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Administrative Measures on Health Food Function Claim Directory and Raw Material Inventory (Draft)

保健食品保健功能目录与原料目录

管理办法

Chapter 1 - General Provisions

Article 1 [Purpose and basis] A view of standardizing the management of the Health Food Function Claim Directory and Raw Material Inventory, which are permitted in health food. Provisions are formulated in accordance with Food Safety Law of the People's Republic of China.

Article 2 [Scope of application] The provisions apply to the establishment, adjustment and announcement of Health Food Function Claim Directory and Raw Material Inventory.

Article 3 [Definition of health function claim directory] Health Function claim directory is an information list, which contains name of functions that allowed to be claimed. For these claims, they have passed system assessment and verification, and they have specific identification methods and criteria.

Article 4 [Definition of Health Food Raw Materials Inventory] Raw material inventory is list of raw materials, which can be used in health food meeting the evaluation of products' safety and functions along with all related information. The main contents of this inventory are the raw material's name, compatibility, dosage, allowed health function claims, quality standards, active ingredients, the inspection methods and relative explanation etc.

The Health Food Raw Materials Inventory is divided into materials supplementing vitamins and minerals and materials with other health functions.]

Article 5 [Application principles] The manufacture of filed health food products should follow the requirements listed on the health food material inventory. The processing of products using materials of the inventory involves extraction, purification, and other reprocessing techniques should to be registered as health food.

The combination of materials from Vitamins minerals is allowed. Materials from other categories is not allowed to be combined with others.

Health Food with more than two ingredients having coordinating or promoting effects and sufficient scientific evidence and application history can be enrolled in health food material inventory in line with relevant requirements of this regulation.

Health Claims of health food products should in strict accordance with the statements of health claim inventory with no modification and combination.

Article 6 [Segregation of duties] China State Food and Drug Administration (CFDA), National health and family planning commission (NHFPC), State Administration of Traditional Chinese Medicine of the P.R.C (SATCM) will be responsible for the establishment, adjustment and announcement of health food raw materials and health functions directory.

China State Food and Drug Administration (CFDA), National health and family planning Commission (NHFPC), State Administration of Traditional Chinese Medicine of the P.R.C (SATCM) will set up a health food function claim directory and material inventory committee of experts who are responsible for technology review for the establishment and adjustment of health food raw material and health function directory. The committee is composed of experts from food science and engineering, basic medicine, clinical medicine, public health and preventive medicine, traditional Chinese medicine, integrated traditional and western medicine, pharmaceutical science, traditional

Chinese pharmaceutical science, chemistry and other relevant field. CFDA, NHFPC and SATCM are members of the committee as institutions.
A secretariat of Expert committee will be set up by Health food review Center in CFDA to undertake organizations of the expert committee and daily work management.

Article 7 [Dynamic management] China will implement dynamic management on the directory of health food raw materials and health functions. CFDA, NFPHC and SATCM will adjust Health Food Raw Materials Inventory and health functions directory based on the scientific progresses and the health food registration condition.

Article 8 [Management principles] According to the needs of supervision, CFDA can use ways like application, Project approval, tender and delegation to choose institution which are capable of undertaking studies and demonstration of health food raw material and health function inventory. These institutions will carry out the establishment and adjustment of health claim inventory and health food material inventory in due course.

Article 9 [Encouraging research] The State encourages operators of the health care food production, scientific research institutions, social organizations and individuals to carry out fundamental research and application research studies regards to the establishment and adjustment of health food function claim directory and health food raw material inventory and to submit application of health food function claim directory and health food raw material inventory.

Article 10 [Basic principle] The establishment, adjustment and announcement of health food function claim directory and health food raw material inventory should aim to protecting public health and food safety, and also should adhere to principles of being scientific, open, just and fair.

Chapter - 2 Management of health function directory

Article 11 [Inclusion criteria] Health functions included in the health function directory should conform to the following requirements:

(1) For the purpose of regulating body function, improving health and reducing the risk of disease. Health function for prevention, diagnose and therapy should not be involved.

(2) Utilize rigorous and easy to understand scientific evidence.
(3) Utilize scientific identification methods and criteria.
(4) Utilize specific suitable crowds and unsuitable crowds.
(5) Apply to wide crowds' specific health care needs
(6) Guided by traditional theory of health care and conform to Traditional Chinese medicine theory.

