Regulatory Insights

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Information Requirement for Nutritional Supplement (Draft)
《营养素补充剂资料要求（征求意见稿）》

Regulation Full Text

1. Product formula

A. Nutritional supplement manufacturers shall be responsible for the credibility,integrity and legitimacy of the product formula.

B. The preparation of the formula should be in 100,000 units, liquid preparation, powder preparation and granules preparation should be in 100,000ml or 100,000g units, and all the active ingredients, other ingredients, dosage and product specification shall be listed clearly in the formula. Products with complex compounds shall include the individual name of each components and its dosage form. The flavoring, and coating materials included in the formula should be according to the national standard, industry standard and local standard. If the amount of flavorings and coating materials accounts for less than 25% of the formula, those can be exempt from the formula, however, manufacturers must ensure these components meet the national standard. Refer to Appendix 1 “Product Formula Format (Example)”.

The list of regulated ingredients shall refer to “Nutritional Supplement Raw Material List and Quality Requirement” and “Nutritional Supplement Raw Material List and Quality Requirement for Infants”.The list of regulated other ingredients shall refer to the national standard, and those active ingredients shall be listed in “Approved Raw Material List for Health Food Products”

2. Manufacturing Procedures

A. Manufacturing procedures and manufacturing flow chart of a large-scale production shall be provided. Manufacturers must ensure their manufacturing process produces stabile and safe products.The manufacturing additives shall be accordance with the “National Standard for Food Addictive”(GB 2760) appendix C, as well as the industry standard and regulation requirement. Information of the manufacturing additives is required, including the name, source and quality level.

Manufacturing procedures for products in solid dosage form must include pretreatment of the active ingredients, blending, preparation molding, sterilization, packaging, etc.

Manufacturing procedures for products in liquid dosage form must include pretreatment of the active ingredients, compound, filtration, filling, sterilization, packaging, etc.

B. Shall describe the quality control methods and requirements for all phrases of production to final product.
C. Shall describe the other factors that can affect the quality of the finished product.

3. Testing Report and Other Relevant Information
A. Products must be tested by CFDA authorized health food testing agencies in China
B. Testing report must include:
- Product stability testing report for 3 consecutive batches;
- Shall go through all the testing items required by the product technical requirement regulation;
- The same product with different packaging shall provide separate stability test report for 3 consecutive batches.

4. Product Manufacturing Technical Requirements
Product manufacturing technical requirements shall be in accordance with the national law, regulations, technical standards and documents. Refer to Appendix 2 Nutritional Supplements Technical Requirements Text Format. The form shall be completely filled.

A. Manufacturing procedures:
Shall describe the necessary manufacturing procedures of the product

B. Sensory Requirement:
Shall describe the normal appearance of the product (color,shape,etc.), and the product's contents color, shape, smell, taste and impurities, etc., use semicolons between each item; the color shall be described as precisely as possible, the sequence of color in description shall be from light color to dark color. Main color shall come before accent color in terms of the product with composite colors.
- For coating tablets or soft gel, the color, shape, taste and impurities, etc, of the inside contents and the coating shall be described in a clear way accordingly.
- Information shall be provided in spread sheet form.
- The appearance description of the packaging is not a requirement.

C. Physical and Microbe Index
Testing items, index limits, testing methods or implementation standards shall meet the national standards, regulations and food hygienic standards. Information shall be provided in spread sheet. Product formula that contains synthetic pigment, anti-corrosive, sweetener and antioxidant shall refer to the regulations and national standards that require maximum limits of these addictive, the percentage of which shall be tested and listed in the product technical requirement. The dosage and the proof of its edible safety shall be provided, and the limits shall meet the relevant national requirement.

· If processing additives are used, the residues shall be tested according to the current regulation and relevant national standard. Testing items and results shall be stated in the physical index clearly.

· Physical index, microbe indications and its upper limits shall be in accordance with the requirement by GB16740 Health/Functional Food General Standards.
· Apart from that, the other information that is relate to the dosage form, ingredients and processing method shall be documented.

D. Determination of the Functional Components

- The name of the functional components, the percentage and test method shall be listed respectively.
- All the vitamins and minerals that are claimed in a product shall be determined as functional components.
- The vitamin content in a product shall be within 80%-180% of the stated value on the label; for minerals, within 75%-125%. The index value shall follow the Daily Recommended Intake Value(DRI). The DRI of the vitamins and mineral content shall not exceed the upper limit that is regulated in the "Nutritional Supplement Types and Intake Amount".
- Health food manufacturers shall follow the testing methods, which are regulated by the national standard or approved by the government. If their product cannot apply the current testing methods or no testing instructions to follow, health food manufacture shall do an independent scientific research by themselves, and submit their testing method and testing result.
- Testing method shall include scope of application, principle, reagent and standard product or reference product (shall indicate the source, specification, purity,etc.), equipment or operating system,Sample preparation, operation sequence, result description(including calculating formula), standard and sample product atlas (when necessary).

