FDA Circular
No. _____

SUBJECT: **Guidelines for the Classification of Vitamins and Minerals for Food/Dietary Supplements under Processed Food Product Repealing the Provisions for Food in the Office Order No. 22 s. 1991 entitled "Guidelines for the Classification of Vitamins and Minerals as Drug or as Food"**

I. RATIONALE

It is a policy of the State as embodied in Article II, Section 15 of the 1987 Constitution to protect and promote the right to health of the people and instill health consciousness among them. It is also stated under Section 12, Article XIII of the same document that an effective food and drug regulatory system shall be established and maintained to undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

The FDA issued Office Order No. 22 s. 1991 on 18 October 1991 that sets the limit for vitamins and minerals to be classified as food supplements. After thorough review and evaluation, and to keep pace with the advances in energy and nutrient requirements, the FDA shall use the different international references in setting the limits of vitamins and minerals such as Association of Southeast Asian Nations (ASEAN), Codex Alimentarius Commission, Food and Agriculture Organization/World Health Organization (FAO/WHO), European Food Safety Authority (EFSA), USFDA, among others.

The establishment of limit of vitamins and minerals in food/dietary supplements aims to ensure that the manufacturers use safe levels of vitamins and minerals in their products. Thus, use of the products under the instruction or direction for use provided by the manufacturers will be safe for the consumers

Accordingly, with the aim to provide coherence in the regulation of food/dietary supplements containing vitamins and minerals under the FDA-Center for Food Regulation and Research, the issuance of this Circular is deemed imperative.

II. OBJECTIVES

This Circular aims to:

A. provide guidelines to all Food Business Operators (FBOs) on the classification of vitamins and minerals as food/dietary supplements; and

B. set updated limit of vitamins and minerals to be classified as food/dietary supplements under processed food products.

III. SCOPE

This Circular shall cover all local and imported food/dietary supplements intended to be manufactured, used, imported, distributed and offered for sale in the Philippines.

IV. DEFINITION OF TERMS

For purposes of these Guidelines, the following definitions shall apply:

A. Food refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water and other substances which are intentionally incorporated into the food during its manufacture, preparation and treatment.

B. Food/Dietary Supplements means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It is usually in the form of capsules, tablets, liquids, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

C. Nutrient means any substance normally consumed as a constituent of food:

1. which provides energy; or
2. which is needed for growth, development and maintenance of life; or
3. a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

D. Philippine Dietary Reference Intakes (PDRI) is the collective term comprising reference value for energy and nutrient levels of intakes.

E. Recommended Energy/Nutrient Intake (REI/RNI) refers to the level of intake of energy or nutrient which is considered adequate for the maintenance of health and well-being of healthy persons in the population.

V. GENERAL GUIDELINES

A. The intended use of the product shall be as food/dietary supplement.

B. The product to be classified as food/dietary supplement shall be in form of capsules, tablets, liquids, gels, powders or pills and is not represented for use as a

conventional food. It shall not be in parenteral forms, sublingual, and among other routes of administration not taken directly into the mouth.

C. There is no additional active pharmaceutical ingredients or drug ingredients.

D. There is no clinical therapeutic indication or claims.

E. Food/dietary supplements with vitamins and minerals shall supplement the diet but these will not correct nutritional deficiencies.

F. Levels of vitamins and minerals shall be reviewed/revised based on safe levels established by latest generally accepted scientific evidence based on national food consumption surveys and population exposure assessment.

VI. SPECIFIC GUIDELINES

A. The following maximum level for adults shall be applied to vitamins and minerals to be classified as food/dietary supplement:

Maximum amounts of vitamins and minerals in food/dietary supplements shall be set, taking the following criteria into account:

i. Maximum levels based on Upper Levels of Vitamins and Minerals (*see Table 1*), considering sensitivities of individuals to certain vitamins/minerals
ii. The daily intake of vitamins and minerals from other dietary sources.