Article 12 [Exclusion clause] Those words and expressions as following should not be used in health functions:

(1) Express or implied effects of disease prevention, treatment and diagnosis or words that can be mixed up easily.
(2) False, exaggerated or absolutize
(3) Vulgar or feudal superstitions
(4) Hard for consumers to understand
(5) Likely to mislead consumers

Article 13 [Assessment methods and criteria] The assessment methods and criteria should conform to following requirements:

(1) Should conform to relevant national rules and project requirements, and have specific application scope and adequate principle basis.
(2) The assessment routine should be brief, to the point and well organized and also could determine the test item, principle and result. The assessment routine should keep consistent with relative content of the testing methods.
(3) Settings for testing methods and evaluation index should be scientific, reasonable, suitable, stable and operable.

Article 14 [Research application] Any institution or individual could apply for the health food function claim to be listed in the health food function claim directory or the adjustment of health

food function claim directory to health care food review center of CFDA along with reasons, basis and relevant materials.

The adjustment of health food function claim directory includes the adjustment of the names, reviewing methods, criterions and deleting certain function claims.

Article 15 [Application materials] Materials should be submitted when apply for the health function to be listed in the health food directory:

(1) Name of health functions;
(2) Nomenclature principle/basis of the health functions;
(3) R&D report including the crowd health demand analysis, health function, analysis material of health care function and the body health effect and Summary etc. The report should also contain principle basis of health function test, application scope and other relative scientific study material;
(4) Functional assessment methods, criteria and responding functional testing report of the sample;
(5) Application situation of the same function or similar function both at home and abroad;
(6) Relative scientific document basis and other related materials.

Article 16 [Project review] Health care food review center of CFDA should review the application material and give review comments after receiving the relative materials:

(1) For those applications that fail to meet the requirements, Health care food review center of CFDA will inform the applicant (institution or individual) in writing and tell reasons for the failure;
(2) For those application material that meet the requirements, Health care food review center of CFDA shall ask for public comments and arrange for relative experts and technicians to carry out a comprehensive assessment and verification of the health function claim and basis, assessment method, criteria and application scope etc.

Article 17 [System assessment] Health care food review center of CFDA will give review conclusions based on system assessment, validation, results from public comments and the previous approval situation of the health function.

(1) For those applications that fail to meet the requirements, Health care food review center of CFDA will inform the applicant (institution or individual) in writing and tell reasons for the failure;
(2) For those applications that meet the requirements, Relative materials and the comprehensive review opinions shall be submitted to health food function claim directory and material inventory committee of experts.

Article 18 [Joint hearing release] Expert committee should audit the relative materials and the comprehensive review opinions, then give audit conclusion:

(1) If the application fails the joint hearing, the result and reason in writing will be told to the applicant (institutions or individual);
(2) If the application pass the joint hearing, the results will be submitted to China State Food and Drug Administration (CFDA), National health and family planning commission (NHFPC), State Administration of Traditional Chinese Medicine of the P.R.C (SATCM).

Article 19 [Directory adjustment] China State Food and Drug Administration (CFDA) should carry on the adjustments of health food function claims directory and release the announcement along with the National health and family planning commission (NHFPC), State Administration of Traditional Chinese Medicine of the P.R.C (SATCM) based on the conclusion of experts committee and the result of reevaluation.

Article 20 [Reevaluation] CFDA along with NHFPC and SATCM will arrange a reevaluation of the health function in the health function directory in any of the following circumstances:

(1) Practical application and new scientific knowledge find out there exists problems on the assessment methods and criteria in health function, which need to reevaluate and demonstrate;
(2) There exists great gap between the Health function listed in the directory and realistic health care needs;
(3) Other circumstances that need to reevaluate the process and requirements of revaluation of health food function claim directory is in accordance with article seventeen to nineteen of this regulation.

Chapter - 3 The administration of health food raw material inventory

Article 21 [Adopt requirements] Raw materials adopted by health food raw material directory should meet following requirements:

(1) With long-term edible history at home and abroad and sufficient scientific evidence;
(2) With a specific range of dosage and a corresponding health function listed in health food function claim directory;
(3) With quality technical requirements that are stable and controllable;
(4) With the science basis that are safe and effective;
(5) With scientific, applicable, stable and reliable functional ingredient(s) or iconic ingredient(s) and its range of content and corresponding testing methods;
(6) It should be safe and harmless to the suitable group if taken according to the instructed dosage and method.

