

Draft Regulations Governing the Labeling which shall be labeled of Infant and Follow-up Formula

1. The Regulations are established under the provisions of Article 22 Paragraph 1 Subparagraph 10 of the Act Governing Food Safety and Sanitation.
2. Infant and Follow-up formula shall have container or external packaging labeled with the following information, as required in addition to general information of the packaged food requirements:
 - (1) Products with iron content less than 1 milligram per 100 kilocalories shall be labeled with the warning statement "For infants, Additional Iron May Be Necessary", or the synonyms.
 - (2) Products with iron content of 1 milligram per 100 kilocalories or more shall be labeled with the warning statement "Infant Formula With Iron", or the synonyms.
 - (3) Instructions of storage before and after opening.
 - (4) Directions for product preparation and amount of using.
 - i. Products in powder form shall be labeled with the weight of a spoonful filled with the attached measuring spoon, and the amount of the product and water required for preparation.
 - ii. Concentrated products in liquid form shall be labeled with the warning statement "Must be prepare with water before feeding" or the synonyms, and the amount of the product and water required for preparation.
 - (5) The warning statement "Prepare and dilute with water that has been boiled and then cooled to warm and in totally sterilized containers only", or the synonyms.
 - (6) The warning statement "Inappropriate preparation will cause health hazard of the baby", or the synonyms.
 - (7) Products in liquid form shall be labeled with the warning statement "Shake the bottle till the solution is evenly mixed before feeding", or

the synonyms.

- (8) The warning statement "From the age over six months, infant shall receive complementary foods in addition to the formula", or the synonyms.
 - (9) The warning statement "User shall follow the advice of health care worker and nutritionists to determine whether the need for infant formula and the proper method of use", or the synonyms.
 - (10) The recognized label shall be clearly printed on the container or external packaging. The image and specifications are regulated in the Appendix.
 - (11) Infant formula in liquid form shall be labeled with the warning statement, "For hospital use only".
3. In addition to the foregoing requirements, the container or external packaging shall be labeled with the following information depending on the product categories:
- (1) Infant formula:
 - i. The phrase "infant formula" shall be labeled.
 - ii. A statement of the superiority of breastfeeding shall be labeled.
 - iii. The baby's weight shall be added in the feeding table.
 - (2) Follow-up infant formula: The phrase "follow-up infant formula " shall be labeled.
 - (3) Infant formula for special medical purposes: The characteristics of the products and applicable users.
4. Phrases like "humanized", "maternalized" or other similar phrases suggesting superiority to breast milk shall not be labeled on the container or external packaging of infant and follow-up formula. Nor shall there have pictures of infants or phrases and pictures which may idealize the use of product.
5. The label contents specified in Articles 2 and 3 shall follow the specifics approved by registration review of the products. For any changes,

applications shall be filed in accordance with the Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products. The changes can be made only with the approval granted.

6. If the labeling of the product does not comply with this regulation, and appears to be false, exaggerated or misleading, it shall be fined in accordance with the relevant regulations of this law.

Appendix

Image and Specifications of the recognized label on the container or external packaging of Infant and Follow-up Formula:

1. Image:



2. Specifications:

- (1) The words of the image "Breast milk is the best food for your baby" and " Ministry of Health and Welfare cares for you" shall be printed using at least font size 8.
- (2) The image shall be printed using CMYK colors: green (Y100C60) and orange (Y100M60).
- (3) The size of the image may be determined by the user, but shall not be smaller than 3 cm (height) × 3 cm (width).