U.S. – China HPA Health Products Association 美中健康产品协会

Regulatory Insights

Date Released
July 28, 2015

Government Agency
China Food and Drug Administration

Date Translated
August 8, 2015

Measures for the Registration and Filing of Health Food (Draft)

保健食品注册与备案管理办法
（征求意见稿）

Measures for the Registration and Filling of Health Food (Draft)

Chapter 1. General Provisions

Article 1 [Purpose and basis] According to "Food Safety Law of the People's Republic of China" and "Administrative licensing law of the people's Republic of China", this measure is developed to regulate the registration and filing of health food.

Article 2 [Scope of application] The registration and filing of health food that are manufactured and sold in the territory of the People's Republic of China apply to this measure.

The registration of health food refers to the review process of CFDA conduct systematical evaluation and review, according to the application of the applicant, to the application materials of health food products intended to be registered and make an decision (Approve or Disapprove) in accordance with the legal procedures, conditions and requirements.

The filing of health food refers to the process of the health food manufactures submit the application materials of manufacturing and sales to CFDA for registration, archiving, open to the public and references in accordance with the legal procedures, conditions and requirements.

Article 3 [Duties of head office] The China Food and Drug Administration (CFDA) is responsible for the regulation of registration and filing of the health food nationwide. Main Responsibilities:

1) Develop administrative measures for related work of the registration and filing of health food.

2) Develop technical review rules for the registration of health food;

3) Management of health food registration and inspection agency, and technical review agency;

4) To be responsible for the registration of health food;

5) To be responsible for the filing of first time imported health food such as vitamins, minerals and other nutrients;

6) Organize the supervision and administration for the registration and filing of health food.

Article 4 [Duties of provincial bureau] Provincial, autonomous regions or municipalities level Food and Drug Administration is responsible for the regulation of registration and filing of the health food within the administrative region. Main responsibilities:

1) Undertake the filing of health food within the administrative region.

2) Conduct verification and sampling work for the trial manufacture field of domestic health food within the administrative region;

3) To be responsible for the regulation of registration and filing of the health food within the administrative region;

4) Undertake other works such as registration renewal and change registration entrusted by CFDA.

Article 5 [Duties of bureau at the grass-roots level] City or Town Food and Drug Administration is responsible for the regulation of registration and filing of the health food within the administrative region. Main responsibilities:

1) Undertake the regulation of registration and filing of the health food within the administrative region;

2) Undertake other works entrusted by the higher food and drug administration.

Article 6 [Duties of technical review institutions] The technical review institution for the registration of health food of CFDA is responsible for the technical review of health food and some other works applied for registration. Main responsibilities:

1) Create the technical review procedure for health food registration.

2) Organize and conduct technical review includes research report, formulation, production process, safety, health functions, labels, brochures, etc. of the product, and then give synthetic technical review suggestion and conclusion;

3) Undertake the management of technical review experts and technical workers, the evaluation of technical review suggestion, the regulation, direction and supervision of the technical review experts and technical workers' performances;

4) Conduct on-site verification, sampling, facility inspection and other related issues;

5) Undertake other technical works related to technical review and filing of health food.

Article 7 [Duties of experts] Technical review experts and technical workers needs to in accordance with the related national regulations, follow the principle of prevent the conflict of interest, and responsible for the review suggestion.

Article 8 [Duties of applicants and filers] Applicants or filers are responsible for the application of registration, safety and health function and quality of health foods that have been filed; undertake the corresponding legal responsibility. Main responsibilities:

1) Create quality management system related with research and manufacture, and maintain effective operation;

2) Ensure the manufacture proof process in accordance with related regulations, as well as the reality, integrity and traceability of the data;

3) Staffs who handle the health food registration or filing must have relevant professional knowledge, and familiar with health food registration or filing law, regulation, guidance and technical requirements;

4) Submit complete application materials according to the submission requirements; ensure the sufficiency and reliability of the research data and scientific evidence. The application material can support the safety, health functions and quality control of the product. Applicants or filers are responsible for the reality the application material;

5) Assist with conduct on-site verification, sampling, facility inspection and supervision related with registration or filing in accordance with the requirements.

