

Regulations Governing the Labeling of Formula for Certain Disease

(Draft)

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 containers or packages labeled with the following information, as required in addition to general information 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 words of similar meaning. (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 words of similar meaning.
 - (6) Warning statement: "This product is not for intravenous use", or words of similar meaning.
 - (7) Tube-feeding formulas must specify the osmotic pressure.
 - (8) Precautions.
 - (9) Others.
3. In addition to the foregoing requirements, different categories and natures of formula food for certain disease 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 the three major nutrients, fiber, lactose and other nutrient content recommended in the dietary reference intakes for citizens.
 - (2) Nutritionally complete food with customized formula:
 - A. All products must specify the percentage calories of the three major nutrients, fiber, lactose and other nutrient content recommended in the dietary reference intakes for citizens.

- B. Products customized with additional or reduced nutrients/ingredients based on either empirical evidence or clinical trial must specify the “added”, “enhanced”, “reduced” or “removed” nutrient/ingredient.

(3) Nutrition adjusted supplementary formula food:

- A. All products must specify the percentage calories of the three major nutrients, fiber, lactose and other nutrient content recommended in the dietary reference intakes for citizens.
- B. Products customized with additional or reduced nutrients/ingredients based on either empirical evidence or clinical trial must specify the “added”, “enhanced”, “reduced” or “removed” nutrient/ingredient.
- C. Where a product does not contain the essential fatty acids, such must be clearly stated on the product (e.g. “This product does not contain the essential fatty acids.”). Where a product does not contain one of the two essential fatty acids, Linoleic acid (LA) or α -Linolenic acid (ALA), such must be clearly stated on the product (e.g. “This product does not contain Linolenic acid, an essential fatty acid” or “This product does not contain α -Linolenic acid, an essential fatty acid”).
- D. The product label must contain this warning message in bold: “This product should not be used as the sole source of nutrients”.

(4) Special modular formula food:

- A. Products with nutritional contents or ingredients adjusted according to empirical evidence or clinical trial must specify so on the label.
- B. The product label must contain this warning message in bold: “This product should not be used as the sole source of nutrients”.