Table 1. *Maximum level of vitamin and minerals for adults to be classified as food/dietary supplement.*

Vitamins/Minerals	Maximum Level
Vitamin A (Retinol)	1500 mcg RE/day
Vitamin D	25 mcg/day
Vitamin E	536 mg/day (800 IU/day)
Vitamin K	120 mcg/day
Vitamin C	1000 mg/day
Vitamin B1	100 mg/day
Vitamin B2	40 mg/day
Vitamin B6	100 mg/day
Folic acid	0.9 mg/day or 1500 mcg DFE/day
Vitamin B12	600 mcg/day
Biotin	0.9 mg/day
Nicotinic acid	15 mg/day
Nicotinamide	450 mg/day
Pantothenic acid	200 mg/day
Calcium	1200 mg/day
Phosphorous	800 mg/day
Magnesium	350 mg/day

Boron	6.4 mg/day
Chromium	0.5 mg/day
Copper	2 mg/day
Iodine	150 mcg/day
Iron	15 mg/day
Manganese	3.5 mg/day
Molybdenum	0.36 mg/day
Selenium	200 mcg/day
Zinc	15 mg/day

B. As food/dietary supplements forms only part of the diet of consumers, the levels of vitamins and minerals shall not reach the maximum levels for food supplements as other sources of nutrients from the diet are expected to contribute to nutrient intakes. This is to ensure safety and protect consumers as the amount beyond the Upper levels of vitamins and minerals will pose adverse health effects.

C. A recent (within 24 months from the date of application) Certificate of Analysis reflecting quantitative vitamins and minerals assay, validated reference methods of analysis, the limit of detection for the method used in the analysis, and complete name and signature of Competent Technical Analyst/Staff, and Stability Data of the finished product with at least six (6) months result shall be submitted as part of the registration requirements, from an accredited laboratory of the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of origin.

D. The percent (%) REI/RNI from the PDRI 2015 prescribed by the DOST-FNRI shall be used in the nutrition information in replacement of the 2002 Recommended Energy and Nutrition Intake (RENI).

E. For the Vitamin K, the form shall only be Vitamin K1 and/or Vitamin K2, and the intended use shall be in oral form of multivitamin or mineral preparations for adults and not as a single ingredient. Also, a precaution "Consult a health care practitioner prior to use if you are on anticoagulant therapy or taking blood thinners such as warfarin" shall be reflected on the label.

F. For nutrients not included in the Table 1, and that have no established hazards at high intakes, their maximum intake levels with sufficient evidence of safety (observed safe level) established by scientific risk assessment based on generally accepted scientific data shall be submitted.

G. The process for registration and other requirements not mentioned in this Circular shall follow the Administrative Order 2014-0029 and FDA Circular 2020-033 or their latest revisions.

H. The label shall contain advice to the consumer not to exceed the maximum recommended use per day.

I. The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

J. The labeling shall be in accordance with Administrative Order No. 2014-0030,

Bureau Circular 02 s. 1999, other related issuances and their latest revisions.

K. All nutrients that will exceed the maximum level as prescribed in Table 1 shall be denied for registration application.

VII. TRANSITORY PROVISION

Affected manufacturers, traders, importers and distributors of food/dietary supplement products distributed in the Philippines are given a transition period as follows:

A. All affected food/dietary supplements that needs to reformulate and has a valid CPRs expiring within five (5) years from effectivity of this Circular shall file for initial application in compliance to this issuance before the date of expiration.

B. Those CPR with less than a year of validity upon effectivity of this Circular shall be renewed for a maximum of two (2) years, provided they are qualified for renewal, to give time for reformulation, after which, an initial application shall be filed.

C. In cases where there are still existing stocks of labels on the current CPR and stocks may be still available by the time of filing of new CPR and its approval, a request for an exhaustion may be filed (inventory of remaining stocks shall be declared), and once approved the exhaustion may be allowed within maximum of six (6) months.

VIII. REPEALING CLAUSE

The provisions for Food in Office Order No. 22 s. 1991 entitled "Guidelines for the Classification of Vitamins and Minerals as Drug or as Food", and other FDA issuances inconsistent with this Circular are hereby repealed accordingly.

IX. MONITORING AND REVIEW CLAUSE

This FDA Circular shall be reviewed and evaluated within three (3) years of its implementation to determine whether the policy's objectives, impact, and effectiveness are achieved.

X. SEPARABILITY CLAUSE

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and effect.

XI. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

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Director General

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