FOOD ACT 1983
FOOD (AMENDMENT) (NO. 1) REGULATIONS 2014

New regulation 389B

1. The principal Regulations is amended by inserting after regulation 389A the following regulation:

389B: INFANT FORMULA FOR MEDICAL PURPOSES

(1) Infant formula for medical purposes means a substitute for human milk or infant formula that is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

(2) Infant formula for medical purposes is a product based on ingredients based of animal, plant and/or synthetic origin suitable for human consumption. All ingredients and food additives shall be gluten-free.

(3) The composition of infant formula for medical purposes shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended, as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

(4) No product shall be labelled as an infant formula for medical purposes except those categories listed in Table I of the Twenty-first B Schedule or with prior written approval from the Director. In addition to the general requirements stipulated in this Regulation, infant formula for medical purposes shall comply with the specific requirements appropriate for the category listed in Table 1 of the Twenty-first B Schedule.

(5) The energy content and nutrient composition of infant formula for medical purposes shall comply with subregulation 389 (3) and 389 (4) except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

(6) In addition to the requirements in (5), the following requirements shall also be taken into account, where appropriate-

	Minimum (µg/100 kcal)	Maximum (µg/100 kcal)
Chromium	1.5	10
Molybdenum	1.5	10

(7) Infant formula for medical purposes may contain optional nutrients as specified in column (1) of Table II to the Twenty-first Schedule in amount of not more than the maximum permitted proportions as specified against in column (2) of the Table when prepared ready for consumption in accordance with instruction of the manufacturer.

(8) Other optional nutrients may be used in order to provide substances ordinarily found in human milk or required to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of his/her disease, disorder or medical condition with the written approval from the Director.

(9) The suitability, benefits and safety for the particular nutritional uses of infants and the safety of these other optional nutrients shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.

(10) Only L(+)lactic acid producing cultures may be used in infant formula for medical purpose if shown to be safe and appropriate for use in these vulnerable populations.

(11) Infant formula for medical purposes or the ingredient used in making the formula shall not have been treated by ionizing radiation.

(12) Commercially hydrogenated oils and fats shall not be used in infant formula for medical purposes.

(13) Only the food additives specified in column (1) of the Table III to the Twenty-first Schedule are acceptable for use in the preparation of infant formula for medical purposes in amount of not greater than the maximum permitted proportions specified opposite thereto in column (2) of the said Table.

(14) Food additive listed in Table III to the Twenty-First Schedule maybe present as a result of carryover from raw materials, nutrients, or other ingredient provided the food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice.

(15) There shall be written in the label on a package containing infant formula for medical purposes, in not less than 10 point lettering –

(a) the words **"RUMUSAN BAYI UNTUK TUJUAN PERUBATAN [STATE THE NAME OF THE PRODUCT CATEGORY]"**. These words shall be more prominent in visual emphasis and position and not less than half the height when compared with the brand name of the formula.; and

(b) a statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful should follow in close proximity on the product label.

(16) Listing of ingredients for infant formula for medical purposes shall be as follows-

(a) a complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion;

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

(c) the name of the animal or plant from which the ingredients are derived. The name of the name of animal or plant shall be written in bold; and

(d) the sources of protein in the product shall be clearly shown on the label.

(17) Notwithstanding subregulation 18B, the declaration of nutrition information for infant formula for medical purposes shall be as follows-

(a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepare according to the instructions on the label;

(b) the total quantity of each vitamin, mineral, choline as listed in Table I of Twenty-First Schedule and any other ingredient as listed in Table II of Twenty-First Schedule of this Standard per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label; and

(c) in addition, the nutrients listed in (a) and (b) shall also be declared as per 100 kilocalories (or per 100 kilojoules)

(18) The following details shall be written in the principal display panel in the label of a package containing infant formula for medical purposes-

(a) the words **"NOTIS PENTING"** and **"SUSU IBU ADALAH MAKANAN TERBAIK BAGI BAYI"**. These words shall be in not less than 10 point size lettering for 500 g package and the size of lettering shall increase proportionately with the size of the package;

(b) in not less than 4 point lettering and in bold, the words :-

(i) **"RUMUSAN BAYI BUKANLAH MAKANAN TUNGGAL BAGI BAYI YANG BERUMUR LEBIH DARIPADA 6 BULAN";**

(ii) **"SILA DAPATKAN NASIHAT PROFESIONAL PERUBATAN SEBELUM MENGGUNAKAN PRODUK INI";**

(c) the terms "humanized", "maternalized" or other similar terms shall not be used; and

(19) The label of an formula for medical purposes shall not display any picture or graphics of infants or babies or parts of infants or babies, mothers, feeding bottles or teats. But for purposes of illustrating the methods of preparation of an infant formula for special medical purposes, graphics may be used.

(20) No label of an infant formula for medical purposes shall display any claim of superiority of the product to breast milk.

(21) There shall be written on the label on the package containing infant formula for medical purposes the following information for use-

(a) products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children;

(b) the method of preparing the food which shall include a statement of the quantity or the amount of food directed to be used in the preparation to be given to the infant;

(c) a statement suggesting the amount of the prepared food to be given at one time, and the number of times such amount is to be given per day; such statement to be provided for each month or age up to six months or may include six months onwards or may include per kg body weight;

(d) adequate directions regarding the appropriate disposal the formula remaining after feeding;

(e) the instructions for correct preparation and a warning against the health hazards of incorrect preparation;

(f) direction for storage and information regarding its keeping before and after the package has been opened;

(g) a prominent statement **"GUNAKAN DI BAWAH PENGAWASAN PERUBATAN"** shall appear on the label in bold letters in an area separated from other written, printed, or graphic information;

(h) an additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if infant formula for medical purposes poses a health hazard when consumed by infants who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended;

(i) a prominent statement indicating that the product is/ or is not intended as the sole source of nutrition shall appear on the label; and

(j) labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.

(k) Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from over 6 months of age that is appropriate for their specific growth and development needs, unless otherwise advised by health professional.

(22) In addition, the information on a complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable shall be included on the label or be provided separately from the package.

(23) The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and infant formula for medical purposes.

(24) Any descriptive matter appearing on or attached to or supplied with any package of infant formula for medical purposes shall not include any information on the promotion or advertisement of another product.