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State Administration for Market Regulation

《市场监管总局关于公开征求将凝胶糖果、粉剂 纳入保健食品备案剂型意见的公告》

Announcement on publicly soliciting opinions on the inclusion of Gummy and Powder in the health food recording (Exposure Draft)

Technical requirements for health food recording dosage form – Gummy Candy

1. Overview of gummy candy

Gelatin candy is made of sugar or syrup or sweetener, edible gum (or starch) as the main raw materials, and is made into elastic and chewy candy through related processes.

2. Related content of the gummy candy product introduction book

The following content only stipulates the relevant requirements that need to be met for the shape of the gummy candy, but does not involve other regulations that the raw materials need to meet when the product is made.

The relevant content requirements in the product introduction book are as follows:

[Suitable crowd] People over 4 years old

[Unsuitable crowd] People under 3 years old

[Consumption amount and consumption method] The maximum daily consumption is 20g; the consumption method is "should chew thoroughly before taking."

[Specifications] Each capsule does not exceed 6g

[Shelf Life] Not more than 24 months

[Precautions] Do not swallow. People who consume this product should have the ability to chew solid food. At the same time, it is recommended to add a reminder that "should be chewed and eaten under the supervision of adults for those under 13 years of age".

3. The index setting of the technical requirements of gummy candy products

The following content only stipulates the relevant requirements that need to be met for the shape of the gummy candy, but does not involve other regulations that the raw materials need to meet when the product is made.

The relevant content requirements of product technical requirements are as follows:

【Sensory requirements】

Item	Specification
Color	Filling in requirements: conform to the appearance characteristics of the corresponding product, and have the color and luster that the variety should have.
Taste and Odor	Taste and smell Filling requirements: have the smell and taste that the product should have, no unpleasant smell, no peculiar smell
Status	The block shape is relatively complete, the size is basically the same, there is no obvious deformation, no adhesion. In addition, the following requirements should be met for different glue types: Vegetable gum type: slightly elastic and chewy. Animal glue type: elastic and chewy, no wrinkle skin. Starch type: Tough taste, slightly chewy, no starch binding phenomenon, using starch as raw material, there may be a small amount of uniform cooked starch on the surface, with elasticity and toughness. Mixed rubber type: elastic and chewy. Sandwich type: elastic and chewy; closed sandwich type without leakage of filling Coating, coating polishing type: the coating is relatively complete. Other types: in line with the expected state of the variety.

【Physical and Chemical Index】

Item	Specification
Pb, mg/Kg	≤0.5
As, mg/Kg	≤0.5
Hg, mg/Kg	≤0.3
Loss on drying, g/100g	Vegetable glue type: ≤18.0 Animal glue type: ≤20.0 Starch type: ≤18.0 Mixed type: ≤35.0 Sandwich type, coating and coating polishing type: meet the requirements of the main candy Other glue types: ≤20.0
Reducing sugar (calculated as glucose), g/100g	≥10.0 Sandwich type, coating and coating polishing type: meet the requirements of the main candy. Sugar-free gummy does not have this indicator.
Monosaccharides and disaccharides, g/100g	≤0.5, only sugar-free gelatinous candies set this index

【Microbiological indicators】

Item	Specification	Testing Method
Total number of colonies, CFU/g	≤30000	GB 4789.2
Coliform flora, MPN/g	≤0.92	GB 4789.3MPN counting method
Mold and yeast, CFU/g	≤50	GB 4789.15
Staphylococcus aureus	≤0/25g	GB 4789.10
Salmonella	≤0/25g	GB 4789.4

【Net content and allowable negative deviation index】

Net content and allowable negative deviation indicators should meet the requirements of JJF 1070

4. Product name

Brand name + common name + gummy candy

Technical requirements for health food recording dosage form – Powder

1. Overview of powder

Powder is a dry powder finished product made by pulverizing and uniformly mixing raw materials and auxiliary materials.

