

DRAFT

17 March 2010

ADMINISTRATIVE ORDER

No. 2010- _____

SUBJECT: Revised Rules And Regulations Governing The Labeling of Prepackaged Food Products Amending for the Purpose, Administrative Order No. 88-B s. 1984 or the “Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines,” and For Other Purposes.

I. RATIONALE

Food safety is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

One indispensable and effective national food safety and control system is consumer information. In fact, in declaring under Republic Act No. 7394 or the Consumer Act of the Philippines as a policy to protect the interests of the consumer, promote his general welfare and to establish standards of conduct for business and industry, the State is empowered to implement measures to achieve, *inter alia*, the following objectives: protection against hazards to health and safety; provision of information and education to facilitate sound choice and the proper exercise of rights by the consumer.

Product label is the most readily available material to inform the consumer on the product contents, shelf life and traceability. Thus, with the aim to attain the above objectives and provide coherence in the Food and Drug’s regulatory system for establishments and products under its jurisdiction, this Order, amending certain provisions of Administrative Order No. 88-B s. 1984 or the “Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines,” and for other purposes, is hereby issued.

II. OBJECTIVE

This Order is hereby issued mandating all manufacturers, repackers, traders, importers, or distributors to indicate in all labels of their respective prepackaged food products the minimum information required under this revised rules and regulations.

III. SCOPE OF APPLICATION

This Order covers all prepackaged food products as defined herein whether locally manufactured or imported for distribution in the Philippines.

IV. DEFINITION OF TERMS

For the purpose of this labeling regulation, the term:

1. *Brand Name* refers to the name appropriated by the manufacturer, repacker, distributors, trader or importer to distinguish its product on the market.
2. *Container* means any form of packaging material which completely or partially enclose the food (including wrappers). A container may enclose the food as a single item or several units or types of prepackaged food when such is presented for sale to the consumer.

3. *Direction/Instruction for Use* refers to the relevant information regarding the reconstitution, preparation and consumption of a food product.
4. *Expiry or Expiration Date* means the date stated on the label of food after which they are not expected to retain their claimed safety and quality and it is no longer permissible to sell and consume.

Use-by-Date, Recommended last consumption date, best before date may be used however, if this is use, the label shall indicate that the product is no longer safe to be consumed the day after the indicated date.

5. *Food* means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substance which have been used as an ingredient in the manufacture, preparation or treatment of food.
6. *Food Additive* means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of the intended use.
7. *Food Allergen* is an ingredient that is one of the following foods or is an ingredient that contains protein, peptide derived from any of, but not limited to, the following: Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
8. *Food Authorization Number* means the number designated to a particular food product as proof that it is authorized by the Food and Drug Administration (FDA) to be manufactured, imported, exported, and/or distributed.
9. *Food Standard* is a regulatory guideline that defines the identity of a given food product (i.e. its name and the ingredients used for its preparation) and specifies the minimum quality factors and, when necessary, the required fill of container. It may also include specific labeling requirements other than or in addition to the labeling requirements generally applicable to all prepackaged foods.
10. *Information Panel* means that part of the label immediately contiguous to the principal display panel and in the case of rectangular, cylindrical or four-sided (tetra-pak) containers, any of the sides adjacent to the principal display panel except the bottom side which serves as the base of package.
11. *Ingredient* means any substance, including a food additive, used as a component in the manufacture or preparation of food and present in the final product (in its original or modified form).
12. *Label* means a display of written, printed or graphic matter upon the immediate container of any article and a requirement made by or under authority of this Ac that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article or easily legible through the outside container or wrapper.(RA9711)

13. *Labeling* means any written, printed or graphic matter (1) upon any article or any of its container or wrappers or (2) accompanying the packaged food. (AO 88-B)

Label, Labeling means which includes any tag, brand, mark, pictorial, or other descriptive matter embossed or impressed on the immediate container, wrappers or accompanying the packaged food product.

14. *Lot* refers to the quantity of food products produced under essentially the same condition during a particular production schedule.

15. *Nutrition facts* mean the express statement or declaration of the particular nutritional properties of a food product including but not limited to the energy value and to the content of protein, fat and carbohydrates, and dietary fiber as well as vitamins and minerals.

16. *Nutrition Labeling* is a description intended to inform the consumer of the nutrient content of a food.

