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# **Report Name:** Technical Requirements for Health Food Products with American Ginseng as Ingredient

**Country:** China - People's Republic of

**Post:** Beijing

**Report Category:** Agricultural Situation, FAIRS Subject Report, MISC-Commodity, Trade Policy Monitoring, Vegetables

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**Report Highlights:**

On April 30, the State Administration for Market Regulation (SAMR) released an announcement on the Technical Requirements for Health Food Product Filing with Ginseng, American Ginseng, and Ganoderma Lucidum as Ingredients. These requirements, which took effect on May 1, 2024, provide the technical requirements for excipients, dosage forms, and production processes that can be used for the three materials during product filing. They also clarify that product quality and safety index requirements such as contaminants indicators must comply with relevant national food safety standards. This report contains an unofficial translation of these requirements.

**Summary**

*The Technical Requirements for Health Food Product Filing with Ginseng, American Ginseng, and Ganoderma Lucidum as Ingredients* includes allowable excipients and their usage requirements, product dosage forms, raw materials and product processing requirements, product naming, chemical and physical indicators, testing results, sources of raw materials, and testing requirements. This is the first time that health food products with traditional Chinese medicinal ingredients have been included in the filing management system. Health food manufacturers need to file their health food products using these three ingredients with SAMR based on these requirements. Health food products required for filing must be products that have been registered with SAMR.

In December 2023, SAMR announced it was including ginseng, American ginseng, and *ganoderma lucidum* in the health food ingredient catalog (see GAIN report CH2024-0002). In other words, these three traditional Chinese medicinal materials can be used as health food ingredients.

On November 17, 2023, SAMR and the National Health Commission (NHC) jointly announced their plan to regulate nine traditional Chinese medicinal materials, including American ginseng, as both Chinese medicines and food, which means American ginseng has been approved as a food ingredient (see GAIN report CH2023-0181).

The General Administration of Customs of the People's Republic of China (GACC) has requested USDA provide a list of U.S. facilities that produce or process plant-origin Chinese medicinal materials to be exported to China. The list will include information related to the facility such as enterprise name, address, export product category, etc. GACC will publish the final list on its website. U.S. exporters interested in registering to export to China can email FASChinaDAPQRegistrations@usda.gov for additional information.

BEGIN TRANSLATION

**Announcement of the State Administration for Market Regulation on the Technical Requirements for Health Food Product Filing with Ginseng, American Ginseng, and *Ganoderma Lucidum* as an Ingredient**

SAMR No. 18 of 2024

April 28, 2024

In accordance with "Food Safety Law of the People's Republic of China", "Health Food Ingredient Catalog of Ginseng", "Health Food Ingredient Catalog of American Ginseng" and "Health Food Ingredient Catalog of *Ganoderma Lucidum*", the State Administration for Market Regulation (SAMR) has established "*Technical Requirements for Health Food Product Filing with Ginseng, American*

*Ginseng, and Ganoderma Lucidum as Ingredients*", which is hereby promulgated and shall take effect on May 1, 2024.

**Technical Requirements for Health Food Product Filing with Ginseng, American Ginseng, and *Ganoderma Lucidum* as Ingredients**

(2024 Version)

1. Requirements for use of excipients in the filed products

1) List of excipients allowed to be used

Honey, sucrose, glucose, monocrystalline rock sugar, polycrystalline rock sugar, maltose, oligofructose, white sugar, soft white sugar, fructose, glucose syrup, fructose syrup, fructose, lactose, xylitol, menthol, sorbitol, D-mannitol, maltodextrin, dextrin, hydroxypropylmethylcellulose, carboxymethylcellulose, carboxymethylstarch sodium, polyvinyl ketone K30, milk powder, soybean lecithin, palm oil, beeswax soybean oil, gelatin, glycerin, drinking water, purified water, polyethylene glycol, vitamin C, vitamin E, citric acid, L-Malic acid, aspartame, talc, sodium bicarbonate, steviol glycosides, edible corn starch, edible wheat starch, tapioca starch, potato starch, edible sweet potato starch, oligomeric isomaltulose, microcrystalline cellulose, silicon dioxide, magnesium stearate, sodium benzoate, potassium sorbate, gelatin hollow capsule, hydroxypropyl starch hollow capsule, coloring, flavor, fruit and vegetable powder