2. Related contents of the powder product introduction book

The following content only stipulates the relevant requirements that need to be met for the form of powdered foods, but does not involve other requirements that need to be met when the raw materials are made into products.

The relevant content requirements in the product introduction book are as follows:

[Suitable crowd] The dosage form should be suitable for all crowd

[Unsuitable crowd] There is no specific unsuitable crowd for this dosage form

[Dosage and method of consumption] The maximum daily consumption is 20g; package increase indicates that "powder is generally dissolved or dispersed in water or other liquids, or it can be taken directly with water". For the "direct oral" eating method, the unsuitable crowd should include "people under 6 years old".

[Specifications] For large-dose packaging, the volume per package is limited to no more than 500g (in principle, no more than 1 month's dosage). Large-dose packaging should be accompanied by dividing utensils.

[Shelf Life] Not more than 24 months

3. Technical requirements for powder products

The following content only stipulates the relevant requirements that need to be met for the form of powdered foods, but does not involve other requirements that need to be met when the raw materials are made into products.

The relevant content requirements of product technical requirements are as follows:

【Sensory requirements】

Item	Specification
Color	Filling in requirements: conform to the appearance characteristics of the corresponding product, and have the color and luster that the variety should have.
Taste and Odor	Taste and smell Filling requirements: have the smell and taste that the product should have, no unpleasant smell, no peculiar smell
Status	Should be dry, loose, evenly mixed, consistent in color

【Physical and Chemical Index】

Item	Specification
Particle size	Comply with any of the coarsest powder, coarse powder, medium powder and fine powder in the Chinese Pharmacopoeia
Pb, mg/Kg	≤2.0 Infant solid health food ≤0.3
As, mg/Kg	≤1.0 Infant solid health food ≤0.3
Hg, mg/Kg	≤0.3 Infant solid health food ≤0.02
Moisture,%	≤9.0
As,%	Required

【Microbiological indicators】

Item	Specification	Testing Method
Total number of colonies, CFU/g	≤30000	GB 4789.2
Coliform flora, MPN/g	≤0.92	GB 4789.3MPN counting method
Mold and yeast, CFU/g	≤50	GB 4789.15
Staphylococcus aureus	≤0/25g	GB 4789.10
Salmonella	≤0/25g	GB 4789.4

【Net content and allowable negative deviation index】

Net content and allowable negative deviation indicators should comply with JJF 1070 regulations

4.product name

Brand name + common name + powder (if the raw material name contains "powder", it will not be added again)

Dosage form and main production processes of health food recording products (2020 version) (Exposure draft)

The main production process of health food recording products is suitable for recordable health food. At present, the following dosage forms (or food forms) and main production processes can be used when recording vitamin and mineral supplement products. In the future, according to the successive release of the "Health Food Raw Materials List", the dosage forms (or food forms) that can be prepared with different raw materials will be subject to the dosage forms (or food forms) specified by the "Health Food Raw Materials List" and its supporting documents. The main production processes of each dosage form (or food form) 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. Soft capsules: drying, mixing, homogenizing, filtering, pelletizing, packaging, etc.
4. Oral solution: mixing, dissolving, preparing, filtering, filling, packaging, etc. (If sterilization is involved, the specific sterilization method and process parameters should be filled in, such as moist heat sterilization, autoclaving, circulating steam sterilization, etc.) .
5. Granules: crushing, sieving, mixing, granulating, drying, packaging, etc.
6. Jelly candy: sol, sugar, boiling, blending, filtering, aeration, forming, drying, sand mixing, coating, polishing, coating, packaging, etc.
- Seven, powder: crushing, sieving, mixing, packaging, packaging, etc.
8. The pre-processed raw materials that have been pre-mixed, embedded, and microencapsulated, should be marked as pre-mixed(**、**、**), embedded(**、**、**), microencapsulated(**、**、**).

