

Mary Jordan

From: Food Medicine Interface
Sent: Monday, 17 June 2019 10:01 AM
To:

s22

Subject: FoodMed Interface draft Assessment outcome – Souvenaid - Nutricia
 [SEC=OFFICIAL]
Attachments: [D19-5458856] FMI - Assessment - Souvenaid - Nutricia.DOCX;
 [D19-5633512] FMI - Website capture - Souvenaid website - Souvenaid -
 Accessed 13 June 2019.PDF

Dear Food Medicine Interface Contact Officers

The TGA has informed FSANZ of the outcome of an Assessment of Souvenaid from Nutricia under the Food Medicine Interface Protocol. Documentation relating to this Assessment is attached and includes:

- Completed Product Presentation Notification/Assessment form
- Product pictures

The TGA is of the view that Souvenaid is **likely a therapeutic good** for the following reasons:

- It does not appear to meet the definition of a food for special medical purpose as the product is not for exclusive or partial feeding; there is no additional nutrient requirement for patients with early stage Alzheimer's compared to the normal population.
- There is not a use of the product as food for humans, though it does contain macronutrients, vitamins, and minerals.
- The overall presentation of the goods suggests therapeutic purposes rather than dietary management.

TGA are seeking input from food regulators on the interpretation and applicability of **Food Standard 2.9.5 – Food for Special Medical Purposes** to the goods, particularly **NSW** who appear to be the Home Jurisdiction, as the goods were previously determined to be unlikely a therapeutic good and captured under Standard 2.9.5 in August 2013.

Should you have any queries about the outcome of the TGA's assessment, including having a different view about the determination of the product please provide your response by **COB Friday 05 July 2019**. If you would like further time to review this product and assessment outcome, please let me know.

If there are no queries, this matter will move into the Action phase under the Protocol.

The completed notification assessment form has been uploaded into the FMI Bulletin Board site:
<https://extranet.foodstandards.gov.au/WG/FMI>

Kind regards

s22

Food Safety and Response Section



t s22
@foodstandards.gov.au

www.foodstandards.gov.au

Level 4, 15 Lancaster Place Majura Park, ACT 2609
PO Box 5423, Kingston ACT 2604



From: s22
Sent: Friday, 14 June 2019 2:23 PM
To: Food Medicine Interface <Food.MedicineInterface@foodstandards.gov.au>
Cc: s22
Subject: FMI Assessment Referral for input - Souvenaid - Nutricia [SEC=OFFICIAL]

Good afternoon

The TGA wishes to notify you of a recent Food Medicine Interface assessment completed by the TGA's internal working group for the product **Souvenaid – Nutricia**. The Food Medicine Interface assessment and Souvenaid website capture are attached to this email.

This product was assessed by the TGA as part of an internal project concerning goods presented as foods for special medical purposes. The product was assessed out of session by the TGA Food Medicine Interface Internal Working Group. It was determined that it is **likely to be a therapeutic good** on the basis that it appears it does not fall within the **Food standard 2.9.5 - Food for special medical purposes** and the product also does not appear to have a **tradition of use as a food in the form in which it is presented**.

Our assessment is based on the information available to us at this time and our current understanding of the Australia New Zealand Food Standards Code. As always, the TGA welcomes input from food regulators on our assessment and interpretation of the Food Standards Code.

Can you please refer this information to the relevant state authorities for their input? It appears the home jurisdiction for the goods is NSW.

The reason I am sending this product out for referral is the following: the TGA is aware that in August 2013 an FMI assessment was done on the product where it was determined to be unlikely to be a therapeutic good and most likely captured under Standard 2.9.5. We are unsure of the outcome of this referral as we do not have access to any correspondence from that time. However, our current assessment is based on different circumstances and has come to the determination that the product is likely to be a therapeutic good. On this basis we would appreciate input from NSW as to our assessment, on the applicability of Food standard 2.9.5 and if the product has a tradition of use as a food in the form in which it is presented.

We would be grateful if a response could be provided by **COB 05 July 2019** as we hope to progress towards appropriate regulatory action without delay.

If you require any further information please do not hesitate to contact me.

Kind regards,

s22

Listing Compliance | Complementary and OTC Medicines Branch
Medicine Regulation Division
Therapeutic Goods Administration | Australian Government Department of Health
PO Box 100, Woden ACT 2606, Australia
www.tga.gov.au

T: [REDACTED] | E: [REDACTED]



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.

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