

SCIENTIFIC OPINION

Natural Push-Up[®] Tablets and Capsules and female breast-enhancement process

Scientific substantiation of a health claim related to a Natural Push-Up[®] Tablets and Capsules, and imitating the female breast-enhancement process pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-784)

Adopted on 15 May 2009

PANEL MEMBERS

Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Karin Hulshof, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

SUMMARY

Following an application from The Natural Push-Up Company submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of The Netherlands, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to Natural Push-Up[®] Tablets and – Capsules and imitating the female breast-enhancement process.

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

The foods which are subject of the health claim are two products: Natural Push-Up[®] (NPU) tablets and NPU[®] capsules containing hops as the claimed active ingredient. The Panel considers that the food (NPU tablets and NPU capsules) which is the subject of the claim is sufficiently characterized.

The claimed effect is breast enhancement in terms of firmer and fuller breasts. The target group is women between 18 years and menopause. The Panel considers the evidence provided

¹ For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Natural Push-Up Company on Natural Push-Up[®] Tablets and – Capsules and imitating the female breast-enhancement process. *The EFSA Journal* (2009) 1100, 1-9.

does not establish that firmer and fuller breasts *per se* is a measure of breast function or beneficial to human health.

The application contains two reports of randomised controlled trials which are proprietary and confidential, one analytical study published on the company's website, and one study in rats. The analytical study and the study in rats are not considered pertinent to the claim.

The Panel considers that the significant weaknesses of these two intervention studies limit their value as a source of data to substantiate the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between Natural Push-Up[®] tablets and capsules and the female breast enhancement process.

Key words: Natural Push Up (NPU) tablets and capsules, *Humulus Lupulus Strobuli* L., 8-Prenylnaringenin, Hopein, female breast enhancement

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BACKGROUND

Regulation (EC) No 1924/2006² 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 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 European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 18/12/2008.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006.
- The scientific evaluation procedure started on 18/12/2008.
- During the meeting on 15 May 2009, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to Natural Push-Up[®] tablets and capsules and female breast enhancement process.

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 Natural Push-Up[®] Tablets and Capsules and imitating the female breast-enhancement by 8-PN.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of Natural Push-Up[®] Tablets and Capsules, a positive assessment of its safety, nor a decision on whether Natural Push-Up[®] Tablets and Capsules are, or are 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.

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

² 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.

outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group for the preparation of this opinion: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

1. Information provided by the applicant

Applicant's name and address:

The Natural Push-Up Company, Vuurdoornstraat 25, 6101 MB, Echt, The Netherlands.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006. The applicant claims proprietary the data presented in section 1.4.2 ("Relationship between the food/constituent and the claimed effect") and in section 2.1.1 ("Name and characteristics").

1.1. Food/constituent as stated by the applicant

a) Natural Push-Up[®] Tablets (sold under various names).

Composition: NPU Tablets contain the Breast Formulation PS-20063. Per tablet: 436 mg Hops, enriched with 1.2 mg natural Soy-extract, 504 mg flour mix (20% Buckwheat, 20% Oats, 10% Barley, 10% Rye, 10% Wheat, 10% Maize, 20% Malt). The net weight per tablet is 1010 mg.

Other ingredients: Magnesium stearate (E470b), Anti-caking agents: Silicon dioxide (E551).

Presentation: One package contains 160 capsules of 1010 mg.

b) Natural Push-Up[®] Capsules (sold under various names).

Composition: NPU Capsules contain the Breast Formulation PS-1099. Per capsule: 221 mg Hops, enriched with 68.6 mg natural Soy-extract, 221 mg flour mix (20% Buckwheat, 20% Oats, 10% Barley, 10% Rye, 10% Wheat, 10% Maize, 20% Malt). The net weight per capsule is 540 mg.

Other ingredients: Magnesium stearate (E470b), Anti-caking agents: Silicon dioxide (E551), Glyceryl monostearate. Vegetable capsule (Hydroxy propyl methyl cellulose, Quinoline yellow (E104), Erythrosine (E127), Patent blue V (E131), Titanium dioxide (E171).

Presentation: One package contains 128 capsules of 540 mg.

1.2. Health relationship as claimed by the applicant

NPU Tablets imitate the female breasts enhancement process.

1.3. Wording of the health claim as proposed by the applicant

NPU Tablets imitates the female breast enhancement process by 8-PN (8- Prenylningenin).

1.4 Specific conditions of use as proposed by the applicant

Take the tablets or the capsules with water, preferably after a meal.

Course dosage

The first week: 2 tablets or capsules a day (1 after breakfast and 1 after dinner). The following weeks 5 tablets or 4 capsules a day. For the firming effect, the applicant suggests a course for 3 months and for the enlargement effect a course for 6 to 8 months.

2. Assessment

2.1. Characterisation of the food/constituent

The application describes the main botanical (hops, *Humulus lupulus Strobuli* L.) that is the subject of the claim with respect to scientific (Latin) name, part used and the preparation procedure.