Article 22 [Exclusion clause] A raw material should not be listed into the health food raw material directory upon any of the following cases:

(1) A raw material lacks either usage record of approved and registered health food or current materials that are already in the market that do not have effective edible evaluation data;
(2) A raw material found to have potential harm and uncertain factors to human health may exist after scientific and systematic risk evaluation;
(3) A raw material, which is prohibited of use or violates laws and regulations regarding national wild life and plant protection;
(4) A raw material, which fails to be standardized, managed and industrially produced through the establishment of general requirements;
(5) Other raw materials that should not be added.

Article 23 [Initiate an application] Any institution or individuals could submit the application of a new raw material to be listed in the health food material inventory or adjustment of existed materials of the inventory to Health Food Review Center, CFDA based on certain research.

Article 24 [Application materials] Following materials should be submitted upon the application of a health food raw material to be listed in the directory:

(1) Name of the raw material, including standard Chinese name, Latin name, family, genera and variety;
(2) Source and specification;
(3) Range of daily intakes and corresponding functions;
(4) Records and reports of adverse food safety issues;
(5) Major technical requirements;
(6) Quality standards;
(7) The functional ingredient or iconic ingredient, the range of content and the testing methods;
(8) The materials regarding the suitable group and unsuitable group;
(9) Restrictive conditions of use and matters needing attention;
(10) The usage of raw material at home and abroad including its usage in existing health food products in China;
(11) Relevant scientific literature;
(12) Other relevant materials.
The application should include the used part, references from traditional Chinese medical literature if the material is sourcing from animals or plants.
The application of adjusting exited health food material directory should provide a proper reason and relevant proving materials.

Article 25 [Review the application] Health Food Review Centre of CFDA should organize experts and technical personnel to review the application in time upon the receipt, and a result should be provided.
(1) If not qualified, the applicant (institution or individual) should be notified with the reasons in writing;

(2) If qualified, public opinions should be sought and relevant experts and technical personnel should be called up to conduct system evaluation and verification on the raw material and its dosage as well as the functions.

Article 26 [CFDA reviews the project] In view of the registration and approval progress of health food, health Food Review Centre of CFDA should carry out timely processing all relevant materials and review on newly approved health food raw materials which conform to Article 25.

Article 27 [Systematic assessment] Health Care Food Review Center of CFDA will give comprehensive review opinions based on systematic assessment, validation, public opinions as well as the usage situation of previously approved raw materials:

(1) If not qualified, the applicant (institution or individual) should be notified with the reasons in writing;

(2) If qualified, relative materials and the comprehensive review opinions shall be submitted to CFDA.

Article 28 [Auditing from the Committee] Expert committee is in charge of reviewing relevant materials and comprehensive reviewing opinions of the application and making an audit conclusion:

(1) If the application fails the joint hearing, the applicant (institutions or individual) should be notified with both the result and reasons in writing.

(2) If the application passes the joint hearing, the raw material should be listed in the health food raw material directory and corresponding announcement should be released.

Article 29 [Inventory adjustment and announcement] China State Food and Drug Administration (CFDA) should carry on the adjustments of health food function claims directory and release the announcement along with the National health and family planning commission (NHFPC), State Administration of Traditional Chinese Medicine of the P.R.C (SATCM) based on the conclusion of experts committee and the result of reevaluation.

Article 30 [Reevaluation] CFDA along with NHFPC and SATCM will arrange a reevaluation of the health function in the health function directory in any of the following circumstances:

(1) Any edible food safety problem is detected in the raw materials listed in the Directory by new research;
(2) Any edible safety risk or problem is detected in the raw materials listed in the Directory during risk monitor or health food safety surveillance;
(3) It is found necessary by new research that the range of daily intakes and corresponding functions be adjusted, or, the functional claims are not exactly scientific or rigorous;
(4) Records and reports of adverse effects occur;
(5) Other cases where a reevaluation is necessary.

The procedures and requirements of the reevaluation of health material inventory is accordance with article 27 to article 29 of this regulation.

Chapter - 4 Supplementary Provisions

Article 32 [Post-treatment of the adjustment] For adjustment of the directory and inventory made, CFDA should organize discussions jointly with NHFPC and SATCM to propose the post-treatment measures regarding relevant products that have been filled and registered earlier.