According to the testing method provided by the health food manufacturers, the methodology validation report and review of inspection report shall be provided by two separate heath food registration and testing agencies.

E. Net weight and Controlled Negative Deviation
Net weight and controlled negative deviation of the minimum sales package shall apply the rules of the "General standards for Health/Functional Foods" GB 16740.

F. Quality Requirement of the Active Ingredients and Other Ingredients
Health food manufacturers shall provide the quality requirements for active ingredients and other ingredients that are used in their products, including the edition number and complete standard name; or they shall provide all the quality control index and requirement in spread sheet form, and also provide the source and basis of the quality requirement.

5. Example of the Product Instructions

(Preface) This health product is made of xx, xx (active ingredients), which can help or supplement xxxxxx (health functions).

[Active ingredients](Shall follow the sequence of the formula, and all the active ingredients shall be listed accordingly.)

[Other Ingredients] (Shall follow the sequence of the formula, and all the other ingredients shall be listed accordingly.)

[Functional ingredients and content] X Per Serving / Unit
1. Shall indicate the nutrient content per serving / unit
2. The nutrient content indication value shall be a definite number, not a ranged value.
3. Indication value shall apply to the product formula, actual material consumption, manufacture technology, stability value and the quality standard value. Indication value and stability value shall apply to the quality standard and the specified limit.

[Health Function] Supplementing the deficiency of ....., or.....
1. Health Function indicate vitamins and/or minerals that are included in this product.
2 Health claims shall cover the functions of the vitamins and minerals that are contend in this product (functions of the other ingredients are exempt from the health claims)
3.The DRI of the nutrients in this product shall be according to the indication of its functional ingredients, and shall follow the current regulation.
4.Product that contents more that 3 or more vitamins or minerals shall be named as multi-vitamin or multi-mineral.

[Suitable Users]

[Unsuitable Users]
(1. Unsuitable users shall be determined according to the DRI, "Chinese Residents' Nutrient Intake Condition and Epidemic Disease Survey", edible safety and dosage forms. The group shall be divided based on a clear and specific standard, which meet the current regulation and national standards.
2. The product shall target a specific applicable user group, and the unsuitable users are those who have intake safety concerns.
3. Infants, prenatal women and lactating women shall be listed as unsuitable users if they are not the targeted group for this product.
4. If the suitable users for this product are "All Adults", when the DRI of the product cannot meet that of the prenatal women and lactating women, so those women shall be listed as inapplicable users.
5.Capsule, chew-able tablets and big-sized tablets shall not be given to infants.)

[Directions for Use]
(1.Shall describe the serving size in the first place, and then describe the consumption method, including the blending method, brewing method, etc. Serving size shall be indicated as X per day, X each time. Serving size can be indicated in quantity or volume, such as Xg, X ml, or indicated per Cup.
2. The net weight of minimum sales packaging shall be comply with the serving size each time. If measuring is needed, the method shall be described in detail.
3. For one product, if different consumption amount and method are used by different age groups, that information shall be described in detail.
4.The DRI of the product shall be limited in a certain amount, the format shall be tablets, capsule, granules, or liquid. The consumption limit for granules shall not over 20g per day, liquid shall not over 30ml per day.)

[Product Specification]
1.Product format shall be determined by the consumption amount and consumption method; if

measuring is needed, it shall be listed after the product specification. Product specification shall indicate the minimum consumption net weight, and shall determine the amount in each minimum consumption packaging. Net weight shall be indicated in the following way: 1. Liquid health food product: by volume, in 毫升 or ml；
2. Solid or half-solid health food product: by quantity, in 毫克，克，or mg, g.
3. For capsule or soft gel, the product format means the content in a capsule or soft gel.

[Shelf Life] X months (1. If a product's shelf life is less than a month, it shall be defined in days. 2. The shelf life of a product shall be determined by the result of stability research, 3-month accelerated stability test result can determine the shelf life of 24 months.)

[Storage method] (Shall be based on the specification and stability testing result)

[Precautions] This product cannot replace medical treatment; shall not exceed the DRI or be taken with the similar nutritional supplement. (Supplement containing selenium shall caution " those people living in high selenium intake areas shall not take this supplement". Other precautions shall be added according to relevant standards and product specifications.)

