

Regulations for Application and Evaluation of Nutritional Supplement (interim)

Article 1 For standardizing the evaluation of nutritional supplement, the regulations are formulated in accordance with Food Assanation of the People's Republic of China and Provisions for Health Food Registration (interim).

Article 2 Nutritional supplement refers to those products which can supply vitamin, minerals rather than providing energy. The function is to supplement any deficiency in nutrition intake from diet, prevent nutrition deficiency and reduce the danger of chronically degenerative diseases.

Article 3 Nutritional supplement shall be in accordance with the following requirements:

- (I) Nutritional supplement is limited to supplement vitamin and minerals. The kinds of vitamin and minerals shall meet the Kind and Dosage of Vitamin and Minerals.
- (II) The raw material of Nutritional supplement comes from the Article, which is in the List of Vitamin and Mineral Chemical Compound.
- (III) The purpose of the adjuvant is just satisfying with the requests of product artwork or improves the color, perfume, and the taste of the product. Moreover it shall conform to the proportional national standardization.
- (IV) If the suitable crowd is adult, the recommended everyday intake of the vitamin, minerals should conform to regulations of the Kind and Dosage of Vitamin and Minerals. If the suitable crowd is pregnant woman, wet nurse and the crowd under 18 years old, the recommended everyday intake of the vitamin, mineral matter should be controlled in the $1/3 \sim 2/3$ level of the recommended intake (RNIs or AIs) , which accords with those people in our country.
- (V) The ingested total amount of the product should be smaller, which is recommended. The main form of the product is tablets、collocystis、drug granules or the liquid by taking orally. The everyday edible dosage of the drug granules shouldn't exceed 20 gram. The everyday edible dosage of the liquid by taking orally shouldn't exceed 30 milliliter.

Article 4 If the Article that has been used is in the List of Vitamin and Chemical Compound in Minerals, generally the test report in safe toxicology cannot be supplied with. Because its product material, artwork and quality standard accords of the national relevant regulations. If the Article that have been used is outside the List of Vitamin and Chemical Compound in Minerals, the documents should be provided, which includes of the effect in nutriology of material, the science records of metabolic process and safe intake in vivo, together with the report of evaluation test in safe toxicology which is showed by relevant request according to the safe evaluation of new resource foods.

Article 5 The applicant should provide the quantitation test method of nutrients in nutritional supplement.

Article 6 The signal value of nutritional supplement indicates that the product labeling and the definite figure of some nutrients content, which is showed in the directions, but cannot be labeled the scope value. The signal value of nutritional supplement and the scope value of nutrients content in product quality criteria should be consistent with the relevant regulation ,which is in mentioned the third and forth regulation.

Article 7 The multivitamins or mineral supplement should be vitamins above three kinds or nutritional supplement of mineral.

Article 8 The product should be adopted commitment pack, which is easily edible for consumer and maintains product stability. The packing material must accord with the regulation of the relevant hygienic guide or sanitary requirement, which directly contacts with nutritional supplement.

Article 9 The label of nutrients nutritional supplement, directions should be in accord with the relevant regulation of nation, meanwhile should indicate the following contents:

- (I) The word of “nutritional supplement”.
- (II) The nutritional ingredient should be labeled with the smallest edible unit of nutrients content.
- (III) The edible method and dosage should have the concretely recommended intake of different crowd.
- (IV) Announcements: the product shouldn't be instead of medicine, cannot exceed the recommended intake or eats them together with the congener nutritional supplement.

Article 10 The State Food and Drug Administration (SFDA) institutes and issues the Kind and Dosage of Vitamin and Minerals, the List of Vitamin and Chemical Compound in Minerals.

Article 11 The State Food and Drug Administration (SFDA) take responsibility to interpret the regulations.

Article 12 The regulations shall go into effect as of July 1, 2005. The issued regulations, if not in accordance with this one, should conform to this one.

Table 1: the Kind and Dosage of Vitamin and Minerals

Table 2: the List of Vitamin and Chemical Compound in Minerals

Table 1

The Kind and Dosage of Vitamin and Minerals

| Name | Minimum | Maximum |
|--|-----------|-----------|
| Ca | 250mg/d | 1000mg/d |
| Mg | 100mg/d | 300mg/d |
| K | 600mg/d | 1200mg/d |
| Fe | 5mg/d | 20mg/d |
| Zn | 5mg/d | 20mg/d |
| Se | 15µg/d | 100µg/d |
| Cr ³⁺ | 15µg/d | 150µg/d |
| Cu | 0.5mg/d | 1.5mg/d |
| Mn | 1.0 mg /d | 3.0 mg /d |
| Mo | 20µg/d | 60µg/d |
| retinol equivalent(vitamin A or vitamin A adds □—carrotin) | 250µgRE/d | 800µgRE/d |

| | | |
|--|-------------|--|
| □—carrotin | 1.5mg/d | 5.0mg/d (composition) 7.5mg/d (nature) |
| VitD | 1.5µg/d | 10µg/d |
| VitE (by α—tocopherol equivalent gauge) | 5mg a—TE/d | 150mg a—TE/d |
| VitK | 20µg/d | 100µg/d |
| VitB ₁ | 0.5mg/d | 20mg/d |
| VitB ₂ | 0.5mg/d | 20mg/d |
| VitPP | pellagramin | 5mg/d |
| | iacin amide | 5mg/d |
| VitB ₆ | 0.5mg/d | 10mg/d |
| acidum folicum | 100µg/d | 400µg/d |
| VitB ₁₂ | 1µg/d | 10µg/d |
| pantothen | 2mg/d | 20mg/d |
| bilineurin | 150mg/d | 1500mg/d |
| Vit biotin | 10µg/d | 100µg/d |
| VitC | 30mg/d | 500mg/d |

