

09 January 2008

**DEPARTMENT CIRCULAR**

No. 2008- 0006

**TO : ALL MILK COMPANIES AND OTHERS CONCERNED**

**SUBJECT: Amendments to Department Circular No. 2007-0276 dated 07 December 2007, Re: Guidelines for the Labeling of breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51, otherwise known as the “Milk Code”, and to Department Circular No. 2007-0272 dated 17 December 2007, Re: Containers and Labels of Milk Products within the Scope of EO 51 otherwise known as the “Milk Code”**

**I. Rationale**

It is a common knowledge that the two leading causes of infant mortality- diarrheal diseases and malnutrition- are often rooted in improper and artificial feeding practices. Only 33.50 percent of infants less than 6 months old are exclusively breastfed but exclusive breastfeeding is very low for 4-5 months at 16 percent. The median duration of exclusive breastfeeding in the Philippines is very short for only less than a month. The decline of breastfeeding, compounded by inappropriate complementary feeding practices, is a cause for alarm because of the consequent undernutrition and risk for childhood mortality and morbidity. Thus, the Philippines has adopted the Global Strategy for infant and young child feeding jointly developed by the WHO and UNICEF, to promote exclusive breastfeeding and timely and adequate complementary feeding with continued breastfeeding as stated in the Administrative Order (AO) No. 2006-0012, “Revised Implementing Rules and Regulations (RIRR) of Executive Order No. 51, Otherwise known as the “Milk Code,” Relevant International Agreements, Penalizing Violations Thereof and for Other Purposes”.

As provided for in Rule VII of AO No. 2006-0012, the containers and labels shall be designed to provide the necessary information about the appropriate use of the products within the scope of the Code and in such a way as not to undermine, or equate it to, breastfeeding. Likewise, the BFAD is mandated to enforce the necessary rules and regulations on the informational requirements that should be reflected in the containers and labels.

## II. Objectives

The objectives of this Order are the following:

1. To set a standard labeling for breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51, which will be used in the evaluation and screening of the labeling materials/containers of the said products;
2. To guide the milk companies as defined in AO No. 2006-0012; manufacturers, importers, exporters, owners, distributors of other milk products, foods and beverages, and other related products within the scope of the Code.

## III. Scope and Coverage

These guidelines apply to the labeling of the following products: breastmilk substitutes, including infant formula, other milk products, foods and beverages, including bottled-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

## IV. Definition of Terms

*Breastmilk substitute* - means any food being marketed or otherwise represented as partial or total replacement of breastmilk whether or not suitable for that purpose (adopted from EO 51);

*Complementary* - means any food except milk substitutes, whether manufactured or locally prepared, suitable as a complement to breastmilk to satisfy the nutritional requirements of infants.

*Container* - means any form of packaging of products for sale as a normal retail unit, including wrappers (adopted from AO 88-B s. 1984);

*Expiration date*- It is the date which signifies the end of the estimated shelf life of the product under a storage condition beyond which the quality of the product is significantly impaired. After this date, the food should not be regarded as marketable (adopted from FDA Regulation No. 001 s. 1982);

*Food for Special Medical Purposes* - is a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used under medical supervision (adopted from Codex STAN 180-1991);

*Halal food* - defined by FAO/WHO as food permitted under Islamic Law (adopted from Codex CAC/GL 24-1997);

*Health Claim* - means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health; (adopted from Codex CAC/GL 23-1997, Rev. 1-2004);

*Healthful (adj)*- means good for one's wellness. Healthy is a positive descriptive of a person's physical state; healthful of something that favorably affects or promotes that state (Adopted from Roget's New Millenium, Thesaurus);

*Infant* - shall refer to a person within the age bracket of 0-12 months (adopted from AO 2006-0012);

*Infant Formula* -means one of the breastmilk substitutes formulated industrially in accordance with applicable Codex Alimentarius Commission (CAC) standards (adopted from AO 2006-0012);

*Label* - means any tag, brand, pictorial or other descriptive matter, written, printed, stenciled, marked embossed or impressed on, or attached to a container of any product within the scope of the code (adopted from AO 88-B. s. 1984);

*Lot* - refers to a quantity of food produced under essentially the same conditions during particular production schedule; (adopted from A.O. 88-B s. 1984)

*Milk Company* -shall refer to the owner, manufacturer, distributor, of infant formula, follow-up milk, milk formula, milk supplement, breastmilk substitute or replacement, or by any other description of such nature, including their representatives who promote or otherwise advance their commercial interests in marketing those products (adopted from AO 2006-0012);