Appendix 1

Product Formula Format (Example)

For "X product"

Ingredients：
Vitamin A Xg
Vitamin B Xg
……

Other Ingredients (all the components and amounts must be listed below)
Vitamin B Complex(Amount Xg)：Vitamin B1 Xg
Vitamin B6 Xg
……
Mineral Complex(Amount Xg)：Calcium Carbonate Xg
Zinc Gluconate Xg
……

Other Ingredients:
Flavoring's name Xg
Xg
Xg
Xg
……

Made into 100,000 tablets/bottles/X/X Product Specification: Xg (ml) tablets/ bottles/X/X

Appendix 2

China Food and Drug Administration
Nutritional Supplement Product Technique Requirement
（No.xxxxxxxxxx）

Chinese Name
Chinese PinYin Name

【Manufacturing Procedure】

【Sensory Requirement】

【Physical Index】

【Microbe Index】

【Determination of the Functional Components】

【Net weight and Controlled Negative Deviation】

【Quality Requirement of the Active Ingredients and Other Ingredients】

Appendix 3

Product Instruction Format

For “X product”

This health food product is made of ..... , whose active ingredients are..... , and is used to support .....function.

【Active Ingredients】

【Other Ingredients】

【Functional Ingredients and Content】

【Health Function】

【Suitable Users】

【Unsuitable Users】

【Directions for Use】

【Product Specification】

【Shelf Life】

【Storage Method】

【Precautions】

Date of Release	Administrative Regulations for Nutritional Supplements (Draft) 《营养素补充剂管理规定（征求意见稿）》
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Regulation Full Text

Article 1 This administrative regulation is made in accordance with <Food Safety Law of People's Republic of China> for completing the management of nutritional supplements.

Article 2 Nutritional Supplements are products not aiming at providing energy but supplementing the deficiency of Vitamins, Minerals for their health care functions. Apart from supplementing the dietary deficiency, nutritional supplement has its function in preventing potent deficiency and reducing the risk of some chronic and degenerative disease.

Article 3 China Food and Drug Administration is responsible for drafting the < Classification and Acceptable Daily Intake of Nutritional Supplements >, < List of Nutritional Supplements and its Safety Standard>,< List of Nutritional Supplements and its Safety Standard (Infant)>, and < Allowed List of Other ingredients of Health Care Food>. Health care products companies, industry associations, academy associations and related experts are encouraged to participate in completing and revising the draft.

Article 4 The samples used in nutritional supplements test should undergo three consecutive batch of scale production. Producing workshop and procedure must comply with <Producing Specifications of Health care Products>. Imported nutritional supplements should have more than one year overseas production and marketing record and comply with <Producing Specifications of Health care Products> and local producing regulations.

Article 5 Three batch samples for local health care companies or imported health care products should be tested at registered institutions along with related documents. Registered institutions should accomplish the stability test on all technically required inspecting items by applicable methods from the company.

Article 6 Nutritional Supplement products must meet the following requirements:

a. <Classification and Acceptable Daily Intake of Nutritional Supplements >
b. < List of Nutritional Supplements and its Safety Standard>
c. Nutrient products for group under 3 years old must meet the requirements of < List of Nutritional Supplements and its Safety Standard (Infant)>. Nutrients extracted from edible part of food must not contain other bioactive substances with effective dose. Industries are encouraged to apply higher manufacturer's standards than national standards.
d. <Allowed List of Other Ingredients of Health Care Food>

e. Other ingredients should only be used in meeting the need of product process and quality or improving its appearance and flavor.
f. The main forms of the products are pills, capsules, granules, powder, oral liquid or etc. Daily intake cannot exceed 20 gram for products in solid forms and 30 ml for products in liquid forms.

Article 7 The product formula should specify the name, classification, dosage (or proportion) of the nutrient and the name, dosage of the other ingredients.

Article 8 The manufacturing process must meet the requirements of <Producing Specifications of Health care Products>. For example, Nano materials or improper drying and sterilization process of Vitamins are prohibited.

Article 9 Health care product companies must apply their own technical requirements of the product which include manufacturing techniques, flavor requirements, physicochemical norms, microbial norms, test method for content of functional ingredients, net content and allowed negative deviation, the quality standard of materials and other requirements in accordance with different regulations in terms of materials, forms and techniques. All the requirements for product technology must meet the national standards. Industries are encouraged to apply higher standards for product technology than national standards.

Technical requirements should include normative, integral and applicable information of the functional ingredient and its qualitative, quantitative test methods. Health care company should choose proper test methods in accordance with national standards or which are formally published by related departments and are applicable for health care food. If there is no applicable method, the company should launch related research and submit a test method with detailed research data to registration institutes. The test method submitted by the company should also include the results of research methodology, research methodology verification report and recheck report provided by registration institutes.

Net content and allowed negative deviation of functional ingredients must be rational. The contents of Vitamins should be among 80%-180% of labeling value; minerals should be among 75%-125% of labeling value. The upper and lower intake value is recalculated according to daily intake recommendation. The daily intake must meet the requirements of <Classification and Acceptable Daily Intake of Nutritional Supplements>.

