SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Immune Balance Drink and strengthening body's defences pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following an application from Rudolf Wild GmbH & Co. KG submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to Immune Balance Drink and strengthening body's defences.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.

The food that is the subject of the health claim is Immune Balance Drink (IBD). IBD comprises green tea extract, grape skin extract, grape seed extract, shiitake extract, vitamin C, some additives and flavouring agents. The exact composition and the manufacturing process was provided in the application. The Panel considers that Immune Balance Drink, which is the subject of the health claim, has been sufficiently characterised.

The claimed effect is "to strengthen body's defences by reducing infectivity of pathogens and stimulating immune response". The target population is the general population. The body's defence includes the immune system, and a well functioning immune system is crucial for the defence against pathogens. Decreasing susceptibility to pathogens is beneficial to human health. The Panel considers that strengthening body's defences by supporting the immune system and reducing susceptibility to pathogens is beneficial to human health.

1 On request from Rudolf Wild GmbH & Co. KG, Question No EFSA-Q-2009-00517, adopted on 15 October 2009.

2 Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen.
Correspondence: nda@efsa.europa.eu

3 Acknowledgement: The Panel wishes to thank the members of the Working Group on claims for the preparation of this opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Immune Balance Drink and strengthening body's defences. EFSA Journal 2009; 7(11):1357. [8 pp.]. doi:10.2903/j.efsa.2009.1357. Available online: www.efsa.europa.eu

The applicant identified 21 human studies as being pertinent to the health claim. One was a human intervention study with the product IBD; eight studies dealt with mechanisms and bioavailability of constituents of IBD in humans; the remaining were both randomised and non-randomised intervention studies on constituents of IBD. In addition five meta-analyses were provided by the applicant: 4 on vitamin C supplementation and 1 on cranberry products. Finally 35 non-human studies were identified, 14 of which were animal studies and 21were *in vitro* studies.

The study with IBD was a double-blind, randomised, placebo-controlled, multicentre clinical study. In this study 98 patients, reporting common cold symptoms that began no longer than 24 hours before study intervention were randomly assigned to consume either 250 ml IBD or placebo twice a day for 6-10 days. The endpoints investigated relate to general feeling of sickness, headache and/or joint aches, sore throat and/or difficulty in swallowing, hoarseness and/or cough and stuffy nose/sniffle.

The Panel notes that the study investigated the effect of IBD on the severity and duration of symptoms in individuals already suffering from common cold. However the evidence provided does not establish that results obtained in studies on subjects with common cold infections relating to the treatment of symptoms of common cold can be extrapolated to the claimed effect of strengthening body's defences by supporting the immune system and reducing susceptibility to pathogens in healthy people (without common cold infections). Therefore no scientific conclusion can be drawn from this study for the substantiation of the claimed effect.

No other studies were provided on the food for which the claim is made. The Panel considers that in the absence of evidence for substantiation of the claim from studies on the food for which the claim is made, the studies on the effects of individual constituents cannot be used for substantiation of the claim for the product itself.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Immune Balance Drink and strengthening the body's defences by supporting the immune system and reducing susceptibility to pathogens.

KEY WORDS

Immune Balance Drink, vitamin C, green tea, grape skin extract, shiitake extract, immune system, pathogens.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of that Regulation lays down provisions for addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence or include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of that Regulation, an application for authorisation or inclusion in the Community list of permitted claims referred to in Art 13(3) shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA:

- The application was received on 20/04/2009.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.
- The scientific evaluation procedure started on 20/04/2009.
- On 15/07/2009 the applicant was requested to provide additional information related to the characterisation of Immune Balance Drink.
- The applicant submitted its responses on 05/08/2009.
- During the meeting on 15/10/2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to Immune Balance Drink and strengthening body's defences.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: Immune Balance Drink and strengthening body's defences.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Immune Balance Drink, a positive assessment of its safety, nor a decision on whether Immune Balance Drink is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

[4] European Parliament and Council (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Rudolf Wild GmbH & Co. KG - Rudolf-Wild-Straße 107-115, 69214 Eppelheim/Heidelberg - Germany

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

Immune Balance Drink (IBD) consists of the following biologically active compounds: vitamin C, green tea extract, grape skin extract, grape seed extract, and shiitake mushroom extract.

Health relationship as claimed by the applicant

IBD comprises constituents that have been shown to strengthen body's defences by reducing infectivity of pathogens and stimulating immune response. According to the applicant, the IBD supports natural defences presumably by reducing infectivity of pathogens and by stimulating the immune system.

Wording of the health claim as proposed by the applicant

The Immune Balance drink activates body's defence.
The Immune Balance drink strengthens body's defence.
The Immune Balance drink stimulates body's defence.
The Immune Balance drink stimulates the immune system.
The Immune Balance drink enhances immunity.
The Immune Balance drink supports your nature defences.
The Immune Balance drink activates the immune system.