2) Requirements for the use of excipients

Product formulations should minimize the types and amounts of excipients to meet the formulation of molding, stability, and the role of the characteristics of the requirements. The selection of excipients should not cause chemical changes with the raw materials to avoid affecting the testing of product technical indicators.

3) Requirements for the use of unlisted excipients

For those who really need to use excipients outside the above list but are included in the "Allowable Excipients and Their Usage Regulation for Filed Health Food Products," the following information should be provided:

A. Research and development data (including testing data, indicator selection, etc.) on the basis for the use of excipients, process necessity, ensuring product stability, no chemical changes with packaging materials in direct contact with the product, and no impact on product testing, product functions, formulation formability and stability, etc.

B. Toxicological evaluation information of the finalized product, health function evaluation information, and scientific literature or research materials on the basis for the use of similar products on the domestic or international market.

The above information should be submitted to the filing system under "other materials indicating product safety and health care functions".

2. Dosage forms for product filing

1) General requirements for dosage forms

When ginseng, American ginseng and ganoderma lucidum are filed for record, the available dosage forms of the products include tablets (containing tablets, chewable tablets, and oral tablets), hard capsules, soft capsules, powder, oral liquid, combination, granules, paste and tea (bagged tea). When using the above dosage forms, product technical requirements should be consistent with the current "Chinese Pharmacopoeia" part IV "General Principles of Preparation" under the dosage form of the relevant technical requirements. Tea filter bag materials and auxiliary materials should be consistent with food-related national standards. If the above ingredients are filed for record in liquid preparations, no restrictions shall be made on the maximum daily intake amount based on ensured accuracy of daily consumption of the ingredients.

2) Other requirements

A. Tablets allowed to be used in filed products do not currently include tablet products (such as ginseng honey tablets) obtained by soaking decoction pieces (or adding excipients). After the above-mentioned honey tablet products are registered and approved, other products can be filed according to the relevant technical requirements of the registered products.

B. For registered products produced in dosage forms other than those mentioned above, the specific requirements are as follows:

a) Based on the registration of health food and application of dosage forms, the General Administration will additionally expand other pharmaceutical dosage forms in the current four parts of the "Chinese Pharmacopoeia" when necessary.

b) Any individual or organization may apply at the technical agency of SAMR to add common food forms based on sufficient research on the food forms of filed products. Common food forms included in the filing must have corresponding national food safety standards, national recommended standards, or industry quality control standards. The dosage form or product form should meet the requirements for the population groups who are suitable for the health food and comply with the requirements for accurate quantification of individual daily recommended intake. And the product should comply with the quality and safety requirements during consumption.

3. Requirements for production process of the product

1) Requirements for raw materials during product processing

When filing unilateral products of ginseng, American ginseng, and ganoderma lucidum, the raw materials should come from fixed sources and origins (production area). The raw materials used to produce filed products should be traditional Chinese medicine pieces that comply with the current "Chinese Pharmacopoeia". When using raw materials that comply with the current "Chinese Pharmacopoeia", the filing party should have the pre-processing capabilities for the raw materials and process the raw materials into pieces that meet the specifications for preparation use according to production needs.

2) Requirements for processing technology

When filed products using ginseng, American ginseng, and ganoderma lucidum as raw materials, production processes that only use physical crushing or heating and extraction using water as a solvent are allowed. No other production processes (such as steaming) that cause changes in the material basis are allowed.

A. Process requirements for products made after physical crushing

The main processes include cutting, crushing, sterilization (generally using sterilization methods such as moist heat sterilization or radiation sterilization), drying, and screening. When the raw materials are physically pulverized, ultrafine pulverization should not be used. In principle, the pulverized raw materials should not exceed 200 mesh.

