



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



October 18, 1991

OFFICE ORDER
No. 22 s. 91

TO : The Product Services Division and All Personnel Concerned

SUBJECT : Guidelines for the Classification of Vitamins and Minerals as Drug or as Food

The National Drug Committee (NDC) in a letter dated August 5, 1991 has recommended to BFAD the guidelines for the classification of vitamins and minerals as food or as drug. The said recommendation is hereby adopted, and we quote:

1. Vitamins and Minerals FDC shall be **classified as drug** based on the following criteria:
 - a. the clinical therapeutic indication or claim made for the preparation is for the preparation is for a specific vitamin deficiency or state or disease;
 - b. the strength or concentration per dosage form is $>105\%$ RDA for fat soluble and $>150\%$ RDA for water soluble vitamins;
 - c. it is in pharmaceutical dosage form/or injectable form;
 - d. it is highly purified; and
 - e. additional pharmacologically active ingredient(s) is (are) present.

2. Vitamins and Minerals FDC shall be **classified as food supplements** based on the following criteria:
 - a. the indication for the preparation is as dietary supplement;
 - b. the strength or concentration per dosage form is $<105\%$ RDA for fat soluble and $<150\%$ RDA for water soluble vitamins;
 - c. it may be available as non-pharmaceutical or pharmaceutical dosage form except parenterals;
 - d. it may be available as purified or as natural product; and
 - e. there are no additional pharmacologically active ingredient(s)



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SUMMARY:

CRITERIA	DRUG	FOOD
1. Clinical Therapeutic Indication or claims made for the preparation	Specific Vitamin deficiency state or disease	Dietary Supplement
2. Strength or concentration / dosage form	Fat Soluble: >105% RDA Water Soluble: >105% of RDA	Fat Soluble: <105% = of RDA Water Soluble: <150% = of RDA
3. Form	Pharmaceutical dosage forms and all injections	Pharmaceutical dosage form except parenterals or non-pharmaceutical form
4. Purity	Purified	Natural product or purified
5. Additional Pharmacologically Active Ingredients	Present	None

Henceforth, these guidelines shall govern the registration of vitamins and minerals. Any matters or any issues not covered by this Order shall be submitted to the Office of the Director and/or BFAD Management Committee for decision.

(Original Signed)

QUINTIN L. KINTANAR, MD, PhD

Director

Assistant Secretary of Health
For Standards and Regulation