Article 9 [Duties of inspection institutions] Inspection institutions selected by CFDA are responsible for the required formula inspection of health food technical review evaluation and in accordance with the principle of prevents conflict of interest. Inspection institution and staff are responsible for the facility inspection report and conclusion.

Article 10 [Public notice the table of content of the application materials and typical format] CFDA needs to show affairs, basis, conditions, procedures, deadlines related with health food registrations and filling to

the public on the government website or office, as well as the table of content of application materials and typical format.

Article 11 [Followed principle] The registration and filing of health food should follow the scientific, fair, open, efficient and convenient principle. CFDA should open the evidences and results of the health food registration and filling to the public.

Article 12 [Duties of confidentiality] Food and drug administration, technical review institutions, inspection institutions and other departments and individuals involved in the registration and filing of health food shall be obliged to keep confidential any trade secret provided during application and filing period.

Article 13 [Supervision of society] Any companies and individuals have the right to make a report to CFDA regarding illegal actions during health food research, registration and inspection, accept and hear cases, technical review, administrative review and so on.

Chapter 2 Registration of health food

Sub-Chapter 1 Application requirements for the registration

Article 14 [Scope of registration] Scope of registration of health food includes:

1) Health food that is manufactured using raw materials that are not listed in the health food raw material catalog need to be registered;

2) First time imported health food.

Article 15 [applicant qualifications] For the first time registration of healthy food, the applicant shall meet the following conditions:

1) When applying for registration of domestic health food, entities should be legal person or other corporations registered in China; when applying for registration of imported health food, entities should be lawful brand owner of the product;

2) When two or more entities jointly develop a health food only one entity can apply for registration.

Article 16 [registration application materials requirements] For first time registration of health food entities shall submit the following materials:

1) Application form of health food registration;

2) The original effective legal registration certification of applicant and the copy;

3) Documentation verifying the generic name of the health food to be registered is not the same as an already approved registered drug;

4) R & D materials include: development time, research and development process, research basis, research data, and information of researchers. The legal responsibility commitment that applicant can't constitute an infringement of R & D activities and reporting information;

5) Product formulation materials include: formulation and dosage based on compatibility, legal source, use basis, certificates of inspection of raw materials and auxiliary materials, and appraisal report of raw materials;

6) Product materials mainly include: diagram and description of production process, instructions of key process control points. The types, name, quality standards and selection basis of packaging materials in direct contact with persons;

7) Product safety and health function evaluation documents include: safety and health function test evaluation documents, population consumption evaluation document, effective ingredients test report, hygiene test report, stability test report, virulent bacteria test report and other test reports for stimulants and illicit drugs; The test methods of product safety and health function compound inspection (Indicate sample treatment procedure and testing circle), detailed description and other related research documentation of production process;

8) Technical requirement documents include sensory requirements, identification, physical and chemical indicators, microbial indicators, effective ingredients and measurement method (Indicate sample treatment procedure and testing circle), technological process of production, key control points, raw material standard and source, detail description and other related research documents of production process;

9) Product labels and package inserts, which includes the following information: raw materials, functional ingredients or effective ingredients, suitable and non-suitable groups, health function claim, consumption method, specifications, storage method, shelf life, and precaution including its related explanation and determination basis;

10) A comprehensive report of products' safety, health function and quality controllability and its related scientific basis;

11) Three unopened packages of the product's smallest size within the warranty period;

12) Other documents helpful to review products

Article 17 [first registration material requirements of imported products] For the first time imported healthy food registration; applicants shall submit the required documents by the Article 16 (besides No.2) and the following supplementary material:

1) The certification and its expiration date granted by relevant government of the manufacturing country (region) that recognize that the applicant is the legal holder of marketed product;