17. *Prepackaged* means packaged or made up in advance in a container ready for sale to the consumer.

18. *Principal Display Panel* means that part of the label which, either through design or general use, is presented or shown to the consumer under customary conditions of display for retail sale.

19. *Processing Aid* means a substance or material not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of food to achieve a certain technological purpose which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

20. *RENI* - Recommended Energy and Nutrient Intakes.

21. *Spices* mean any aromatic vegetable substance in the whole, broken, ground or any other form, except those substances which have been traditionally regarded as food.

22. *Storage Condition* refers to the prevailing specified temperature range, humidity and other environmental factors within which optimal stability of the food product is ensured based on laboratory data.

V. RULES AND REGULATION

A. General Provisions

1. Prepackaged food shall not be described or presented in any label or labeling in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character in any respect.

2. Prepackaged food shall not be described or presented in any label or labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

3. Food packages shall be labeled of the required information, which information shall be contained in the principal display or information panel.

4. Every word, figure or statement required to appear on the label or labeling shall be printed legibly with such conspicuousness and in such terms as to render it likely to be understood under customary condition of purchase and use.
5. Where the label of a food package is so small that it prevent the use of letters of the prescribed size or where it concerns secondary or optional information, letters or proportionately reduced size may be used provided the prescribed particulars are visible and legibly shown and the designated label space is proportional to the size of the package.

B. Mandatory Label Information

The labels of all prepackaged food shall bear the following minimum mandatory information:

1. Product Name of the Food

- 1.1. The product name shall indicate the true nature of the food and shall normally be specified and not generic.
 - a) Where a product name or names have been established for a particular food in a Food Standard, any one of the names shall be used.
 - b) In other cases, a common or usual product name, or in the absence thereof, an appropriate descriptive product name shall be used.
 - c) A “coined” or “fanciful” name may be used provided it is not misleading or confusing.
- 1.2. For the consumer’s better understanding of the true nature and condition of the food, there shall appear in the label either in conjunction with, or in close proximity to the product name of the food, such additional words or phrases, as necessary, to state the type of packing medium, form or style, and the condition or type of treatment it has undergone (e.g. dried, freeze-dried, concentrated, smoke, reconstituted).
- 1.3. The product name of the food shall be presented in the principal display panel in all capital and bold letters and must be permanently legible.

2. Use of Brand Name and/or Trademark

Any brand name and/or trademark used must not be misleading or confusing and shall be in conjunction with the product name referred in paragraph 1.1. a & b.

3. Complete List of Ingredients

The complete list of ingredients, in descending order of proportion, shall be declared on either the principal display panel or information panel. Added water shall also be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared. Where an ingredient is itself a product of two or more ingredients, such a compound ingredient, may be declared in the list of ingredients, provided that it is immediately accompanied by a list, in brackets in descending order of proportion (m/m). Where a compound ingredient constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

A specific name, not a collective (generic) name shall be used for an ingredient.

“Except for those ingredients listed in section B11, and unless a general class name would be more informative, the following class names may be used:

| <i>NAME OF CLASSES</i> | CLASS NAMES for Use in Ingredients Listing |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Refined fats | ‘Fat’ together with either, the term ‘vegetable’ or ‘animal’, as appropriate |
| Starches, other than chemically modified starches | Starch |
| All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish | Fish |
| All types of poultrymeat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not refer to a specific type of poultry meat | Poultry meat |
| All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese | Cheese |
| All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food | ‘Spice’, ‘spices’, or ‘mixed spices’, as appropriate |
| All types of gum preparations used in the manufacture of gum base for chewing gum | Gum base |
| All types of sucrose | Sugar |
| Anhydrous dextrose and dextrose monohydrate | ‘Dextrose’ or ‘glucose’ |
| All types of caseinates | Caseinates |
| Milk products containing a minimum of 50% of milk protein (m/m) in dry matter * | Milk Protein or Milk Powder |
| Press, expeller or refined cocoa butter | Cocoa Butter |
| All crystallized fruit not exceeding 10% of the weight of the food | Crystallized Fruit |

*Calculation of milk protein content : Kjeldahl nitrogen × 6.38

3.1. Flavors and flavoring substances whether in any of the category below shall also be declared as part of the list of ingredients.

