

Regulations Governing the Labeling of Formula for Certain Disease

1. The Regulations are established under the provisions of Article 22 Paragraph 1 Subparagraph 10 of the Act Governing Food Safety and Sanitation.
2. Formula for certain disease shall have container or external packaging labeled with the following information, as required in addition to general information on regulations of prepackaged food requirements:
 - (1) The applicable subjects.
 - (2) Storage instructions before and after the package is opened.
 - (3) Usage and dosage instructions.
 - (4) Warning statement: "This product is a formula food for certain disease, and it is not suitable for the general population and must be taken under the instruction of a doctor or registered dietitian", or the synonyms. Text shall appear bold and be distinct from the background color.
 - (5) Warning statement: "Increasing dosage will not help improve this type of disease", or the synonyms.
 - (6) Warning statement: "This product is not for intravenous use", or the synonyms.
 - (7) Tube-feeding formulas must specify the osmotic pressure.
 - (8) Other precautions related to nature thereof and characteristics of product.
3. In addition to the foregoing requirements, different categories shall have the following additional information printed on the container or package:
 - (1) Nutritionally complete food with balance formula:

All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products.
 - (2) Nutritionally complete food with customized formula:
 - A. All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review,

Registration and Issuance of Permit Documents for Food and Related Products.

- B. Products with adjusted nutrients/ingredients must specify the “increased”, “reduced” or “eliminated” nutrient/ingredient, or the synonyms.

(3) Nutrition adjusted supplementary formula food:

- A. All products must specify the percentage calories of protein, fat and carbohydrate, fiber, lactose and nutrient content with lower limits on the Schedule in Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products.
- B. Products with nutrients/ingredients adjusted must specify the “increased”, “reduced” or “eliminated” nutrient/ingredient, or the synonyms.
- C. Where a product does not contain the essential fatty acids, such must be stated on the product (e.g. “This product does not contain the essential fatty acids.”). Where a product does not contain one of the essential fatty acids, Linoleic acid (LA) or α -Linolenic acid (ALA), such must be stated on the product (e.g. “This product does not contain Linoleic acid, an essential fatty acid” or “This product does not contain α -Linolenic acid, an essential fatty acid”).
- D. “This product should not be used as the sole source of nutrients” label in bold.

(4) Special modular formula food:

- A. Products with a specific nutrient or ingredient must specify the nutrient and nutrient content on the label.
- B. “This product should not be used as the sole source of nutrients” label in bold.

- 4. The label of the two foregoing requirements with particularity is set after approving the application through examination procedure. In the event of changes in the information of the label, the application of modification according to Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products shall be submitted for approval.