NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Dietary Supplement Regulations, 2019

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Dietary Supplement Regulations, 2019

ARRANGEMENT OF REGULATIONS

Regulations

Dietary Supplement Regulations, 2019

[ ] **Commencement**

In exercise of the powers conferred on it Sections 5 and 30 of the National Agency for Food and Drugs Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Honorable Minister of Health makes the following Regulations –

1. **Scope of application**

   These Regulations apply to dietary supplements manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

2. **Prohibition**

   (1) A dietary supplement shall not be manufactured, imported, exported, advertised, sold or distributed in Nigeria, unless it has been registered in accordance with the provisions of these Regulations.

   (2) Dietary Supplements shall not include any of the following:
   (a) any product as a sole item of a meal or diet;
   (b) any injectable and sterile preparation
   (c) any product that is defined otherwise in these regulations

   (3) A dietary supplement shall not contain a medicinal ingredient.

3. **General provisions**

   (1) Dietary supplements shall be presented to the consumer only in a pre-packaged form.

   (2) Dietary supplements shall not be specifically intended for infants below the age of 12 months.

   (3) Notwithstanding regulations 3 (2) to these Regulations, dietary supplements may be specifically intended for infants below the age of 12 months where there is significant scientific evidence establishing the safety of the supplement for that purpose. The use of the dietary supplement shall be in accordance with the current Marketing of Infant and Young Children Food (and other designated) Product.

   (4) A dietary supplement shall not bear a medicinal claim. The labelling, presentation and advertising of dietary supplements shall not attribute to dietary supplements the property of treating or curing a human disease, or refer to such properties.

   (5) Dietary supplements shall only contain vitamins and minerals in the forms as listed in the First Schedule to these Regulations for the manufacture of dietary supplements. Where other dietary

ingredients other than vitamins and mineral are used, it shall be as prescribed in the First Schedule to these Regulations.

(6) Products containing vitamins shall not be at the therapeutic levels. The vitamins and the levels above which they are deemed to be therapeutic are as listed in Fourth Schedule of these Regulations.

(7) Novel dietary ingredients are not permitted for use in dietary supplements except where there is scientific evidence establishing the safety.

4. **Safety and quality requirements**

(1) Dietary supplements shall comply with the safety and quality requirements provided in these Regulations.

(2) Dietary supplements shall not;

(a) contain any other substances except those stated on the label;

(b) contain any human part or substance derived from any part of the human body;

(c) make any claim to directly or indirectly refer to any diseases and disorder

5. **General requirements for labeling of dietary supplement**

In addition to the provisions of the Pre-packaged Food, Water and Ice (Labelling) Regulations, 2019, the following shall apply in the labelling of dietary supplement;

(a) a statement of identity that contains the words "dietary supplement." The word "dietary" may be replaced by the name of the predominant dietary ingredient.

(b) statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which shall not exceed the maximum daily dose and, if the dietary supplement is suitable for children, the recommended daily dose for children

(c) the declaration of the scientific name of the plant if the dietary ingredient is a botanical or common or usual name standardized in the reference herbs of plant. A statement of the part of the plant used, if a herb or botanical is used

(d) a warning not to exceed the stated recommended daily dose and avoid overdose

(e) a statement to the effect that dietary supplements shall not be used as a substitute for a varied diet

(f) a statement to the effect that the product shall be stored out of the reach of children

(g) the declaration of the safety information that is considered relevant to the consequences that may result from the use of the supplement where applicable.

(h) declaration of the disclaimers "This statement has not been evaluated by National Agency for Food and Drug Administration and Control" and "This product is not intended to diagnose, treat, or cure any disease", if the supplement bears a claim to affect the structure or function of the body (structure/function claim), a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease.

(i) where the size, shape or nature of the final product or package does not permit the full listing of labelling information, the use of inserts, leaflets, hang tags, in appropriate format, will be allowed.

6. **Declaration of nutrients**

(1) The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the label.

(2) Information on vitamins and minerals shall also be expressed as a percentage of the nutrient reference values.

(3) The declared values shall be average values based on the manufacturer's analysis of the product.

7. **Contents of vitamins and minerals**

(1) The minimum level of each vitamin and mineral contained in vitamin and mineral Dietary supplement per daily portion of consumption as suggested by the manufacturer shall be 15% of the Nutrient Reference Value (NRV).

(2) Maximum levels of vitamins and minerals contained in vitamin and mineral dietary supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

8. **Packaging**

Dietary supplement shall be packed in packaging material which shall be made only of substances which are safe and suitable for their intended use.

9. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N500,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N750, 000.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association ;or

(e) person who purports to act in a capacity referred to in paragraphs (a) to (d) of this sub-regulation,

is severally liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

10. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;

(b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

(2) In this regulation, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

11. **Interpretation**

In these Regulations, unless the context otherwise requires

Agency means National Agency for Food and Drug Administration and Control.

Batch means a quantity of dietary supplement produced under essentially the same conditions during a particular period, and usually from a particular "line" or other identifiable processing unit.

Common name means In relation to a dietary supplement, means the name by which the dietary supplement is generally known, being a noun defined in a dictionary of the English language of authority.

Packaging material means any form of packaging of dietary supplementary for sale as a single item whether by completely or partially enclosing the dietary supplementary and includes wrappers, but does not include leaves traditionally used as food wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

Dietary supplement means is a product (other than tobacco) that

(a) is intended to supplement the diet;

(b) contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;

(c) is intended to be taken by mouth as a pill, capsule, tablet, or liquid;

(d) is labeled on the front panel as being a dietary supplement.

Dose form means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;

Incidental constituent means any extraneous substance, toxic substance, or pesticide that is contained or present in or on any dietary supplement; but does not include any preservative, antioxidant, colouring substance, artificial sweetener, flavouring substance, Dietary conditioner, anti-caking agent, gaseous packing agent, propellant, or vitamin, or any mineral.