- a) *Natural flavors* – flavoring substance derived through appropriate physical processes from spices, herbs, fruits or fruit juices, vegetable or vegetable juices, edible yeast, bark, bud, root, leaf of plant materials, meat, fish, poultry, eggs, dairy products or fermentation products thereof.
- b) *Nature – identical flavoring substance* – substances chemically derived from aromatic materials or obtained synthetically, which are chemically identical to substances present in natural products intended for human consumption.
- c) *Artificial flavoring substances* – substances that impart flavor but which have not been identified in natural products or natural sources of flavorings.

3.2. Flavor as classified above shall be declared as “Natural Flavor(s)”, “Nature – identical flavor(s)” or “Flavor(s)” for (a), (b) and (c) respectively. In the case of combination of Natural Flavors and Nature – identical flavors it shall be declared as such or simply “Flavors.”

3.3. Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food shall be declared as artificial flavor or artificial smoke flavor. *Provided that, no representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoke flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other food will result in a smoked product or one having a true smoked flavor.*

3.4. Coloring substances shall be declared by their common name or as “Food Color(s)” or “Color(s)” for those that are derived from or identical with substances derived from plant materials, and as “Artificial Color(s)” for coal-tar dyes or other synthetic chemical compounds.

3.5. The specific names of vegetable or mineral oil used shall be indicated. In the case of mixture of two or more vegetable or mineral oils the declaration shall be in the following manners “vegetable and mineral oil” (name of oils in decreasing order of proportion) “or blend of vegetable or mineral oil” (name of possible oil blends). In case two or three vegetable oils are used interchangeably, declaration such as coconut oil and/or palm oil (in decreasing order or proportion) may be indicated.

3.6. Declaration of Food Additives

3.6.1. Food additives shall be declared by their common name and must be consistent with the functional class names provided under Bureau Circular No. 2006-016 or other issuances of FDA. Class name which indicate their functional categories may also be indicated.

3.6.2 Processing aids and food additives carried over into food (from another food that was used as an ingredient) at levels less than those required to achieved technological function, need not be declared in the list of ingredients.

4. Net Contents and Drained Weight

4.1 The net content shall be declared using the metric system of measurement or “SI” (International System of Units) on either the principal display panel or the information panel and in line generally parallel to the base of the package. The Declaration shall be made in the following manner:

- a) for liquid foods, by volume;

- b) for solid foods, by weight, except that when such foods are sold by number, a declaration of count shall be made;
- c) for semi-solid or viscous foods, either by weight or volume.

4.2 Foods packed in a liquid medium normally discarded before consumption shall carry a declaration of drained weight. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices, in canned fruits and vegetables only or vinegar, either singly or in combination.

4.3 For multi unit retail packages, a statement of the quantity of contents on the outside package shall include the number of individual units, the net content of each individual unit, and in parenthesis the total quantity of contents of the multiunit package.

A multi unit retail package may thus be properly labeled.

“20 x 10 g sachets (net wt. 200 g)” or

“6 x 300 ml bottles (1.8 L or 1000 ml)”

5. Name and address of Manufacturer, Packer and Distributor

5.1 The complete name and address of the manufacturer, packer/repacker and/or distributor (for locally produced food) or importer (for imported food) of the food shall be declared on the label. However, for establishment with multiple manufacturing plants, the corporate head office address would suffice as long as a product code that would identify the plant where the product was manufactured is provided.

5.2 If the food is not manufactured by the person or company whose name appears on the label, the name must be qualified by “manufactured for” or “Packed for” or similar expression.

5.3 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 manufacture for the purposes of labeling.

6. Lot Identification

The lot identification code shall be embossed or otherwise permanently marked on the immediate individual packages or containers. Except for small packs not sold individually and with size less than 10 cm² surface area.

7. Food Authorization Number

The assigned food authorization number to the food product authorized by the Food and Drug Administration (FDA) to be manufactured, imported, exported, and/or distributed must be printed clearly and indelibly on the principal display panel or immediate container.

8. Storage Condition

For products that need special storage condition other than normal room temperature, the storage condition shall be printed clearly, conspicuously and indelibly on all product label or labeling. Direction/ Instruction for Use shall also be printed, where applicable.