Article 10 Nutritional Supplements and its other ingredients which are not in the list of < Classification and Acceptable Daily Intake of Nutritional Supplements >, < List of Nutritional Supplements and its Safety Standard>,< List of Nutritional Supplements and its Safety Standard (Infant)> and those with special manufacturing techniques should submit an application along with approvals for its safety and effectiveness including reference of dosage, safety data, qualification requirements and ect.

Products using special manufacturing techniques must submit additional safety and effectiveness certificate. The products and techniques will be evaluated by CFDA Authority Board. The qualified ones will implement the system of public of notice.

Article 11 The indication value of nutritional supplements refers to the exact value of functional ingredients in product formula. Range Values are not acceptable.
The labeling value of nutritional supplements should be set by overall consideration of products formula, processing technique, stability test and technique requirements. Labeling values and stability test values must meet limited values of the product technology requirements.

Article 12 All health care functions of Vitamins, minerals included in the product except for the other ingredients should be in the health claim.

Article 13 Naming of the product must meet the requirements of <Naming Rules for Health Care Products>. Nutritional supplement products should be named by the nutrient which the product is supplementing. The other ingredients cannot be used in naming the product. Nutritional supplements with over three Vitamins or minerals can be named as multivitamins or multi-minerals supplementing products.

Article 14 The classification of suitable or unsuitable population
The division of population should be scientific, accurate, and clear which meets the requirements of related laws and regulations. Daily Recommended Intake of the product, dietary intake and nutritional status of residents, products safety, and products forms should be considered when dividing the population.

Suitable population refers to the specific group which product development targets; Unsuitable population refers to the group related with food safety risk.
Infants, pregnant and lactating women should be included in unsuitable population if the product is not specifically developed for them.

Article 15 Product packaging should be set for the convenience of consumers and the stability of the products. The packing materials in direct contact with nutritional supplements should be in accordance with national standards or health related regulations.

Article 16 Manufacture's data sheets should be in accordance with related national regulations, labeling following details:
· "Nutritional supplements" is marked;
· Nutritional facts should be labeled as the level of related nutrients in the minimum unit;
· The serving size and direction should be recommended to different groups respectively;
· Notifications should make it clear that "This product is not a substitute of medicine and may not be used at the level in excess of recommended maximums or with other nutritional supplements of the same kind".
· Selenium products should be labeled " This product is not suitable for people at high selenium regions".

Article 17 China Food and Drug Administration reserves the right to the interpretation of the above terms and conditions.

Article 18 These regulations shall go into effect on …….
In case of any contradiction with previous regulations, this circular shall prevail

Appendix 1

Classification and Acceptable Daily Intake of Nutritional Supplements (I)

Nutrient	Age	0.5～	1～	4～	7～	11～	14～	First Trimester	Second Trimester	Third Trimester	Lactation	Adult
Ca mg/Day	Lower Limit	100	180	200	250	300	250	200	250	250	250	250
	Upper Limit	250	400	600	800	1000	800	800	800	800	800	1000
Fe mg/Day	Lower Limit	3.0	3.0	3.0	4.0	5.0	5.0	5.0	7.0	9.0	7.0	5.0
	Upper Limit	9.0	10.0	10.0	13.0	16.0	18.0	25.0	25.0	25.0	20.0	20.0
Zn mg/Day	Lower Limit	1.0	1.2	1.5	2.0	3.0	4.0	2.5	2.5	2.5	3.0	3.0
	Upper Limit	6.0	6.5	7.0	8.5	10.0	12.0	10.0	10.0	10.0	12.0	20.0
K mg/Day	Lower Limit	——	——	300	400	500	600	500	500	500	500	600
	Upper Limit	——	——	1000	1300	1600	1800	1700	1700	1700	1700	2000
Mg mg/Day	Lower Limit	——	——	50	70	100	100	120	120	120	100	100
	Upper Limit	——	——	150	200	300	300	350	350	350	300	300
Cu mg/Day	Lower Limit	——	——	0.13	0.17	0.21	0.25	0.30	0.30	0.30	0.30	0.30

	Upper Limit	——	——	0.40	0.50	0.70	0.80	0.90	0.90	0.90	1.40	1.50
Se μg/Day	Lower Limit	——	——	8.0	10.0	14.0	15.0	16.0	16.0	16.0	20.0	15.0
	Upper Limit	——	——	25.0	35.0	45.0	50.0	55.0	55.0	55.0	65.0	100.0
Cr μg/Day	Lower Limit	——	——	5.0	6.0	8.0	8.0	8.0	9.0	9.0	9.0	15.0
	Upper Limit	——	——	15.0	20.0	25.0	25.0	30.0	30.0	30.0	30.0	150.0
Mo μg/Day	Lower Limit	——	——	6.0	8.0	10.0	10.0	20.0	20.0	20.0	20.0	20.0
	Upper Limit	——	——	30.0	40.0	50.0	50.0	60.0	60.0	60.0	60.0	60.0
Mn mg/Day	Lower Limit	——	——	——	——	——	——	——	——	——	——	1.00
	Upper Limit	——	——	——	——	——	——	——	——	——	——	3.00
Vitamin A* / μgRE	Lower Limit	100	100	120	160	200	200	200	200	200	300	250
	Upper Limit	350	400	450	500	650	700	750	750	750	1300	800
β—carotene mg/Day	Lower Limit	——	——	——	——	——	——	——	——	——	——	1.5
	Upper Limit	——	——	——	——	——	——	——	——	——	——	7.5

