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Measures for the Registration and Filing of Health Food

保健食品注册与备案管理办法

Regulation's Main Points

Measures for the Registration and Filling of Health Food

Chapter 1. General Provisions

Article 1 According to "Food Safety Law of the People's Republic of China", this measure is developed to regulate the registration and recording of health food.

Article 2 The registration, recording and supervision management of health food in the territory of the people's Republic of China apply to this measure.

Article 3 The registration of health food refers to a systematic evaluation and review process of health food safety, health function, quality control and other aspects based on the application materials of health food products intended to be registered and make a decision (Approve or Disapprove) in accordance with the legal procedures, conditions and requirements.

The recording of health food refers to the process of the health food manufacturer submitting the application materials of product safety, health function and quality control to CFDA for recording, archiving, open to the public and references in accordance with the legal procedures, conditions and requirements.

Article 4 The registration and recording of health food should follow the scientific, fair, open, efficient and convenient principle.

Article 5 The China Food and Drug Administration (CFDA) is responsible for registration management of all Health Food and recording management of the first time imported nutrients belong to vitamins and minerals. And also direct provincial, autonomous regions, municipalities level FDA conduct related works of health food registration and recording.

Provincial, autonomous regions or municipality level FDA is responsible for the management of health food recording within the administrative region. And also follow CFDA conduct on-site inspection and other works for health food registration.

City or Town FDA is responsible for the supervision management of registration and recording of health food within the administrative region and also conduct some other works assigned by upper level FDA.

Article 6 CFDA administrative accepting institution (Accepting Institution) is responsible for receiving health food registration materials and imported health food recording materials.

Provincial, autonomous regions or municipalities level FDA is responsible for receiving health food recording materials.

CFDA health food review board (Review Board) is responsible for conducting health food review process, managing review experts and some related works about health food recording.

CFDA inspection institution (Inspection Institution) is responsible for on-site inspection of health food registration.

Article 7 The applicant of health food registration and recording should have relevant professional knowledge, and familiar with health food registration or recording law, regulation, guidance and technical requirements.

The applicant of health food registration and recording must be responsible for the authenticity, integrity and traceability of the application materials, and take the legal responsibility of the authenticity.

The applicant of health food registration and recording should assist with FDA conduct on-site inspection, sample randomization, retest, supervision management and other works related with registration or recording.

Article 8 Above provincial level FDA should enhance information construction, improve informative level of health food registration and recording management, build up electronic registration and recording gradually.

Chapter 2 Registration of health food

Article 9 Products should apply for health food registration:

1) Its raw materials are not listed on the Health Food Raw Material List;
2) First time imported Health Food (Except vitamins, minerals).

First time imported Health Food is the health food sold in the China market but come from different countries, different companies and use different formulations.

Article 10 The health function claims of the product should have been included in Health Food Function List.

Article 11 The applicant of domestic health food registration should be legal person or other corporation registered in China; the applicant of imported health food should be a foreign manufacturer of health food, which are sold in that foreign market. The entity that applies for the registration of imported health food should be its representative office in China or authorized agency in China.

Foreign manufacturer is the legal person or other organization and its product conform to their local legal requirements.

Article 12 Apply for health food registration should submit the application materials as below:

1) Application Form and the letter of commitment;
2) The copy of business license of the applicant;
3) Research and Development report of the product, which include researchers, time, research process, validation data of the test above pilot scale, raw materials not listed on the health food raw materials list, verification report and related scientific evidences of product safety, health function, quality controllability, product technical requirements base on research results and other information.
4) Formula of the product, which include name, dosage, manufacturing technology, quality standard of raw materials and auxiliary materials. Basis of use of raw materials, explanation of the used part, inspection qualify certificate, variety analysis report and other information may be needed when necessary;
5) Manufacturing process of the product, which include diagram and description of production process, instructions of key process control points;
6) Product safety and health function evaluation information, which include safety, health function evaluation and population tasty quality evaluation of raw materials not list on the health food raw materials list and the product; test report of functional component, hygiene, stability, species identification and species toxicology; test report refer to stimulant and illegal drugs;
7) Type, name and related standards of the Package materials that directly touch the product;

8) Sample of Label and instruction book; retrieval materials show that the general name of the product is not in duplicate of registered drugs;
9) Three sample sales packages;
10) Other related information.

Article 13 For the first time imported health food registration, except all the information mentioned in article 12, supplementary materials have to be submitted as below:

1) Business License of the applicant issued by its local governmental or legal officials;
2) The certificate issued by its local governmental or legal officials to show that the product has been produced and sold at least one year there; Or its oversea sales report and the safety report of population consumption condition;
3) Health Food Technology regulation or standard of its manufacturer country or international organization;
4) Sample of product package, label, instruction book in its manufacturer country.

If the representative office in China conducts the registration, they have to submit 'The Foreign Company Resident Representative China office Registration Certificate' and its copy.

If the authorized agency does the registration, they have to submit the verified authorization letter and a copy of their business license.

Article 14 After the accepting institution receive all the application materials; the following decisions can be made:

1) If the items of application do not need registration, notify the applicant that it is not acceptable;
2) If the items of application do not belong to CFDA's responsibility, make the 'not acceptable' decision and inform the applicant resubmit application to the right administrative agency;
3) If any mistakes existed in the application materials can be corrected immediately, allow the applicant to make corrections;
4) If the application material is incomplete or does not conform, should inform the applicant immediately or within 5 business days all supplementary information as needed at a time; No

notice past the due day, which means accept the application by the day that received the application dossier.

5) If the items of application belong to CFDA's responsibility, application materials are complete and conform to the regulation, and the applicant also submit all supplementary application materials, should accept the registration application;

The letter of 'Accept' or 'Not Accept' registration application should have the CFDA accept stamp and the exact date on it.