9. Nutrition Facts

Nutrition facts, in tabular form, shall be printed on the label or in the labeling and must conform to the requirements of this section. It must contain the following energy and nutrients per serving size:

- 9.1. The nutrition facts shall be presented through the declaration of protein, carbohydrate (including dietary fiber and sugar), fat (including saturated fat, trans fat and cholesterol), sodium and energy value, vitamins A and c, and minerals iron and iodine in tabulated form as shown below.
- 9.2. The declaration of nutrient quantities shall be on the basis of the food as packaged.
- 9.3. All nutrient quantities shall be declared in relation to the average or usual serving in terms of slices, pieces or a specified weight or volume.
- 9.4. Carbohydrates, protein, fats (cholesterol expressed in *mg*), sugar and dietary fiber, shall be expressed in nearest Gram (*g*). Energy values shall be expressed in Calories (*kcal*). Sodium shall be declared in *mg*.
- 9.5 Vitamins and minerals shall be expressed in Milligram (*mg*) or Microgram (*m_{cg} or _{ug}*), with their corresponding Recommended Energy and Nutrients Intakes (RENI) values in actual percentage expressed in whole numbers.
- 9.6 For imported prepackaged product expressed in RDA, the RDA values shall be based on the Philippine RENI except that in the absence thereof for certain nutrients, the CODEX or U.S. RDA values may be cited and shall be specified.
- 9.7 For purposes of computing the nutrient content expressed in terms of % RENI the computation shall be based on the Philippine Recommended Energy and Nutrient Intake (RENI) for male adults ages nineteen (19) to twenty nine (29). For certain nutrients without corresponding Philippine Recommended Energy and Nutrient Intake (RENI) value, the CODEX, US RDA or other acceptable International nutrient values may be used in the computation which must be cited and shall be specified. In cases of food products intended for a specific group, RENI values for the said group shall be made as the basis of RENI declaration and such fact shall be indicated on the label.
- 9.8 Nutrients present in amounts less than 2 percent of the RENI shall be indicated by zero, or by the statement “contains less than 2% of the RENI” or by an asterisk referring to this statement or not declared at all.
- 9.9 Fatty acid composition content may also be declared.
- 9.10 The rules on any use of nutrition claims or health claims in food, except for those covered by the Philippine food fortification guidelines, shall be covered by the CODEX Guidelines for use of Nutrition and Health Claims under CAC/GL 23-1997, amended in 2001, 2008 and 2009.
- 9.11 The declaration of Nutrition Facts shall be as follows:

| | |
|-------------------------------------|-------------------|
| Nutrition Facts | |
| Serving Size: | |
| No. of Servings per container/pack: | |
| Amount per Serving: | |
| Calories (kcal) | Calories from Fat |
| | % RENI* |
| Total Fat (g) | |

| | |
|-------------------------|--|
| Saturated fat (g) | |
| Trans Fat (gm) | |
| Cholesterol (mg) | |
| Sodium (mg) | |
| Total Carbohydrates (g) | |
| Dietary Fiber (g) | |
| Sugar (g) | |
| Total Protein (g) | |
| Vitamin A (mcg) | |
| Vitamin C (mg) | |
| Iron (mg) | |
| Iodine (mcg) | |

*Percent RENI values are based on FNRI reference adult requirement of 19-29 yrs. old.

9.12 For the purpose of compliance with nutrient label declarations;

- a) The nutrient content of a food shall be at least equal to 80 percent of the value for that nutrient declared on the label at any point in time within the expected shelf-life of the product.
- b) The carbohydrate, protein, fat or energy value shall not exceed 20 percent of the value declared on the label.

9.13 If a food product does not contain nutrient(s) (based on the composition of the product, added or inherent) required to be declared, analysis may not be submitted.

9.14 Nutrition Labeling Exemptions

9.14.1 Foods for Special Dietary Uses and foods for special medical purposes covered by a separate guideline where nutrition labeling is prescribed, or codex standards.

9.14.2 Bottled drinking water which has its own prescribed labeling guidelines.

9.14.3 Prepackaged foods in multi-units retail packages such as candies with surface area less than 10 cm² may be exempted from the requirements of nutrition labeling when sold together with the primary packaging.

9.14.4 Pre-packaged fresh agricultural commodities

9.14.5 Local Small and Medium Enterprises (SME) business based on capitalization classification provided in the current guidelines on schedule of fees.

9.14.6 Foods served or sold in restaurants which are not labeled or prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes, and retail stores) for immediate consumption.