Classification and Acceptable Daily Intake of Nutritional Supplements (II)

Nutrient	Age	0.5～	1～	4～	7～	11～	14～	First Trimester	Second Trimester	Third Trimester	Lactation	Adult
Vitamin D μg/Day	Lower Limit	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	1.5
	Upper Limit	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	15.0
Synthetic Vitamin E mg/Day	Lower Limit	——	——	1.5	2.0	3.0	4.0	5.0	5.0	5.0	5.0	5.0
	Upper Limit	——	——	7.0	9.0	13.0	14.0	15.0	15.0	15.0	15.0	150.0
Natural Vitamin E mg/Day	Lower Limit	——	——	1.5	2.0	3.0	4.0	10.0	10.0	10.0	10.0	10.0
	Upper Limit	——	——	7.0	9.0	13.0	14.0	30.0	30.0	30.0	30.0	150.0
Vitamin C mg/Day	Lower Limit	15.0	15.0	15.0	20.0	30.0	30.0	30.0	35.0	35.0	40.0	30.0
	Upper Limit	40.0	40.0	50.0	70.0	90.0	100.0	120.0	120.0	120.0	150.0	500.0
Vitamin B_1 mg/Day	Lower Limit	0.10	0.20	0.25	0.30	0.40	0.40	0.40	0.40	0.40	0.40	0.50
	Upper Limit	0.30	0.60	0.80	1.00	1.30	1.60	1.20	1.40	1.50	1.50	20.00
Vitamin B_2 mg/Day	Lower Limit	0.15	0.15	0.20	0.30	0.40	0.40	0.60	0.60	0.60	0.50	0.50
	Upper Limit	0.50	0.50	0.70	1.00	1.30	1.40	2.20	2.20	2.20	1.70	20.00

Vitamin B_6 mg/Day	Lower Limit	0.20	0.30	0.20	0.30	0.35	0.40	0.60	0.60	0.60	0.50	0.50
	Upper Limit	0.60	0.65	0.70	1.00	1.30	1.40	2.20	2.20	2.20	1.70	10.00
Vitamin B_{12} µ g/Day	Lower Limit	0.20	0.30	0.30	0.40	0.50	0.60	0.70	0.70	0.70	0.80	1.00
	Upper Limit	0.60	1.00	1.20	1.60	2.10	2.40	2.90	2.90	2.90	3.20	10.00
Pantothenic acid Acid (Vitamin B5) mg/Day	Lower Limit	0.60	0.65	0.80	1.10	1.50	1.60	2.00	2.00	2.00	2.00	2.00
	Upper Limit	1.90	2.10	2.50	3.50	4.50	5.00	6.00	6.00	6.00	7.00	20.00
Folic Acid µ g/Day	Lower Limit	30	40	50	60	70	80	120	120	120	100	100
	Upper Limit	150	150	150	200	250	300	400	400	400	400	400
Choline mg/Day	Lower Limit	60	70	80	90	100	120	100	100	100	120	150
	Upper Limit	150	200	250	300	400	500	400	400	400	500	1500
Biotin µ g/Day	Lower Limit	2.4	3.2	4.0	5.0	6.0	7.0	8.0	8.0	8.0	10.0	10.0
	Upper Limit	9.0	17.0	20.0	25.0	35.0	40.0	40.0	40.0	40.0	50.0	100.0
Vitamin K µ g/Day	Lower Limit	3.0	6.0	10.0	15.0	20.0	20.0	25.0	25.0	25.0	25.0	20.0
	Upper Limit	10.0	30.0	40.0	50.0	70.0	75.0	80.0	80.0	80.0	80.0	100.0
Nicotinic Acid mg/Day	Lower Limit	1.0	2.0	2.0	3.0	4.0	4.0	3.0	3.0	3.0	4.0	5.0

	Upper Limit	4.0	6.0	8.0	11.0	13.0	15.0	12.0	12.0	12.0	15.0	15.0
Nicotinamide mg/Day	Lower Limit	——	——	——	——	——	——	——	——	——	——	5.0
	Upper Limit	——	——	——	——	——	——	——	——	——	——	50.0

