From: MCEWEN, John
To: MURPHY, Casey

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 9:28:34 AM

Attachments: image001.png

image002.png image003.png

## **Dear Casey**

Many thanks. I will stay tuned!

#### John McE

**From:** MURPHY, Casey

**Sent:** Thursday, 6 September 2018 9:12 AM

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]

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

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 Fase-a-Cold issue.

Regards

John McE

Dr John McEwen PSM
MBBS MSc MPS
Medical Adviser (part time)
Therapeutic Goods Administration
Mobile \$22

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: <a href="mailto:cheryl.mcrae@health.gov.au">cheryl.mcrae@health.gov.au</a> 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 < <u>Casey.Murphy@health.gov.au</u>>

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** 

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