

Review of Current Practices related to Regulating Innovative Functional Food Ingredients and Claims PHILIPPINES

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Sec. 1. The Four Centers. There shall be, under the Office of the Director-General, four (4) Centers covering the four (4) major product categories that are regulated under FDA Act of 2009. These four (4) Centers are:

- a. Center for Drug Regulation and Research (to include veterinary medicines, vaccines and biologicals);
- b. Center for Food Regulation and Research;
- c. Center for Cosmetics Regulation and Research (to include household/urban hazardous substances); and
- d. Center for Device Regulation, Radiation Health, and Research.

Sec. 2. Powers and Functions of the Centers. Each of these Centers, with respect to its major product category, shall have the following powers and functions:

- a. To regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products;
- b. To conduct research on the safety, efficacy, and quality of health products;
- c. To institute standards for the safety, efficacy, and quality of health products;

- d. To operate the respective Center's testing and/or calibration laboratories;
- e. To inspect and evaluate establishments covered by the particular Center and issue appropriate licenses;
- f. To evaluate and issue appropriate authorizations for all health products and health product establishments regulated by each Center;
- g. To conduct audits of regional field offices in coordination with the Deputy Director General for Field Regulatory Operations Office;
- h. To conduct postmarketing surveillance on health products;
- i. To conduct technology assessment of health products that may have the potential to affect human health, whether or not in the market;
- j. To employ a consultative risk management approach to decision-making across all product classes;

C. CENTER FOR FOOD REGULATION AND RESEARCH

Sec. 9. Product Jurisdiction. The Center for Food Regulation and Research shall regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of food products and food/dietary supplements.

The Center shall likewise conduct research on the safety and quality of food products and food/dietary supplements, and institute standards for the same.

- g. To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy and quality;
- h. To conduct health technology assessment, as necessary;
- i. To accredit private testing laboratories; and
- j. To exercise such other powers and perform such other functions as may be assigned or necessary to carry out its duties and responsibilities.

ADMINISTRATIVE ORDER

No. 2010 - 0008

MAR 18 2010

SUBJECT: Directive Specific to the Change in the Use of the Phrase “No Approved Therapeutic Claim” in all Advertisement, Promotional, and/or Sponsorship Activities or Materials concerning Food/Dietary Supplements.

For purposes of this Order, **Food/Dietary Supplement** shall mean a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines.

A. Accordingly, the use of the message or phrase “*No Approved Therapeutic Claim*” shall no longer be allowed in any form of advertisement, promotion and/or sponsorship activities or materials concerning Food/Dietary Supplements commencing from the effectivity of this Order. Instead, the following rules shall apply:

1. All Food/Dietary Supplement owners, manufacturers, distributors, importers, exporters, advertisers, and/or their agents are mandated to strictly carry, *in Filipino*, the standard message or phrase;

“MAHALAGANG PAALALA: ANG (NAME OF PRODUCT) AY HINDI GAMOT AT HINDI DAPAT GAMITING PANGGAMOT SA ANUMANG URI NG SAKIT.

in every advertisement, promotion and/or sponsorship activities or any materials used concerning Food/Dietary Supplements.



MANUAL

REGISTRATION APPLICATION OF FOOD/DIETARY SUPPLEMENTS

March 2025

B. Below are the risks classification for food/dietary supplements:

1. Medium Risk

a. Food Supplement/Herbal Food/Herbal Dietary Supplements

- i. Vitamins and minerals
- ii. Amino acids

2. High Risk

a. Food Supplement

- i. Herbs and botanicals and/or products with other nutritional substances and/or combination as food supplement

7. Certificate of Analysis (physical, chemical (including quantitative analysis of vitamins and minerals), microbiological, and/or heavy metals) signed/verified by competent technical staff/QA Analyst/Manager, and the following shall be reflected:
 - a. Product description/name
 - b. Specifications
 - c. Method of Analysis/Methodology
 - d. Batch Code
 - e. Expiry Date
 - f. Manufacturing Date
 - g. Specific or actual results of analysis
 - h. Limit of detection
 - i. No. of representative samples

8. For Analysis conducted locally, COA must be certified by an analyst with technical expertise and professional competence in compliance to applicable existing laws (e.g., RA No. 11052, RA No. 10657, RA No. 10918, etc.):

Local in-house laboratories shall be verified by FDA to attest applicable testing capacities, technical competence and availability of laboratory equipment through on-site inspection of the facility.

9. Stability Data or Shelf-Life signed/verified by competent technical staff/QA Analyst/Manager, and shall contain the following information:
 - a. Type of Stability Data (E.g. Accelerated, Real time, etc.)
 - b. Critical parameters of the finished products as determined by the manufacturer
 - c. Period conducted
 - d. Name and signature of competent technical staff
 - e. Conclusion

10. As applicable, safety data (E.g. LD50 Toxicity Test for ingredients not listed in the Official Pharmacopeias, Generally Recognized as Safe (GRAS), other international official references, or other applicable test procedures or reports and studies to assess potential toxicity) to address uncertainty on safety.

L. The use of bacterial strains not found in the above list shall be subject to (1) demonstration of evidence of safe use as food/dietary supplement and (2) analysis of the bacterial species found in formulation. Likewise, FDA shall use as reference: WHO-FAO “Guidelines for the Evaluation of Probiotics in Food” (2002).