2) The certification document and its expiration date granted by the relevant agency of the manufacturing country (region) that show that the manufacturer qualify for the local Good Manufacturing Practice;

3) Foreign manufacturers which are represented by permanent representative office in China for registration should provide the copy of Registration Certificate for Permanent Chinese Representative Agency of Foreign Companies;

4) The documents of the products which have been produced and sold at least one year in the manufacturing country (region) should be issued by the relevant government of the manufacturing country (region);

5) Summary of product sales in countries other than production country and consumer feedback analysis;

6) The related product standards in manufacturing country or international organizations;

7) Package, label and samples that are intended to be used for marketing in manufacturing country;

8) Three samples each from three consecutive batches

All application materials must be written in Chinese and attach with the original application package, foreign language materials can be attached at the end for references. Domestic certification institution must certify the Chinese version, which ensures the consistency of the translation. The certification documents issued by foreign institutions shall be confirmed with the production country (region) notary public and the Chinese Embassy. The quality standard (Chinese version) of the product must be qualified for the format of China Health Food Quality Standard.

Sub-Chapter 2 Alteration and Renewal of Registration and Approval

Article 18 [Application scope of Alteration] The application scope of registration alteration includes:

1) Change the content of the health food license and its appendix.

2) Change domestic agency, the name and address of the health food license holder.
3) Change the health food license holder.

Article 19 [Qualifications of applicant] The applicant of health food registration alteration and renewal should be the holder of the health food license.

The Applicant of change health food license holder should be the license holder after merger by absorption or merger by new establishment, or the license holder before establish a wholly owned subsidiary, or possessor and assignee of proposed transfer of health food registration.

Transfer of Imported health foods or domestic health foods within China, the assignee should be registered legal person or other organization within China. Transfer of imported health foods out of China, the assignee should be the health food manufacturer compliance with the requirements of local Good Manufacturing Practice.

Article 20 [Registration Renewal] Health food with approved registration needs renewal after the expiration date. The applicant needs to apply for the renewal three months before the expiration date.

Article 21 [Application dossiers for Health Food Alteration and Renewal] For the registration alteration and renewal of domestic health food, applicants shall submit the following materials:

1) Application form for health food registration alteration or health food registration renewal;

2) The original document of effective legal registration certification and its copies;

3) The copies of approval document of health food and its appendixes;

4) The name, reason and foundation of the special Article alteration, also the analysis report compared with original application dossier to testify that the alteration affect the safety and health function and relevant research data and test reports;

5) The draft of the health food license and its appendix content for revision with detailed revision statement enclosed;

6) For dosage alteration, the applicant must provide test report granted by the designated inspection institution that conducts functions assessment test according to the planned dosage. Also the applicant for dosage increase should provide the test report granted by the designated inspection institution which conducts toxicology safety test according to the planned dosage increase, as well as the function assessment report according to the comparison between the planned dosage alteration and the original dosage;

7) 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 three consecutive batch numbers;

8) 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;

9) 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. A letter of commitment states that there was no illegal issues happen to the marketed product within two years needs to be provided;

10) In the event of registration renewal application for health food, the applicant must provide records of manufacture and distribution, population consumption analysis report, internal audit report of quality management system operation status, the whole project inspection report for proposed registration renewal issue by health food inspection institution;

11) In the event of change license holder, the applicant must submit the following materials:

1. Technology transfer: the effective legal registration certification of holder and assignee, certified agreement of transfer with both holder and assignee's signature, product approval certification and its copies.

2. Merger by absorption or merger by new establishment: copies of business license before and after merger; merger and register cancel certification issued by the local industrial and commercial administrative department; consent statement and its certification of the ownership of product approval certificate.