Ingredient means any substance, other than an incidental constituent, that is;
(a) used in the manufacture or preparation of a dietary supplement; and
(b) present, whether in a modified form or not, in the final product

Medicinal claim means a health claim, which states or implies that a product has the property of treating, preventing or curing human disease.

Nutrients means the following substances:
(a) vitamins,
(b) minerals;

Nutrient Reference Value; NRV means a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims.

Other substances means any substance falling within one of the categories listed in the third Schedule to these Regulations.

Principal Display Panel means that part of the label that bears the brand name or trade name and product name in greatest prominence and which is likely to be seen at first glance by the consumer at the time of purchase, that enables the consumer to immediately identify a product in terms of its character or nature;

Printed means written, typewritten, engraved, lithographed or otherwise traced or copied.

12. **Citation**

These Regulations may be cited as Dietary Supplement Regulations, 2019

FIRST SCHEDULE

Vitamins and Minerals which may be used in the manufacture of Dietary Supplements

Vitamins	**Forms in which they may be used**
Biotin (µg)	D-biotin
Folic acid (µg)	Pteroylmonoglutamate acid
Niacin (Mg NE)	Nicotinic acid Nicotinamide
Pantothenic acid (mg)	D-pantothenate calcium D-pantothenate sodium
Vitamin A (µg RE)	Retinol Retinyl acetate Retinyl palmitate Beta-carotene
Vitamin B1 (mg)	Thiamin hydrochloride Thiamin mononitrate
Vitamin B2 (mg)	Riboflavin Riboflavin 5-phosphate
Vitamin B6 (mg)	Pyridoxine hydrochloride Pyridoxine 5-phosphate
Vitamin B12 (µg)	Cyancobalamin Hydroxocobalamin
Vitamin C (mg)	L-ascorbic acid Sodium-L-ascorbate Calcium-L-ascorbate Potassium-L-ascorbate L-ascorbyl 6-palmitate
Vitamin D (µg)	Cholecalciferol Ergocalciferol
Vitamin E (mg α-TE)	D-alpha-tocopherol DL-alpha-tocopherol D-alpha-tocopheryl acetate DL-alpha-tocopheryl acetate D-alpha-tocopheryl acid succinate
Vitamin K (µg)	Phylloquinone (phytomenadione)
Minerals	**Forms in which they may be used**
Calcium (mg)	Calcium carbonate Calcium chloride Calcium gluconate

	Calcium glycerophosphate Calcium hydroxide Calcium lactate Calcium oxide Calcium salts of citric acid Calcium salts of orthophosphoric
Chronium (µg)	Chromium (III) chloride Chromium (III) sulphate
Copper lysine complex (µg)	Cupric carbonate Cupric citrate Cupric gluconate Cupric sulphate
Iron (mg)	Ferric ammonium citrate Ferric diphosphate (ferric pyrophosphate) Ferric saccharate Ferric sodium diphosphate Ferrous carbonate Ferrous citrate Ferrous fumarate Ferrous gluconate Ferrous lactate Ferrous sulphate
Mangnesium (mg)	Magnesium acetate Magnesium carbonate Magnesium chloride Magnesium gluconate Magnesium glycerophosphate Magnesium hydroxide magnesium oxide Magnesium salts of citric acid Magnesium salts of orthophosphoric acid Magnesium lactate Magnesium sulphate Manganese carbonate Manganese chloride Manganese citrate Manganese gluconate Manganese glycerophosphate Manganese sulphate
Potassium (mg)	Potassium bicarbonate Potassium carbonate

	Potassium chloride Potassium citrate Potassium fluoride Potassium gluconate Potassium glycerophosphate Potassium hydroxide Potassium iodide Potassium iodate Potassium lactate Potassium salts of orthophosphoric acid
Sodium (mg)	Sodium iodide Sodium iodate Sodium bicarbonate Sodium carbonate Sodium chloride Sodium citrate Sodium fluoride Sodium gluconate Sodium hydroxide Sodium hydrogen selenite Sodium lactate Sodium molybdate [molybdenum (VI)] Sodium salts of orthophosphoric acid Sodium selenate Sodium selenite
Zinc (mg)	Zinc acetate Zinc chloride Zinc citrate Zinc carbonate Zinc gluconate Zinc lactate Zinc oxide Zinc sulphate

THIRD SCHEDULE

Illustrative List of Categories of Substances other than Nutrients which may be present in Dietary Supplements

Herbs

Botanical products

Other plant-derived substances

Amino acids

Fatty acids

Enzymes

Organ tissues

Glandular tissues

Constituents, concentrates, metabolites and extracts of plant or animal origin

FOURTH SCHEDULE

Nutrients at Medicinal Levels

Nutrients	**Forms**	**Medicinal level**
Vitamin A	Retinol Retinyl Acetate Retinyl Palmitate	2250ug / 7500IU 2250ug / 7500IU 2250ug / 7500IU
Vitamin D	Cholecalciferol Ergocalciferol	75ug / 0.0075mg / 3000IU 75ug / 0.0075mg / 3000IU
Vitamin K	Phylloquinone (Phytomenadione)	
Niacin	Nicotinic Acid Inositol Hexanicotinate (Inositol Hexaniacinate)	600mg
Folic Acid	Pteroylmonoglutamic Acid	500ug
Vitamin B6	Pyridoxine Hydrochloride	50mg
Vitamin B12	Cyanocobalamin	25ug
	Hydroxocobalamin 25ug	25ug

MADE at Abuja this……..day of …….2019

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Inuwa Abdulkadir Esq

Chairman Governing Council

National Agency for Food and Drug Administration and Control (NAFDAC)