* The subtotal of Vitamin A and β—carotene is calculated in Retinol equivalent (mgRE) in terms of Vitamin A products (β—carotene as ingredients) for the group under 18 as well as pregnant and lactating groups. Vitamin A(mgRE)= Vitamin A(mg)+ β—carotene (mg)/2

Appendix 2

List of Nutritional Supplements and its Safety Standard

	Nutrient	Compound	Safety Standard
1	Vitamin A	Vitamin A Retinyl Acetate	GB 14750 National food safety standard for Food Additive – Vitamin A
			<Chinese Pharmacopeia> 2010 (Part II) P894
		Vitamin A Retinyl Palmitate	GB29943 National food safety standard for Food Additive - Retinyl Palmitate (Vitamin A Palmitate)
2	β —carotene	β- carotene	GB 8821 National food safety standard for Food Additive - β- carotene
			GB 28310 National food safety standard for Food Additive - β- carotene (Fermentation)
3	Vitamin D	VitaminD2	GB 14755 National food safety standard for Food Additive - VitaminD2
			<Chinese Pharmacopeia> (Part II) VitaminD2
		VitaminD3	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
4	Vitamin E	DL-α-tocopheryl acetate	GB 14756 National food safety standard for Food Additive - Vitamin E (DL-α-tocopheryl acetate)
			<Chinese Pharmacopeia> (Part II)
		Natural Vitamin E D-α-tocopheryl acetate	GB 19191 Food Additive Natural Vitamin E
			<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
		D-α- Tocopherol	GB 19191 Food Additive Natural Vitamin E

		Natural Vitamin E (D-α Tocopherol Succinate)	GB 19191 Food Additive Natural Vitamin E
		DL-α- Tocopherol	GB 29942 National food safety standard for Food Additive - Vitamin E (DL-α-Tocopherol)
5	Vitamin K	VitaminK1	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
6	Vitamin B1	Thiamine	GB 14751 National food safety standard for Food Additive - VitaminB1 (Thiamine)
			<Chinese Pharmacopeia> (Part II)
7	Vitamin B2	Riboflavin	GB 14752 National food safety standard for Food Additive - VitaminB2 (Riboflavin)
			<Chinese Pharmacopeia> (Part II)
		Riboflavin-5-monophosphoric acid sodium salt (FMN-Na)	GB28301 National food safety standard for Food Additive - Riboflavin-5-monophosphoric acid sodium
			<Chinese Pharmacopeia> (Part II)
8	Vitamin B6	Pyridoxine Hydrochloride	GB 14753 National food safety standard for Food Additive - VitaminB6 (Pyridoxine Hydrochloride)
			<Chinese Pharmacopeia> (Part II)
9	Vitamin B12	Cyanocobalamin	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
10	Vitamin C	L- Ascorbic Acid	GB 14754 National food safety standard for Food Additive - Vitamin C
			<Chinese Pharmacopeia> (Part II)
		Ascorbyl Palmitate	2010 MOH* Announcement, No.8 Related Standard
		Ascorbic Acid Sodium	GB16313 Food Additive - L-Ascorbic Acid Sodium
			<Chinese Pharmacopeia> (Part II)

		Ascorbic Acid Calcium	GB15809 Food Additive - Ascorbic Acid Calcium
			<Chinese Pharmacopeia> (Part II)
11	Nicotinic acid	Nicotinic acid	GB 14757 National food safety standard for Food Additive - Nicotinic acid
			<Chinese Pharmacopeia> (Part II)
		Nicotinamide	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
12	Pantothenic acid	Pantothenic acid Calcium	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
13	Folic acid	Pteroylglutamic acid	GB 15570 National food safety standard for Food Additive - Folic acid
			<Chinese Pharmacopeia> (Part II)
14	Iron	Ferrous sulfate	GB 29211 National food safety standard for Food Additive - Ferrous sulfate
			<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
		Ferrous gluconate hydrate	<Chinese Pharmacopeia> (Part II)
		Iron(II) fumarate	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
		FERROUS LACTATE	GB 6781 National food safety standard for Food Additive - FERROUS LACTATE
		Ferrous Succinate	CFDA The National Drug Standards WS1-(X-005)-2001Z- Ferrous Succinate
15	Calcium	Calcium carbonate	GB 1898 National food safety standard for Food Additive - Calcium carbonate
			<Chinese Pharmacopeia> (Part II)
		Calcium Gluconate	GB 15571 National food safety standard for Food Additive - Calcium Gluconate
			<Chinese Pharmacopeia> (Part II)