Article 15 The accepting institution have to send the completed application materials to the review board within 3 days.

Article 16 Review board should organize review experts to evaluate the application materials, conduct on-site inspection and retest as needed. The review process will be finished within 60 days. The review board have to submit the review results and comments to CFDA.

Any special situations need to extend the review time can get another extra 20 days once approved by the director of review board. A letter of extension decision has to be issued to the applicant.

Article 17 The review board should review the application materials based on the principles as below, and ensure the terminology of product health function claims base on sufficient scientific evidences:

1) Evaluate research and development report regarding science, completeness and reasonability.
2) Evaluate product formulation regarding to science, health function and safety
3) Evaluate the controllability, feasibility and reasonability of raw materials not listed on the Health Food Raw Materials list and the product
4) Evaluate product technical requirements and testing method regarding to practicability and science.
5) Evaluate the name, label and instruction book of the product regarding to standardization.

Article 18 The review board can review the original research materials during the product technical review period.

If the review board affirm that the application materials are false, or product safety issues or quality controllability problems still remain to be further demonstrated, or the product do not possess its health function, they will terminate the review process and suggest 'not allow to be registered'.

Article 19 If the review board requests the applicant to submit supplementary materials, they have to inform the applicant all the information at once. The applicant should provide all the information based on the notice within 3 months. The review time should be re-calculated after the review board receive the supplementary materials.

If the applicant could not provide supplementary materials exceed the time limit, which cannot demonstrate the product safety, health function and quality controllability, the review board should terminate the process and suggest 'not allow to be registered'.

Article 20 If the review board decide to conduct on-site inspection, they have to inform the inspection agency conduct the inspection based on the product research and development report, formulation, manufacturing technology and other information; also send the product sample to conduct a retest.

The inspection agency should finish on-site inspection within 30 days since they receive the notice, and send the inspection report to the review board.

If the inspection report show that the application materials are false, not traceable or exist significant defects, the review board should terminate the process and suggest 'not allow to be registered'.

Article 21 The retest agency should conduct the test in accordance with the test method, sample treatment and other relevant instructions of the application materials; validate the practicability, science and applicability of testing method, quality controllability of the product. The retest agency

should finish the retest within 60 days since they receive the notice and send the retest report to the review board.

If the retest report shows that the test method is not scientific, not practical, not applicable or not controllable, the review board should terminate the process and suggest 'not allow to be registered'.

Article 22 For the Time Limit of on-site inspection and product sample retest of the first time imported health product, it depends on each manufacturer's actual situation.

Article 23 Any test or inspections refer to health food review should be conducted by CFDA selected food testing agency.

Article 24 Registration application should be approved if the review board affirm that the application is authentic, scientific, safe, health function is clear and effective, production process is reasonable and controllable, product testing method and technical requirements are scientific and practicable. When the review board make a decision 'not allow to be registered', they have to issue a written letter to the applicant. The applicant can request second review with reasons within 20 business days if the applicant disagree with the final decision. The content of the second review will be only the original application items and materials.

The review board should make decisions for the second review within 30 business days since they receive the application. If any changes happen to the final decision after the second review, the review board should inform the applicant by a written letter.

Article 25 The review board should give the review conclusion and comments to CFDA with in 5 business days.

Article 26 CFDA should review validity, standards and integrity of the review process and reach a conclusion within 20 business days after they receive those information, and make the decision 'approve to be registered' or 'not allow to be registered'.

Article 27 The time required to conduct on-site inspection, retest and the second review should not be calculated into the time limit of review and issue decision of registration.

Article 28 The accepting institution should issue the letter of 'approve to be registered' or 'not allow to be registered' within 10 business days since CFDA make the final decisions.

Article 29 If the applicant disagrees with the final decision of 'not allow to be registered', they can request a second review from CFDA or initiate an administrative lawsuit to the court.

Article 30 Regarding transfer technology of health food registration, the person or corporation that wants to get the registration should submit a new product registration application, in which the product technical requirements have to conform to the original application materials.

The review board should simplify the review process base on related regulation. CFDA should issue the new registration certificate and withdraw the old one if the application is qualified.
Expect all the application materials, the applicant also has to submit a verified agreement.

Article 31 If any changes existed in the content of the health food registration certificate and its attachments, the registration owner has to submit a written letter with reasons and basis.
If the owner has been changed, the new owner has to apply for the changes.

Article 32 Health food with approved registration needs renewal after the expiration date. The applicant needs to apply for the renewal 6 months before the expiration date.

When the owner wants to apply for alteration or renewal of the registration, the registered health food raw material is on the list and conform to related technical requirements, it can go through the recording process.

Article 33 Application dossiers for Health Food Alteration include: Application form for health food registration alteration or health food registration renewal; the business license of the applicant and its copies; a copy of health food registration certificate and its attachments and other information depend on each conditions as below:

1) In the event of alteration application for owner's name and address, the applicant should provide some materials to show the name and address.
2) In the event of the application for alteration of product specifications, expiration date, processing technology, additive and technical requirements, the applicant should provide the all items testing report of the products from 3 consecutive lot numbers.
3) In the event of alteration application for increasing health food function dossiers, the applicant must provide the function test report for the increased function article.
4) In the event of application for the name alteration, the applicant must provide the product's generic name to be used after alteration and the search material to testify that the name is different from the drug names whose registration have been approved.
5) In the event of alteration application for product label, instruction book, the applicant should provide samples of the new label and instruction book.