Table 2

The List of Vitamin and Chemical Compound in Minerals

| nutrients | English name |
|-----------|--|
| Ca | Calcium acetate |
| | Calcium carbonate |
| | Calcium caseinate |
| | Calcium Chloride |
| | Calcium citrate |
| | Calcium citrate malate |
| | Calcium Gluconate |
| | Calcium Lactate |
| | Calcium malata |
| | Calcium monophosphate (Calcium phosphate,Secondary) |
| | Calcium phosphate,monobasic (Calcium phosphate,Primary) |
| | Calcium phosphates |
| | Calcium sulfate |
| | Calcium—L—ascorbate |
| | Calcium glycerol phosphate |

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|----|------------------------------|
| Mg | Magnesium carbonate |
| | Magnesium chloride |
| | Magnesium citrate |
| | Magnesium gluconate |
| | Magnesium lactate |
| | Magnesium phosphate,dibasic |
| | Magnesium phosphates |
| | Magnesium glycerol phosphate |
| K | Potassium carbonate |
| | Potassium phosphate dibasic |
| | Potassium chloride |
| | Potassium citrate |
| | Potassium gluconate |
| | Potassium lactate |
| | Potassium Sulphate |
| | Potassium glycerol phosphate |
| Mn | Manganese sulphate |
| | Manganese gluconate |
| | Manganese chloride |
| | Manganese citrate |
| | Manganese glycerol phosphate |
| Mo | Ammonium Molybdate |
| | Sodium Molybdate Dihydrate |
| Fe | Ferric ammonium citrate |
| | Ferric chloride |
| | Ferric citrate |
| | Ferric carbonate |
| | Ferrous citrate |
| | Ferrous fumarate |
| | Ferrous gluconate |
| | Ferrous sulfate |
| | Ferrous lactate |
| | Heme iron(Ferrous porphyrin) |
| | Hemin (ferriheme) |
| | Ferrous succinate |
| | Ferric pyrophosphate |
| Zn | Zinc acetate |
| | Zinc carbonate |
| | Zinc chloride |
| | Zinc citrate |

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|-------------|--|
| | Zinc gluconate |
| | Zinc lactate |
| | Zinc sulfate |
| | Zinc oxide |
| Se | Selenium carrageenan |
| | Selenium cysteine |
| | Selenium—rich yeast |
| | Sodium selenate |
| | Sodium selenite |
| | selenomethionine |
| Cr | Chromium trichloride |
| | Chromium nicotinate |
| | Chromium picolinate |
| | Chromium yeast |
| Cu | Copper carbonate |
| | Copper citrate |
| | Copper gluconate |
| | Copper sulfate |
| Vitamin A | All trans Retinol |
| | Vitamin A acetate |
| | Retinyl palmitate |
| | All trans beta—Carotene |
| Vitamin D | Vitamin D2 |
| | Vitamin D3 |
| Vitamin B1 | Thiamin hydrochloride |
| | Thiamin mononitrate |
| Vitamin B2 | Riboflavin |
| | Riboflavin—5'—phosphate,sodium |
| Vitamin B6 | Pyridoxine hydrochloride |
| | Pyridoxine 5'—phosphate |
| Vitamin b12 | Cyanocobalamin (Vitamin B12) |
| | Hydroxocobalamin |
| Vitamin PP | Nicotinic acid |
| | Nicotinamide |
| Folic Acid | Pteroylmonoglutamic acid (Folic Acid) |
| Biotin | D—biotin |
| Bilineurin | Choline chloride |
| | Choline bitartrate |
| Vitamin C | L—ascorbic acid |

| | |
|------------------|-----------------------------------|
| | Ascorbyl palmitate |
| | Calcium—L—ascorbate |
| | Potassium—L—ascorbate |
| | Sodium—L—ascorbate |
| Vitamin k | Vitamin K1 (Phytonadione) |
| | Vitamin K2 (Menaquinones) |
| Pantothenic Acid | Pantothenic Acid |
| | Calcium pantothenate |
| | D—panthenol |
| | D—pantothenate,sodium |
| | D—pantothenate,calcium |
| Vitamin E | D—alpha—tocopherol |
| | DL—alpha—tocopherol |
| | DL—alpha tocopheryl acetate |
| | Mixed tocopherols |
| | D—alpha—tocopheryl acetate |
| | D—alpha—tocopheryl acid succinate |