1. For a Probiotic to be effective, the following properties should be demonstrated:
 - a. beneficial effect on the host organism
 - b. should be able to survive in the digestive tract
 - c. should adhere to the mucosal epithelial cells
 - d. should exhibit enhancement and protection of the intestinal ecology
 - e. should remain viable during periods of storage and use.

FDA CIRCULAR

No. _____

**SUBJECT: Guidelines on the Creation of Center for Food Regulation and Research
Joint Scientific Expert Group (CFRR JSEG) and the Use of its Online
System**

Draft Guidelines July 2025

Enshrined in Republic Act (RA) No. 10611 known as the Food Safety Act of 2013, the Food and Drug Administration through the Center for Food Regulation and Research (CFRR) shall be responsible for implementing a performance-based food safety control management system which shall include but is not limited to the development of food standards and regulations.

Further, Rule 18b1.1 of the same Act stated that the FDA CFRR Product Research and Standards Development Division shall be responsible for developing, adopting, and/or amending/revising food safety standards and codes of practice for processed and prepackaged foods. It shall strengthen and ensure sustained development of science-based policies and continued updating of quality work procedures. The policies and procedures shall be incorporated in the FDA systems including but not limited to food standards and regulations to be researched, developed, amended/revised, or updated, and the development of protocol, procedures and qualifications for the identification, recognition or organization of a pool of multi-disciplinary food experts from relevant regulatory, health, academe, research institutions, professional organizations with full disclosure and without conflict of interest to be known as the Department of Health (DOH) Joint Scientific Expert Group (JSEG) which shall provide scientific advice to the DOH and its joint undertaking with other agencies including the National Codex Organization (NCO).

Specifically, it aims to:

- A. Provide guidelines to all technical experts on how to apply for membership in the JSEG through the online system.
- B. Create a scientific expert group that will assist CFRR in the development of policy/standard anchored in research and scientific data.
- C. Provide expertise for health research projects or studies.
- D. To provide criteria in the selection of technical experts

- B. **Joint Scientific Expert Group (JSEG)** refers to a pool of multi-disciplinary food technical experts from government agencies, health, academic and research institutions, duly recognized related international and local food professional organizations and food industry associations, and private sector, which shall provide scientific advice to the CFRR.
- C. **Standards** refer to a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods.
- D. **Regulations refer to** any legal instrument that gives effect to a government policy intervention and includes licensing, imposing information obligation, compliance to standards or payment of any form of fee, levy, charge or any other statutory and regulatory requirements necessary to carry out activity.
- E. **Technical Expert** refers to any person with professional competence, in-depth knowledge, extensive experience or expertise in the field of food science and technology, food safety and/or related fields thereof, as defined in this Circular and/or its future amendments.
- F. **Recommended Code of Practice** refers to a document providing guidance on the minimum practices used to prevent or reduce the risk of hazards occurring during production.
- G. **Health research** refers to a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge to improve health.

FDA CIRCULAR

No. _____

SUBJECT: Guidelines on the Use of Acceptable Nutrition and Health Claims in the Labeling, Advertisement, Sponsorships, Promotions, and Other Marketing Activities of Prepackaged Processed Food Products

This Circular adopts the consolidated nutrition and health claims recognized within the ASEAN region, and serves as a supplement to Bureau Circular No. 2007-002, entitled “Guidelines in the Use of Nutrition and Health Claims in Food,” which implements the Codex Alimentarius Commission Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) in the evaluation of nutrition and health claims in food labeling and advertising of processed food products.

Draft Guidelines December 2025

General guidelines

- C. The use of approved nutrition and health claims remains subject to evaluation and prior approval by the FDA–Center for Food Regulation and Research (CFRR) before being used in the labeling, advertising, sponsorship, promotion, and other marketing materials of processed food products.

Specific guidelines

- C. A validated method shall be available to measure the nutrient or food constituent forming the basis of any claim. Consequently, all claims on labels shall be supported by a recent Certificate of Analysis (within 12 months of application), including quantitative assay results, official or validated reference methods, method detection limits (if applicable), and the full name and signature of a Competent Technical Analyst/Staff from an ISO/IEC 17025-accredited laboratory or its equivalent in the country of origin.

G. The use of nutrition and health claims (except disease risk reduction claims) not included in the acceptable list in the Annexes shall be subjected to evaluation in accordance with Annex of CAC/GL 23-1997 (Recommendations on the Scientific Substantiation of Health Claims, Nutrition and Health Claims). Additional documents to substantiate the claims shall be required as follows:

1. Shall be in accordance with the *Annex: Recommendations on the Scientific Substantiation of Health Claims, Nutrition and Health Claims (CAC/GL 23-1997)*
2. A copy of independent peer-reviewed reports of human intervention studies (at least 2, and preferably published in the last 10 years), which have been carried out with regard to the health claim; Animal model studies, ex vivo or in vitro data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient per se to substantiate any type of health claim.
3. Where available, the official statements by recognized Regulatory/Health Authority (for example, World Health Organization and Food/Health Authorities of countries) that have been verified and validated over time regarding the health claim to be made;
4. A proposal for the wording of the health claim for which the application is intended for, and the specific conditions for use; and
5. Where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification.