From:	MURPHY, Casey
To:	MCEWEN, John
Cc:	MCRAE, Cheryl; COOK, Jane; MCLAY, Nicole; TEOH, Kenneth; FRANCIS, Jenny; BARCLAY, Sasha; MACNAUGHTON, Emily; COOK, Adam
Subject:	RE: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [DLM=For-Official-Use-Only]
Date:	Thursday, 6 September 2018 9:12:11 AM
Attachments:	image005.png image006.png image002.png Grunbiotics - Neurofolin - response to Clayton Utz.pdf

Good morning John,

I am working to gain compliance with Grunbiotics Pty Ltd. Please see attached the response to Clayton Utz with regards to the product Neurofolin.

I am expecting a response to this correspondence no later than 19 September 2018.

Regards

Casey Murphy
A/g Assistant Director
Senior Compliance Officer

Regulatory Education and Compliance Branch | Regulatory Practice and Support Division
Health Products Regulation Group
Australian Government Department of Health

T: s22 | M s22 | E: s22 @health.gov.au
Location: Ground Floor, A Block, 136 Narrabundah Lane, Symonston, ACT

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: MCEWEN, John
Sent: Thursday, 6 September 2018 8:50 AM
To: MURPHY, Casey
Cc: MCRAE, Cheryl; COOK, Jane; MCLAY, Nicole; TEOH, Kenneth; FRANCIS, Jenny
Subject: FW: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [DLM=For-Official-Use-Only]

Dear Casey,
I followed up with Cheryl yesterday about the status of this product (Neurofolin) because both the product and the promotional pamphlet are still available at the Priceline Pharmacy in Manuka.
In addition to the ASMI complaint, I raised the issue of this being a therapeutic good and not a special food for depression with Larry Kelly several months ago.

Has there been any progress since the letter to you from Clayton Utz? I am sure that Jenny and

Ken will be interested to note this involvement of this firm which has also been involved in the Ease-a-Cold issue.

Regards

John McE

Dr John McEwen PSM
MBBS MSc MPS
Medical Adviser (part time)
Therapeutic Goods Administration
Mobile s22 [redacted]

From: MCRAE, Cheryl
Sent: Wednesday, 5 September 2018 4:59 PM
To: MCEWEN, John
Cc: COOK, Adam
Subject: FW: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [SEC=UNCLASSIFIED]

John
As discussed

Dr Cheryl McRae
Assistant Secretary
Complementary & Over the Counter Medicines Branch

Medicine Regulations Division
Health Products Regulation Group
(incorporating the Therapeutic Goods Administration and the Office of Drug Control)
Department of Health

T: (02) 6232 8793
E: cheryl.mcrae@health.gov.au
Location: 136 Narrabundah Lane
Symonston ACT
PO Box 100, Woden ACT 2606, Australia

From: COOK, Adam
Sent: Sunday, 29 July 2018 9:36 PM
To: MCRAE, Cheryl
Cc: MURPHY, Casey; MACNAUGHTON, Emily
Subject: RE: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [SEC=UNCLASSIFIED]

Hi Cheryl,

Correct. It's the one John McEwan questioning the Larry about a couple of months ago.

Recent email thread between Gunbiotics and ECT attached, along with our FMI Assessment and

Decision Letter (referral to ECT). Judging by this latest letter, Casey spoke to Grunbiotics on Friday.

Emily and I can meet with Casey about it on Tuesday and provide any necessary information for Regulatory Compliance to decide on next steps and respond to Clayton Utz. I/we will keep you updated.

Adam

From: MCRAE, Cheryl
Sent: Sunday, 29 July 2018 6:03 PM
To: COOK, Adam
Cc: MURPHY, Casey
Subject: FW: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [SEC=No Protective Marking] [SEC=UNCLASSIFIED]
Importance: High

Adam and Casey
What's the issue? Doesnt satisfy the Food Standard and is making theraputic claims??
Cheryl

Sent with BlackBerry Work
(www.blackberry.com)

From: Gerakiteys, Dean <dgerakiteys@claytonutz.com>
Date: Sunday, 29 Jul 2018, 5:20 pm
To: MURPHY, Casey <Casey.Murphy@health.gov.au>
Cc: MCRAE, Cheryl <Cheryl.McRae@health.gov.au>, Sibley, Cain <CSibley@claytonutz.com>
Subject: GRUNBIOTICS PTY LTD: NEUROFOLIN [CU-Legal.FID2423051] [SEC=No Protective Marking]

Dear Ms Murphy

Please see the attached correspondence on behalf of Grunbiotics Pty Ltd.