Article 34 Application dossiers for Health Food Renewal should include:

1) Application form for health food registration alteration or health food registration renewal;
2) A copy of the business license of the applicant;
3) A copy of health food registration certificate and its attachments;
4) Records of manufacturing and sales of the health food within the expiration date of the registration letter issued by provincial or above level FDA;
5) Population tasty analysis report, internal audit report of quality management system operation status and test report that show the product conform to technical requirements.

Article 35 Apply for import health food registration alteration or renewal have to submit application base on the Article 33, Article 34 and Article 13.

Article 36 If the reason of alteration is reasonable, which will not affect product safety, health function and quality controllability, it can be approved; otherwise, it can not be approved.

Article 37 If the product safety, health function and quality controllability of the health food which apply the registration renewal conform to the requirements, it can be renewed.

If the product safety, health function and quality controllability of the health food which apply the registration renewal not conform to the requirements; or haven't been manufactured within the expiration date of the registration certificate; or haven't submit the renewal application within the time limit, it can not be renewed.

Article 38 FDA have to make the final decision before the registration expired. If no decisions have been made within the expiration date, it will be recognized as approve to be renewed.

Article 39 A new health food registration certificate will be issued if the alteration or renewal applications be approved, the old one will be withdraw.

Article 40 Any conditions not listed under the alteration or renewal sections will be apply to the health food registration.

Chapter 3 Management of the Registration Certificate

Article 41 Health food registration certificate should include product name, name and address of the registration owner, registration number, issue date and validity date, health function, functional component and its quantity, specification, expiration date, applicable population, not applicable population and warnings.

The health food registration certificate attachments should have produce label, instruction book and product technical requirements.

Technical requirements materials include product name, formulation, manufacturing process, sensory requirements, identification, physical and chemical indicators, microbial indicators, effective ingredients or iconic ingredients and measurement method, weight variation index, raw material quality standard and other contents.

Article 42 The validity period of registration certificate of health food is 5 years. The validity period of alteration registration certificate is the same as the original one.

Article 43 Format of registration number of domestic health food is '国食健字 G+Year (XXXX)+sequence number (XXXX); while format of overseas health food is '国食健字 J+Year (XXXX)+sequence number (XXXX).

Article 44 If the registration certificate of health food is lost or destroyed during the validity period, holder of registration can put forward written application to FDA to explain reason. Generally, there are two situations, one is lost, another is damaged. If original certificate is lost, original lost declaration published on the national public offering newspapers. If original certificate is damaged, the original certificate should be returned.

FDA should reissue certificate in 20 business days after acceptance. And the original approval date should be labeled on the reissued certificate, also 'reissue' is indicated.

Chapter 4 Recording

Article 45 Any domestic or import health food as below can follow recording process:

1) Raw materials of health food are listed on the health food raw materials list.

2) First time imported health food which belong to vitamins, minerals and other nutrients. Other nutrients should be listed on the Health food raw materials list.

Article 46 The recording owner of domestic health food should be health food manufacturer; its registration owner can be the recording owner; the recording owner of import health food should be foreign health food manufacturers.

Article 47 The product formulation, raw materials name and its quantity, function, manufacturing process of the recording product should conform to law, regulation, guidance, forced standard and technical requirements of health food raw materials list.

Article 48 Apply for health food recording, expect the application materials listed in Article 12 4-8, the following materials have to be submitted:

1) Recording application Form and the letter of commitment;
2) The copy of business license of the applicant;
3) Materials about product technical requirements;
4) All items testing report conform to technical requirements which is issued by qualified testing agency.
5) Other materials show product safety and health function.

Article 49 Apply for import health food recording, all the information listed in Article 48 and Article 13 have to be submitted.

Article 50 After receive the application materials of recording, approve it if the application conform to the regulation, otherwise, inform the applicant any supplementary information have to be provided at a time.

Article 51 FDA should finish archive the recording information and issue the recording number. Regarding health food already in the recording system, FDA should create recording voucher in accordance with the required format and release the information of the recording form on its website.

Format of recording number of domestic health food is '食健备 G+Year (XXXX)+Province number (XX)+sequence number (XXXXXX); while format of overseas health food is '食健备 J+Year (XXXX)+00+sequence number (XXXXXX).

Article 52 Any changes happen on-file health food, the owner should submit a statement that explain those changes and its related proof documents, and also submit recording alteration to the original recording department. FDA should update the alteration information and fill the new documents if it does conform to the required format.

Article 53 Health food recording information include product name, the name and address of recording owner, recording number, issue date, product label, instruction book and technical requirements.

Chapter 5 Label and Instruction Book

Article 54 The content of product label and instruction book samples includes product name, raw materials, auxiliary materials, functional components and its quantity, applicable population, not applicable population, health function, dosage, directions, specifications, storage information, expiration date, warning and other information as needed.

Article 55 The label and instruction content cannot be related with disease prevention and treatment, have to claim that "This product cannot be used instead of drugs."

Article 56 Each Health Food has to have 3 names, which are Brand name, General name and Attribute name:

Brand Name has to be either registered or follow the trademark law.

General Name show the main raw material and other characters.

Attribute Name show the dosage form or food category etc.

Article 57 Any information as below cannot be included in health food name:

1) False, exaggerate, absolute words;
2) Express or implicit disease prevention and treatment;
3) Any words related with feudal superstitions;
4) Human body organ or tissue;
5) Any symbol except " ";
6) Other mislead words.

Except brand name and any raw material name contain alphabet or number which conform to national standard in the general name, No person's name, address, pinyin, alphabet or number can be used in health food name.

Article 58 General name cannot include:

1) General name of drugs;
2) Any words describe health function;
3) Misleading raw material abbreviation;
4) Vitamins or minerals of the product formulation;
5) Any other words are forbidden to be used by the law and regulation.

Article 59 General name of recording health food should use formal raw material name.