*Milk supplement* -this product name shall be used in place of "follow-up" formula. It means a food intended for use as a liquid part of the complementary food for the infant from the 6<sup>th</sup> month on and for young children; (adopted from Codex STAN 156-1987 stated that designated name is allowed in accordance with national usage)

*Natural and indigenous food*- means locally grown or produced food which are neither artificial nor processed (adopted from AO 2006-0012);

*Nutrition Claim* -means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. However, The mention of these nutrients in the list of ingredients and the qualitative and quantitative nutritive value/nutrition information declaration in the information panel as part of mandatory labeling do not constitute nutrition claims; (adopted from Codex CAC/GL 23-1997, Rev. 1-2004);

*Nutritional (adj)*- nutritious, nourishing, nutritive, food etc. ; of or relating to or providing nutrition (Adopted from Encarta World English Dictionary);

*Products within the Scope of the Code* -shall pertain to breastmilk substitutes and infant formula, including bottle-fed complementary foods as well as teats and other commodities, which intend to replace or substitute, in whole or in part, breastmilk and breastfeeding (adopted from AO 2006-0012);

*Other Milk Products, Foods and beverages* -refers to any provision or drink marketed as a partial or total replacement of breastmilk (adopted from AO 2006-0012);

*Other Related Products*- refers to all materials used to administer breastmilk substitutes; such as, but not limited to, feeding bottles, teats and other artificial feeding paraphernalia; (adopted from AO 2006-0012);

*Shelf-life* - means the period wherein the product retain an acceptable level of eating quality from a safety and organoleptic point of view (labuza, 2002);

*Superlative*- relating to, or constituting the degree of grammatical comparison that denotes an extreme or unsurpassed level or extent; surpassing all others like supreme ; very high quality like excellent (Adopted from Merriam Webster Dictionary)

## **V. General Guidelines**

1. All breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51, that are to be advertised, imported and exported must have the approval of BFAD and must be covered with a Certificate of Product Registration (CPR). In particular, their label must conform to these guidelines and be in accordance with the pertinent rules provided for in the Revised Implementing Rules and Regulations (RIRR) of E.O. 51.
2. All breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51 that are to be exclusively exported and will not be distributed in the Philippines, the labelling specifications may be in accordance with the labeling regulations of the country of destination. However, in case a product is to be distributed in the Philippines and abroad, the label must conform to these guidelines and be in accordance with the pertinent rules provided for in the Revised Implementing Rules and Regulations (RIRR) of E.O. 51.
3. Any information, whether in text or graphical form, which are not mentioned in these guidelines may be a ground for the denial of the label applied for.

4. All breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51 shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character in any respect.
5. All breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51 shall not be described or presented on any label or in any labeling by words, pictorial or other devices to be suitable to be used in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition.
6. Food products with special dietary needs or special medical purposes must be in accordance with the Codex STAN 180-1991 and Codex STAN 72-1981 Revised 2007 in addition to the requirements of E.O. 51 and RIRR.
7. Consistent with Rule VI of AO 2006-0012, all health and nutrition claims for food products within the scope of the Code are absolutely prohibited except those provided in item V no. 6 of these guidelines.
8. The approved label of all food products within the scope of the Code shall not be construed as an authority or approval for advertising, promotion, or marketing materials and activities, the latter shall be subject to specific IAC approval.

## **VI. Specific Guidelines**

The label of all food products within the scope of the Code shall contain the following information (See the sample label attached herein as "Annex 1"):

### **A. The principal display panel shall contain the following:**

#### **1. Product and Brand Name (Name of the Food)**

- (i) The product name shall be "Infant Formula," Formula for Special Medical Purposes Intended for Infants" or "Milk Supplement" or other food standard names in accordance with relevant Codex Standards.
- (ii) The sources of protein in the product shall be clearly shown on the label
- (iii) If cow's milk is the only source of protein, the product may be labeled "Infant Formula Based on Cows' Milk.
- (iv) A product which contains neither milk or any milk derivative shall be labeled "contains no milk or milk products" or an equivalent phrase.
- (v) It shall be contrary to public policy to use as brand name and/or trade mark any word or set of words that may be

considered as nutritional, healthful, and superlative and other terms of similar import.

## 2. Net Contents and Drained Weight

### Net Contents

- (i) The net contents shall be declared in the metric system (“System International” units).
- (ii) The net contents shall be declared in the following manner:
  - for liquid foods, by volume;
  - for solid foods, by weight;
  - for semi-solid or viscous foods, either by weight or volume.

### Drained Weight

- (i) Foods packed in a liquid medium normally discarded before consumption may carry a declaration of drained weight.

