

Food Supplement Label & Claims Review

Product	Marine magnesium + vitamin B6 · 60 capsules
Brand	Vernelle
Target market	Ireland, then the Netherlands
Documents received	Carton artwork v2 (PDF), quantitative formula, ingredient specifications and certificates of analysis, list of planned claims
Reference	BF-REV-CA-0318
Reviewed by	Justine Teruel, formulator and regulatory consultant

Conclusion : Do not print as is. The main claim is not authorised and three mandatory particulars are missing or incomplete. Once the 4 blocking points are fixed, the carton can go to print; the 'to fix' points must be handled before the product goes on sale.

4

blocking

4

to fix

2

to watch

8

compliant points

Blocking: prevents market placement or exposes to withdrawal. To fix: non-compliance to solve before sale. To watch: step to plan or point to document.

1. Artwork received, annotated

Each number refers to the finding with the same number. Dashed frame: particular missing from the artwork.

FRONT

VERNELLE

Marine Magnesium + B6

'Food supplement' missing 2

Reduces stress and anxiety 1

Instant anti-fatigue High absorption

No additives 7

60 capsules · 42 g

BACK

Ingredients: marine magnesium 6, fish gelatin 5, pyridoxine hydrochloride, anti-caking agent: magnesium stearate.

Directions: 2 capsules a day with a large glass of water. A varied and balanced diet and a healthy lifestyle are important.

Per capsule	
Magnesium	150 mg
Vitamin B6	0.7 mg

3

Warnings missing 4

Vernelle Ltd, 12 Linden Street, Dublin · Best before and batch: see base

0.9 mm characters 8 · English only 10

Prior notification: not planned 9

2. Findings and fixes

#	Item	Finding	Reference	Priority	Proposed fix
1	Front claim	'Reduces stress and anxiety' is not an authorised claim, and 'anxiety' refers to a disease.	Reg. (EC) 1924/2006, Art. 10; Reg. (EU) 432/2012; Reg. (EU) 1169/2011, Art. 7(3)	Blocking	Replace with a register claim: 'Magnesium and vitamin B6 contribute to normal psychological function'.
2	Name of the food	The words 'food supplement' appear nowhere.	Directive 2002/46/EC, Art. 6	Blocking	Add on the front 'Food supplement with magnesium and vitamin B6'.
3	Nutrient amounts	Amounts given per capsule only, with no percentage of the nutrient reference values (NRV); the daily dose is 2 capsules.	Directive 2002/46/EC, Art. 8	Blocking	Table 'per 2 capsules': magnesium 300 mg (80% NRV), vitamin B6 1.4 mg (100% NRV).
4	Warnings	'Do not exceed the recommended daily dose' and 'Keep out of the reach of young children' are missing.	Directive 2002/46/EC, Art. 6(3)	Blocking	Add both sentences on the back, next to the directions.
5	Allergen	Fish gelatin capsule: the word 'fish' is not emphasised.	Reg. (EU) 1169/2011, Art. 21 and Annex II	To fix	Put 'fish' in bold in the ingredient list.
6	Magnesium form	'Marine magnesium' does not state which chemical form is used.	Directive 2002/46/EC, Annex II; Reg. (EU) 1169/2011, Art. 18	To fix	Write 'marine magnesium oxide', in line with the certificate of analysis.
7	'No additives'	The product contains magnesium stearate (anti-caking agent).	Reg. (EU) 1169/2011, Art. 7(1)	To fix	Remove the statement.

8	Font size	Back-panel particulars at 0.9 mm x-height; the largest face is 96 cm², so the minimum is 1.2 mm.	Reg. (EU) 1169/2011, Art. 13(2) and Annex IV	To fix	Go to at least 1.2 mm, even if brand copy has to shrink.
9	Notification in Ireland	No notification planned before first sale.	S.I. No. 506/2007 (notification to the FSAI)	To watch	Notify the FSAI before first placing the product on the Irish market.
10	Netherlands	Sales planned in the Netherlands with an English-only carton.	Reg. (EU) 1169/2011, Art. 15 (language of the Member State)	To watch	Provide the mandatory particulars in Dutch, or one carton per country.

3. Claims: before / proposed

Before	Proposed	Why
Reduces stress and anxiety	Magnesium and vitamin B6 contribute to normal psychological function	Only claims from the EU register are allowed; 'anxiety' refers to a disease.
Instant anti-fatigue	Contribute to the reduction of tiredness and fatigue	Authorised wording; 'instant' is not shown.
High absorption	Magnesium of marine origin	'High absorption' is not an authorised claim for this nutrient.
No additives	(removed)	Magnesium stearate is present.

4. Mandatory particulars

Particular	On the carton	Status
Name 'food supplement'	Missing	Blocking
Nutrient categories	Missing	Blocking
Ingredient list	Present (points 5 and 6)	To fix
Recommended daily dose	2 capsules a day	Compliant
Do not exceed the daily dose	Missing	Blocking
Out of reach of young children	Missing	Blocking
Varied and balanced diet	Present	Compliant
Amounts per daily dose + % NRV	Per capsule, no % NRV	Blocking
Net quantity, best before, batch, operator	Present	Compliant

Action plan

1. Before print: points 1 to 4 (claim, name, amounts, warnings).
2. Before sale: points 5 to 8, then the FSAI notification (point 9).
3. Before the Netherlands: Dutch particulars (point 10).
4. In your product file: certificates of analysis, % NRV calculation and substantiation for each claim kept.

Already compliant

Recommended daily dose, varied diet statement, net quantity, best before and batch, operator name and address,

authorised vitamin B6 form, doses within usual national limits, no botanical or Novel Food ingredient.

Scope of the review

This review covers the label and claims based on the documents received. It does not include the national notification, filings in other countries, or any nutritional or medical advice. One round of questions is included within 15 days of delivery.

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