B. Process requirements for heating and extraction of raw materials using water as solvent

The main processes include cutting, crushing, sieving, boiling, solid-liquid separation (including filtration), concentration, and drying. For processes such as water decoction, key process parameters (number of decoctions, amount of water added, decoction time, etc.) and range should be determined.

a) The production research data submitted by the filing party should be generated from commercial production at certain scale. The research data includes how to ensure that the intermediate products are obtained without changing the raw material input amount during large-scale production under the premise that the process route and key process parameters remain unchanged. The finished product rate should be relatively stable, and the quality of the intermediate should be stable (such as content of main components, relative density, moisture content, etc.).

b) For solid preparations of the filed product, if it is necessary to use water as the solvent for extraction, drinking water is generally used, and its quality must comply with the current national standard of the People's Republic of China on "Hygienic Standard for Drinking Water" (GB5749). If the filed product is a liquid preparation, drinking water or purified water can be used for water extraction.

c) Water decoction should comply with traditional decoction methods, and the production process parameters should be set to ensure the full release of the active ingredients in the medicinal materials. Extraction methods such as dipping and low-temperature percolation are not suitable. For filed products, parameters such as raw material pre-treatment method, number of decoctions, amount of water added, and decoction time should be determined based on the product research status.

d) After the raw materials are heated and extracted with water as the solvent, physical methods should be used for solid-liquid separation, and separation should not be conducted through refining methods (such as water extraction and alcohol precipitation, membrane filtration, centrifugation, etc.).

e) When concentrating and drying the above-mentioned decoction liquid, appropriate process methods should be selected to make extracts or dried products based on the requirements for preparation molding and factors affecting the concentration and drying effects.

f) Under the premise that the raw material input amount of the product is fixed, the amount of auxiliary materials should not only have clear process necessity and rationality, but also ensure that the amount of final product in different batches is stable and consistent. For solid preparations whose production process includes an extraction process, the amount of filler can be an appropriate amount, and the amount of diluent for liquid preparations can be an appropriate amount.

g) The filing party can submit a product made by mixing the raw materials and extracting water by themselves. The name of the raw materials in the product formula is ginseng/American ginseng/Ganoderma lucidum. For health foods that have been approved for registration, those that use crushed raw materials and/or water extracts as formula raw materials (such as Ganoderma lucidum and Ganoderma lucidum extract) should be transferred to the filing management.

3) Main production processes of product dosage forms

The filing party can reasonably select the main production processes based on the actual production conditions and reuse them when necessary.

A. Mixture: processes such as extraction, filtration, concentration, mixing, dissolution, preparation, volume setting, potting, sterilization, and packaging.

B. Ointment: extraction, filtration, concentration, mixing, preparation (or honey refining), potting, sterilization, packaging, and other processes.

C. Tea preparation: extraction, drying, crushing, mixing, packaging and other processes.

D. The main production processes of other dosage forms should comply with the relevant requirements in the current "Dosage Forms and Technical Requirements for Filed Health Food Products". If the raw materials have been sterilized by irradiation, the product labels and instructions should comply with the relevant requirements for food labels.

4. Technical requirements for the product

In addition to the technical requirements for the filed products that clearly characterize the dosage form of the corresponding product and the microbiological indicators that comply with the "National Food Safety Standard for Health Food" (GB16740), the technical requirements for the filed products should also meet the following requirements:

1) Product name

When filing products using ginseng as raw materials, the product name should be "brand + ginseng + attribute name". "Garden ginseng" and "forest ginseng" should not be used as the common name of the product, nor should “forest ginseng” be mentioned in the file certificate, product instructions, and the product technical requirements. Products using forest ginseng as raw materials can apply for health food registration. When registering products using Ganoderma lucidum as raw material, the product names should be "brand + ganoderma lucidum + attribute name", "brand + ganoderma lucidum (red) + attribute name", "brand + ganoderma lucidum (purple) + attribute name". When registering products using American ginseng as raw material, the product name should be "brand + American ginseng + attribute name".

