

Application for Health and Nutrition Claim Evaluation



Content of the Application



Data provided in the application should be organised into four parts:

- Contains the specific information related to the applicant.
- Contains information for the characterization of the food/constituent that is the target for the claim.
- Contains information for the characterization of the claimed effect.
- Contains all pertinent scientific data which form the basis for substantiation of the health claim.

Application for Claim Evaluation



Part 1: Information of the applicant

Please fill the data below:

- The name and address of the company or organization
- Country
- The authorized contact to communicate with Saudi Food and Drug Authority on behalf of the applicant.
- Telephone\Phone number
- E-mail

Please select one of the options below:

The application contains for:

- Health claim
- Nutrition claim

The application has a product safety certification from the Saudi Food and Drug Authority

- Yes
- No

If the answer is (yes), please attach proof of that

The application contains of:

- New claim based on newly scientific evidence
- claim modification of an authorized claim by the Saudi Food and Drug Authority

If the application is to modify a claim previously authorized by the Saudi Food and Drug Authority, the following must be applied:

- The authorized claim and modifications required
- The authorization letter of the claim
- The part which should be modified

Confidential data

State whether the application includes confidential data

- Yes
- No

If yes, please specify the Part(s) in the application (including unpublished studies) which contains confidential data, section numbers, data sets, page number, and verifiable justification (s)/reasons(s). why do we need the information above kept confidential ?

Elements of the application record of which a request for confidentiality treatment was filed by the applicant	Section(s) , data sets, and page number(s)	reasons(s)

Evaluation status outside the Kingdom of Saudi Arabia:

If this claim or a similar one has been submitted by the applicant to any regulatory body for authorisation outside the KSA, please indicate the status of the evaluation of that claim by each regulatory body

Under consideration

Withdrawn

Specify the claim effect, wording, food/constituent for which the claim was withdrawn, the date of withdrawal and the reason for withdrawal and indicate the regulatory body.

Approved

Specify the approved claim effect and wording of the claim, food/constituent for which the claim has been approved, and the date of approval. Please indicate the authorizing regulatory body and provide a copy of the scientific opinion of the authorizing regulatory body.

Rejected

Specify the rejected claimed effect and the wording of the claim, the food/constituent for which the claim has been rejected, the date of rejection and the reasons for rejection with Indicate the regulatory body which rejected the health claim.

Claim particulars

- Specify the food/constituent for which the health claim is made.
- Describe the relationship between the food/constituent and the claimed effect, including the outcome variable(s) used to assess the claimed effect in the body and the methods of measurement.
- Provide a proposal for the wording of the claim (the proposed wording should be in Arabic).

Conditions of use

- Specify the target population.
- Indicate the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect, and whether this quantity could reasonably be consumed as part of a balanced diet.
- Provide, where appropriate, a statement addressed to the categories of the population who should avoid using the food/constituent for which the claim is made and include a rationale.
- Specify, where applicable, a warning for any food/constituent that is likely to present a health risk if consumed in excess and provide a rationale.
- Specify, where applicable, other restrictions of use, and provide a rationale.
- Specify, where applicable, directions for preparation and/or use.

Part 2: Characterization of the food/constituent:

Indicate if the food/constituent that is the subject of the health claim is:

- A single constituent or a fixed combination of constituents.
- A food or a food category.

If it is a single component or fixed combination of ingredients, please specify:

- Vitamins and / or minerals
- Non-vitamins or minerals, (for example, a blend of EPA + DHA + GLA24 in a 9: 3: 1 weight ratio)

If it is a vitamin or a mineral

Please select:

- The name of the food/constituent
- The chemical forms to which the health claim applies

if it is food/constituent other than vitamins or minerals

Please select:

- Name, the characteristic(s), source and specifications (e.g. physical and chemical properties, composition, and where applicable, microbiological constituents) of the constituent(s), or fixed combination of constituents, for which the health claim is made should be provided.

If it is Food or a category of food:

Please provide:

- A brief description of the food or food category, including characterization of the food matrix and the overall composition (including the nutrient content of the food), should be provided.
- The source and specifications of the food or food category for which the health claim is made should be provided.

Stability information

A brief summary of the studies undertaken 28 (e.g. conditions, batches and analytical procedures), and of the results and conclusions of the stability studies, should be provided. Conclusions with respect to storage conditions and shelf-life should be given.

Part 3: Characterization of the claimed effect

Function claims:

The proposed health claim is based on the essentiality of a nutrient:

- Yes
- No

If yes, please specify:

- A) The function of the body that is the subject of the claimed effect.
- B) The rationale/reasons why the body function is a beneficial physiological effect for the target population for which the claim is intended.

If the answer is no, please specify:

- A) The specific body function that is the subject of the claimed effect.
- B) The rationale/reasons why the specific body function is a beneficial physiological effect for the target population for which the claim is intended.
- C) How the specific body function can be assessed in vivo³¹ in humans by generally accepted methods. Please indicate the outcome variable(s) and the methods of measurement proposed to assess the claimed effect in human studies.

Part 4: Identification of pertinent scientific data:

Claims based on the essentiality of nutrients

Please attach the scientific studies as follows:

- Secondary studies: (a meta-analysis, or a systematic review)
- Interventional studies
- depletion–repletion studies in humans
- A case report of clinical signs and symptoms of nutritional deficiency in humans
- Animal studies
- In vitro studies

Claims other than those based on the essentiality of nutrients:

Please attach the scientific studies as follows:

- Studies that provide reports regarding intervention studies such as randomized controlled studies
- Publications on observational studies, such as cohort studies
- Brief publication reports of observational / intervention studies such as systematic reviews, Meta-analyses

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