Regulatory Insights

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State Administration for Market Regulation (SAMR)

关于发布《辅酶 Q10 等五种保健食品原料备案产品剂型及技术要求》的公告

Announcement on the Dosage Forms and Technical Requirements for Recording of Five Health Food Ingredients Including Coenzyme Q10

Dosage Forms and Technical Requirements for Recording of Five Health Food Ingredients Including Coenzyme Q10

1. Dosage Forms and main production processes of five health food ingredients including Coenzyme Q10.

The available dosage forms and main production processes of Coenzyme Q10, fish oil, broken Ganoderma lucidum spore powder, spirulina and melatonin when recording health food are as follows:

(1) Tablets: crushing, sieving, mixing, granulating, drying, tableting, coating, packaging, etc.

(2) Hard capsules: crushing, sieving, mixing, granulating, drying, encapsulating, packaging, etc.

(3) Softgel: mixing, homogenizing, filtering, pressing, drying, packaging, etc.

(4) Granules: crushing, sieving, mixing, granulating, drying, packaging, etc.

(5) Powder: crushing, sieving, mixing, sub-packing, packaging, etc.

2. ‘Health Food Ingredients List Coenzyme Q10’ technical requirements for recording.

2.1 Available Accessories

Vitamin E, sodium ascorbate, povidone K30, neotame, talc, magnesium stearate, sucrose, steviol glycosides, dextrin, lactose, microcrystalline cellulose, β-cyclodextrin, crospovidone, Citric acid, aspartame (also known as aspartame), edible glucose, silicon dioxide, oligofructose, pregelatinized starch, low-substituted hydroxypropyl cellulose, hydroxypropyl methyl fiber Vegetarian, titanium dioxide, polyethylene glycol, D-mannitol, sorbitol and sorbitol liquid, sodium carboxymethyl cellulose, vitamin C, edible corn starch, potato starch, tapioca starch, edible wheat starch, edible sweet potato starch , Sodium carboxymethyl starch, hollow capsules (including hydroxypropyl starch hollow capsules, gelatin hollow capsules), gelatin, glycerin, purified water, drinking water, ethyl p-hydroxybenzoate and its sodium salt, sorbic acid and its potassium salt (Calculated as sorbic acid), soybean oil, corn oil, sunflower oil, olive oil, powdered soybean phospholipids, concentrated soybean phospholipids, soybean phospholipids, polyoxyethylene sorbitan monooleate, beeswax.
Food flavor and coloring.

2.2 Available Dosage Forms

When recording a health food with Coenzyme Q10 as a single raw material, the available product dosage forms include tablets (oral tablets, lozenges, chewable tablets), granules, hard capsules, and softgel.

2.3 Product Technical Requirements

The technical requirements of each dosage form products shall follow the required technical indicators of each dosage form, the microbiological indicators shall follow the National Food Safety Standard Health Food GB16740, and also need to meet the following requirements:

[Signature ingredient] is "Coenzyme Q10". According to the daily dosage requirements of the health food ingredients list, the maximum value of the range of the signature ingredients per 100g shall not exceed the maximum daily dosage after conversion, and the minimum shall not be lower than the minimum daily dosage.

3.‘Health Food Ingredients List Coenzyme Q10’ technical requirements for recording

3.1 Available Accessories

Edible corn starch, potato starch, tapioca starch, edible wheat starch, edible sweet potato starch, hydroxypropyl methylcellulose, xanthan gum (also known as xanthan gum), magnesium stearate, silicon dioxide, carboxymethyl fiber Sodium, vitamin C, dextrin, microcrystalline cellulose, povidone K30, sorbitol and sorbitol liquid, vitamin E, calcium hydrogen phosphate, sodium carboxymethyl

starch, hollow capsules (including hydroxypropyl starch hollow capsules) , Gelatin hollow capsules), triethyl glycerol.

3.2 Available Dosage Forms

When recording a health food with broken Ganoderma lucidum spore powder as the single raw material, the available product dosage forms include tablets (oral tablets), granules, hard capsules, and powders.

3.3 Product Technical Requirements

The technical requirements of each dosage form products shall follow the required technical indicators of each dosage form, the microbiological indicators shall follow the National Food Safety Standard Health Food GB16740, and also need to meet the following requirements:

3.3.1 [Physical and chemical indicators] "BCC" and "DDT" should be updated; powders should be updated with "peroxide value".

3.3.2 [Significant Ingredients] should cover at least two indicators including "polysaccharides" and "total triterpenes". When setting the index value, it should comply with the daily dosage and raw material technical requirements in the health food ingredient list.