Specific conditions of use as proposed by the applicant

IBD is intended for use by adult subjects of the general population since every person of the general population is at risk for infectious diseases (such as common cold). To obtain the claimed effect, 250 ml of the IBD should be consumed twice daily.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Immune Balance Drink (IBD). IBD comprises 3.0 g/l green tea extract, 12.0 g/l grape skin extract, 0.5 g/l grape seed extract, and 0.05 g/l shiitake extract, 200 mg/l vitamin C, some additives, and flavouring agents.

Grape skins and seeds are derived from the red grape *Vitis vinifera*. The plant source of green tea is not given, but the Panel assumes this is *Camellia sinensis*. Shiitake extract is derived from dried fruit of the cultivar *Lentinus edodes*. The extracts are produced with common well described procedures.

The individual extracts as well as the final product are well characterised in terms of brix, total acidity, and relative density. In addition, the final product is standardised on polyphenols. Caffeine

(from green tea extract) is limited to 3 g/kg. Information on low or absent microbiological contamination is provided.

The applicant has shown stability of the product over 9 months by valid methods.

The Panel considers that Immune Balance Drink, which is the subject of the health claim, has been sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "to strengthen body's defences by reducing infectivity of pathogens and stimulating immune response". The target population is the general population.

The body's defence includes the immune system, and a well functioning immune system is crucial for the defence against pathogens. Decreasing susceptibility to pathogens is beneficial to human health.

The Panel considers that strengthening body's defences by supporting the immune system and decreasing susceptibility to pathogens is beneficial to human health.

3. Scientific substantiation of the claimed effect

The MEDLINE-database was searched from 1975 to March 2008 for each constituent (vitamin C, green tea extract, grape seed and peel extract, and shiitake extract). If available, the Natural Standard Monographs were considered and finally, the Cochrane library was searched for relevant meta-analyses. Twenty-one human studies were identified as being pertinent to the health claim: one was an unpublished randomised placebo-controlled intervention study with IBD; eight studies dealt with mechanisms and bioavailability of constituents of IBD in humans; the remaining were both randomised and non-randomised intervention studies on constituents of IBD. Five meta-analyses were provided: 4 on vitamin C supplementation and 1 on cranberry products. Finally 35 non-human studies were identified, 14 of which were animal studies and 21 were *in vitro* studies.

A double-blind, randomised, placebo-controlled, multicentre clinical study on IBD was conducted by Graubaum (unpublished, claimed to be confidential by the applicant). In this parallel study, 98 patients, aged 20-65 years, reporting common cold symptoms that began no longer than 24 hours before study intervention were randomly assigned to consume either 250 ml IBD or placebo twice a day for 6-10 days (with an average of 7 days per patient). The endpoints investigated relate to general feeling of sickness, headache and/or joint aches, sore throat and/or difficulty in swallowing, hoarseness and/or cough and stuffy nose/sniffle.

The Panel notes that the study investigated the effect of IBD on the severity and duration of symptoms in individuals already suffering from common cold. However the evidence provided does not establish that results obtained in studies on subjects with common cold infections relating to the treatment of symptoms of common cold can be extrapolated to the claimed effect of strengthening body's defences by supporting the immune system and reducing susceptibility to pathogens in healthy people (without common cold infections). Therefore no scientific conclusion can be drawn from this study for the substantiation of the claimed effect.

No other studies were provided on the food for which the claim is made. The Panel considers that in the absence of evidence for substantiation of the claim from studies on the food for which the claim is made, the studies on the effects of individual constituents cannot be used for substantiation of the claim for the product itself.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Immune Balance Drink and strengthening the body's defences by supporting the immune system and reducing susceptibility to pathogens.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food Immune Balance Drink, which is the subject of the health claim is sufficiently characterised.
- The claimed effect is "to strengthen body's defences by reducing infectivity of pathogens and stimulating immune response". The target population is the general population. The Panel considers that strengthening the body's defences by supporting the immune system and reducing susceptibility to pathogens is beneficial to human health.
- A cause and effect relationship has not been established between the consumption of Immune Balance Drink and strengthening the body's defences by supporting the immune system and reducing susceptibility to pathogens.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Immune Balance Drink and strengthening body's defences pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0251_DE). April 2009. Submitted by Rudolf Wild GmbH & Co. KG.

REFERENCES

Graubaum H-J (unpuplished) Double-blind, randomized, placebo-controlled, multi-centric clinical study to examine the therapeutic efficacy of Immune-Balance-Drink (IBD) for common cold.

GLOSSARY AND/OR ABBREVIATIONS

IBD: Immune Balance Drink