The attribute in the product name of tea preparations (tea preparations in bags) is "tea", such as "brand ginseng tea" and "brand ginseng tea bag".

When filing products for the above raw materials, the age of the raw materials should not be added after the common name of the product, such as "brand + ginseng (6 years) + attribute name".

2) Identification

Generally, methods with stronger specificity, higher sensitivity, and better reproducibility should be used. In principle, for products made directly from physical crushing, a microscopic identification method should be established, and specific identification indicators can be added according to the raw material conditions.

3) Physical and chemical indicators

It should include general quality control indicators (such as moisture, ash, pH value, etc.), contaminant indicators (such as lead, total arsenic, total mercury, etc.), mycotoxins, and limited amounts of synthetic colors, preservatives, sweeteners, antioxidants, and necessary pesticide residue indicators, etc.

4) Iconic ingredients

The main raw materials of the product should contain characteristic ingredients that are stable in nature, can be accurately quantified, and are relevant to the health functions of the product. According to the production process of the filed product, product characteristics can be characterized in various ways such as formulating the content of monomer components and the content of major components. For

single formula ginseng and American ginseng products, the technical indicators include total saponins, etc.; for single formula Ganoderma lucidum products, the technical indicators include polysaccharide ingredients, etc. One can also refer to approved and registered products and the relevant requirements of the current Chinese Pharmacopoeia for the same variety to develop indicators and index value. For additional indicators, existing documents and reports should be provided, as well as information that explains the dose-effect relationships.

5. Other requirements for product filing

1) Requirements for source of raw materials

When filing products, the raw materials must comply with the requirements stipulated in the Food Safety Law and other relevant laws and regulations. In Annex 2 of the filing certificate, the raw material quality requirements of the product technical requirements should indicate the source of the variety, place of origin (production area), suppliers (no more than 2), quality standards (the technical indicators should at least meet those in the raw material catalog), etc. Of which, the suppliers of raw materials should have the legal qualifications, and the business license should at least cover the business scope of selling raw medicinal materials or slices. In the process of managing and tracing the filed raw materials of health foods of ginseng, American ginseng, and ganoderma lucidum, the provincial market regulatory departments should strengthen the control of raw materials based on the raw material technical requirements of the health food raw material catalog and refer to the current Chinese Pharmacopoeia and national food safety standards. The testing and regulation of safety indicators such as pesticide residues and heavy metals, as well as exogenous substances related to product quality and safety.

2) Product filing requirements

When applying for filing of health food products, a full-item inspection report issued by a legally qualified inspection and testing agency for the same batch of raw materials used in trial production (different suppliers and production areas should be provided separately), and the inspection report is valid for 2 years from the date of issuance until the date of submission of the filing application in the health food filing management information system. The inspection agency should draw conclusions on whether the raw materials comply with current regulations.

3) Requirements for raw materials using water extraction process

For products newly applied for filing, if the production process adopts extraction processes using water as a solvent, the filing party should have the corresponding pre-processing capabilities such as raw material extraction. If the production conditions are not yet met, they will not be included in the filing management. For products that are transferred from registration to filing system and contain water extracts in product formula, if the original registrant entrusts the production of the extracts during product filing, the filing party shall be responsible for the quality and safety of the extracts. The quality

requirements for the raw material extracts shall be specified in the product technical requirements, including extract entrusted processing contract, extract's raw material source, composition, production method (including production process, key process parameters, etc.), extraction rate, sensory requirements, general quality control indicators (such as moisture, ash, particle size, etc.), pollutant indicators (such as lead, total arsenic, total mercury, etc.), pesticide residues, iconic component indicators, microbial indicators and other indicator items. The provincial market regulatory departments implement production licenses for raw materials based on the requirements for raw material extracts transferred from registration to filing.

END TRANSLATION

**Attachments:**

No Attachments.