		Calcium citrate	GB 17203 National food safety standard for Food Additive Calcium citrate
			<Chinese Pharmacopeia> (Part II)
		Calcium Lactate	GB 6226 National food safety standard for Food Additive - Calcium Lactate
			<Chinese Pharmacopeia> (Part II)
		Calcium Phosphate Tribasic	GB 25558 National food safety standard for Food Additive - Calcium Phosphate Tribasic
		Calcium monophosphate	GB 1889 National food safety standard for Food Additive - Calcium monophosphate
			<Chinese Pharmacopeia> (Part II)
		Calcium acetate	GB 15572 National food safety standard for Food Additive - Calcium acetate
		Calcium chloride	GB 22214 National food safety standard for Food Additive - Calcium chloride
			<Chinese Pharmacopeia> (Part II)
		Calcium sulfate	GB 1892 National food safety standard for Food Additive - Calcium sulfate
		Calcium Ascorbate	GB 15809 National food safety standard for Food Additive - Calcium Ascorbate
			<Chinese Pharmacopeia> (Part II)
		Calcium dihydrogen phosphate	GB 25559 National food safety standard for Food Additive - Calcium dihydrogen phosphate
16	Zinc	zinc sulfate	GB 25579 National food safety standard for Food Additive - zinc sulfate
			<Chinese Pharmacopeia> (Part II)
		Zinc Gluconate	GB 8820 National food safety standard for Food Additive - Zinc Gluconate
			<Chinese Pharmacopeia> (Part II)

		Zinc oxide	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
		Zinc Citrate	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
17	Magnesium	Magnesium chloride	GB 25584 National food safety standard for Food Additive - Magnesium chloride
		Magnesium carbonate	GB 25587 National food safety standard for Food Additive - Magnesium carbonate
		Magnesium oxide	<Chinese Pharmacopeia> (Part II) 2010 MOH* Announcement, No.18 Related Standard
18	Copper	Cupric sulfate	GB 29210 National food safety standard for Food Additive - Cupric sulfate
19	Manganese	Manganese sulphate	GB 29208 National food safety standard for Food Additive - Manganese sulphate
20	Potassium	Potassium Citrate	GB 14889 National food safety standard for Food Additive - Potassium Citrate
			<Chinese Pharmacopeia> (Part II)
		Potassium carbonate	GB 25588 National food safety standard for Food Additive - Potassium carbonate
		Potassium lactate	G28305 National food safety standard for Food Additive - Potassium lactate
		Dipotassium phosphate	GB 25561 National food safety standard for Food Additive - Dipotassium phosphate <Chinese Pharmacopeia> (Part II)
		Potassium chloride	GB 25585 National food safety standard for Food Additive - Potassium chloride
			<Chinese Pharmacopeia> (Part II)
21	Selenium	Sodium selenite	CFDA The National Drug Standards Sodium selenite

22	Biotin	Biotin	CFDA The National Drug Standards (Trial Act) WS-10001- (HD-1052) - Biotin
23	Choline	Choline bitartrate	CFDA The National Drug Standards (Trial Act) WS-10001-(HD-1050) - Choline bitartrate

Note：1. The related standard cited in the list is subject to the latest edition of national standard.
2. β—carotene is a supplement for Vitamin A in product formula for pregnant and lactating Women.
3. Ministry of Health of the People's Republic of China (MOH)

Appendix 4

Allowed List of Other Ingredients of Health Food Product

Listed in Chinese phonetic alphabet order

A Acacia Senegal, Aspartame

B Carnauba Wax, white granulated sugar, β-cyclodextrin, Betacyclodextrin, Benzoic Acid, Sodium benzoate, 1,2-Propanediol or 1,3-Propanediol, Aceticacid(carbonyl process), Spinach powder, pineapple juice

C Theaflavin, Tea Green Pigment, Erythrosine aluminium lake, meso-Erythritol, Sodium acetate trihydrate, Starch acetate

D D-Mannitol, DL-TARTARIC ACID, DL-Malic acid, Soybean phospholipids, Soy protein concentrate, soybean salad oil, soybean oil, aspartame, custard powder, mono- and di-glycerin fatty acid ester(Oleic acid, linoleic acid, α-Linolenic acid, palmitic acid, Docosanoic acid, Stearic acid, Lauric acid), syrupus simplex, Isomalto-oligosaccharide, Low substituted hydroxypropyl cellulose , starch, C.I. Pigment blue 63, Butyl hydroxyanisole, Methyl 4-hydroxybenzoate, Sodium Methyl Parahydroxybenzoate, Ethyl 4-hydroxybenzoate, Sodium ethyl p-hydroxybenzoate

E Dibutyl hydroxy toluene, silicon dioxide, titanium dioxide

F Beewax, Pineapple Fruit Powder , fumaric acid

G Improved Soybean Lecithin, Mandarin yellow, Olive juice freeze-dried powder, olive oil, mannitol, glycerol, guar gum, pectin, Fruit grape pulp , fructose