Article 60 The company is not allowed to use the same formula to register or record health food with different name; is not allowed to use the same name to register or record health food with different formula.

Chapter 6 Supervision Management

Article 61 CFDA should create and publish health food registration application service guide and review rules on time, which will be used by the registration applicant.

Article 62 Any institution and officers responsible for health food review, inspection and test should responsible for review comments, inspection report and test report issued by them.

Any institutions and officers responsible for health food review, inspection and test should conduct those activities base on related law, regulations, guidance, food safety standard and technical guidance; ensure the related works are scientific, objective and fair.

Article 63 Any departments or person who get involve in health food registration and recording management should keep all the information confidential.
The applicant of registration and recording should mark the confidential information in the application materials.

Article 64 FDA should confirm and handle the issue when they receive any reports about health food registration accepting, review, inspection, test and approval.

Article 65 Except any information related with national secrets or trade secrets, FDA should publish Health food registration/recording list and other information within 20 business days since they finish the process.

Article 66 CFDA should revoke food approval certificate when any one of below situations appears:

1) Approve the registration by any administrative officers who abuse their power.
2) Approve registration violate legal process or beyond legal responsibility.
3) Approve registration which submitted by some applicants who are not qualified.
4) Other situations.

FDA should revoke the health food registration certificate if the applicant gains the registration by deception and bribery or other improper means.

Article 67 CFDA should cancel registration when one of below situations appears:

1) During the validity of health food registration, the owner didn't apply for renewal or the

application has been disapproved.

2) Health food registration's owner applies for removal.
3) The registration owner legally terminated the registration.
4) The registration is revoked or the certificate is withdrawn legally.
5) It is confirmed that the registered health food has safety issue.
6) Violation of any law or regulation.

Article 68 CFDA should cancel health food recording when one of below situations appears:

1) Recording application materials are false
2) Safety issues existed in the manufacturing process and product formulation
3) Manufacturing license or registration certificate have been revoked
4) The recording owner request to cancel the recording
5) Other situations

Chapter 7 Legal Liability

Article 69 Any illegal actions of Health food registration and recording should follow the related articles in food safety law.

Article 70 CFDA will not accept or approve registration application and will give a warning if the applicant conceals or provide false materials; the applicant cannot apply for the same health food in the following one year; if it constitutes a crime, criminal responsibilities shall be affixed.

Article 71 CFDA should revoke the certificate and impose a penalty between 10-30 thousand RMB if the applicant gains health food registration certificate by deception and bribery or other improper means. The applicant cannot apply for the registration in the following 3 years; if it constitutes a crime, criminal responsibilities shall be affixed.

Article 72 City or above level FDA should impose a penalty between 10-30 thousand RMB when one

of below situations appears; if it constitutes a crime, criminal responsibilities shall be affixed.

1) Transfer Health food registration certificate without getting permission from FDA;
2) Counterfeit, obliterate, resell, rent or borrow the health food registration certificate

Article 73 Food Safety Law Article 144 will be applied if any departments or officers of FDA approve registration which submitted by some applicants who are not qualified.

Food safety law Article 145 will be applied if any departments or officers of FDA abuse authority, neglect duty.

Chapter 8 Appendix

Article 74 Apply for first time imported health food registration, import health food recording and alteration, Chinese application materials have to be submitted and Foreign language materials can be attached at the end. The Chinese version has to be verified by domestic verification agency to ensure the content conform to the original version; the quality standard (Chinese version) of the product have to conform to China health food quality standard. Any documents issue by foreign agency should be verified by its local verification agency or confirmed its embassy located in China.

Article 75 This regulation goes into effect on July 1st 2016.

Measures for the registration of health food was published on April 30th 2005 (Former national food and drug supervision administration decree No.19) shall be repealed on July 1, 2016.

Original Chinese Version

保健食品注册与备案管理办法

第一章 总 则

第一条 为规范保健食品的注册与备案，根据《中华人民共和国食品安全法》，制定本办法。

第二条 在中华人民共和国境内保健食品的注册与备案及其监督管理适用本办法。

第三条 保健食品注册，是指食品药品监督管理部门根据注册申请人申请，依照法定程序、条件和要求，对申请注册的保健食品的安全性、保健功能和质量可控性等相关申请材料进行系统评价和审评，并决定是否准予其注册的审批过程。

保健食品备案，是指保健食品生产企业依照法定程序、条件和要求，将表明产品安全性、保健功能和质量可控性的材料提交食品药品监督管理部门进行存档、公开、备查的过程。

第四条 保健食品的注册与备案及其监督管理应当遵循科学、公开、公正、便民、高效的原则。

第五条 国家食品药品监督管理总局负责保健食品注册管理，以及首次进口的属于补充维生素、矿物质等营养物质的保健食品备案管理，并指导监督省、自治区、直辖市食品药品监督管理部门承担的保健食品注册与备案相关工作。