3. Establish a wholly owned subsidiary: copies of business license of the applicant and its wholly owned subsidiary; certification of establish a wholly owned subsidiary issued by the local industrial and commercial administrative department; the resolution and approval documents state that all manufacturing rooms, facilities, staffs and product approval letter belong to the broad of directors or other department of the wholly owned subsidiary; a letter of commitment states that there is no change of manufacturing room, facilities, technology, quality standard, staffs and other conditions related with quality and safety during the transfer; copies of product approval certification and its attachments.

Article 22 [Application dossiers for imported health food alteration and renewal] In the event of application for imported health food alternation and renewal, besides the mentioned materials in Article 21 No. 2, applicants should submit the following supplementary material:

1) The certification and its expiration date granted by relevant government of the manufacturing country (region) that recognize that the applicant is the legal holder of marketed product;

2) The certification document and its expiration date granted by the relevant agency of the manufacturing country (region) that show that the manufacturer qualify for the local Good Manufacturing Practice;

3) The certification and other related documents granted by the relevant agency of the manufacturing country (region) that allow to sell products and other related issues has been changed;

4) In the event of the alteration application of foreign manufacturer conducted by its permanent representative office in China, the applicant must provide the copy of the registration certificate for foreign company's permanent representative office in China. In the event of the alteration for foreign manufacturer entrusting the agency in China, the applicant must provide the notarized original letter of trust and the copy of the business license of the trusted agency;

5) The health food registration approval certificate and the certifications that state the name and address of the holder has been changed granted by the relevant agency of the manufacturing country (region);

6) Overseas transfer agreement that certified by assignee's country (region);

7) Analysis report of overseas sales and population tasty;

8) Package, label and manual samples are intended to be used for marketing in manufacturing country;

9) For compound inspection, the quantity of three continued batches of marked product or samples required special handling need to be tripled.

All application materials must be written in Chinese and attach with the original application package, foreign language materials can be attached at the end for references. Domestic certification institution must certify the Chinese version, which ensures the consistency of the translation. The certification documents issued by foreign institutions shall be confirmed with the production country (region) notary public and the Chinese Embassy. The quality standard (Chinese version) of the product must be qualified for the format of China Health Food Quality Standard.

Sub-Chapter 3 Acceptance and Approval

Article 23 [Independent R&D] Before apply for the health food registration, the applicant should have done enough research testing and verifications for the proposed registered health food in order to certify the safety, health function and quality Controllability.

Article 24 [Application submission] Apply for health food registration and imported health food registration alteration and renewal, the applicant should submit the application materials and samples to Health Food registration department of State CFDA (Beijing)

Apply for domestic health food registration alteration and renewal, the applicant should submit the application materials and samples to the Health Food registration department of the provincial, autonomous regions or municipalities level Food and Drug Administration.

Article 25 [Initial Qualification Review] Once the registration department received the application dossiers, the registration department should make formal examination on the completeness and standardization of the application dossier within 5 days:

1) For the application, which include in terms of reference and also passed the formal examination, the registration department should accept the application and issue the notice of acceptance to applicant;

2) If the application articles of the applicant are incomplete and do not conform to the legal formats, the registration department should inform the applicant of the dossiers needed at a time. No notice past the due day, which means accept the application by the day that received the application dossier. The applicant should be permitted to alter mistakes outright in the application dossier submitted if any mistakes in the application dossiers are found outright;

3) For the application, which out of terms of reference and has not passed the formal examination, the registration department should issue the rejection notice and a written statement should be given to applicant for detail reason.

Article 26 [Material transfer] the registration department of CFDA should send the application dossier and reviewing opinion together to health food technical evaluation agency within 5 days.

Article 27 [Technical evaluation] After receiving the application dossier, experts should be organized to evaluate the product safety, health function and quality controllability and give the technical evaluation comments to the applicant in 60 days:

1) Evaluate research and development report regarding scientific soundness, completeness, reasonability and truth;

2) Evaluate and review dispensation and dispensation bases of product regarding to scientific soundness, health function and safety;

3) Evaluate product process controllability, feasibility and reasonability;

4) Evaluate product technical requirements and testing method regarding to practicability and scientific soundness;

5) Evaluate the name, label and instruction of the product regarding to standardization and the representation of product safety and function;

6) Comprehensively evaluate safety and validity of health food, controllability of quality and sufficiency of science foundation and final evaluation comments should be given.

