Australian Government

Department of Health
Therapeutic Goods Administration

Our reference: RIES26886

[redacted]
Clayton Utz
Level 10, NewActon Nishi
2 Phillip Law Street
Canberra ACT 2601

By email: [redacted]

Dear [redacted]

Grunbiotics Pty Ltd: Neurofolin

I refer to previous correspondence regarding Grunbiotics Pty Ltd (**Grunbiotics**) and its product Neurofolin, including your letter dated 25 October 2018 attaching reports from:

- FoodLegal Pty Ltd dated 30 August 2018; and
- Engel Hellyer & Partners dated 12 September 2018.

I have now had the opportunity to review these reports and the revised presentation of Neurofolin and claims on the Neurofolin website (www.neurofolin.com.au).

1. Is Neurofolin a food?

Notwithstanding these revisions, and as raised in previous correspondence including our correspondence to you dated 13 August 2018, a threshold issue is whether Neurofolin is a food for special medical purposes within the meaning of Standard 2.9.5 (**FSMP**).

The requirement to meet the definition of a FSMP and hold appropriate evidence was also recognised in the report by FoodLegal Pty Ltd (refer paragraph 6.3).

A copy of the relevant part of the definition is set out below:

2.9.5—2 Definitions

Note 1 Section 1.1.2—5 (Definition of ***food for special medical purposes***) provides as follows:

(1) In this Code:

food for special medical purposes means a food that is:

(a) specially formulated for the dietary management of individuals:

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

(ii) whose dietary management cannot be completely achieved without the use of the food; and

(b) intended to be used under medical supervision; and

(c) represented as being:

(i) a food for special medical purposes; or

(ii) for the dietary management of a disease, disorder or medical condition.

I note that the TGA wrote to Mr Jamie Hughes of Grunbiotics in an email dated 7 June 2018 and 15 June 2018 asking Grunbiotics to address the issue of whether Neurofolin satisfied the definition of an FSMP (among other issues).

Grunbiotics responded to TGA on 29 June 2018 and also offered to provide further evidence in support of its email response including the scientific references for its statements.

There are a number of requirements necessary to satisfy the definition of an FSMP. I have set out below the various aspects of the definition including whether they appear to have been satisfied.

1.1 Food specially formulated for the dietary management of individuals (para (1)(a))

At present, there is a paucity of material in support of Neurofolin meeting the description of being **specially formulated** for the **dietary management** (as opposed to **treatment**) of individuals (my emphasis added). By the terms of paragraph (1)(a) it is clear that an FSMP's function is to fully or partially meet the specific nutritional requirements of an identifiable individual. Its function is not therapeutic use; its function is not to (relevantly) treat, cure or alleviate any disease state. FSMP is required when the dietary management of an individual cannot be completely achieved with other dietary modification including the use of special purpose foods.

Indeed, the Standard also makes a clear distinction between a food for the purpose of dietary management and food for the purpose of a therapeutic use, i.e., (relevantly) the treatment, cure or alleviation of a disease (depression); see for example, see cl 2.9.5-4 of the Standard.

The TGA notes that there are products on the Australian Register of Therapeutic Goods with single related active ingredients as Neurofolin and that, like Neurofolin, carry indications for therapeutic use.

I invite you therefore to give reasons, including evidence, in support of the view that Neurofolin is a food which has been specially formulated for the dietary management of individuals.

1.2 Exclusive or partial feeding for an individual with a special medically determined nutrient requirement (para (1)(a)(i))

In its email to the TGA dated 29 June 2018, Grunbiotics submits that Neurofolin is for partial feeding with a "*nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment*".

Reference is also made to certain studies with the conclusion that "*overall, despite inconsistencies in the methods used in research papers, the finding that depression diagnosed patients show a deficiency in folate levels has been replicated sufficiently to highlight the need for a FSMP that can address the medically determined nutrient requirement of these patients*".

Also, you state "*[t]he ingredients in Neurofolin are all food ingredients: food acid as citric acid, mineral salts as sodium bicarbonate and sodium carbonate, sweetener as glucose syrup (rice), inulin (from chicory), natural flavour as grapefruit extract, sweetener as sucralose, vegetable gum as xanthan gum, natural colour as safflower extract and vitamins as L-methylfolate calcium and cyanocobalamin*".

At present, it is unclear whether Neurofolin could be considered a food for partial feeding for an individual who has special medically determined nutrient requirements. The ordinary meaning of 'feeding' suggests something that provides a person with macro nutrients, e.g., protein, fats and carbohydrates, or sufficient energy, which would otherwise be obtained from ordinary food, in addition to any micro nutrients in the food.

