FDA CIRCULAR
No. 2025-001

06 JAN 2025

SUBJECT: **Guidelines on the Classification of Vitamins and Minerals for Food/Dietary Supplements for Adults under Processed Food Product, Repealing the Level Set 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 Section 15, Article II 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 Department of Health (DOH) through the Food and Drug Administration (FDA), was mandated to establish and adopt standards and quality measures to ensure purity, quality and safe supply of processed foods distributed locally based on provisions of Republic Act No. (RA) 3720, as amended by Executive Order (EO) No. 175, RA No. 7394 and RA No. 9711.

The FDA issued Office Order No. 22 s. 1991 entitled "Guidelines for the Classification of Vitamins and Minerals as Drug or as Food" on 18 October 1991 that set the limit for vitamins and minerals to be classified as food supplements. After 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 the Association of Southeast Asian Nations (ASEAN), Codex Alimentarius Commission, Food and Agriculture Organization/World Health Organization (FAO/WHO), European Food Safety Authority (EFSA), US Food and Drug Administration (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 these substances 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 (CFRR), the issuance of this Circular is deemed imperative.

II. OBJECTIVES

This Circular intends to establish a guideline on the product registration of food supplements. Specifically, it aims to:

A. Provide guidance to all Food Business Operators (FBOs) on the classification of vitamins and minerals as food/dietary supplements for adults; and

B. Set updated limit of vitamins and minerals to be classified as food/dietary supplements for adults.

III. SCOPE

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

This shall not cover the maximum level for pregnant, lactating and other vulnerable age group (e.g., infants, young children) which shall be based on percent Recommended Energy Intakes and Recommended Nutrient Intakes (REI/RNI) of the Philippine Dietary Recommended Intakes (PDRI) 2015 and its latest revision, processed food products intended for micronutrients supplementation, and ready-to-use therapeutic food.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the following terms shall be defined as follows:

A. Active Pharmaceutical Ingredients refers to substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).

B. Certificate of Product Registration (CPR) refers to authorization issued by the FDA for specific health products after evaluation and approval of submitted registration requirements.

C. 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.

D. Food/Dietary Supplements refers to 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.

E. **Maximum level (ML)** refers to the maximum concentration of the substance recommended to be permitted in food supplements.

F. **Minerals** refers to the elements on the earth and in foods that our bodies need to develop and function normally. Those essential for health include calcium, phosphorus, potassium, sodium, chloride, magnesium, iron, zinc, iodine, chromium, copper, fluoride, molybdenum, manganese, and selenium.

G. **Nutrient** refers to substance normally consumed as a constituent of food which provides energy, is needed for growth, development and maintenance of life, and a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

H. **Philippine Dietary Reference Intakes (PDRI)** refers to the collective term comprising reference value for energy and nutrient levels of intakes.

I. **Processing** refers to any action that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes intended to produce food.

J. **Recommended Energy Intake/Recommended 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.

K. **Vitamins** refers to the substances that our bodies need to develop and function normally. These include vitamins A, C, D, E, and K, choline, and the B vitamins (thiamin, riboflavin, niacin, pantothenic acid, biotin, vitamin B6, vitamin B12, and folate/folic acid).

V. GUIDELINES

A. Vitamins and Minerals as Food/Dietary Supplement

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

2. The product to be classified as food/dietary supplement shall not be in parenteral forms, sublingual, and among other routes of administration not taken directly into the mouth.

3. The food/dietary supplement shall not contain any active pharmaceutical ingredients or components considered as drug other than vitamins and minerals.

4. The food/dietary supplement shall not have any clinical therapeutic indications or therapeutic claims.

5. The food/dietary supplements with vitamins and minerals shall supplement the diet but these will not correct nutritional deficiencies.

6. The use of brand name and product name approved under other FDA Centers (i.e. Center for Drug Regulation and Research) shall not be allowed.

7. The percent (%) REI/RNI from the PDRI 2015 or its latest amendment prescribed by the Department of Science and Technology-Food and Nutrition Research Institute (DOST-FNRI) shall be used in the nutrition information in replacement of the 2002 Recommended Energy and Nutrition Intake (RENI).

8. The process for product registration and other requirements not mentioned in this Circular shall follow AO No. 2014-0029 entitled "Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes" and FDA Circular No. 2020-033 entitled "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" or their latest revisions.

9. The labeling shall be in accordance with AO No. 2014-0030 entitled "Revised Rules and Regulations Governing the Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Pre-packaged Food Products Distributed in the Philippines," and for Other Purposes", Bureau Circular 02 s. 1999 entitled "Amendment to BFAD M.C. No. 25, s. 1992 otherwise known as "Additional Labelling Requirement for Food Supplements", other related issuances and their latest revisions.

10. The label shall contain advice to the consumer not to exceed the maximum recommended use per day (i.e., Precaution: Do not exceed the recommended usage per day).

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

12. For the Certificate of Analysis (COA) of locally manufactured products, analysis conducted in-house may be allowed provided that the manufacturers have a capability to conduct testing, stability study, and has been verified by the FDA inspectors and reflected in the inspection report.

B. Level of Vitamins and Minerals for Adults

1. The maximum amounts of vitamins and minerals shall be set to be classified as Food/Dietary Supplement, with the following

criteria:

a. Maximum levels based on Upper Levels of Vitamins and Minerals (***see Table 1***), considering sensitivities of individuals to certain vitamins/minerals.

b. 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

2. For Vitamin K, it shall only be in the form of 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.

3. For Iron, a higher iron limit of 30 mg/day based on WHO as recommended by DOH may be used for food/dietary supplements for pre and antenatal

use in women.

4. In case that a vitamin or mineral is not listed in the Table 1, the 150% of RNI for water soluble and 105% RNI for fat soluble shall be used.

5. The food/dietary supplement shall contain at least 15% RNI of vitamins and minerals.

6. As food/dietary supplements form 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.

7. Any nutrient found in the food supplement that will exceed the maximum level as prescribed in Table 1 of this circular shall be denied for product registration application.

8. In the event of special circumstances such as national requirements based on country exposure assessment, safety, consumption survey (E.g. National Nutrition Survey), or product classification type, the established maximum levels shall be reviewed and revised accordingly.

VI. TRANSITORY PROVISION

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

A. All affected food/dietary supplements that needs to reformulate shall file for initial application in compliance to this issuance before the date of expiration provided those expiring within one (1) to two (2) years may file for renewal.

B. A CPR with less than one (1) year of validity upon effectivity of this Circular shall be allowed to renew for another two (2) years to give time for reformulation. After which, initial application shall be filed.

C. In cases where there are still existing stocks of labels on the current CPR and stocks may still be available by the time of filing of new CPR and its approval, a letter of request for an exhaustion may be filed (inventory of remaining stocks shall be declared), and once approved the exhaustion may be allowed for a maximum of twelve (12) months.

VII. MONITORING AND REVIEW

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

VIII. REPEALING CLAUSE

All provisions in relation to the FDA Center for Food Regulation and Research in Office Order No. 22 s. 1991 entitled "Guidelines for the Classification of Vitamins and Minerals as Drug or as Food" is hereby repealed. Other related issuances inconsistent or contrary to the provisions of this Circular are hereby repealed accordingly.

IX. SEPARABILITY CLAUSE

If any part, term, or provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

X. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center

DR. SAMUEL A. ZACATE
Director General

DTN 20231019152551