Article 28 [Evaluation contents] Health food technical review institution can review the original research materials during the product technical review period, audit the process according to the application dossier, and inspect the Quality Management System relevant to research and manufacturing. Dynamic sampling test should be done for the required compound inspection.

Article 29 [Management System verification] The domestic quality management system verification need to be conducted by the provincial, autonomous regions or municipalities level Food and Drug Administration after being noticed by CFDA.

Article 30 [On-site verification] The provincial, autonomous regions or municipalities level Food and Drug Administration should finish on-site verification in accordance with the relevant requirements within 30 days. Staff should random sample and send it to the inspection agency that is selected by the technical review institution to do the compound inspection as needed.

Article 31 [Overseas on-site verification] The overseas on-site verification of Quality Management System should be conducted by the technical review institution of CFDA. Staff should random sample and send it to the inspection agency that is selected by the technical review institution to do the compound inspection as needed.

Article 32 [Formula Inspection] The health food inspection institution selected by CFDA is responsible for the formula inspection. The inspection institution should conduct the test in accordance with the test method, sample treatment, test cycle and other relevant instructions of the application materials. The inspection institution should conduct formula inspection for practicability and scientific accuracy of testing method, safety and quality stability and health function of the product, and also give the formula inspection comments.

Article 33 [Technical review time limit] Time needed for on-site inspection and formula inspection, and the delay time if is caused by the applicant issue should not be considered in the time limit.

Article 34 [On-site verification and formula inspection requirement] The reason and contents of on-site verification and formula inspection for the Quality Management System need to be clarified with sufficient evidences in accordance with related rules.

Article 35 [Material Review and On-site verification & Formula inspection] The on-site verification and formula inspection will not be applied if the application materials cannot meet the requirements or qualify

for the technical review; Dynamic Sampling Test and formula inspection will not be applied if the on-site verification of Quality Management System is not qualify.

Article 36 [Evaluation comments] The health food technical evaluation office should review the evaluation comments from experts and submit the final evaluation comments and conclusions to CFDA：

1) Registration application should be approved if the application of the applicant 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; or the reason of changing request is sufficient and reasonable, and won't influence product safety, health function and quality controllable.

2) Registration application should not be approved if the application of the applicant is false, insufficient in scientific basis, safety and health function still remain to be further demonstrated, production process is unfeasible and uncontrollable, product testing method or technical requirements are Non-scientific Non-repeatable; or the reason of changing request is insufficient and unreasonable, and the items planning to be changed will influence product safety, health function and quality controllability.

The testing report issued by certificated inspection lab is required regarding to product inspection method feasibility and product safety, validity and function.

Article 37 [Evaluation decision] CFDA should evaluate comments and conclusions from technical evaluation institution within 10 days. Evaluation decision is given to applicant regarding technical review procedures, validity and completeness and standardization of technical review comments and conclusions.

Return to the health food technical review institution. Make corrections and supplements as needed within the required time to finalize technical review comments and conclusions if it is not qualify.

Article 38 [Certificate Delivery] Food and drug administration should notice applicants in ten days after making decision on registration or not. And FDA should issue < registration certificate of health food> or < notification on no approval of registration> and deliver the above documents to applicant. Regarding registration alteration or renewal approval, FDA should issue a new <registration certificate of health food>, and recall the original certificate.

Article 39 [Application of second evaluation] The applicant should submit written application and explain reasons for the second evaluation within 10 days after receive <notification on disapproval of registration> if disagree with the evaluation decisions.

The contents of the second evaluation only include the original items of application and original application dossier.