4.‘Health Food Ingredients List Spirulina’ technical requirements for recording

4.1 Available Accessories

Maltodextrin, microcrystalline cellulose, pregelatinized starch, magnesium stearate, sodium carboxymethyl cellulose, silicon dioxide, sodium carboxymethyl starch, glycerin, hydroxypropyl methyl cellulose, titanium dioxide, polyethylene Glycol, edible corn starch, potato starch, tapioca starch, edible wheat starch, edible sweet potato starch, dextrin, white sugar, lactose, vitamin E, povidone K30, isomalt oligosaccharide, sodium bicarbonate, citric acid, sucrose , Polyvinyl alcohol, polyoxyethylene sorbitan monooleate, sorbitol and sorbitol liquid, milk powder, calcium carbonate, crospovidone, hydroxypropyl cellulose, stearic acid, honey, soft white sugar, Empty capsules (including hydroxypropyl starch hollow capsules, gelatin hollow capsules), concentrated soybean phospholipids, powdered soybean phospholipids, fractionated soybean phospholipids, transparent soybean phospholipids, soybean phospholipids.
Food flavor and coloring.

4.2 Available Dosage Forms

When recording a health food with spirulina as the single raw material, the available product dosage forms include tablets (oral tablets, chewable tablets), granules, and hard capsules.

4.3 Product Technical Requirements

The technical requirements of each dosage form products shall follow the required technical indicators of each dosage form, the microbiological indicators

shall follow the National Food Safety Standard Health Food GB16740, and also need to meet the following requirements:

4.3.1 [Physical and chemical indicators] "Protein" shall be added.

4.3.2 [Significant Ingredients] At least shall add two indicators including " β - carotene" and "phycocyanin". When setting the index value, it should comply with the daily dosage and technical requirements in the health food ingredients list.

4.3.3 "Vibrio parahaemolyticus" shall be added in [Microbial Indicators].

5. 'Health Food Ingredients List fish oil' technical requirements for recording

5.1 Available Accessories

Vitamin E, gelatin, glycerin, purified water, drinking water, ethyl p-hydroxybenzoate and its sodium salt, soybean lecithin, caramel color.

5.2 Available Dosage Forms

When recording a health food with fish oil as the single raw material, the available product dosage form is softgel.

5.3 Product Technical Requirements

The technical requirements of softgel products shall follow the required technical indicators, the microbiological indicators shall follow the National Food Safety Standard Health Food GB16740, and also need to meet the following requirements:

5.3.1 [Physical and Chemical Index] "Moisture and Volatile Matter", "Iodine Value", "Benzo[a]pyrene" shall be added.

5.3.2 [Significant Ingredients] At least three indicators including "DHA", "EPA" and "DHA+EPA" shall be included. When setting the index value, it should comply with the daily dosage and raw material technical requirements in the health food ingredients list.

6. ‘Health Food Ingredients List Melatonin’ technical requirements for recording

6.1 Available Accessories

Edible corn starch, potato starch, tapioca starch, edible wheat starch, edible sweet potato starch, calcium carbonate, citric acid, microcrystalline cellulose, magnesium stearate, pregelatinized starch, silicon dioxide, lactose, hydroxypropyl cellulose , Dextrin, beeswax, soybean oil, gelatin, glycerin, titanium dioxide, polyethylene glycol, purified water, drinking water, sorbitol and sorbitol liquid, powdered soybean lecithin, corn oil, maltodextrin, D-mannitol , Stearic acid, croscarmellose sodium, talc, sodium carboxymethylcellulose, white sugar, polyoxyethylene sorbitan monooleate, povidone K30, triethyl glycerol, carboxymethyl Sodium starch base, calcium hydrogen phosphate, oligofructose, hydroxypropyl methylcellulose, ethyl p-hydroxybenzoate, calcium sulfate, walnut oil, edible glucose, hollow capsules (including hydroxypropyl starch hollow capsules, gelatin hollow capsules)). Food flavor and coloring.

6.2 Available Dosage Forms

When melatonin is used as a health food raw material, the health food can be recorded with only melatonin as the single raw material, or together with vitamin B6 (in accordance with the vitamin B6 standard in the nutrient supplement raw material list, and the daily dosage must not exceed the amount of the corresponding population in the raw material list) .The available product dosage forms include tablets (oral tablets, lozenges), granules, hard capsules, and softgel.

6.3 Product Technical Requirements

The technical requirements of each dosage form products shall follow the required technical indicators of each dosage form, the microbiological indicators shall follow the National Food Safety Standard Health Food GB16740, and also need to meet the following requirements:

6.3.1 [Significant ingredients] At least include "melatonin", which should be marked as a range value, and should meet the daily dosage requirements of the health food ingredients list. The maximum value of the range of the ingredients per 100g shall not exceed the daily consumption after conversion The maximum value and the minimum value should not be lower than the minimum daily dose.