省、自治区、直辖市食品药品监督管理部门负责本行政区域内保健食品备案管理，并配合国家食品药品监督管理总局开展保健食品注册现场核查等工作。

市、县级食品药品监督管理部门负责本行政区域内注册和备案保健食品的监督管理，承担上级食品药品监督管理部门委托的其他工作。

第六条 国家食品药品监督管理总局行政受理机构（以下简称受理机构）负责受理保健食品注册和接收

相关进口保健食品备案材料。

省、自治区、直辖市食品药品监督管理部门负责接收相关保健食品备案材料。

国家食品药品监督管理总局保健食品审评机构（以下简称审评机构）负责组织保健食品审评，管理审评专家，并依法承担相关保健食品备案工作。

国家食品药品监督管理总局审核查验机构（以下简称查验机构）负责保健食品注册现场核查工作。

第七条 保健食品注册申请人或者备案人应当具有相应的专业知识，熟悉保健食品注册管理的法律、法规、规章和技术要求。

保健食品注册申请人或者备案人应当对所提交材料的真实性、完整性、可溯源性负责，并对提交材料的真实性承担法律责任。

保健食品注册申请人或者备案人应当协助食品药品监督管理部门开展与注册或者备案相关的现场核查、样品抽样、复核检验和监督管理等工作。

第八条 省级以上食品药品监督管理部门应当加强信息化建设，提高保健食品注册与备案管理信息化水平，逐步实现电子化注册与备案。

第二章 注 册

第九条 生产和进口下列产品应当申请保健食品注册：

（一）使用保健食品原料目录以外原料（以下简称目录外原料）的保健食品；

（二）首次进口的保健食品（属于补充维生素、矿物质等营养物质的保健食品除外）。

首次进口的保健食品，是指非同一国家、同一企业、同一配方申请中国境内上市销售的保健食品。

第十条 产品声称的保健功能应当已经列入保健食品功能目录。

第十一条 国产保健食品注册申请人应当是在中国境内登记的法人或者其他组织；进口保健食品注册申请人应当是上市保健食品的境外生产厂商。

申请进口保健食品注册的，应当由其常驻中国代表机构或者由其委托中国境内的代理机构办理。

境外生产厂商，是指产品符合所在国（地区）上市要求的法人或者其他组织。

第十二条 申请保健食品注册应当提交下列材料：

（一）保健食品注册申请表，以及申请人对申请材料真实性负责的法律责任承诺书；

（二）注册申请人主体登记证明文件复印件；

（三）产品研发报告，包括研发人、研发时间、研制过程、中试规模以上的验证数据，目录外原料及产品安全性、保健功能、质量可控性的论证报告和相关科学依据，以及根据研发结果综合确定的产品技术要求等；

（四）产品配方材料，包括原料和辅料的名称及用量、生产工艺、质量标准，必要时还应当按照规定提供原料使用依据、使用部位的说明、检验合格证明、品种鉴定报告等；

（五）产品生产工艺材料，包括生产工艺流程简图及说明，关键工艺控制点及说明；

（六）安全性和保健功能评价材料，包括目录外原料及产品的安全性、保健功能试验评价材料，人群食用评价材料；功效成分或者标志性成分、卫生学、稳定性、菌种鉴定、菌种毒力等试验报告，以及涉及兴奋剂、违禁药物成分等检测报告；

（七）直接接触保健食品的包装材料种类、名称、相关标准等；

（八）产品标签、说明书样稿；产品名称中的通用名与注册的药品名称不重名的检索材料；

（九）3 个最小销售包装样品；

（十）其他与产品注册审评相关的材料。

第十三条 申请首次进口保健食品注册，除提交本办法第十二条规定的材料外，还应当提交下列材料：

（一）产品生产国（地区）政府主管部门或者法律服务机构出具的注册申请人为上市保健食品境外生产厂商的资质证明文件；

（二）产品生产国（地区）政府主管部门或者法律服务机构出具的保健食品上市销售一年以上的证明文件，或者产品境外销售以及人群食用情况的安全性报告；

（三）产品生产国（地区）或者国际组织与保健食品相关的技术法规或者标准；

（四）产品在生产国（地区）上市的包装、标签、说明书实样。

由境外注册申请人常驻中国代表机构办理注册事务的，应当提交《外国企业常驻中国代表机构登记证》及其复印件；境外注册申请人委托境内的代理机构办理注册事项的，应当提交经过公证的委托书原件以及受委托的代理机构营业执照复印件。

第十四条 受理机构收到申请材料后，应当根据下列情况分别作出处理：

（一）申请事项依法不需要取得注册的，应当即时告知注册申请人不受理；

（二）申请事项依法不属于国家食品药品监督管理总局职权范围的，应当即时作出不予受理的决定，并告知注册申请人向有关行政机关申请；

（三）申请材料存在可以当场更正的错误的，应当允许注册申请人当场更正；

（四）申请材料不齐全或者不符合法定形式的，应当当场或者在 5 个工作日内一次告知注册申请人需要补正的全部内容，逾期不告知的，自收到申请材料之日起即为受理；

（五）申请事项属于国家食品药品监督管理总局职权范围，申请材料齐全、符合法定形式，注册申请人按照要求提交全部补正申请材料的，应当受理注册申请。

受理或者不予受理注册申请，应当出具加盖国家食品药品监督管理总局行政许可受理专用章和注明日期的书面凭证。

第十五条 受理机构应当在受理后 3 个工作日内将申请材料一并送交审评机构。

第十六条 审评机构应当组织审评专家对申请材料进行审查，并根据实际需要组织查验机构开展现场核查，组织检验机构开展复核检验，在 60 个工作日内完成审评工作，并向国家食品药品监管管理总局提交综合审评结论和建议。

特殊情况下需要延长审评时间的，经审评机构负责人同意，可以延长 20 个工作日，延长决定应当及时书面告知申请人。

第十七条 审评机构应当组织对申请材料中的下列内容进行审评，并根据科学依据的充足程度明确产品保健功能声称的限定用语：

（一）产品研发报告的完整性、合理性和科学性；

（二）产品配方的科学性，及产品安全性和保健功能；

（三）目录外原料及产品的生产工艺合理性、可行性和质量可控性；

（四）产品技术要求和检验方法的科学性和复现性；

（五）标签、说明书样稿主要内容以及产品名称的规范性。

第十八条 审评机构在审评过程中可以调阅原始资料。

审评机构认为申请材料不真实、产品存在安全性或者质量可控性问题，或者不具备声称的保健功能的，应当终止审评，提出不予注册的建议。

第十九条 审评机构认为需要注册申请人补正材料的，应当一次告知需要补正的全部内容。注册申请人应当在 3 个月内按照补正通知的要求一次提供补充材料；审评机构收到补充材料后，审评时间重新计算。