Article 40 [Second evaluation decision] FDA should evaluate the original application dossier in accordance with technical review time limit and requirements after receive the second evaluation application, a second evaluation decision needs to be given. FDA should issue health food approval certificate to the applicant if withdraw the disapproval registration decision. No more evaluations applied if still keep the disapproval registration decision.

The applicant could apply for the administrative review to CFDA or submit administrative litigation to the people's court according to related legal provisions.

Article 41 [Validity period of certificate] The validity period of registration certificate of health food are five years and of <registration certificate of health food> on changed information of health food is the same as approval certificate of original health food.

Article 42 [Approval numbers of certificate] Format of approval numbers 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 43 [Reissue of certificate] If the registration certificate of health food is lost 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, and 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 days after acceptance. And the original approval date should be labeled on the reissued certificate; also 'reissue' is indicated.

Chapter 3 Filing of health food

Sub-Chapter 1 Requirements of filing application

Article 44 [Filing scope] Filing scope of health food includes:

1) Raw materials of health food that is in the catalog of health food raw materials;

2) Imported health food for the first time, which belong to supplement of vitamins, minerals and other nutrients;

3) The filing information is changed and applies for refilling.

Article 45 [Qualification of filer] Qualification of filer is as follows:

1) Filer who want to produce domestic health food with raw materials listed in the directory of health food should have qualification to produce health food;

2) Filer who apply for filing imported health food should be the legal brand owner of marketed product.

Article 46 [Filling materials] In the event of application for health food filling, the following materials should be submitted:

1) Registration form of health food filling;

2) Copy of effective qualification certificate of filler;

3) Product formula, manufacturing process, label sample, package insert, quality standard and other documents related to product safety and health function.

Article 47 [Filing materials of imported product] In the event of application for imported health food filling, besides the mentioned materials in Article 46 No. 2, applicants should submit the following supplementary material:

1) The certification and its expiration date granted by relevant government of the manufacturing country (region) that recognize that the applicant is the legal holder of marketed product;

2) The certification document and its expiration date granted by the relevant agency of the manufacturing country (region) that show that the manufacturer qualify for the local Good Manufacturing Practice;

3) In the event of the alteration application of foreign manufacturer conducted by its permanent representative office in China, the applicant must provide the copy of the registration certificate for foreign company's permanent representative office in China;

4) The certificate document granted by the competent department of manufacturing country (region) that demonstrate the product has been on the market at least one year;

5) Summary of product sales in countries other than production country and consumer feedback analysis;

6) The related standard granted by the manufacturing country (region) or international organization;

7) The test report of three consecutive batches which was issued by the health food inspection institution to show that the product quality matches the standard;

8) Package, label and manual samples are intended to be used for marketing in manufacturing country.

All application materials must be written in Chinese and attach with the original application package, foreign language materials can be attached at the end for references. Domestic certification institution must certify the Chinese version, which ensures the consistency of the translation. The certification documents issued by foreign institutions shall be confirmed with the production country (region) notary public and the Chinese Embassy. The quality standard (Chinese version) of the product must be qualified for the format of China Health Food Quality Standard.

Sub-Chapter 2 Filing review

Article 48 [Filing application] Application should be submitted to State CFDA (Beijing) if filing is for imported health food. Domestic health food filling should be submitted to the provincial CFDA where applicant is located.

Article 49 [Acceptance and Filing] Apply for health food filling, the applicant should submit the application materials in accordance with the filling requirements. If it does qualify, CFDA should fill those documents on the spot. If it is incomplete or does not conform to legal format, CFDA should inform the applicant of the dossiers needed at a time, and then the filler can resubmit after corrections and supplements.
Regarding on-file health food, CFDA should create filling voucher in accordance with the required format and release the information of the filling form on its website.

Article 50 [Filing alteration] Any changes happen on-file health food, filling form and filed technology requirements, filler should submit a statement that explain those changes and its related proof documents, And also submit filling alteration to the original filling department. CFDA should update the alteration information and fill the new documents if it does conform to the required format.