Regards

Dean Gerakiteys, Senior Associate
Clayton Utz
Level 15, 1 Bligh Street, Sydney NSW 2000 Australia | D +612 9353 4850 | F +612 8220 6700 | M s 11C(1)(a) | dgerakiteys@claytonutz.com | **www.claytonutz.com**

Australian Government
Department of Health
Therapeutic Goods Administration

Cain Sibley
Partner
Clayton Utz
csibley@claytonutz.com

Our reference: RIES26886 **Grunbiotics PTY LTD: Neurofolin**

Dear Cain,

In response to your request of 3 August 2018 for a face-to-face meeting with the Therapeutic Goods Administration (TGA) to clarify our determination relating to the product Neurofolin, we trust that the following will be sufficient to provide the clarification that is sought.

In consultation with our Complementary Medicines Branch, the following information addresses the questions and concerns outlined in your letter dated 29 July 2018.

Subsection 3(1) of the Therapeutic Goods Act (1989) provides that ***therapeutic goods*** means goods:

(a) 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:

(i) **for therapeutic use**; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, **but does not include**:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) **goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*);** or

(f) **goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented**; or

(g) goods covered by a determination under subsection 7AA(1) (excluded goods); or

(h) goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination.

Are the goods "*goods for which there is a standard*" in the Food Standards Code?
A 'standard' as defined by *Food Standard Australia New Zealand Act 1991* ('the FSANZ Act') includes standards included in the Australia New Zealand Food Standards Code. The TGA considered *Standard 2.9.5 - food for special medical purposes*, which includes the following definition for food for special medical purposes:

'***food for special medical purpose'*** means a food that is: (emphasis added)

(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.

The TGA has considered the following in determining whether Neurofolin meets this definition:

- The active ingredients of Neurofolin**,** listed on the label of the goods as *L-methylfolate* in a dissolvable powder form.

- The webpage of the goods, last accessed 31 July 2018, which states that the goods

  - are to be taken once daily with water,
  - are not for parenteral use,
  - should form part of a normal healthy diet and
  - are not suitable as a sole source of nutrition.

Based on this available information, the TGA finds that:

- in the absence of further justification, individuals with depression do not have a special medically determined nutrient requirement, namely a NRV, differing from that of the healthy Australian population for L-methylfolate, and
- depression does not cause a limited or impaired ability to take, digest, absorb, metabolise or excrete *L-methylfolate* from ordinary food, and
- individuals with depression are not unable to achieve dietary management without the use of Neurofolin.

As such, the good is not considered to fit within *Standard 2.9.5 - food for special medical purposes.*

Is there a tradition of use of the goods as foods for humans in the form in which they are presented?
The dosage form of the goods is '*powder*'. There is no tradition of use of the goods as 'food for humans' in Australia or New Zealand in this dosage form.

Do the goods fit within para (a) of definition of "*therapeutic goods"?*
The definition of 'therapeutic use' in subsection 3(1) of the Act states that (emphasis added):
therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
(b) influencing, inhibiting or modifying a physiological process in persons; or
(c) testing the susceptibility of persons to a disease or ailment; or
(d) influencing, controlling or preventing conception in persons; or
(e) testing for pregnancy in persons; or
(f) the replacement or modification of parts of the anatomy in persons.

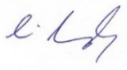
The website of the goods makes a variety of statements that were considered against the definitions of *therapeutic goods* and *therapeutic use*. Based on the statements on the website, the TGA finds that the goods, including presentation, meet the definition of therapeutic use since references are made to curing or alleviating a disease, ailment, defect or injury in persons and influencing, inhibiting or modifying a physiological process in persons as seen above.

Further, paragraph (a) of the definition of a therapeutic good specifically states (emphasis added) *'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****'*.

Conclusion
Taking into consideration the above points, it is the TGA's finding that Neurofolin does not meet a standard under *Food Standards Australia New Zealand Act 1991*, does not have a tradition of use as food for humans, and does meet the definition of a therapeutic good under the Act. Therefore, based on the findings above and the current information available to us, the TGA considers Neurofolin to be a therapeutic good.

Next steps
The TGA is willing to provide further time for Grunbiotics Pty Ltd to reach a decision with regards to the product Neurofolin, that is they are either discontinuing trade in the product, including it in the Australian Register of Therapeutic Goods as a listed product or redesigning the presentation, including claims, for the product to be considered a food for special medical purposes and not a therapeutic good. **Please provide a response within 28 days from the date of this letter.**

Yours sincerely



Casey Murphy
Compliance Officer
Therapeutic Goods Administration
13 August 2018