Article 33 [Explanation of the regulation] China Food and Drug Administration is responsible for the interpretation of the Measures.

Article 34 [Date of Implementation] This measure enters into force as of 20XX-XX-XX.

Original Chinese Version

第一章 总 则

第一条 [目的依据] 为规范保健食品保健功能目录和保健食品原料目录的管理工作，根据《中华人民共和国食品安全法》，制定本办法。

第二条 [适用范围] 中华人民共和国境内生产经营的保健食品保健功能目录和原料目录的制定、调整和公布适用本办法。

第三条 [功能目录定义] 保健功能目录，是指经系统评价和验证，具有明确的评价方法和判定标准的允许保健食品声称的保健功能信息列表。

保健功能目录包括保健功能名称及说明等内容。

第四条 [原料目录定义] 保健食品原料目录，是指经安全性和功能性评价，可用于保健食品的物质及其对应的相关信息列表。主要内容包括原料名称、配伍、用量、允许声称的保健功能、质量标准、功效成分和检验方法及相关说明等。

保健食品原料目录分为补充维生素、矿物质等营养物质的原料目录和其他保健功能的原料目录。

第五条 [使用原则] 备案的保健食品，应当严格按照保健食品原料目录载明的要求组织生产。使用保健食品原料目录内的原料生产保健食品，经提取、纯化等再加工工艺的，属于依法应当注册的保健食品。

补充维生素、矿物质等营养物质的原料目录内的原料可以根据需要复配，其他的不能随意复配、组合。

对于两种以上原料配伍，可起到协同或促进作用，有充足的科学依据和应用历史，并符合本办法相关要求的，该配伍可纳入保健食品原料目录。

保健食品声称的保健功能，应当严格按照保健食品功能目录的表述进行标识，不得随意增减词语，不得随意组合。

第六条 [职责划分] 国家食品药品监督管理总局会同国家卫生和计划生育委员会、国家中医药管理局制定、调整并公布保健食品原料目录和保健功能目录。

国家食品药品监督管理总局会同国家卫生和计划生育委员会、国家中医药管理局组建保健食品功能目录和原料目录专家委员会（以下简称专家委员会），负责保健食品保健功能目录与原料目录制定、调整的技术审查工作。专家委员会委员主要由食品科学与工程、基础医学、临床医学、公共卫生与预防医学、中医学、中西医结合、药学、中药学、化学等相关领域专家组成，国家食品药品监督管理总局、国家卫生和计划生育委员会、国家中医药管理局作为单位委员。

国家食品药品监督管理总局保健食品审评中心设立专家委员会工作秘书处，承担专家委员会的组织和日常管理工作。

第七条 [动态管理] 国家对保健食品原料目录与保健功能目录实施动态管理。国家食品药品监督管理总局根据科学研究的进展以及保健食品注册情况，会同国家卫生和计划生育委员会、国家中医药管理局及时调整保健食品原料目录和保健功能目录。

第八条 [管理原则] 根据监管工作需要，国家食品药品监督管理总局可以采取申请、立项、招标和委托等形式，择优选择具备相应技术能力的单位承担有关保健功能目录和保健食品原料目录的研究和论证。

第九条 [鼓励研究] 国家鼓励保健食品生产经营者、科研机构、社会团体和个人开展与保健功能目录、保健食品原料目录制定和调整相关的基础研究和应用研究，提交保健食品功能目录、保健食品原料目录申请。

