Application form for submission of health claim assessment

Company/Partnership/Shop.....

Address.....

.....

Tel.....Fax.....

E-mail.....

Date.....Month.....B.E.....

Re: Request to submit health claim assessment

To: Secretary General of Food and Drug Administration

Attachment: 1. Two copies of health claim assessment report and supporting evidenced documents

2. One set of recording device contained data as in attachment 1

Since I am..... on behalf of (Company/Partnership/Shop)..... . intend to submit the health claim assessment result of food or its compositions from the efficacy and suitability of health claim assessment unit recognized by the FDA that be summarized as follows:

1. Name of food product or composition of food requested for health claim assessment
   - in Thai.....
   - in English.....
   - Food Serial Number .....

2. Statement of Health claim

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3. Type of Health claims
   - ☐ Nutrient function claims
   - ☐ Other function claims
   - ☐ Reduction of disease risk claims

4. Use of statement of health claim such as label or advertising media

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In this regard, I have submitted supporting evidenced documents for health claim assessment as attachments 1 to 2 to consider for health claim of food or its composition, it will be appreciated.

Sign..... applicant

(.....)

Checklist supplementing for submit the health claim assessment result

Part 1 General information

Name of Product (in Thai).....

Name of Product (in English).....

Name –last name of the applicant/authorized person.....

Tel.....E-mail .....

Name of producing/import premise.....

License No. of production /import/producing premise.....

Part 2 Preliminary Checklist supplementing for submit the health claim assessment result

Evidenced documents	Number (issue)	Applicant		Official check	
		yes	none	Yes	none
1. Application form for health claim assessment that presenting clear statement of health claim					
2. Letter of power of attorney from business operator which specify power for submission and receiving for additional correction, notification and following of consideration results together with a copy of ID card of granter and attorney that been certified (in case of assigning authority).					
3. One copy of identification card of the applicant					
4. Health claim assessment report from the efficacy and suitability of health claim assessment unit recognized by the FDA and supporting evidenced documents as follow;					
4.1. Documents presenting product details					
1) Documents of Food Serial Number permission					
2) Product formula express as percentage by weight					
3) Production process					
4) Specification of food or its composition					
5) Nutritional analysis report					
6) Packaging and packing size					
7) Consumption purpose					
8) Method of consumption					
9) Consumption dosage					
10) Recommendation for consumption and warning statement (if any)					
11) Targeted group					
12) Product label					
13) Stability report of product that specified condition of storage and shelf life (if any)					
14) Result of variability of active ingredient from batch to batch					

Evidenced documents	Number (issue)	Applicant		Official check	
		yes	none	Yes	none
15) Certification of sale of the health claim product and its label used in foreign countries (if any)					
4.2 Scientific supporting evidences for consideration on health claim assessment					
5. Recording device contained supporting documents and evidences for consideration					

I do hereby certify that supporting evidence documents for consideration on health claim assessment attached herewith are true and trustworthy and if an official have any query in these documents, I agree to give more additional data for official when requesting

Sign ..... applicant

(.....)

- **Additional explanation relevant to information supporting health claim assessment**

1. Well-designed human intervention study is randomized control trial clinical study (RCT) which study effect of treatment or either effect of any process in specific representative sample and be able to well control environment of intervention under optimum condition that are divided into 2 groups: study group and control group by randomization and having systematically study plan according to Good Clinical Practice (GCP). When design for human intervention study, the following details shall be considered:

(a) Study group shall be representative of targeted population;

(b) Control group shall be appropriate;

(c) Adequate exposure period and surveillance for expected result;

(d) Presenting of basic food consumption in study group and life style relevant to other areas;

(e) Composition and quantity of food being studied and other consumed food that effect to function of a particular health claim;

(f) Monitoring of implementing requirements relevant to consumption of food or its composition under testing of volunteer;

(g) Statistical data analysis should be made with appropriate method that recognized in scientific society for a particular study and appropriate statistical significance interpretation

(h) Result of the study, at least variation or defined factors shall be specified include variety and category of product, dosage of consumption and duration to have expected effect;

(i) If the study cannot directly measure the result because of adverse effect to health or long term to gain the effect or ethical issue and limited resource such as high analysis cost, suitable biomarker may be used instead such as concentration of Cholesterol plasma for CVD risk, however biomarker shall relate to final effect and variation in targeted population and analysis method of such biomarker shall be precise and accurate.

2. Systematic review and meta-analysis is collation of reliable scientific evidences by use of distinctly systematic procedure in searching, selection and quality assessment of study report which having the same study pattern and making quantitative analysis of data by meta-analysis or synthesize to have summary of interested study result that able to reduce bias or random error of each relevant study and systematic review are most accurately done.

3. Recognized and reliable technical recommendation from internationally recognized and reliable scientific agency, organization or expert committee such as Scientific committee under Codex, European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN) or Food Standard Australia New Zealand (FSANZ), etc.

4. Relevant peer-reviewed published articles that are able to search from reliable data base such as Elsevier (Science direct, Embase, Scopus), The Cochrane Library, Pubmed, BIOSIS, TOXNET, NAPRALERT, Thai-journal citation index centre or Food Safety Authority of foreign countries.

5. *In vivo study* is testing in body of animal or Eukaryote such as mouse or rabbit.

6. *Ex vivo study* is testing in organ, cell or tissues brought outside of living body.

7. *In vitro study* is testing without use of animal or living organisms or their component except for bacteria, microorganism cultures.

8. Observational evidence in epidemiological study is one type in human study by collecting data from epidemiological study that factors and behavior observed without defining of factors or treatment during study are divided into

- Descriptive studies are systematic collection and analysis of data by observation of factors and behavior relate to interesting effect or area without defining of any comparison group or experiment.

- Case Report or Case Series

- Cross-sectional study is a study during specified period to present situation of problem at that time which factors and output will be measured in the same period.

- Analytical studies are studies of relation between one factor and occurring effect by having control or comparison group and study group that the study should come from more than one research centre or one research group consisted of

- Epidemiological study in form of cohort study which is forward surveillance of effect between treated and control group.

- Epidemiological study in form of case-control study is afterward surveillance by starting from effect and find out its cause from the past

9. Evidence-based reference texts or other recognized and reliable text in a particular field.

Note: Such scientific evidence-based documents shall be published in internationally recognized journal.

Reference

1. Codex Alimentarius. Codex guidelines for use of nutrition and health claims (CAC/GL 23-1997, Rev. 1-2004). Codex Alimentarius 1997.
2. Aggett PJ, Antoine JM, Asp N-G, Bellisle F, Contor L, Cummings JH, et al. PASSCLAIM - Process for the assessment of scientific support for claims on foods. International Life Sciences Institute 2005.