6.3.2 When “vitamin B6” is used as the raw material, “vitamin B6” should be added and indicated as the range value. The maximum value of the range value of each 100g of the ingredient shall not exceed the vitamin B6 in the nutritional supplement raw material list after conversion. The maximum value and the

minimum value should not be lower than the minimum daily intake of vitamin B6 in the nutrient supplement raw material list.

Original Chinese Document listed Below

辅酶 Q10 等五种保健食品原料备案产品剂型及技术要求

一、辅酶 Q10 等五种保健食品原料备案产品剂型及主要生产工艺

辅酶 Q10、鱼油、破壁灵芝孢子粉、螺旋藻和褪黑素五种保健食品原料目录在产品备案时，可用剂型及主要生产工艺如下：

（一）片剂：粉碎、过筛、混合、制粒、干燥、压片、包衣、包装等。

（二）硬胶囊：粉碎、过筛、混合、制粒、干燥、装囊、包装等。

（三）软胶囊：混合、均质、过滤、压丸、干燥、包装等。

（四）颗粒剂：粉碎、过筛、混合、制粒、干燥、包装等。

（五）粉剂：粉碎、过筛、混合、分装、包装等。

二、《保健食品原料目录　辅酶 Q10》备案产品技术要求

（一）可用辅料

维生素 E、抗坏血酸钠、聚维酮 K30、纽甜、滑石粉、硬脂酸镁、蔗糖、甜菊糖苷、糊精、乳糖、微晶纤维素、β-环状糊精、交联聚维酮、柠檬酸、天门冬酰苯丙氨酸甲酯（又名阿斯巴甜）、食用葡萄糖、二氧化硅、低聚果糖、预胶化淀粉、低取代羟丙纤维素、羟丙基甲基纤维素、二氧化钛、聚乙二醇、D-甘露糖醇、山梨糖醇和山梨糖醇液、羧甲基纤维素钠、维生素 C、食用玉米淀粉、马铃薯淀粉、木薯淀粉、食用小麦淀粉、食用甘薯淀粉、羧甲基淀粉钠、空心胶囊（包括羟丙基淀粉空心胶囊、明胶空心胶囊）、明胶、甘油、纯化水、饮用水、对羟基苯甲酸乙酯及其钠盐、山梨酸及其钾盐（以山梨酸计）、大豆油、玉米油、葵花籽油、橄榄油、粉末大豆磷脂、浓缩大豆磷脂、大豆磷脂、聚氧乙烯山梨醇酐单油酸酯、蜂蜡。

食用香精、色素。

（二）可用剂型

以辅酶 Q10 为单一原料的保健食品备案时，可选择的产品剂型包括片剂（口服片、含片、咀嚼片）、颗粒剂、硬胶囊、软胶囊。

（三）产品技术要求

各剂型产品技术要求中除应含有符合不同剂型要求的技术指标，微生物指标符合《食品安全国家标准　保健食品》（GB16740）规定外，还应符合以下要求：

【标志性成分】为“辅酶 Q10”，以范围值标示。根据保健食品原料目录的每日用量要求，每 100g 的标志性成分范围值中的最大值经折算后不得超过每日服用量最高值，最小值不应低于每日服用量最低值。

三、《保健食品原料目录　破壁灵芝孢子粉》备案产品技术要求

（一）可用辅料

食用玉米淀粉、马铃薯淀粉、木薯淀粉、食用小麦淀粉、食用甘薯淀粉、羟丙基甲基纤维素、黄原胶(又名汉生胶)、硬脂酸镁、二氧化硅、羧甲基纤维素钠、维生素 C、糊精、微晶纤维素、聚维酮 K30、山梨糖醇和山梨糖醇液、维生素 E、磷酸氢钙、羧甲基淀粉钠、空心胶囊（包括羟丙基淀粉空心胶囊、明胶空心胶囊）、甘油三乙酯。

