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Therapeutic Goods Administration
PO Box 100
Woden, ACT 2606

Trapeze Associates Pty Ltd
49 087 656 657
Suite 27, 6 Meridian Place
Norwest Business Park
Bella Vista, NSW 2153

Tel: 02 8814 4300
www.trapeze.net.au

Dear Sir/Madam

Increased Online Access to Ingredient Information

I am writing in response to the proposed changes detailed in the above titled document.

Trapeze Associates have a number of proprietary Ingredients that have the potential to be impacted by this change should Option 1A be determined to be the best way forward.

Trapeze supports either

- 1) **Option 1B:** Publish names of excipients except those used in any proprietary ingredient mixes. This would be our #1 preference.

or

- 2) **Option 2:** Status Quo. This would be our #2 preference

Trapeze **does not** support

- **Option 1A:** Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes

TRAPEZE PREFERRED OPTION

Our preferred Option is Option 1B.

We cannot support Option 1A, as it would appear to make the concept of a proprietary Ingredient (except for flavour and fragrances) completely pointless. Irrespective of whether an ingredient is a flavour or a fragrance, an ingredient is either proprietary or it is not.

We represent a number of overseas companies who value the current TGA PI system as a way of protecting their intellectual property, be it an active premix or an excipient premix.

By effectively withdrawing the possibility for a proprietary ingredient manufacturer to preserve a much needed level of confidentiality, it opens up the possibility for a manufacturers IP to be compromised, not just in terms of sales potential but also in relation to the proprietary nature of the composition.

Trapeze quite clearly understands the need for label disclosure for consumers, especially where there is a potential for an allergic reaction. By adopting Option 1B, this would greatly reduce that risk by increasing visibility for consumers.

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At the present time, PI's containing actives and excipients with 'use restrictions' are flagged at the time of lodgement on eBS by a Sponsor. The onus is on the Sponsor to ensure that they are in compliance with labelling and other requirements based on the presence of ingredients.

Currently, we are always requested by our customers not just to complete TGO 92 declarations but to complete more comprehensive declarations covering the requirements of other global agencies, including food agencies.

Approval for use by our customers is conditional on the completion of this type of Free-from declaration. I have attached a copy of our current Free-From Questionnaire, which covers more than just TGO 92.

RISKS & BENEFITS

- By adopting Option 1B, then there would be increased ingredient visibility for consumers, albeit not 100%.
- The confidential nature of a proprietary ingredient would be preserved for a manufacturer, ensuring that their IP composition is not compromised, enabling them to grow and develop their business in Australia without the risk of either "copy-cat" products or "deconstructed" products to their component ingredients.

COLLABORATION

In terms of possible collaboration, this would very much depend upon the level of collaboration required, but in principle we would certainly consider a level of involvement.

Your sincerely

A solid black rectangular box used to redact the signature of Michael Travers.

Michael Travers

QRT Director