注册申请人逾期未提交补充材料或者未完成补正，不足以证明产品安全性、保健功能和质量可控性的，审评机构应当终止审评，提出不予注册的建议。

第二十条 审评机构认为需要开展现场核查的，应当及时通知查验机构按照申请材料中的产品研发报告、配方、生产工艺等技术要求进行现场核查，并对下线产品封样送复核检验机构检验。

查验机构应当自接到通知之日起 30 个工作日内完成现场核查，并将核查报告送交审评机构。

核查报告认为申请材料不真实、无法溯源复现或者存在重大缺陷的，审评机构应当终止审评，提出不予注册的建议。

第二十一条 复核检验机构应当严格按照申请材料中的测定方法以及相关说明进行操作，对测定方法的科学性、复现性、适用性进行验证，对产品质量可控性进行复核检验，并应当自接受委托之日起 60 个工作日内完成复核检验，将复核检验报告送交审评机构。

复核检验结论认为测定方法不科学、无法复现、不适用或者产品质量不可控的，审评机构应当终止审评，提出不予注册的建议。

第二十二条 首次进口的保健食品境外现场核查和复核检验时限，根据境外生产厂商的实际情况确定。

第二十三条 保健食品审评涉及的试验和检验工作应当由国家食品药品监督管理总局选择的符合条件的食品检验机构承担。

第二十四条 审评机构认为申请材料真实，产品科学、安全、具有声称的保健功能，生产工艺合理、可行和质量可控，技术要求和检验方法科学、合理的，应当提出予以注册的建议。

审评机构提出不予注册建议的，应当同时向注册申请人发出拟不予注册的书面通知。注册申请人对通知有异议的，应当自收到通知之日起 20 个工作日内向审评机构提出书面复审申请并说明复审理由。复审的内容仅限于原申请事项及申请材料。

审评机构应当自受理复审申请之日起 30 个工作日内作出复审决定。改变不予注册建议的，应当书面通知注册申请人。

第二十五条 审评机构作出综合审评结论及建议后，应当在 5 个工作日内报送国家食品药品监督管理总局。

第二十六条 国家食品药品监督管理总局应当自受理之日起 20 个工作日内对审评程序和结论的合法性、规范性以及完整性进行审查，并作出准予注册或者不予注册的决定。

第二十七条 现场核查、复核检验、复审所需时间不计算在审评和注册决定的期限内。

第二十八条 国家食品药品监督管理总局作出准予注册或者不予注册的决定后，应当自作出决定之日起10个工作日内，由受理机构向注册申请人发出保健食品注册证书或者不予注册决定。

第二十九条 注册申请人对国家食品药品监督管理总局作出不予注册的决定有异议的，可以向国家食品药品监督管理总局提出书面行政复议申请或者向法院提出行政诉讼。

第三十条 保健食品注册人转让技术的，受让方应当在转让方的指导下重新提出产品注册申请，产品技术要求等应当与原申请材料一致。

审评机构按照相关规定简化审评程序。符合要求的，国家食品药品监督管理总局应当为受让方核发新的保健食品注册证书，并对转让方保健食品注册予以注销。

受让方除提交本办法规定的注册申请材料外，还应当提交经公证的转让合同。

第三十一条 保健食品注册证书及其附件所载明内容变更的，应当由保健食品注册人申请变更并提交书面变更的理由和依据。

注册人名称变更的，应当由变更后的注册申请人申请变更。

第三十二条 已经生产销售的保健食品注册证书有效期届满需要延续的，保健食品注册人应当在有效期届满6个月前申请延续。

获得注册的保健食品原料已经列入保健食品原料目录，并符合相关技术要求，保健食品注册人申请变更注册，或者期满申请延续注册的，应当按照备案程序办理。

第三十三条 申请变更国产保健食品注册的，除提交保健食品注册变更申请表（包括申请人对申请材料真实性负责的法律责任承诺书）、注册申请人主体登记证明文件复印件、保健食品注册证书及其附件的复印件外，还应当按照下列情形分别提交材料：

（一）改变注册人名称、地址的变更申请，还应当提供该注册人名称、地址变更的证明材料；

（二）改变产品名称的变更申请，还应当提供拟变更后的产品通用名与已经注册的药品名称不重名的检索材料；

（三）增加保健食品功能项目的变更申请，还应当提供所增加功能项目的功能学试验报告；

（四）改变产品规格、保质期、生产工艺等涉及产品技术要求的变更申请，还应当提供证明变更后产品的安全性、保健功能和质量可控性与原注册内容实质等同的材料、依据及变更后3批样品符合产品技术要求的全项目检验报告；

（五）改变产品标签、说明书的变更申请，还应当提供拟变更的保健食品标签、说明书样稿。

第三十四条 申请延续国产保健食品注册的，应当提交下列材料：

（一）保健食品延续注册申请表，以及申请人对申请材料真实性负责的法律责任承诺书；

（二）注册申请人主体登记证明文件复印件；

（三）保健食品注册证书及其附件的复印件；

（四）经省级食品药品监督管理部门核实的注册证书有效期内保健食品的生产销售情况；

（五）人群食用情况分析报告、生产质量管理体系运行情况的自查报告以及符合产品技术要求的检验报告。

第三十五条 申请进口保健食品变更注册或者延续注册的，除分别提交本办法第三十三条、第三十四条规定的材料外，还应当提交本办法第十三条第一款（一）、（二）、（三）、（四）项和第二款规定的相关材料。