Original Chinese Document listed Below

保健食品备案剂型凝胶糖果的技术要求

(2020 年版)

(征求意见稿)

一、凝胶糖果概述

凝胶糖果是以食糖或糖浆或甜味剂、食用胶（或淀粉）等为主要原料，经相关工艺制成具有弹性和咀嚼性的糖果。

二、凝胶糖果产品说明书有关内容

以下内容仅针对凝胶糖果食品形态规定了需要满足的有关要求，不涉及使用的原料在制成产品时还需要符合的其他规定。

产品说明书中有关内容要求如下：

【适宜人群】 4 岁以上人群

【不适宜人群】 3 岁以下人群

【食用量及食用方法】 每日最大食用量为 20g；食用方法为“应充分咀嚼后服用”。

【规格】 每粒不超过 6g

【保质期】 不超过 24 个月

【注意事项】 请勿吞服。食用本产品的人群应当具备有咀嚼固体食物的能力。同时对于适宜人群含有“13 岁以下”的，建议增加“应在成人监督下充分咀嚼食用”的提示。

三、凝胶糖果产品技术要求的指标设定

以下内容仅针对凝胶糖果食品形态规定了需要满足的有关要求，不涉及使用的原料在制成产品时还需要符合的其他规定。

产品技术要求有关内容要求如下：

【感官要求】

项目 [↵]	指标 [↵]
色泽 [↵]	填写要求：符合相应产品的外观特性,具有品种应有的色泽。 [↵]
滋味、气味 [↵]	填写要求：具有产品应有的气味和滋味,无异臭,无异味 [↵]
状态 [↵]	<p>块形较完整,大小基本一致,无明显变形,无黏结。[↵]</p> <p>此外,对于不同胶型应符合以下要求:[↵]</p> <p>植物胶型:略有弹性,有咀嚼性。[↵]</p> <p>动物胶型:有弹性和咀嚼性,无皱皮。[↵]</p> <p>淀粉型:口感韧性,略有咀嚼性,无淀粉裹筋现象,以淀粉为原料的,表面可有少量均匀熟淀粉,具有弹性和韧性。[↵]</p> <p>混合胶型:有弹性和咀嚼性。[↵]</p> <p>夹心型:有弹性和咀嚼性;密闭的夹心型无馅心外漏[↵]</p> <p>包衣、包衣抛光型:包衣较完整。[↵]</p> <p>其他型:符合品种应有的状态。[↵]</p>

【理化指标】

项目 [↵]	指标 [↵]
铅(以Pb计), mg/kg [↵]	≤0.5 [↵]
总砷(以As计), mg/kg [↵]	≤0.5 [↵]
总汞(以Hg计), mg/kg [↵]	≤0.3 [↵]
干燥失重, g/100g [↵]	<p>植物胶型: ≤18.0[↵]</p> <p>动物胶型: ≤20.0[↵]</p> <p>淀粉型: ≤18.0[↵]</p> <p>混合型: ≤35.0[↵]</p> <p>夹心型、包衣和包衣抛光型:符合主体糖果的要求[↵]</p> <p>其他胶型: ≤20.0[↵]</p>
还原糖(以葡萄糖计), g/100g [↵]	<p>≥10.0[↵]</p> <p>夹心型、包衣和包衣抛光型:符合主体糖果的要求。[↵]</p> <p>无糖胶型凝胶糖果不设该指标。[↵]</p>
单糖和双糖, g/100g [↵]	≤0.5, 仅无糖胶型凝胶糖果设定该指标 [↵]

【微生物指标】

项目	指标	检测方法
菌落总数, CFU/g	≤30000	GB 4789.2
大肠菌群, MPN/g	≤0.92	GB 4789.3MPN 计数法
霉菌和酵母, CFU/g	≤50	GB 4789.15
金黄色葡萄球菌	≤0/25g	GB 4789.10
沙门氏菌	≤0/25g	GB 4789.4