## 3. The primary messages

The principal panel of each container/label shall contain the following messages:

- (i) **ENGLISH : “BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND”**

**FILIPINO : “ANG GATAS NG INA ANG PINAKAMABUTI PARA SA BATA HANGGANG 2 TAON O HIGIT PA”**

This message shall be printed bold in all capital letters at the center uppermost level of the principal display panel, the font type is Arial and font size of which must be one-third (1/3) of the size of the biggest letter on the label.

- (ii) **ENGLISH: “IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK”**

**FILIPINO: “MAHALAGANG PAALALA: WALANG ANUMANG GATAS ANG PWEDENG IPALIT SA GATAS NG INA”**

This message shall be printed bold in all capital letters at the center lowermost level of the principal display panel, the font type is Arial and font size of which must be one-third (1/3) of the size of the biggest letter on the label.

**B. The information panel shall contain the following:**

**1. List of ingredients**

A complete list of ingredients shall be declared in descending order of proportion except in the case of added vitamins and minerals. Added vitamins and minerals shall be arranged as separate groups (indicating the specific nature/chemical name), respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

All ingredients shall be printed on the information panel. There shall be no elaboration of ingredients and nutrient contents on the principal and information panel.

The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class name for these ingredients and additives may be included on the label.

**2. Declaration of Nutritive Value**

The declaration of nutritive value or nutrition information shall be printed containing the following information in the following order:

- 2.1. the amount of energy, expressed in calories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrates and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption;
- 2.2. the total quantity of each vitamin, mineral, (and choline for infant formula), and any optional ingredients as listed in the codex standards of infant formula and milk supplement (follow-up formula) per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption when prepared according to the instructions on the label. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.

**3. Date Marking and Storage Instructions**

**3.1. Expiration Date**

- (i) For products with a shelf-life of less than three (3) months, the expiration date shall be declared by the day, month, and year sequence.
- (ii) For products with shelf-life of three (3) months or more, the month and year will suffice.
- (iii) The day and year may be declared in numerals but the month must be declared in word so as not to confuse the consumer.

### **3.2. Storage Instructions**

- (i) Any condition for the storage of the food shall be indicated if the validity of the date depends thereon. The storage instructions shall be declared in close proximity to the date marking.
- (ii) Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.
- (iii) The label shall carry clear graphic instructions illustrating the method of preparation of the product.
- (iv) The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
- (v) Storage instructions of opened food products within the Scope of the Code shall be included to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.
- (vi) Storage and disposal instructions for the use of the product including its storage and disposal after preparation, i.e. formula remaining after feeding shall be discarded, shall appear on the label.
- (vii) Adequate instructions regarding the storage of the product after the container has been opened, shall appear on the label.

### **4. Information for Utilization**

Directions as to the preparation and use of the food, its storage and keeping after the container has been opened shall appear on the label.

- i. The label must bear the instructions for use. Products in powder form and concentrated liquids shall be directed to be prepared with safe and previously boiled water before feeding.
- ii. Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.
- iii. The label shall carry clear graphic instructions illustrating the method of preparation of the product.



- iv. Information that infants over six months of age should receive indigenous, fresh and natural complementary foods in combination with continued breastfeeding. Such statement shall be:

“Infants six months onwards should be given fresh, indigenous, and natural foods in combination with continued breastfeeding”

This message shall be printed bold and prominent on the lowermost level of the information display panel of the label.

- v. The health hazards of (the use) unnecessary or improper use of infant formula and other related products including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.

**“ENGLISH: “THIS PRODUCT MAY CONTAIN PATHOGENIC MICROORGANISMS AND MUST BE PREPARED AND USED APPROPRIATELY”**

**“FILIPINO: ANG PRODUKTONG ITO AY MAARING MAGKARON NG MIKROBYO NA NAGDUDULOT NG SAKIT AT DAPAT IHANDA AT GAMITIN NG TAMA.”**

**Alternatively, the following can be reflected**

**“ENGLISH: THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY”**

**“FILIPINO: ANG PRODUKTONG ITO AY MAARING MAGKARON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAG-GAMIT”**

This message shall be printed bold in all capital letters at the uppermost level of the information display panel, the font type is Arial and font size of which must be one-six (1/6) of the size of the biggest letter on the label.

## **5. Name and Address**

The complete name and address of either manufacturer, packer/repacker, distributor, importer, exporter of the food shall be declared.

## 6. Country of Origin

- i. The country of origin of the food shall be declared.
- ii. When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purpose of labeling.

## 7. Lot Identification

The lot identification number shall be embossed or otherwise permanently marked on the label/container.

## 8. Food Registration (F.R.) Number

The Food Registration No. of the product shall be reflected on the label except on certain situations as may be allowed by BFAD.

