17 September 2019

Regulatory Compliance Section
Regulatory Compliance and Education Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern

I am writing to provide submissions on the draft *Therapeutic Goods (Declared Goods) Order 2019*. I am happy for this submission to be published on the TGA's website with my name and contact details (which are at the end of this letter) redacted.

I am an investor in Grunbiotics, the developer and manufacturer of Neurofolin. I run a small business in Melbourne therefore my investment of $100,000 in Grunbiotics is significant for my circumstances.

I invested in Grunbiotics in the belief that Foods for Special Medical Purposes (FSMPs) are an innovative and promising medical area, providing distinct patient benefits and a valuable compliment to therapeutic goods.

I am aware that progressive markets internationally including in Europe and the USA are increasingly adopting innovative FSMPs and medical foods. I think it is very important for Australia to also be innovative and progressively minded because I strongly support ventures that improve people's lives and wellbeing. I saw Grunbiotics as an Australian innovation that could benefit many Australian's and potentially lead to a viable export product.

The passing of the proposed declaration will cause the removal of Neurofolin from the Australian market and catastrophic damage to Grunbiotics.

I invested into Grunbiotics on the basis of the legislated definition of FSMPs. Neurofolin is an innovative and progressive FSMP for the dietary management of folate disorders, common in depression sufferers. It is correctly categorised as an FSMP, as confirmed by every independent expert consulted on the matter.

It should be noted that the TGA was contacted before the launch of Neurofolin, but I am informed TGA refused to provide any clarification or confirmation, and directed Grunbiotics to utilise independent expert regulatory consultants as the correct process. I understand more than five detailed expert independent assessments have been conducted to date, all confirming Neurofolin is correctly characterised as an FSMP.

As such, I believe it is grossly unjust and an improper use of power for the TGA to override and bypass the FSMP legislation, particularly when there is insufficient factual or scientific basis for the TGA's position. All manufacturers and the TGA, should be operating from the same transparent set of legislated rules.

The TGA should not pass ad-hoc declarations such as the one proposed. Doing so not only undermines the entire FSMP category and legislated framework, but creates instability and confusion for industry, healthcare professionals and consumers. It makes the category unviable for Australian businesses and restricts Australian public access to safe and useful products.

Furthermore, the declaration as it is currently drafted is excessively broad. It is unsuitable for any declaration with regards to FSMPs to restrict dietary management of inborn errors of metabolism, or make reference to associated nutritional deficiencies, as this unreasonably undermines a core intention of FSMPs, confusing the associated legislation.

Finally, the passing of the proposed declaration and subsequent damage to Grunbiotics would have a significant financial impact on my investment. If the TGA are permitted to make the proposed declaration this is likely to be catastrophic for Grunbiotics, potentially fatal which could lead to the loss of my entire $100,000 investment. I run a small business employing six people and undertook rigorous due diligence prior to making this significant investment.

I ask that you do not proceed with the making of the proposed declaration.

Yours faithfully,

[redacted]