第三十六条 变更申请的理由依据充分合理，不影响产品安全性、保健功能和质量可控性的，予以变更注册；变更申请的理由依据不充分、不合理，或者拟变更事项影响产品安全性、保健功能和质量可控性的，不予变更注册。

第三十七条 申请延续注册的保健食品的安全性、保健功能和质量可控性符合要求的，予以延续注册。

申请延续注册的保健食品的安全性、保健功能和质量可控性依据不足或者不再符合要求，在注册证书有效期内未进行生产销售的，以及注册人未在规定时限内提交延续申请的，不予延续注册。

第三十八条 接到保健食品延续注册申请的食品药品监督管理部门应当在保健食品注册证书有效期届满前作出是否准予延续的决定。逾期未作出决定的，视为准予延续注册。

第三十九条 准予变更注册或者延续注册的，颁发新的保健食品注册证书，同时注销原保健食品注册证书。

第四十条 保健食品变更注册与延续注册的程序未作规定的，可以适用本办法关于保健食品注册的相关规定。

第三章 注册证书管理

第四十一条 保健食品注册证书应当载明产品名称、注册人名称和地址、注册号、颁发日期及有效期、保健功能、功效成分或者标志性成分及含量、产品规格、保质期、适宜人群、不适宜人群、注意事项。

保健食品注册证书附件应当载明产品标签、说明书主要内容和产品技术要求等。

产品技术要求应当包括产品名称、配方、生产工艺、感官要求、鉴别、理化指标、微生物指标、功效成分或者标志性成分含量及检测方法、装量或者重量差异指标（净含量及允许负偏差指标）、原辅料质量要求等内容。

第四十二条 保健食品注册证书有效期为 5 年。变更注册的保健食品注册证书有效期与原保健食品注册证书有效期相同。

第四十三条 国产保健食品注册号格式为：国食健注 G+4 位年代号+4 位顺序号；进口保健食品注册号格式为：国食健注 J+4 位年代号+4 位顺序号。

第四十四条 保健食品注册有效期内，保健食品注册证书遗失或者损坏的，保健食品注册人应当向受理机构提出书面申请并说明理由。因遗失申请补发的，应当在省、自治区、直辖市食品药品监督管理部门网站上发布遗失声明；因损坏申请补发的，应当交回保健食品注册证书原件。

国家食品药品监督管理总局应当在受理后 20 个工作日内予以补发。补发的保健食品注册证书应当标注原批准日期，并注明“补发”字样。

第四章 备 案

第四十五条 生产和进口下列保健食品应当依法备案：

（一）使用的原料已经列入保健食品原料目录的保健食品；

（二）首次进口的属于补充维生素、矿物质等营养物质的保健食品。

首次进口的属于补充维生素、矿物质等营养物质的保健食品，其营养物质应当是列入保健食品原料目录的物质。

第四十六条 国产保健食品的备案人应当是保健食品生产企业，原注册人可以作为备案人；进口保健食品的备案人，应当是上市保健食品境外生产厂商。

第四十七条 备案的产品配方、原辅料名称及用量、功效、生产工艺等应当符合法律、法规、规章、强制性标准以及保健食品原料目录技术要求的规定。

第四十八条 申请保健食品备案，除应当提交本办法第十二条第（四）、（五）、（六）、（七）、（八）项规定的材料外，还应当提交下列材料：

（一）保健食品备案登记表，以及备案人对提交材料真实性负责的法律责任承诺书；

（二）备案人主体登记证明文件复印件；

（三）产品技术要求材料；

（四）具有合法资质的检验机构出具的符合产品技术要求全项目检验报告；

（五）其他表明产品安全性和保健功能的材料。

第四十九条 申请进口保健食品备案的，除提交本办法第四十八条规定的材料外，还应当提交本办法第十三条第一款（一）、（二）、（三）、（四）项和第二款规定的相关材料。

第五十条 食品药品监督管理部门收到备案材料后，备案材料符合要求的，当场备案；不符合要求的，应当一次告知备案人补正相关材料。

第五十一条 食品药品监督管理部门应当完成备案信息的存档备查工作，并发放备案号。对备案的保健食品，食品药品监督管理部门应当按照相关要求的格式制作备案凭证，并将备案信息表中登载的信息在其网站上公布。

国产保健食品备案号格式为：食健备 G+4 位年代号+2 位省级行政区域代码+6 位顺序编号；进口保健食品备案号格式为：食健备 J+4 位年代号+00+6 位顺序编号。

第五十二条 已经备案的保健食品，需要变更备案材料的，备案人应当向原备案机关提交变更说明及相关证明文件。备案材料符合要求的，食品药品监督管理部门应当将变更情况登载于变更信息中，将备案材料存档备查。

第五十三条 保健食品备案信息应当包括产品名称、备案人名称和地址、备案登记号、登记日期以及产品标签、说明书和技术要求。

第五章 标签、说明书

第五十四条 申请保健食品注册或者备案的，产品标签、说明书样稿应当包括产品名称、原料、辅料、功效成分或者标志性成分及含量、适宜人群、不适宜人群、保健功能、食用量及食用方法、规格、贮藏方法、保质期、注意事项等内容及相关制定依据和说明等。