## 9. Secondary Messages

The information display panel of each container/label shall contain the following messages in both English and Filipino languages:

- (i) > **“The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional”**
  - > **Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health professional”**
- (ii) > **“The unnecessary and improper use of this product may be dangerous to your child’s health”**
  - > **Ang maling paggamit ng gatas na ito ay maaaring makasama sa kalusugan ng bata**

These messages shall be printed bold, font type Arial and font size 1/6 size of the biggest letter at the uppermost level of the information display panel.

## 10. Required Language

The language to be used in the declaration of all other information must be in English and maybe written in both English and Pilipino, except for products intended to be exported in which case English and/or the language acceptable to the country of destination may be used.

## **VII. Transitory Provisions**

By August 1, 2008 all labels must be fully compliant to these guidelines. Any product within the scope of the Code which labels are not compliant to these guidelines after said non-extendible deadline shall be subject to recall and the appropriate sanctions as provided by existing laws and pertinent statutes shall be exacted on the erring firms.

## **VIII. Miscellaneous Provisions**

1. Milk companies as defined in AO No. 2006-0012; manufacturers, owners, importers, exporters, distributors of other milk products, foods and beverages; and other related products within the scope of the Code that may be affected by these guidelines should submit a copy of their new label/s for purposes of amending their valid CPR.

2. Upon presentation of a certification duly issued by the appropriate entity or institution, and in accordance with the Islamic law, Halal logo may be allowed to be printed in the label/container for products within the scope of the Code.

## **IX. Repealing Clause**


All orders, issuances, rules and regulations or parts thereof inconsistent with these guidelines are hereby repealed and modified accordingly.

## **X. Separability Clause**

If for any reason, any part or provision of these guidelines is declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

## **XI. Effectivity**

These guidelines shall take effect immediately.

  
**FRANCISCO T. DUQUE III, MD, MSc**  
Secretary of Health

*Annex 1*

**BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE  
OR BEYOND  
ANG GATAS NG INA ANG PINAKAMABUTING PAGKAIN NG BATA  
HANGGANG 2 TAON O HIGIT PA**

**BRAND NAME**

Powdered Infant Formula

Net Wt. 500 grams

**IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK  
MAHALAGANG PAALALA: WALANG ANUMANG GATAS NA  
PWEDENG IPALIT SA GATAS NG INA**

### **Government Warnings:**

- **The use of Infant Formula/Milk Supplement must only be upon the advice of a health professional.**  
*Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health worker.*
- **The unnecessary or improper use of this product may be dangerous to your child's health.**  
*Ang Maling Paggamit ng gatas na ito ay maaaring makasama sa kalusugan ng bata.*
- **THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY.**  
*ANG PRODUKTONG ITO AY MAAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAG-GAMIT.*

**Ingredients:** Non-fat milk, lactose, **Vegetable oils** (coconut oil, soy oil), whey protein concentrate, **Minerals** (potassium citrate, ferrous sulfate, zinc sulfate), **Vitamins:** (Ascorbic acid, niacinamide, vitamin A palmitate), **Nucleotides:** (Cytidine 5-monophosphate, disodium guanosine, 5-monophosphate, disodium uridine 5-monophosphate, adenosine monophosphate)

**Nutrition Facts**

- Average Analysis : Per 100g
- Energy ..... 500 kcal
- Protein ..... 12 g
- 60% whey ..... 8.5 g
- 40% casein ..... 3.8 g
- Carbohydrate ..... 56 g
- Fat ..... 25 g
- Linoleic acid ..... 400 mg
- Linolenic acid ..... 350 mg
- Vitamins:
- Vitamin A ..... 1200 IU
- Vitamin D ..... 300 IU
- Minerals:
- Calcium ..... 350 mg
- Iron ..... 6.2 mg
- Zinc ..... 4.5 mg
- Nucleotides:
- CMP
- UMP

**Directions for Use:** One scoop= 10 gms

Before preparing the formula, clean all utensils:

1. Wash hands and all feeding utensils well.
2. Boil all feeding utensils (cap, bottle etc) for 5 minutes
3. Boil fresh water for 30 minutes then cool before putting into the bottle the correct amount.

Preparing the formula:

1. Mix 1 scoop of formula to 70 ml of safe and previously boiled water.
2. If preparing more than one feed, refrigerate and use within 24 hours
3. Throw away any left over in the bottle after feeding the baby. Use this product within 1 month after opening the can. Store in cool dry place.

Expiry Date: 30 December 2006.

Product of U.S.A.

Imported and distributed by: \_\_\_\_\_

Lot identification no. \_\_\_\_\_

Food Registration (FR) No. \_\_\_\_\_

**“Infants six months onwards should be given fresh, indigenous, and natural foods in combination with breastfeeding”**