第十条 [基本原则] 保健功能目录和保健食品原料目录的制定、调整和公布，应当以保障公众健康和食品安全为宗旨，遵循科学、公开、公正的原则。

第二章 保健功能目录管理

第十一条 [纳入标准] 纳入保健功能目录的功能应当符合以下要求：

（一）以调节机体功能、改善机体健康状态或者降低疾病发生风险为目的，不得涉及疾病的预防、治疗、诊断作用。

（二）具有充足的科学依据，科学、严谨，能够被正确理解和认知；

（三）具有科学的评价方法和判定标准；

（四）具有明确的适宜人群和不适宜人群；

（五）具有适用较为广泛人群的特定保健需求；

（六）以传统养生保健理论为指导的保健功能，符合传统中医药理论。

第十二条 [排除条款] 具有以下情形之一的词语，不得用于保健功能名称：

（一）明示、暗示疾病预防、治疗、诊断作用或者易混淆的；

（二）虚假、夸大或者绝对化的；

（三）庸俗或者带有封建迷信色彩的；

（四）消费者不易理解的；

（五）其他有可能误导消费者的。

第十三条 [评价方法和判定标准] 保健功能评价方法及判定标准应当符合以下要求：

（一）评价程序和检验方法应当符合国家有关规定和项目要求，具有明确的适用范围和充足的原理依据；

（二）评价程序应当简明扼要、条理清晰，应当明确试验项目、原则以及结果判定，并与检验方法的相关内容保持一致；

（三）检验方法及评价指标的设定应当科学、合理、适用、稳定，具有可操作性。充分考虑指标与健康效应的相关性，数据处理应当符合统计学的有关要求，结果判定要全面准确。

第十四条 [立项申请] 任何单位或者个人在开展相关研究的基础上，可以向国家食品药品监督管理总局保健食品审评中心提出拟列入保健功能目录的保健功能申请和保健功能目录调整申请，并提供理由、依据和相关材料。

保健功能目录调整包括调整保健功能名称、评价方法、判定标准以及删减功能等情形。

第十五条 [申请材料] 提交拟列入保健功能目录的保健功能申请时，应当提交以下材料：

（一）保健功能名称；

（二）保健功能命名依据；

（三）保健功能研发报告，包括保健功能的人群健康需求分析、保健功能与机体健康效应的分析材料及综述等、保健功能试验的原理依据、适用范围以及其他相关科学研究资料；

（四）功能评价方法及判定标准以及对应的样品功能检验报告；

（五）相同或者类似功能在国内外的应用情况；

（六）有关科学文献依据及其他有关材料。

申请保健功能目录调整的，还需要提供调整的理由、依据和相关材料。

第十六条 [立项审查] 国家食品药品监督管理总局保健食品审评中心收到有关材料后，应当及时根据本办法第十一条至第十三条的要求，对申请材料进行立项审查，并提出审查意见：

（一）不符合要求的，书面告知提出申请的单位或者个人，并说明理由；

（二）符合要求的，应当公开征求公众意见，并组织有关专家和技术人员对该功能声称名称及依据、评价方法和判定标准、适用范围等进行全面综合评价和验证。

第十七条 [综合评价] 国家食品药品监督管理总局保健食品审评中心根据全面综合评价、验证试验和征求意见的结果，并结合以往批准的功能声称情况，综合做出审查意见：

（一）不符合要求的，书面告知提出申请的单位或者个人，并说明理由；

（二）符合要求的，将相关资料连同综合审查意见提交专家委员会会议审议。

第十八条 [委员会审核] 专家委员会召开会议，对相关资料及综合审查意见进行审核，并作出审核结论：

（一）审核未通过的，书面告知提出申请的单位或者个人，并说明理由；

（二）审核通过的，报送国家食品药品监督管理总局和国家卫生和计划生育委员会、国家中医药管理局。

第十九条 [公告发布] 国家食品药品监督管理总局应当会同国家卫生和计划生育委员会、国家中医药管理局，根据专家委员会的审核结论和再评价结果，对保健功能目录进行调整，并发布公告。

第二十条 [再评价] 有下列情形之一的，国家食品药品监督管理总局应当会同国家卫生和计划生育委员会、国家中医药管理局，及时组织对保健功能目录中的保健功能进行再评价：

（一）实际应用和新的科学共识发现保健功能评价方法与判定标准存在问题，需要重新进行评价和论证的；

（二）列入保健功能目录中的保健功能与实际健康需求存在较大差距的；

（三）其他需要再评价的情形。

保健功能目录再评价的程序和要求按照本办法第十七条至第十九条的规定进行。

第三章 保健食品原料目录管理

第二十一条［纳入要求］列入保健食品原料目录中的原料应当符合以下要求：

（一）具有广泛的国内外食用历史和充足的科学依据；

（二）具有明确的用量范围和对应的符合保健功能目录要求的保健功能；

（三）具有稳定可控的质量技术要求；

（四）具有符合安全性、有效性要求的科学依据；

（五）具有科学适用、稳定可靠的功效成分或者标志性成分、含量范围及检测方法；

（六）按照规定用量及方法食用，对适用人群安全、无害。

第二十二条 [排除条款] 具有下列情形之一的，不得列入保健食品原料目录：

（一）无保健食品食用记录，或者缺乏有效的上市后人群食用评价数据资料的原料；

（二）经食用安全风险评价，对人体健康可能存在一定潜在危害和不确定因素的原料；

（三）禁止食用或者不符合有关国家野生动植物保护法律法规规定的原料；

（四）无法制定通用要求进行标准化管理和工业化生产的原料；

（五）其他不应当列入的原料。

第二十三条 [申请立项] 任何单位或者个人在开展相关研究的基础上，可以向国家食品药品监督管理总局保健食品审评中心提出拟列入保健食品原料目录的原料申请以及已列入保健食品原料目录原料的调整申请。