第五十五条 保健食品的标签、说明书主要内容不得涉及疾病预防、治疗功能，并声明“本品不能代替药物”。

第五十六条 保健食品的名称由商标名、通用名和属性名组成。

商标名，是指保健食品使用依法注册的商标名称或者符合《商标法》规定的未注册的商标名称，用以表明其产品是独有的、区别于其他同类产品。

通用名，是指表明产品主要原料等特性的名称。

属性名，是指表明产品剂型或者食品分类属性等的名称。

第五十七条 保健食品名称不得含有下列内容：

（一）虚假、夸大或者绝对化的词语；

（二）明示或者暗示预防、治疗功能的词语；

（三）庸俗或者带有封建迷信色彩的词语；

（四）人体组织器官等词语；

（五）除“”之外的符号；

（六）其他误导消费者的词语。

保健食品名称不得含有人名、地名、汉语拼音、字母及数字等，但注册商标作为商标名、通用名中含有符合国家规定的含字母及数字的原料名除外。

第五十八条 通用名不得含有下列内容：

（一）已经注册的药品通用名，但以原料名称命名或者保健食品注册批准在先的除外；

（二）保健功能名称或者与表述产品保健功能相关的文字；

（三）易产生误导的原料简写名称；

（四）营养素补充剂产品配方中部分维生素或者矿物质；

（五）法律法规规定禁止使用的其他词语。

第五十九条 备案保健食品通用名应当以规范的原料名称命名。

第六十条 同一企业不得使用同一配方注册或者备案不同名称的保健食品；不得使用同一名称注册或者备案不同配方的保健食品。

第六章 监督管理

第六十一条 国家食品药品监督管理总局应当及时制定并公布保健食品注册申请服务指南和审查细则，方便注册申请人申报。

第六十二条 承担保健食品审评、核查、检验的机构和人员应当对出具的审评意见、核查报告、检验报告负责。

保健食品审评、核查、检验机构和人员应当依照有关法律、法规、规章的规定，恪守职业道德，按照食品安全标准、技术规范等对保健食品进行审评、核查和检验，保证相关工作科学、客观和公正。

第六十三条 参与保健食品注册与备案管理工作的单位和个人，应当保守在注册或者备案中获知的商业秘密。

属于商业秘密的，注册申请人和备案人在申请注册或者备案时应当在提交的资料中明确相关内容和依据。

第六十四条 食品药品监督管理部门接到有关单位或者个人举报的保健食品注册受理、审评、核查、检验、审批等工作中的违法违规行为后，应当及时核实处理。

第六十五条 除涉及国家秘密、商业秘密外，食品药品监督管理部门应当自完成注册或者备案工作之日起 20 个工作日内根据相关职责在网站公布已经注册或者备案的保健食品目录及相关信息。

第六十六条 有下列情形之一的，国家食品药品监督管理总局根据利害关系人的请求或者依据职权，可以撤销保健食品注册证书：

（一）行政机关工作人员滥用职权、玩忽职守作出准予注册决定的；

（二）超越法定职权或者违反法定程序作出准予注册决定的；

（三）对不具备申请资格或者不符合法定条件的注册申请人准予注册的；

（四）依法可以撤销保健食品注册证书的其他情形。

注册人以欺骗、贿赂等不正当手段取得保健食品注册的，国家食品药品监督管理总局应当予以撤销。

第六十七条 有下列情形之一的，国家食品药品监督管理总局应当依法办理保健食品注册注销手续：

（一）保健食品注册有效期届满，注册人未申请延续或者国家食品药品监管总局不予延续的；

（二）保健食品注册人申请注销的；

（三）保健食品注册人依法终止的；

（四）保健食品注册依法被撤销，或者保健食品注册证书依法被吊销的；

（五）根据科学研究的发展，有证据表明保健食品可能存在安全隐患，依法被撤回的；

（六）法律、法规规定的应当注销保健食品注册的其他情形。

第六十八条 有下列情形之一的，食品药品监督管理部门取消保健食品备案：

（一）备案材料虚假的；

（二）备案产品生产工艺、产品配方等存在安全性问题的；

（三）保健食品生产企业的生产许可被依法吊销、注销的；

（四）备案人申请取消备案的；

（五）依法应当取消备案的其他情形。

第七章 法律责任

第六十九条 保健食品注册与备案违法行为，食品安全法等法律法规已有规定的，依照其规定。

第七十条 注册申请人隐瞒真实情况或者提供虚假材料申请注册的，国家食品药品监督管理总局不予受理或者不予注册，并给予警告；申请人在 1 年内不得再次申请注册该保健食品；构成犯罪的，依法追究刑事责任。

第七十一条 注册申请人以欺骗、贿赂等不正当手段取得保健食品注册证书的，由国家食品药品监督管理总局撤销保健食品注册证书，并处 1 万元以上 3 万元以下罚款。被许可人在 3 年内不得再次申请注册；构成犯罪的，依法追究刑事责任。

第七十二条 有下列情形之一的，由县级以上人民政府食品药品监督管理部门处以 1 万元以上 3 万元以下罚款；构成犯罪的，依法追究刑事责任。

（一）擅自转让保健食品注册证书的；

（二）伪造、涂改、倒卖、出租、出借保健食品注册证书的。

第七十三条 食品药品监督管理部门及其工作人员对不符合条件的申请人准予注册，或者超越法定职权准予注册的，依照食品安全法第一百四十四条的规定予以处理。

食品药品监督管理部门及其工作人员在注册审评过程中滥用职权、玩忽职守、徇私舞弊的，依照食品

安全法第一百四十五条的规定予以处理。

第八章 附 则

第七十四条 申请首次进口保健食品注册和办理进口保健食品备案及其变更的，应当提交中文材料，外文材料附后。中文译本应当由境内公证机构进行公证，确保与原文内容一致；申请注册的产品质量标准（中文本），必须符合中国保健食品质量标准的格式。境外机构出具的证明文件应当经生产国（地区）的公证机构公证和中国驻所在国使领馆确认。

第七十五条 本办法自 2016 年 7 月 1 日起施行。2005 年 4 月 30 日公布的《保健食品注册管理办法（试行）》（原国家食品药品监督管理局令第 19 号）同时废止。