[redacted]

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To: TGA

Att: OTC Medicines Section

[redacted]

[redacted]
17 JUN 2019

Re TGA Sunscreens Guidelines - Response to Consultation Scental Pacific P/L

Scental Pacific have been developing and manufacturing sunscreens for 16 years. The option proposed to use either US FDA or ISO Standard 24444 for the in-vivo SPF testing is inconsistent with the approach towards uniformity in testing methodologies. The ISO 24444 Standard has been developed to reduce known inconsistencies in SPF determinations that various methods produce.

In the assessment of various sunscreen products sold overseas, that are not TGA listed, we have noted on several occasions that the claimed SPF's were questionably higher than expected if tested to the current AS / NZS 2604:1998. Our assessment took into consideration factors which influence SPF results and compared these with our known data on what is achievable. Some of these factors include levels of sunscreen actives, absorbance data for each sunscreen active, inclusion of film formers and types of emulsifiers. On some occasions we have purchased these products and found the stability and particle sizes assessment and measurements indicate lack of robustness in the formulation with limited shelf life.
As the cost for SPF testing can run into several thousands of dollars, our budget would not allow us to confirm these assessments with more assurance.

In section X5, mention is made regarding SPF data submitted to TGA in support of SPF claims and the variability found in the results. We ponder if any of these products tested to AS/NZS 2604:1998 were non TGA listed products tested to the US FDA monograph and if so, what the variability was.

We are aware that some overseas companies perform their own in house SPF's testing. By not being tested by an independently certified laboratory, impartiality is not assured, as it is in Australia.

We would strongly object to 2 methods being adopted as this would introduce more variability in SPF ratings between Australian tested products to ISO 24444 (assumes this will be adopted) compared to US FDA method.

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Accord, ASMI and the Technical Committee of the ASCC are currently reviewing the ISO standard 24444 and the in –vitro UVA standard ISO 24443 with the recognition that if they are adopted a positive move would be achieved in moving towards a unified international approved Standard.

Yours faithfully,

[redacted]
Research and Development Manager.

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