Chapter 4 Legal Liability

Article 51 [Administrative penalty] CFDA should deal with cases base on the appeal of interested party or responsibility in accordance with the Administrative Permit Law (Article 69) after verification if any of the following situation will be applied:

1) Administrative staff makes approval decision by misuse of authority and neglect of duty;
2) Unauthorized registration approval;
3) Illegal registration approval;
4) Issue registration to the applicant that disqualify or does not conform to the related rules.
5) Other situation that legally revoke the health food approval certificate.

Article 52 [Administrative penalty] FDA and its staff should be punished in accordance with the Administrative Permit Law (Article 72, 73, 74, 75) if any of the following situations will be applied:

1) Refuse to accept the health food registration application that conform to the related legal conditions;

2) Fail to release the application materials of the health food registration and filling in the place where it accepts applications;

3) Fail to perform the statutory obligations of notifying the applicant during the acceptance, inspection and filling period;

4) Fail to inform the applicant all required supplementary information on time;

5) Fail to explain the reason of unacceptable or disapprove registration application;

6) Make approval decision or unauthorized approval decision to the health food registration application that does not conform to this regulation;

7) Fail to transfer, register and save application materials as required;

8) Refuse to issue approval decision or fail to make approval decision within scheduled time limitation;

9) Illegal charge or changing at discretion the fee standards;

10) Solicit or receive other people's property or seek unjust benefits.

Article 53[Punishment of the applicant] CFDA should not accept or approve the application if the registration applicant conceal and provides false materials. CFDA should give a warning to the applicant. The applicant cannot apply for the registration for the same product in a year.

Article 54 [Cancellation procedure] FDA should deal with the cancellation of the health food filling registration:

1) Filer apply for cancellation;
2) Fail to apply for manufacturing certificate within scheduled time;
3) It is confirmed that the on-filed health food has safety issues;
4) Product formula, process and other technology does not conform to the filled information.
5) The manufacturing certificate has been expired or revoked;
6) Other possible situations not listed can cause cancellation.

Article 55 [Cancel of registration] CFDA should cancel approval number when one of below situations appears:

1) During the validity of health food registration, the product has not been manufactured and sold.
2) The certificate of health registration has been expired but not been reissued.
3) Health food registration's owner applies for removal.
4) It is confirmed that the registered health food has safety issues.
5) Violation of any law or regulation.
6) Other possible situations not listed can cause cancellation.

Article 56 [Revocation of approval] CFDA should revoke food approval certificate when any one of below situations appears:

1) Acquiring health food approval certificate illegally
2) Transfer health food approval certificate without permission
3) Applying health food approval certificate illegally.
4) Alterations, resell, rent or borrow health food approval certificate.

Article 57 [Punishment of deception and bribery] FDA should revoke the health food approval certificate if the applicant gains the certification by deception and bribery or other improper means. The applicant should not submit the registration application in the next three years.

Article 58 [Punishment of inspection institution] CFDA should order the selected health food inspection institution or inspector to make correction within a time limit if they violate the related regulations, and return illegal charges if existed. In terms of serious cases, may have their qualifications revoked. The inspection institution and inspector who issue false report will be investigated liabilities in accordance with <Food Safety Law> Article 138.

Chapter 5 Appendix

Article 59 [Working day calculating method] All the working time mentioned is calculated by working days, not including weekends and national holidays.

Article 60 [Definition] Health food is a category of food with health function or aim to supplement vitamins and minerals; regulate the body function, but not aim to cure diseases; contain special functional components and appropriate for special population with specified amount.

First time imported health food means the health food apply for marketing in China by different country, different company and different formula.

Article 61 [products from Hong Kong, Macao, Taiwan] Health food registration and filing of Hong Kong, Macao and Taiwan is the same as imported health food registration and filing.

Article 62 [Registration fee] Applicant should pay registration fee when applying for health food registration. The charge of health food registration is conducted by the rule of the state council finance department and pricing management department.

