

Regulations governing the labeling of formula for certain disease

1. This standard is established under the provisions of Subparagraph 10 of Paragraph 1 of Article 22 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, it is not suitable for the general population and must be taken under the instruction of a doctor or registered dietitian" (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) Precautions.
 - (7) Others.
3. In addition to the foregoing requirements, different categories of formula food for certain disease shall have the following additional information printed on the container or package:
 - (1) Protein-adjusted formula:
 - A. Contents of sodium, potassium, and protein.
 - B. Protein efficiency ratio (P.E.R., it is not required if the nitrogen content of the product is below 1.8%).
 - C. High protein foods shall be labeled with the words "High Protein Food," whereas low protein foods shall be labeled with the words "Low Protein Food."
 - D. Warning statement: "To achieve balanced diet, please do not take this product on its own", or words of similar meaning. A product that provides the basic

calories and nutrients physiological needs for the patient, may be exempt from this label.

(2) Amino acid adjusted formula:

- A. Contents of essential amino acids.
- B. Phenylalanine-free and low phenylalanine formulas must include a warning statement, "This product is not nutritionally complete " and "This product is only intended for patients with phenylketonuria (PKU), " or words of similar meaning.
- C. Warning statement: "This product is not for intravenous use."

(3) Fatty acid adjusted formula:

- A. Percentage of essential fatty acids (linoleic acid, α -linolenic acid) and energy content.
- B. Product containing no essential fatty acids, must include a warning statement, "This product contains no essential fatty acids," on the label. Product containing no essential fatty acids linoleic acid or α -linolenic acid, must include a warning statement, "This product contains no essential fatty acids linoleic acid," or "This product contains no essential fatty acids α -linolenic acid," on the label.

(4) Mineral adjusted formula:

- A. Contents of electrolyte (e.g. sodium, potassium, chlorine, calcium, magnesium, phosphate, etc.).
- B. Depending on the nature of the product, labels must state "low-sodium food," "sodium restricted food," or "oral rehydration product."
- C. Oral rehydration product must have osmolality and pH value labeled.
- D. Oral rehydration product must include a warning statement, "Conditions such as moderate to severe diarrhea or substantial losses of body fluid or electrolytes must be treated by a physician before taking this product" or words of similar meaning.

(5) Allergen-reduced formula:

- A. The name of the allergen reduced or eliminated.
- B. The name of the specific ingredient substituted for allergen reduced or eliminated, if there is any substitute used.

(6) Weight control formula:

- A. The name and content of the sweetener used, if there is any sweetener used.
- B. The name and content of various nutrients (e.g. energy, protein, fat, carbohydrate, vitamins, and minerals).
- C. "Excessive intake of this product leads to energy accumulation and does not help control body weight" or words of similar meaning.
- D. Other important labeling information (warnings) : "Not intended for children, teenagers and pregnant women," "Seeking advice and instruction from a doctor or registered dietitian before long-term use (or "Not to be taken continuously beyond a certain period of time"), "This product is intended to only replace ___ meal(s) per day, and used in conjunction with a well-designed diet plan," and "Drink enough fluids each day."
- E. Instruction manual and a sample menu for at least one week.

(7) Tube feeding formula:

- A. The name and content of various nutrients (e.g. energy, protein, fat, carbohydrate, vitamins, and minerals).
- B. Osmolality.
- C. Warning statement: "This product is not for intravenous use."