EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to “Femilub” and maintenance of vaginal moisture pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to "Femilub®" and maintenance of vaginal moisture pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a health claim related to "Femilub®" and maintenance of vaginal moisture. The food that is the subject of the health claim, "Femilub®", which is a combination of macadamia oil, borage oil, perilla oil, d-α-tocopherol and biotin, is sufficiently characterised. The claimed effect, maintenance of vaginal moisture, is a beneficial physiological effect. No human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim. A cause and effect relationship has not been established between the consumption of "Femilub®" and maintenance of vaginal moisture.

KEY WORDS

Femilub®, borage oil, perilla oil, macadamia oil, tocopherol, biotin, vaginal moisture, health claims.

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00571, adopted on 12 September 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

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SUMMARY

Following an application from Nutrilinks Sarl submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to "Femilub®" and maintenance of vaginal moisture.

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

The food that is the subject of the health claim is "Femilub®", which is a food supplement that contains on average per capsule 450 mg macadamia oil, 146 mg borage oil and 10 mg perilla oil to which 2 mg d-α-tocopherol (total d-α-tocopherol content: 6 mg) and 8.2 µg biotin are added. The Panel considers that "Femilub®" is sufficiently characterised.

The claimed effect proposed by the applicant is "reduction of vaginal dryness". The target population proposed by the applicant is women with vaginal discomfort. Upon request from EFSA, the applicant confirmed that the claimed effect can be interpreted as maintenance of vaginal moisture. The Panel considers that maintenance of vaginal moisture is a beneficial physiological effect.

One unpublished human intervention study (claimed as proprietary) was provided by the applicant as pertinent to the claim. This was a randomised, double-blind, placebo-controlled parallel study in 40 women who indicated suffering from vaginal dryness and who were randomised to consume daily for four weeks either four tablets of "Femilub®" or placebo. Study groups differed with respect to menopausal status and lubricant use. Intensity of vaginal dryness was scored by subjects in a questionnaire on a 7-point scale, and intensity of itching and "intensity of inflammations" was scored by subjects on a 5-point scale. The Panel notes that even though the applicant was asked to provide a full study report, only a summary report was provided. The Panel also notes that the evidence provided did not establish that the questionnaire used in the study was validated for the outcomes investigated, that the analysis of data did not take into account baseline values, differences between groups in post-menopausal status and lubricant use, that no information on the background diet of subjects was provided, that the study population was not sufficiently characterised in relation to the claimed effect, and that appropriate information on the method of randomisation and blinding was lacking. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of "Femilub®" and maintenance of vaginal moisture.

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BACKGROUND

Regulation (EC) No 1924/2006[3] 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 this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to reduction in disease risk and to children's development and health) which are based on newly developed scientific evidence, or which 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 this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which 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 04/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and included a request for the protection of proprietary data.
- The scientific evaluation procedure started on 06/06/2012.
- On 04/07/2012, the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 06/07/2012 in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- The clock was restarted on 21/07/2012. On 26/07/2012, EFSA received the requested information as submitted by the applicant.
- During its meeting on 12/09/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to "Femilub®" and maintenance of vaginal moisture.

TERMS OF REFERENCE

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 "Femilub®" and maintenance of vaginal moisture.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of "Femilub®", a positive assessment of its safety, nor a decision on whether "Femilub®" 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.

[3] 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. OJ L 404, 30.12.2006, p. 9–25.

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: Nutrilinks Sarl, Chemin de Beau-rivage 7, Case postale 96 CH-1000 Lausanne 21, Switzerland.

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

According to the applicant, the food which is the subject of the claim is "Femilub®", which is a combination of macadamia oil, borage oil, perilla oil, d-α-tocopherol and biotin.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to reducing vaginal dryness.

Wording of the health claim as proposed by the applicant

The following wordings are proposed by the applicant: "helps to reduce vaginal dryness", "helps to reduce intimate dryness", "helps to increase vaginal hydration" and "contributes to increase mucosa hydration".

Specific conditions of use as proposed by the applicant

The applicant proposed the following conditions of use: Four capsules of "Femilub®" daily during four consecutive weeks during a meal. The target population proposed by the applicant is healthy adults in the general population and especially healthy women presenting vaginal discomfort.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is "Femilub®".

"Femilub®" is a food supplement which contains per capsule on average 450 mg macadamia oil, 146 mg borage oil and 10 mg perilla oil, to which 2 mg d-α-tocopherol (total d-α-tocopherol content: 6 mg) and 8.2 µg biotin are added, with a fatty acid composition of around 47 % oleic acid (C18:1, n-9), 16 % palmitoleic acid (C16:1, n-7), 11 % linoleic acid (LA, C18:2, n-6), 9 % palmitic acid (C16:0), 5 % γ-linolenic acid (GLA, C18:3, n-6), 3 % stearic acid (C18:0), 3 % eicosenoic acid (C20:1, n-9), 2 % arachidic acid (C20:0) and 1 % α-linolenic acid (ALA, C18:3). Fatty acids, d-α-tocopherol and biotin can be measured in foods by established methods.