（二）可用剂型

以破壁灵芝孢子粉为单一原料的保健食品备案时，可选择的产品剂型包括片剂（口服片）、颗粒剂、硬胶囊、粉剂。

（三）产品技术要求

各剂型产品技术要求中除应含有符合不同剂型要求的技术指标，微生物指标符合《食品安全国家标准　保健食品》（GB16740）规定外，还应符合以下要求：

1.【理化指标】应增订 “六六六”、“滴滴涕”；粉剂增订“过氧化值”。

2.【标志性成分】至少包括“多糖”和“总三萜”两个指标。指标值设定时应符合保健食品原料目录的每日用量、原料技术要求等的规定。

四、《保健食品原料目录　螺旋藻》备案产品技术要求

（一）可用辅料

麦芽糊精、微晶纤维素、预胶化淀粉、硬脂酸镁、羧甲基纤维素钠、二氧化硅、羧甲基淀粉钠、甘油、羟丙基甲基纤维素、二氧化钛、聚乙二醇、食用玉米淀粉、马铃薯淀粉、木薯淀粉、食用小麦淀粉、食用甘薯淀粉、糊精、白砂糖、乳糖、维生素 E、聚维酮 K30、低聚异麦芽糖、碳酸氢钠、柠檬酸、蔗糖、聚乙烯醇、聚氧乙烯山梨醇酐单油酸酯、山梨糖醇和山梨糖醇液、乳粉、碳酸钙、交联聚维酮、羟丙纤维素、硬脂酸、蜂蜜、绵白糖、空心胶囊（包括羟丙基淀粉空心胶囊、明胶空心胶囊）、浓缩大豆磷脂、粉末大豆磷脂、分提大豆磷脂、透明大豆磷脂、大豆磷脂。

食用香精、色素。

（二）可用剂型

以螺旋藻为单一原料的保健食品备案时，可选择的产品剂型包括片剂（口服片、咀嚼片）、颗粒剂、硬胶囊。

（三）产品技术要求

各剂型产品技术要求中除应含有符合不同剂型要求的技术指标，微生物指标符合《食品安全国家标准　保健食品》（GB16740）规定外，还应符合以下要求：

1.【理化指标】增订“蛋白质”。

2.【标志性成分】至少包括“β-胡萝卜素”和“藻蓝蛋白”两个指标。指标值设定时应符合保健食品原料目录的每日用量、原料技术要求等的规定。

3.【微生物指标】中增订“副溶血性弧菌”。

五、《保健食品原料目录　鱼油》备案产品技术要求

（一）可用辅料

维生素 E、明胶、甘油、纯化水、饮用水、对羟基苯甲酸乙酯及其钠盐、大豆磷脂、焦糖色。

（二）可用剂型

以鱼油为单一原料备案保健食品，可选择的产品剂型为软胶囊。

（三）产品技术要求

产品技术要求中除应含有符合软胶囊要求的技术指标，微生物指标符合《食品安全国家标准　保健食品》（GB16740）规定外，还应符合以下要求：

1.【理化指标】中增订“水分及挥发物”、“碘值”、“苯并[a]芘”。

2.【标志性成分】至少包括“DHA”、“EPA”和“DHA+EPA”三个指标。指标值设定时应符合保健食品原料目录的每日用量、原料技术要求等的规定。

六、《保健食品原料目录　褪黑素》备案产品技术要求

（一）可用辅料

食用玉米淀粉、马铃薯淀粉、木薯淀粉、食用小麦淀粉、食用甘薯淀粉、碳酸钙、枸橼酸、微晶纤维素、硬脂酸镁、预胶化淀粉、二氧化硅、乳糖、羟丙纤维素、糊精、蜂蜡、大豆油、明胶、甘油、二氧化钛、聚乙二醇、纯化水、饮用水、山梨糖醇和山梨糖醇液、粉末大豆磷脂、玉米油、麦芽糊精、D-甘露糖醇、硬脂酸、交联羧甲基纤维素钠、滑石粉、羧甲基纤维素钠、白砂糖、聚氧乙烯山梨醇酐单油酸酯、聚维酮 K30、甘油三乙酯、羧甲基淀粉钠、磷酸氢钙、低聚果糖、羟丙基甲基纤维素、对羟基苯甲酸乙酯、硫酸钙、核桃油、食用葡萄糖、空心胶囊（包括羟丙基淀粉空心胶囊、明胶空心胶囊）。

食用香精、色素。

（二）可用剂型

以褪黑素为保健食品原料时，可以以单一褪黑素原料备案保健食品，也可同时加入维生素 B6（符合营养素补充剂原料目录中的维生素 B6 标准依据，不得超过原料目录中对应人群的每日用量）作为原料组合进行产品备案，可选择的产品剂型包括片剂（口服片、含片）、颗粒剂、硬胶囊、软胶囊。

（三）产品技术要求

各剂型产品技术要求中除应含有符合不同剂型要求的技术指标，微生物指标符合《食品安全国家标准　保健食品》（GB16740）规定外，还应符合以下要求：

【标志性成分】至少包括“褪黑素”，以范围值标示，应符合保健食品原料目录的每日用量要求，每 100g 的标志性成分范围值中的最大值经折算后不得超过每日服用量最高值，最小值不应低于每日服用量最低值。

原料中使用“维生素 B6”时，应增加“维生素 B6”，并以范围值标示，每 100g 的标志性成分范围值中的最大值经折算后不得超过营养素补充剂原料目录中维生素 B6 每日服用量最高值，最小值不应低于营养素补充剂原料目录中维生素 B6 每日服用量最低值。