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Subject: Regulation of products at the cosmetic/therapeutic interface

20/05/2005 11:28 PM

Amway of Australia sells a wide range of personal care and cosmetic products made by our parent company in the USA. As many of these products are at the cosmetic/therapeutic interface, Amway was pleased that an independent consultant was assigned to review the regulation of products at the cosmetic/therapeutic interface. Amway was involved in industry association seminars that reviewed the Draft Discussion Paper and strongly supports the ACCORD submission.

Moisturisers that contain sunscreens with an SPF value that does not exceed 20 are particularly relevant to Amway. Our recent experience has been that many of the new moisturizer with sunscreen formulations now being developed overseas contain excipient ingredients that are not listed on the ARTG. To list a moisturizing sunscreen containing a "new" excipient, it is first necessary to list the new excipients on ARTG – this requires submission of detailed safety and toxicity test data and a \$5,000 fee for TGA to review the data package. It is ironic that some of these "new" excipients are already on the AICS and can be used without further assessment in a cosmetic product. Even if a new excipient is not on AICS, it is likely that a self-assessment of risk under the NICNAS Low Regulatory Concern Chemical scheme would enable it to be used in a cosmetic with a minimum of delay and cost.

Currently the safety assessment processes for new excipient ingredients in moisturizers with sunscreens compared to new excipients in cosmetics are unnecessarily disparate. Amway believes that LRCC provides a robust system to ensure public health and safety of various cosmetic ingredients. However, the TGA topical excipient approval process is far too expensive and time consuming, and does not provide a better public health outcome than LRCC. We believe that the public safety interest is better served by full ingredient disclosure as required under current cosmetic labeling regulations, rather than having product labels with only the active ingredients as required under TGO 69.

Therefore, Amway of Australia strongly supports proposal 4C in the Draft Discussion Paper that moisturizers containing sunscreens should not be classified as therapeutic products.

We also note and strongly support the ACCORD suggestion that low risk products can and should be excluded by immediately implementing an Excluded Goods Order. Immediate action will resolve any uncertainty about future regulatory classifications and allow industry to proceed with timely introduction of new products. Delays in implementation will further delay the introduction of new technology from overseas, thus denying the public the benefits of this new technology.

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