【净含量及允许负偏差指标】

净含量及允许负偏差指标应符合 JJF 1070 规定

四、产品名称

商标名+通用名+凝胶糖果

保健食品备案剂型 粉剂的技术要求（2020年版） （征求意见稿）

一、粉剂概述

粉剂是原料、辅料经粉碎、均匀混合制成的干燥粉末状成品。

二、粉剂产品说明书有关内容

以下内容仅针对粉剂食品形态规定了需要满足的有关要求，不涉及使用的原料在制成产品时另需要符合的其他规定。

产品说明书中有关内容要求如下：

【适宜人群】该剂型应该适宜于所有人群

【不适宜人群】该剂型暂无特定的不适宜人群

【食用量及食用方法】每日最大食用量为 20g；增加提示“粉剂服用时一般溶于或分散于水或者其他液体中服用，也可直接用水送服”。对于食用方法为“直接口服”的，不适宜人群应包括“6岁以下人群”。

【规格】对于大剂量包装的，限定每个包装的装量不超过 500g（原则上不超过 1 个月的服用量）。大剂量包装应附分剂量的用具。

【保质期】不超过 24 个月

三、粉剂产品技术要求有关内容

以下内容仅针对粉剂食品形态规定了需要满足的有关要求，不涉及使用的原料在制成产品时另需要符合的其他规定。

产品技术要求有关内容要求如下：

【感官要求】

项目	指标
色泽	填写要求：符合相应产品的外观特性,具有品种应有的色泽。
滋味、气味	填写要求：具有产品应有的气味和滋味,无异臭,无异味
状态	应干燥、疏松、混合均匀、色泽一致

【理化指标】

项目	指标
粒度	符合《中国药典》中最粗粉、粗粉、中粉、细粉中任意一种
铅 (以 Pb 计), mg/kg	≤2.0 婴幼儿固态保健食品的铅≤0.3
总砷 (以 As 计), mg/kg	≤1.0 婴幼儿保健食品的总砷≤0.3
总汞 (以 Hg 计), mg/kg	≤0.3 婴幼儿保健食品的总汞≤0.02
水分, %	≤9.0
灰分, %	必填项

【微生物指标】

项目	指标	检测方法
菌落总数, CFU/g	≤30000	GB 4789.2
大肠菌群, MPN/g	≤0.92	GB 4789.3MPN 计数法
霉菌和酵母, CFU/g	≤50	GB 4789.15
金黄色葡萄球菌	≤0/25g	GB 4789.10
沙门氏菌	≤0/25g	GB 4789.4

【净含量及允许负偏差指标】

净含量及允许负偏差指标应符合 JJF 1070 规定

四、产品名称

商标名+通用名+粉（原料名称已带“粉”的不再重复添加）

保健食品备案产品剂型及主要生产工艺
(2020年版)
(征求意见稿)

保健食品备案产品主要生产工艺适用于可以备案的保健食品。目前补充维生素矿物质产品在备案时可以使用以下剂型（或食品形态）及主要生产工艺。未来根据《保健食品原料目录》的陆续发布情况，不同原料可以制备的剂型（或食品形态）以《保健食品原料目录》及其配套文件发布时规定的剂型（或食品形态）为准。各剂型（或食品形态）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：干燥、混合、均质、过滤、压丸、包装等。
- 四、口服溶液：混合、溶解、配制、过滤、灌装、包装等（涉及灭菌的，应填报具体灭菌方法及工艺参数，如湿热灭菌、热压灭菌、流通蒸汽灭菌等）。
- 五、颗粒：粉碎、过筛、混合、制粒、干燥、包装等。
- 六、凝胶糖果：溶胶、化糖、熬煮、调配、过滤、充气、成型、干燥、拌砂、包衣、抛光、涂挂、包装等。
- 七、粉剂：粉碎、过筛、混合、分装、包装等。
- 八、经预混、包埋、微囊化等前处理的原料，应以预混（**、**、**）、包埋（**、**、**）、微囊化（**、**、**）等形式在生产工艺中标注经预混、包埋、微囊化等前处理的原料名称。