Information on the manufacturing process has been provided. According to the applicant, a stability study is in progress.

Upon request from EFSA to provide information on how the individual constituents contained in "Femilub®" could contribute to the claimed effect, and to provide a rationale for the use of the specific combination of ingredients, the applicant indicated that for biotin and for vitamin E, health claims on the maintenance of normal mucous membranes and the protection of body cells from oxidative damage, respectively, have been authorised, and that GLA in borage oil and ALA in perilla oil would have an effect on skin hydration through a reduction in trans-epidermal water loss. The

applicant also stated that macadamia oil was chosen because of its content in oleic acid, without providing a rationale as to how oleic acid could contribute to the claimed effect. Upon a further request from EFSA to clarify how the amounts of fatty acids contained in "Femilub®" are related to usual intakes of these fatty acids through a balanced diet, the applicant indicated that habitual dietary intakes in France would provide 940 mg/day (men) and 740 mg/day (women) of ALA and 10.6 g/day (men) and 8.1 g/day (women) of LA (Astorg, 2004) and that the consumption of "Femilub®" would amount to an increase in intakes of ALA and LA of 2-3 %.

The Panel considers that the food, "Femilub®", which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is "reduction of vaginal dryness". The target population proposed by the applicant is women with vaginal discomfort.

Upon request from EFSA, the applicant confirmed that the claimed effect can be interpreted as maintenance of vaginal moisture.

The level of vaginal moisture can be influenced by changes in blood oestrogen concentrations. A reduction in blood oestrogen concentrations may lead to a decrease in collagen and adipose content in the vulvar tissue, resulting in a decrease in the water-retaining ability of the vagina (Leclair and Anandarajah, 2002). The level of vaginal moisture can, for example, be assessed by using investigator-assessed vaginal fluid volume and vaginal moisture scores, or by using validated self-administered questionnaires or visual analogue scales.

The Panel considers that maintenance of vaginal moisture is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Pubmed, ScienceDirect, Blackwell Synergy, Wiley InterScience, Mary Ann Liebert, Scirus, IBIDS, SciFinder Scholar, Pascal, Google and SCOPUS from January 1970 to December 2011 with the following keywords: ["Femilub®"] and ["vaginal dryness" OR "atrophic vaginitis"]. The Panel notes the limitations of the literature search performed.

The applicant did not identify any relevant studies from this search. The applicant provided one unpublished human intervention study (claimed as proprietary) (Le Breton and Lavigne, 2011, unpublished) as pertinent to the claim.

In a randomised, double-blind, placebo-controlled parallel study (Le Breton and Lavigne, 2011, unpublished), 40 women who indicated suffering from vaginal dryness were randomised to consume daily for four weeks either four tablets of "Femilub®" (n=20, age 51.1±11.3 years, 75 % post-menopausal, 25 % using lubricants) or placebo (sunflower oil; n=20, mean age: 47.1±11.9 years, 50 % post-menopausal, 50 % using lubricants). The use of hormone replacement therapy and other medication which could have an impact on vaginal moisture was not permitted throughout the study. The use of lubricants had not to be changed throughout the study. Intensity of vaginal dryness was scored by subjects in a questionnaire on a 7-point scale and intensity of itching and "intensity of inflammations" was scored by subjects on a 5-point scale. None of the subjects dropped out during the study. Differences from baseline between groups were analysed by the Mann-Whitney-U test. Upon request from EFSA on whether the study had been approved by an Ethics Committee, the applicant indicated that the study was a user test, and that no approval by an Ethics Committee was required according to French legislation. Upon another request from EFSA to clarify whether the questionnaire used in the study was validated for the assessed outcome measures, the applicant provided information on a questionnaire other than the one used in the study and validated for the

assessment of female sexual function rather than vaginal dryness. The Panel notes that even though the applicant was asked to provide a full study report, only a summary report was provided. The Panel also notes that the evidence provided did not establish that the questionnaire used in the study was validated for the outcomes investigated, that the analysis of data did not take into account baseline values, differences between groups in post-menopausal status and lubricant use, that no information on the background diet of subjects was provided, that the study population was not sufficiently characterised in relation to the claimed effect, and that appropriate information on the method of randomisation and blinding was lacking. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human intervention studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of "Femilub®" and maintenance of vaginal moisture.

CONCLUSIONS

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

- The food, "Femilub®", which is the subject of the claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is "reduction of vaginal dryness". The target population proposed by the applicant is women with vaginal discomfort. Maintenance of vaginal moisture is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of "Femilub®" and maintenance of vaginal moisture.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on "Femilub®" and maintenance of vaginal moisture pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0346_BE). May 2012. Submitted by Nutrilinks.

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GLOSSARY AND ABBREVIATIONS

ALA	α-Linolenic acid
GLA	γ-Linolenic acid
LA	Linoleic acid