9.14.7 Foods that are not for immediate consumption and are not processed or prepared on the premises, but are packaged and portioned on a consumers' request (e.g. catering, sold directly from the dispenser)

9.14.8 Foods that contain insignificant amounts of all nutrients required to be listed in nutrition labeling (e.g., coffee and most spices, flavor extract, food color as determined by FDA).

9.14.9 Medical Foods (which has its own labeling guidelines based on codex)

9.14.10 Bulk foods for further manufacturing or repacking.

9.14.11 Foods in packages with available label space of less than 10 cm² (e.g. pack of gum) provided that no health and nutrition claim is made.

9.14.12 Food sold from bulk containers, provided that nutrition information is provided at point of sale.

9.14.13 Foods for infants and young children such as infant formula, follow-up formula shall follow the FDA labeling guidelines.

10. Expiry or Expiration Date (RA 7394) or Consume Before Date (Codex Labeling guidelines)

Expiry/expiration date or Use-by-Date shall be printed clearly, conspicuously and legibly on all product label in the following order: Day, Month, Year. The declaration of day and year are numerical while the declaration of month must be in words to avoid confusion (e.g. Expiry date: 09 September 2008 or 09Sept09). The expiry date must be printed on the primary and secondary label, as the case maybe, of all processed food products.

11. Food Allergen

Food allergen, such as but not limited to those listed below shall be indicated clearly, conspicuously and indelibly (e.g. Contains food allergen- egg)

The following ingredients known to cause hypersensitivity should always be declared:

- a) Cereal containing gluten, i.e. wheat, rye, barley, oat, spelt or their hybridized strain and products of these;
- b) Crustaceans and products of these;
- c) Eggs and eggs products;
- d) Fish and fish products;
- e) Peanuts, soybeans and products of these;
- f) Milk and milk products (lactose included);
- g) Tree nut and nut products;
- h) Sulphite in concentrations of 10mg/kg or more

C. Other Requirements

1. Alcoholic Beverages

In addition to the labeling requirements under Section V (B) of this regulation, the Alcohol content in terms of percentages or proof units shall be indicated on the principal display panel of the label of alcoholic beverages.

2. Language

The language used for all information on the label shall be either English or Filipino or a combination thereof. For food products intended for export the language acceptable to the importing country shall be used.

In the case of imported food products, labels where in the information are declared in a foreign language must also carry the corresponding English translation.

3. Additional Information

Whenever aspartame is used in the product, this statement shall be declared legibly "Aspartame warning: Phenylketonurics contain phenylalanine."

Additional information when mandated in a Food Standard or any other FDA regulation or as deemed necessary shall be indicated on the label.

D. Misleading Declaration/ Representations

A food labeled under the provision of this section shall be deemed to be misbranded if its labeling represents, suggests or implies directly or indirectly, such as but not limited to those listed below:

- a. That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation or treatment of any disease or symptom.
- b. That a balanced diet of ordinary foods i.e. food from the family pot, cannot supply adequate amount of nutrients
- c. That the food has dietary properties when such properties are of no significant value or need in human nutrition.
- d. That a synthetic vitamin in a food is superior to natural vitamin.

E. Violations and Sanctions

Any violation of the provision of this Administrative Order shall render the food product misbranded under RA9711 and such misbranded food products and the responsible person shall be subject to ACTIONS AVAILABLE TO THE FDA AND the penalties PROVIDED UNDER the appropriate provisions thereof.

VI. TRANSITORY PROVISION

Six months (6) from the effectivity of this Order, all labels of pre-packaged food covered by this Order must be compliant with the requirements and rules set hereof. Any products by this Order must be compliant with the requirements and rules set hereof. Any products not complying with this Order thereafter are deemed misbranded and appropriate sanctions against the establishment violating this Order shall be imposed. Any provisions under AO 88-B s. 1984 which are not covered by this revised rules and regulations are still in effect until modified accordingly.

VII. REPEALING CLAUSE

Provisions of previous issuances which are not consistent to those reflected hereon are modified, and/or repealed accordingly.

VIII. SEPARABILITY

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

IX. EFFECTIVITY

This regulation shall take effect immediately upon approval and publication in two (2) Newspapers of general circulation.

ENRIQUE ONA, M.D.

Secretary of Health

