

14.03 AMINO ACIDS – SYNTHETIC, FORMULA

Oral powder 400 g

Neocate® Junior Vanilla, Nutricia Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested a formulation change to the existing Authority Required listing of Neocate Junior Vanilla.

2 Requested Listing:

- 2.1 The submission proposed no changes to the existing listing.

3 NPWP Consideration

- 3.1 The Nutritional Products Working Party (NPWP) was requested to provide advice to the November 2018 PBAC for the formulation change to Neocate Junior Vanilla.

- 3.2 The submission claimed the new formulation of Neocate Junior Vanilla was an upgrade of the existing product with the addition of prebiotic fibre. However, the NPWP identified a number of errors and inconsistencies in the submission during the process of evaluation. Some are summarised below:

- the submission discussed the changes to the level of calcium and phosphate in the new formulation. However these changes were not reflected in the nutritional profile data tables;
- inconsistencies in trade names;
- errors in calculations of several nutrients;
- inconsistencies in folate content;
- inconsistencies in Vitamin D and Vitamin B12 quantities;
- discrepancies in the level of niacin; and
- the submission claimed prebiotic fibre had been added to the new formulation, but tables comparing the new formulation to Neocate® Advance Vanilla (non-PBS listed product) indicated the same fibre content in both products.

- 3.3 The NPWP emphasised it is the sponsor's responsibility to provide accurate and consistent information to the NPWP and the PBAC for consideration.

- 3.4 These comments from the NPWP were shared with the Sponsor prior to the PBAC meeting. The sponsor was given an opportunity to provide feedback and clarification to the PBAC in response to these comments.

- 3.5 The NPWP reviewed the amended submission and sponsor's responses, and considered the sponsor had addressed most of the issues satisfactorily except for the last issue regarding prebiotic fibre.
- 3.6 The NPWP remained uncertain regarding the additional prebiotic fibre in this new formulation. The submission claimed the new formulation was upgraded by supplementing a patient's diet with prebiotic fibre to support a highly restricted therapeutic elimination diet which may be low in fibre. However, the NPWP noted that table 1.5 of the revised submission stated that the old and new formulation of contain the same amount of fibre.
- 3.7 Furthermore, NPWP noted that there is an increase in scoop size that was not mentioned in the text of the submission, from 7.3 g to 8.2 g. The NPWP considered that this change will affect the preparation of this product, and advised that the sponsor will need to communicate this essential information to all health professionals and consumers.
- 3.8 The NPWP advised the PBAC it supported the requested formulation change to the existing Authority Required listing of Neocate Junior Vanilla.

4 PBAC Outcome

- 4.1 The PBAC agreed with the change to the formulation processed by the Secretariat and specifically noted the following matters raised in the sponsor's pre-PBAC response:
- The sponsor acknowledged the error in the submission which claimed prebiotic fibre was a new ingredient and noted the prebiotic fibre content had not changed from the old formulation; and
 - The sponsor agreed to notify all relevant healthcare professionals and consumers of the change in scoop size.

5 Recommended listing

- 5.1 No change to the existing listing

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment.