted jointly by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Non-prescription Medicines Branch of the Therapeutic Goods Administration (TGA). We also wish to applaud the approach adopted in the review thus far, with its considered allowances for extensive consultation in Australia and New Zealand.

We have maintained a keen interest in the Review’s development of options for reform and continue to do so through our membership of the Cosmetics, Toiletry and Fragrance Association of Australia (CTFA). The CTFA’s response has been assembled following extensive discussions with its members and its response does very much represent our industry’s considered and collective views on the range of issues examined by Dr. Newgreen’s report. In this respect, we would like to explicitly endorse CTFA’s response and urge the TGA to give the CTFA response its due consideration.


In addition, we would like to underline and reinforce our support for recommendation 4(C) of Dr. Newgreen's report. This recommendation calls for moisturisers which contain sunscreens, used for a secondary purpose with an $SPF \geq 4$, to be classified as cosmetics instead of its current classification as listed therapeutic goods.

We contend that the regulatory regime applicable to moisturisers with sunscreens as a secondary purpose rests most appropriately under the NICNAS regime as these are undeniably cosmetics in their intended primary purpose. Continued classification of these products as therapeutic goods in Australia will only continue to deny the Australian consumer from innovative, technologically advanced and improved products. Given that many of these new products contain ingredients which are not elsewhere classified as therapeutic actives, the data requirements normally required to fulfil TGA's evaluation purposes are quite simply unavailable. Generation of the data specifically to meet Australia's requirements is more often than not simply cost prohibitive and uneconomical given Australia's market size.

We believe that the present circumstances which has stopped us from introducing new secondary sunscreen products into the Australian market are illogical and insufficiently grounded on any public safety or scientific rationale. In many cases, these products are already safely used and available to the public in the significant markets overseas, especially in Europe and the United States. Dr. Newgreen's recommendation 4(C) is a pertinent and important recognition of this issue and outlines the necessary controls to be adopted to meet this recommendation. To this end, we respectfully suggest its adoption and accession at an earliest possible opportunity.

Once again, we thank the TGA and NICNAS for its efforts and organisation of the many aspects related to this Newgreen Review. We applaud the direction of the review thus far and agree with the comments made by our industry association, Accord. However, should there be any aspect of these comments which require further clarification, please do not hesitate to contact the undersigned directly.

Yours sincerely
BEIERSDORF AUSTRALIA LIMITED



Clynton Bartholomeusz
Managing Director

cc. Mr. John M Woods
Executive Director – The Cosmetics, Toiletry and Fragrance Association Inc.