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《保健食品保健功能配方文献审评要点（征求意见稿）》

**Main Points of Review of Health Food Functions and
Formula Literatures (Exposure Draft)**

The content of technical review of the formula and function literature in the health function review report mainly covers the scientific basis for the use of the product formula raw materials, the principle of the formula, the formula compatibility and the dosage of the claimed functions. The research of formula and literature is the research basis for the claimed function of the health food to be developed, and it is an important basis for comprehensively judging whether the health food function evaluation and labeling related content are reasonable based on the results of the function evaluation tests. The technical review points are formulated according to the "Measures for the Management of Health Food Registration and Recording", "Health Food Registration Review and Approval Rules (2016 Edition)" and related regulations.

1. Relevant requirements of the literatures basis

1.1 The Scope of literatures basis

- 1.1.1 Regulations, standards, guidelines, monographs, etc. issued by domestic and foreign government agencies, authorities or organizations
- 1.1.2 Description in traditional Chinese medicine ancient books
- 1.1.3 National unified textbooks, professional works, academic yearbooks, etc
- 1.1.4 Scientific research papers, expert treatises and systematic reviews officially published in domestic core journals or international professional journals.

1.2 The quality requirements of literatures basis

- 1.2.1 The literature basis should be professional, with reliable research quality and credible research data.
- 1.2.2 The literatures basis, national textbooks, professional writings, academic yearbooks and other documents issued by domestic and foreign government agencies, authoritative institutions or organizations, should have industry and academic authority and broad consensus in the professional field. The description of the related functions of raw materials in the literature should have a verifiable correlation with the claimed function.

- 1.2.3 The expressions of the related functions of the raw materials in the literature basis of the traditional Chinese medicine should be related to the claimed functions.
- 1.2.4 The composition of the raw materials in the literature should be consistent with the raw materials of the product. The main components, processes and other information should stay the same with the raw materials used in product. The ratio between extract and raw material should be made clear.
- 1.2.5 The source of the literatures basis should be clear, the traceability information such as query methods of literatures basis such as regulations and standards should be provided.
- 1.2.6 The experimental scientific research papers based on the test population or animal model, research design, test indicators, etc. should correspond to the claimed function and suitable population, the test results and statistical analysis should be reasonable, the conclusion should be exact, and the test dosage should be able to support the claimed function of raw material.
- 1.2.7 The papers on the non-oral administration of the test substance and the in vitro experiment shall not be used as a scientific basis to support the claimed function of the health food formula raw material.

2. Requirements of the product formula literatures and demonstration

2.1 Clarify the purpose of the application of raw materials

The purpose of the raw materials should be specified according to the principle that the main raw materials have the claimed function and the other materials are necessary.

2.2 Documentary evidence that the main raw materials have function

The main raw materials include single raw material and compound raw materials, and the relevant literature basis should support that the main raw materials of the product have the claimed function at the designed dosage.

- 2.2.1 The literature basis from regulations, standards, guides, monographs, ancient Chinese medicine books, scientific research papers, and systematic reviews should be provided to objectively reflect the current domestic and foreign research and application of relevant raw materials, and the claimed function of raw materials should be comprehensively discussed based on the provided literature.
- 2.2.2 Experimental scientific research papers or literature analysis and evaluation reports based on experimental scientific research papers should be provided. Information such as title, first author, publication, test subject, animal or population model, test dosage and equivalent human dosage, evaluation indicators, test results and conclusions in such literature should be listed in the form of a summary table, the effective dosage should be comprehensively discussed based on provided literature. The dietary consumption information should be provided if necessary.
- 2.2.3 If the major raw materials are simple processed ordinary foods, the functional components and content of the raw materials and the dose-effect relationship should also be clearly defined. The provided raw material inspection reports, product test reports and other materials should specify the dosage of the functional ingredients of the raw materials. The

experimental scientific research papers provided can demonstrate the dose-effect relationship between the functional ingredients and the claimed function.