保健食品原料目录的调整包括调整原料用量、对应的功效等原料目录内容及删减原料的情形。

第二十四条 [申请材料] 提交拟列入保健食品原料目录的原料申请时，应当提供以下材料：

（一）原料名称，包括标准中文名，拉丁学名，科属品种；

（二）来源及规格；

（三）每日用量范围及对应功效；

（四）不良食用安全问题记载及报道情况；

（五）主要工艺要求；

（六）质量标准；

（七）功效成分或者标志性成分、含量范围及检测方法；

（八）有关适宜人群和不适宜人群的材料；

（九）限制性使用条件和注意事项；

（十）原料的国内外使用情况，包括在我国已批准的保健食品中的使用情况；

（十一）有关科学文献材料；

（十二）其他有关材料。

原料来源于动植物的还需要提供原料使用部位、传统中医药文献记载等。

申请已列入保健食品原料目录原料调整的，还需要提供调整理由和相关证明材料。

第二十五条 [立项审查] 国家食品药品监督管理总局保健食品审评中心收到有关材料后，应当及时组织专家和技术人员根据本办法第二十一条、第二十二条和第二十四条的要求对申请材料进行立项审查，并作出审查结论。

（一）不符合要求的，书面告知提出申请的单位或者个人，并说明理由；

（二）符合要求的，应当公开征求社会意见，并组织有关专家和技术人员对该原料、用量以及对应的功效等进行全面综合评价和验证工作。

第二十六条 [总局立项] 根据保健食品注册审批情况，对于新批准使用的保健食品原料符合本办法第二十一条规定的，国家食品药品监督管理总局保健食品审评中心应当对注册审批过程中的相关资料进行整理，及时组织立项审查，按照本办法第二十五条的相关要求开展相关工作。

第二十七条 [综合评价] 国家食品药品监督管理总局保健食品审评中心根据全面综合评价、验证试验和征求意见的结果，并结合以往原料批准使用的历史情况，综合做出审查意见：

（一）不符合要求的，书面告知提出申请的单位或者个人，并说明理由；

（二）符合要求的，将相关资料连同综合审查意见提交专家委员会会议审议。

第二十八条 [委员会审核] 专家委员会对接到的相关资料及综合审查意见进行审核，并作出审核结论。

（一）审核未通过的，书面告知提出申请的单位或者个人，并说明理由；

（二）审核通过的，报送国家食品药品监督管理总局和国家卫生和计划生育委员会、国家中医药管理局。

第二十九条 [调整发布] 国家食品药品监督管理总局应当会同国家卫生和计划生育委员会、国家中医药管理局，根据专家委员会的审核结论和再评价结果，及时对保健食品原料目录进行调整，并发布公告。

第三十条 [再评价] 有下列情形之一的,国家食品药品监督管理总局应当会同国家卫生和计划生育委员会、国家中医药管理局及时组织对保健食品原料目录中的原料进行再评价：

（一）新的研究发现保健食品原料目录中原料存在食用安全性问题的；

（二）食品安全风险监测或者保健食品安全监管中发现保健食品原料目录中原料存在食用安全风险或者问题的；

（三）新的研究发现原料每日用量范围与对应功效需要调整的或者功效声称不够科学、严谨的；

（四）出现不良反应记载或者报道的；

（五）其他需要再评价的情形。

保健食品原料目录再评价的程序和要求按照本办法第二十七条至第二十九条的规定进行。

第四章 附则

第三十一条 [调整后处置] 保健食品原料目录与保健功能目录发生调整的，国家食品药品监督管理总局应当会同国家卫生和计划生育委员会、国家中医药管理局组织论证，提出对已备案及注册产品的处理措施。

第三十二条 [实施日期] 本办法自 年 月 日起施行。