The application describes two products: NPU tablets and NPU capsules. The description of the constituents is clear. The hops is specified by the amount of the prenylflavonoid xanthohumol (varying between 0.8 and 1.1 %). Xanthohumol is the precursor of 8-PN (8-Prenylnarginin), claimed by the applicant to be the active ingredient. The concentration of 8-PN is calculated from the amount of xanthohumol present (using a conversion factor of 100:0.4 derived from literature).

It should be noted that the amount of hops in the two preparations is quite different (436 mg per tablet; 221 mg per capsule) and hence the dosage is quite different (2180 mg hops versus 884 mg hops per day). Also the amount of soy in the tablets and capsules is quite different, but soy is not claimed to be the active ingredient.

The Panel considers that the food (NPU tablets and NPU capsules) that is the subject of the claim is sufficiently characterized.

2.2. Relevance of the claimed effect to human health

The claimed effect is breast enhancement in terms of firmer and fuller breasts. The target group is women between 18 years and menopause.

The Panel considers the evidence provided does not establish that firmer and fuller breasts *per se* is a measure of breast function or beneficial to human health.

2.3. Scientific substantiation of the claimed effect

The applicant indicates to have searched a variety of sources of information, but provides neither a clear systematic review of the literature nor a search strategy.

The applicant describes three studies as pertinent to the claim, all of which have not been peer-reviewed: two reports of randomised controlled trials (RCT) which are claimed proprietary and confidential and one analytical study which is published on the company's website. In addition, a 'product master file' has been submitted which contains the same information as in the application dossier. Finally, one study with rats is included in the documentation and considered relevant by the applicant in the text of the application.

The analytical study (NPU-study, 2006) is only published on the company's website and reports estrogenic activity of hops extracts and 8-PN, whereas the mechanism claimed in the application dossier is "non estrogenic". This study is not considered pertinent to the claim.

The study in rats (Christoffel et al., 2006), indicating estrogenic activity of 8-PN, did not measure breast enhancement, but was introduced by the applicant because it showed that 8-PN "activates prolactin". The Panel does not consider this study as pertinent to the claim

The first human study is a placebo-controlled double-blind RCT (NPU-study, 2001), which evaluated the NPU tablets (for up to 32 weeks). The placebo was reported to "consist mainly of calcium carbonate and cellulosis". The study suffers from several weaknesses, the most important of which are the dosage, and the statistics. The dosage is 15 tablets per day, whereas the claimed effects are on 5 tablets per day. The study was powered on breast volume

as the main parameter and was to include 100 persons entering into a two-treatment parallel design. Only 47 completed the study (25 NPU treatments, 22 placebos). Upon statistical analyses no statistically significant differences were found between the placebo and NPU group. Upon further statistical analysis in only subjects using hormonal contraception, breast volume and the distance between the suprasternal notch-manubrium to the center of the right nipple were statistically significant different between placebo (n=16) and NPU group (n= 11). These *post hoc* analyses in subsets were not originally planned in the study protocol and the results reported are clearly coming from an underpowered analysis.

The second human study is a placebo-controlled double-blind RCT (PS 1099-study, 2005), which evaluated the NPU capsules (4 capsules per day, for up to 24 weeks). The study suffers from several weaknesses, the most important of which are the placebo and the statistics. The placebo was not reported in the study report, but in the application the applicant states that this was a “laxantium”, without providing any further detail. The study was powered on breast volume/firmness as the main parameters and was to include 60 persons entering into a two-treatment parallel design. Only 39 completed the study (19 NPU treatments, 20 placebos). Upon statistical trend analysis both the placebo and NPU group showed a significant increase in breast volume, but no statistically significant differences were found between the placebo and NPU group. Upon further statistical analysis, relative breast volume was statistically significant increased in the NPU versus placebo group in subjects with at least one child (n = 10 placebo group versus n = 9 in NPU group) and an age over 35 (n = 9 placebo group versus n = 7 in NPU group), with a clear overlap between these two subgroups. These *post hoc* analyses were not originally planned in the study protocol, and the results reported are clearly coming from an underpowered analysis.

The Panel considers that the significant weaknesses of these two intervention studies limit their value as a source of data to substantiate the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between Natural Push Up (NPU) tablets and capsules and the female breast enhancement process.

CONCLUSIONS

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

- The food which is the subject of the claim (NPU tablets and NPU capsules) is sufficiently characterized.
- The claimed effect is breast enhancement in terms of firmer and fuller breasts. The target group is women between 18 years and menopause.
- The evidence provided does not establish that firmer and fuller breasts *per se* is a measure of breast function or beneficial to human health.
- A cause and effect relationship has not been established between the consumption of Natural Push Up (NPU) tablets and capsules and the female breast enhancement process.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Natural Push-Up[®] Tablets and - Capsules and Female breast enhancement process pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: Serial No: 0299_NL). December 2008. The Natural Push-Up Company.

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