2.3 Documentary evidence showing the necessity of the compatibility of other raw materials The Chinese medicine literature, scientific research papers and other literature basis supporting the compatibility and functions of the rest raw materials with the main raw materials should be provided, and the necessity of the rest raw materials should be discussed accordingly.

3. Requirement of product formula, compatibility, dosage and argumentation

3.1 Formulation standardization

The formula composition should be standardized, clear and complete, and the daily dosage should be clear. The relevant information should meet the relevant requirements of the "Health Food Registration Application Service Guide" (2016 Edition). The extract should be clearly defined as the equivalent amount of the original material.

3.2 Principles of product composition

The principle of product formulation should be clear, and suitable crowd should be reasonable. Combined with the research data of suitable crowd, the target problem, function characteristics and the significance should fully be discussed.

3.2.1 For formulas guided by the traditional Chinese medicine theory, the source of the formula, the basis of application and screening should be explained, the basic compatibility principle of the formula and the function of each raw material should be analyzed, and the formula's health function should be discussed.

3.2.2 For formulas guided by modern medicine and nutrition theories, the health function should be discussed based on modern medicine, nutrition theory combining with relevant scientific evidence.

3.2.3 The formula with claimed function should be discussed combining nature of the formula raw materials and production process. The rationality of formulas containing both traditional animal and plant materials and non-traditional animal and plant materials should be carefully considered

3.2.4 The scientificity and rationality of the claimed connected functions should be discussed when apply for product with multiple functions.

3.3 For summary of product formula with compatibility and dosage claiming functions, the critical analysis should be carried out on the relevant literature basis of raw materials and formulating principles. The analysis should present the meaning and conclusion in the relevant literature basis and comprehensively discuss the product formula compatibility and dosage with the claim functions.

4. Judgment criteria for review conclusions

4.1 If the review recommendation is "application materials meet the requirements", the following requirements shall be met:

The formula material specifications are complete and comply with the regulations; the literature basis of the formula fully supports the claimed function of the product.

4.2 If the review recommendation is "need additional materials", the following requirements shall be met:

The literature basis of the formula fully supports the claimed function of the product, but it is necessary to further standardize and improve the application materials that do not involve the review and recommendations of the health function.

4.3 If the review recommendation is "not to be registered", the following requirements shall be met:

The content of the formula's literature basis is contradictory or inconsistent with the content of the health function demonstration report; the formula's literature basis is insufficient or the content is incomplete to support the claimed function of the product.

Original Chinese Document listed Below

保健食品保健功能配方文献审评要点

保健功能论证报告中配方及文献部分的技术审评内容，主要涵盖产品配方原料使用目的、组方原理、配方配伍及用量具有声称功能的科学依据。配方及文献的研究是拟开发保健食品在声称功能方面的研究基础，是结合功能评价试验结果综合判断保健食品功能评价及标签标识相关内容是否合理的重要依据。根据《保健食品注册与备案管理办法》《保健食品注册审评审批细则（2016年版）》及相关规定，制定本技术审评要点。

一、文献依据的相关要求

（一）文献依据的范围

1. 国内外政府机构、权威机构或组织发布的法规、标准、指南、专论等；
2. 我国传统中医药古籍记述；
3. 国家统编规划教材、专业著作、学术年鉴等；
4. 国内核心期刊或国际专业期刊正式发表的科研论文、专家论著及系统综述类文献。

（二）文献依据的质量要求

1. 文献依据应具有专业性，研究质量可靠、研究数据可信。
2. 国内外政府机构、权威机构或组织发布的文献依据、国家统编规划教材、专业著作、学术年鉴等文献依据在专业领域应具有行业、学术权威性和广泛共识性，文献中原料相关作用的表述应与声称功能具有能够证实的相关性。
3. 我国传统中医药经典古籍类文献依据中对原料相关作用的表述与声称功能具有相关性。
4. 文献依据中原料组成与产品原料相符，主要成分、主要工艺等信息与产品原料具有相关性，使用提取物的应明确其相当于原始物料的量。
5. 文献依据出处应明确，法规、标准等文献依据应提供查询方式等溯源性信息。
6. 实验性科研论文类文献依据中受试人群或动物模型、研究设计、试验指标等应与声称的功能及适宜人群相对应，试验结果及统计分析合理，试验结论明确，试验剂量能支持原料用量具有声称功能作用。