H Potassium alginate, sodium alginate, walnut oil, black bean red , black iron oxide, saflor yellow, monascus yellow, red ferric oxide, dextrin, Fenugreek gum, Peanut oil, French chalk, sodium cyclamate, yellow ferric oxide, xanthan gum

J Methylcellulose, polyvinylpolypyrrolidone, croscarmellose sodium, caramel, gellan gum, Refined corn oil, tartaric acid, ORANGE PINK , polyacrylic resin Ⅱ, polyacrylic resin Ⅲ, polyacrylic resin Ⅳ, polyglyceryl fatty acid ester, polyglucose, polysorbate 80, Povidone K30, Polyoxyethylene sorbitan monooleate, polyethylene glycol, polyethylene glycol 400, Polyethylene Glycol 4000, Polyethylene Glycol 6000, polyvinylpyrrolidone, vinyl alcohol, citric acid, Orange juice concentrate powder

K Carrageenan, cocoa powder, cacao pigment, cacao butter, sunflower seed oil, quinoline yellow

L L (+) tartaric acid, L- malic acid, chilli orange, capsicum red, Blueberry juice powder, Casein phosphopeptides, sodium caseinate, Litchi juice concentrate, condensed milk, Brilliant blue aluminum lake, disodium hydrogen phosphate, calcium hydrogen phosphate, tricalcium phosphate, phosphatide, Orange juice, Sodium Hexametaphosphate

M maltodextrin, maltose, maltitol, maltitol syrup, rose lycopene, gelatin, xylitol

N cream, lemon yellow, lemon concentrate, citric acid, potassium citrate, sodium citrate, orange juice concentrate

P apple concentrate, malic acid, pullulan, grape skin red, glucose

Q Hydroxypropylated starch, hydroxypropyl distarch phosphate, hydroxypropyl methyl cellulose, hypromellose, hydrogenated vegetable oil, hydrogenated palm oil, agar, whole milk powder

R Sun set yellow, lactate, calcium lactate, sodium lactate, lactose, lactitol

S Tripolyglycerol monostearates, sodium tripolyphosphate, trichlorosucrose (sucralose), Seabuckthorn yellow, sorbitol, sorbic acid, potassium sorbate, D-Sorbitol, hawthorn, peach juice powder, sodium starch glycolate, sodium carboxymethyl starch, carboxymethylcellulose sodium

T Sodium carbonate, sodium bicarbonate, saccharin sodium, betanin, orange powder, steviosin, stevioside, condensed milk, Aspartame, Natural cocoa syrup, Natural red amaranth, Dehydrated Pineapple Powder, Dehydration strawberry powder, dried skimmed milk

W Microcrystalline cellulose, Vitamin C, Vitamin E

X Amaranth, Orange juice, Aluminium octenyl succinate starch

Y 1,2- propylene glycol, cochineal red, carminum, annatto, oxidized starch, Oxidized hydroxypropyl starch, iron oxide black, iron oxide red, Goat milk powder, sodium copper chlorophyllin, ethyl cellulose, isomaltulose, acetic acid, acetic ether, acetylated distarch

phosphate , Acesulfame potassium, Chili Powder, octadecanoic acid, magnesium stearate, camellia oleifera seed oil, Allura red, amylum pregelatinisatum, maize yellow, corn syrup, corn oil

Z Spirulina blue, saccharose, Vegetable carbon black, vegetable fat powder, gardenia blue, Gardenia Yellow, Purple ferric oxide, Brown Ferric Oxide

Appendix 5

Test Methods for Functional Ingredients

Calcium (Ca)	GB/T 5009.92 Test Method for Calcium in food
Magnesium (Mg)	GB/T 5009.90 Test Method for Iron Magnesium and Manganese in food
Potassium (K)	GB/T 5009.91 Test Method for Sodium and Potassium and Manganese in food
Manganese (Mn)	GB/T 5009.90 Test Method for Iron Magnesium and Manganese in food
Iron (Fe)	GB/T 5009.90 Test Method for Iron Magnesium and Manganese in food
Zinc (Zn)	GB/T 5009.14 Test Method for Zinc in food
Selenium (Se)	GB 5009.93 National Food Safety Standard Test Method for Selenium
Copper (Cu)	GB/T 5009.13 Test Method for Copper in food
VitaminB1 VitaminB6 Nicotinic acid Nicotinamide	<Technical standards for testing and assessment of health food> Test Method for VitaminB1, VitaminB6, Nicotinic acid , Nicotinamide and Caffeine in Health Care Food

Note：The related standard cited in the list is subject to the latest edition of national standard.

Original Chinese Version

To get the Chinese version, click here:

关于征求《营养素补充剂管理规定（征求意见稿）》和《营养素补充剂资料要求（征求意见稿）》意见的函

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