Please give reasons and evidence in support of the view that persons with depression have a medically determined folate deficiency and Neurofolin provides the necessary nutrients by way of partial feeding.

1.3 *Impaired ability to take, digest, absorb, metabolise etc. (para (1)(a)(i))*

I note that this is an alternative to having a special medically determined nutrient requirement. In its email to the TGA dated 29 June 2018, Grunbiotics states "*some genetic studies suggest that up to 70% of patients with depression have an inborn error of metabolism ...*"

Please also give this evidence to the TGA for consideration of whether it demonstrates the impaired ability of patients diagnosed with depression to metabolise folate.

1.4 *Depressed individuals cannot achieve dietary management without the use of the food (para (1)(a)(ii))*

In its email to the TGA dated 29 June 2018, Grunbiotics states that the 70% of depressed patients with an error of metabolism "*show a markedly reduced ability to metabolise folate to L-5-MTHF, a feature not able to be remedied by intake of normal food*".

Please give this evidence to the TGA for it to evaluate whether it supports the claim that an individual medically diagnosed with depression cannot achieve dietary management without the use of Neurofolin.

1.5 *Intended for use under medical supervision (para (1)(b))*

It appears that this aspect of the definition is satisfied.

1.6 *Represented as being for special medical purposes (para (1)(c)(i))*

It appears that this aspect of the definition is satisfied.

In light of this, I have not considered whether paragraph (1)(c)(ii) of the definition is also satisfied. However, I can consider any submissions you make.

1.7 *Significance of the changes to presentation and claims*

The TGA may have, including by its email and letter to Mr Hughes dated 30 July 2018 and 3 October 2018 and in the Product Defect Alert the TGA requested Neurofolin to send to pharmacies, suggested that it may be possible for Neurofolin to be regulated as a food with changes to Neurofolin's presentation and labels. However, these comments were not intended to be an exhaustive statement of steps Grunbiotics might take to bring Neurofolin into regulatory compliance.

Similarly, the TGA's comments were not intended to detract from its comments in its other correspondence, including in the TGA's letter to you dated 13 August 2018 about the requirement to meet the definition of an FSMP.

In addition, as you would appreciate, regulatory compliance is ultimately a matter for your client.

1.8 *Position of the State food regulator*

On 26 July 2018, Mr Hughes participated in discussions with the State regulator Victoria Health Food Safety (**Food Safety**) and the TGA on whether Neurofolin is a food or medicine. During those discussions and based on information available at the time, Food Safety also indicated that Neurofolin appeared to be a therapeutic good.

In light of those discussions, you may also wish to submit information from Food Safety including any recent view on whether it considers Neurofolin is a medicine or food.

The TGA may also discuss this matter with Food Safety, including any submissions or evidence you provide to the TGA in response to this letter.

1.9 Conclusion

Having regard to the above, and on the basis of the information you have provided to date, I am not satisfied that Neurofolin is an FSMP for the purposes of cl 2.9.5-2 of the Standard.

However, I will consider further submissions to the contrary.

2. Is Neurofolin a therapeutic good?

As I am not satisfied that Neurofolin meets the definition of an FSMP, I maintain the view that Neurofolin meets the definition of a therapeutic good within the *Therapeutic Goods Act 1989* (**TG Act**): "*goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use*".

Therapeutic use is in turn defined in the TG Act to include "*use in or in connection with: preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons*".

Therefore, and notwithstanding the revised presentation of Neurofolin and the claims made on its website, the TGA considers that the goods are presented as being for therapeutic use due to the nature of claims made on the website and label, e.g., relating to mood regulation, depression management and physiological function.

3. Next steps

As set out in my letter to Mr Hughes dated 3 October 2018, offence and criminal penalties apply to the manufacture, supply and advertisement of therapeutic goods not included on the Australian Register of Therapeutic Goods (subject to certain exceptions).

There are also offences and civil penalties for manufacturing therapeutic goods without a manufacturing licence.

While the issue of whether Neurofolin is a medicine or food is being further considered, it is a matter for Grunbiotics whether it wishes to manufacture and supply Neurofolin having regard to the potential risks of unlawful supply.

I would be happy to discuss this matter with you further and can be contacted on [redacted] s22 or via email at: RC@health.gov.au.

[redacted]

[redacted] s22

Therapeutic Goods Administration
16 November 2018