7. 以非经口方式给与受试物的实验及体外实验的论文不作为直接支持保健食品配方原料具有声称功能的科学依据。

二、产品配方原料文献及论述要求

（一）明确原料的使用目的

按照主要原料具有声称功能作用、其余原料具有配伍必要性的原则明确原料的使用目的。

（二）主要原料具有功能作用的文献依据

主要原料包括单一原料和复配原料，其相关文献依据应支持产品主要原料在使用剂量上具有声称功能。

1. 应提供法规、标准、指南、专论、中医药古籍文献记述、科研论文及系统综述类文献依据，客观地反映相关原料的国内外研究、使用现况，并依据所提供的文献综合论述主要原料具有声称功能作用。
2. 应提供实验性科研论文或基于实验性科研论文的文献分析和评价报告，此类文献中篇名、首作者、发表刊物、试验受试物、动物或人群模型、试验剂量及相当人体剂量、评价指标、试验结果及结论等信息可以以文献信息汇总表（见附件）形式列出，并依据所提供的文献综合论述其支持主要原料具有声称功能作用的用量，必要时提供可能的膳食摄入量情况。
3. 主要原料为经简单加工的普通食品的，还应重点明确原料的功效成分和含量以及量效关系。提供的原料检验报告、产品试验报告等资料，应明确原料功效成分的具体用量；提供的实验性科研论文，能论证功效成分与声称功能的量效关系。

（三）其余原料配伍必要性文献依据

应提供其余原料与主要原料配伍使用，支持产品具有声称功能的中医药文献记述、科研论文等文献依据，并相应论述其余原料配伍必要性。

三、产品配方配伍及用量及文献论述要求

（一）配方规范性

配方组成规范、清晰、完整，日用量明确，相关资料应符合《保健食品注册申请服务指南》（2016年版）相关要求，使用提取物的应明确其相当于原始物料的量。

（二）产品组方原理

产品组方原理明确，适宜人群选择合理。结合适宜人群的研究资料，能充分论述产品拟解决的问题、作用特点和意义。

1. 以中医药理论为主指导组方的，应说明组方来源、应用及筛选的依据等情况，对组方的基本配伍原则及各原料作用加以分析，对组方具有拟声称保健功能进行论述。
2. 以现代医学、营养学理论为主组方的，应用现代医学、营养学理论，结合相关科学依据对组方具有拟声称保健功能进行论述。
3. 应根据配方原料的性质、生产工艺等特点，结合相应理论论述组方具有拟声称保健功能，重点关注配方中既含传统动植物原料又含非传统动植物原料的组方合理性。
4. 申报多个声称功能的产品，应论述声称功能关联的科学性、合理性。

（三）产品配方配伍及用量具有声称功能的综述

应对原料、组方原理相关文献依据进行关键性的分析，呈现相关文献依据中的意义及结论，综合论述产品配方配伍及用量具有声称功能。

四、审评结论的判定标准

（一）审评建议为“申请材料符合要求”的，应符合以下要求：

配方材料规范完善并符合规定；配方的文献依据充分支持产品声称功能。

（二）审评建议为“补充材料”的，应符合以下要求：

配方的文献依据充分支持产品声称功能，但需要对不涉及保健功能审评建议的申请材料进一步规范完善的。

（三）审评建议为“不予注册”的，应符合以下要求：

配方的文献依据内容与保健功能论证报告内容矛盾、不符；配方的文献依据不充足或者内容不完整，无法支持产品声称功能的。