Article 63 [Implementation date] This regulation is implemented from the date of 201X-XX-XX

Measures for the registration of health food was published on April 30th 2005 (Former national food and drug supervision administration decree No.19) abolished simultaneously.

保健食品注册与备案管理办法

（征求意见稿）

第一章　　总 则

第一条［目的依据］为规范保健食品的注册与备案工作，根据《中华人民共和国食品安全法》、《中华人民共和国行政许可法》，制定本办法。

第二条［适用范围］在中华人民共和国境内生产、经营的保健食品注册与备案，适用本办法。

保健食品注册，是指食品药品监督管理部门根据申请人申请，依照法定程序、条件和要求，对申请注册的保健食品的安全、功能声称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，将与保健食品生产销售有关的材料提交食品药品监督管理部门进行登记、存档、公开、备查的过程。

第三条［总局职责］国家食品药品监督管理总局负责全国保健食品注册与备案管理工作。主要职责：

（一）制定保健食品注册和备案相关工作管理办法；

（二）制定保健食品注册技术审评工作细则；

（三）保健食品技术审评机构、注册检验机构管理；

（四）负责保健食品注册；

（五）负责首次进口补充维生素、矿物质等营养物质保健食品备案；

（六）组织对注册和备案保健食品的监督管理。

第四条［省局职责］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的保健食品备案及注册相关管理工作。主要职责：

（一）承担本行政区域内保健食品备案工作；

（二）履行本行政区域内国内生产的保健食品试制现场核查和抽样的相关职责；

（三）负责本行政区域内注册与备案的保健食品的监督管理；

（四）承担国家食品药品监督管理总局委托的注册变更与延续的受理等其他工作。

第五条［基层局职责]县、市食品药品监督管理部门负责本行政区域内的注册和备案的保健食品监督管理工作。主要职责：

（一）履行本行政区域内注册和备案保健食品的监督检查职责；

（二）承担上级食品药品监督管理部门委托的其他工作。

第六条［技术审评机构职责］国家食品药品监督管理总局保健食品技术审评机构负责申请注册的保健食品的技术审评等工作。主要职责：

（一）制定保健食品注册技术审评工作规程；

（二）组织开展保健食品研发报告、产品配方、生产工艺、安全性、保健功能、标签、说明书等方面的技术审评工作，并作出综合性技术审评意见和结论；

（三）承担技术审评专家和技术人员的管理以及技术审评意见的审核工作，对技术审评专家和技术人员的工作进行规范、指导和监督；

（四）组织开展相关现场核查、抽样和复核性检验工作；

（五）承担保健食品技术审评、备案相关的其他技术工作。

第七条［专家职责］技术审评专家和技术人员在审评过程中应当依据国家有关规定开展技术审评工作，遵守利益冲突回避原则，对提出的审评意见负责。

第八条［申请人和备案人义务］申请人或备案人应当对申请注册和备案的保健食品的安全性、保健功能和质量可控性负责，承担相应法律责任。主要义务：

（一）建立与产品研制、生产有关的质量管理体系，并保持有效运行；

（二）保证生产研制和研究论证过程规范，所有数据真实、完整和可溯源；

（三）办理保健食品注册或者备案事务的人员应当具有相应的专业知识，熟悉保健食品注册或者备案管理的法律、法规、规章和技术要求；

（四）按照规定提交规范完整的申请材料，保证材料具有充分可靠的研究数据和科学依据，材料能够支持产品的安全性、保健功能和质量可控性，并对材料实质内容的真实性负责；

（五）按照要求协助开展与注册或备案相关的现场核查、抽样、复核性检验和监督检查等工作。

第九条［检验机构义务］国家食品药品监督管理总局遴选的保健食品检验机构承担保健食品技术审查评价所需的复核性检验工作，并遵守利益冲突回避原则，检验机构和检验人对出具的复核检验报告和结论负责。

第十条［申请材料目录和示范文本公示］食品药品监督管理部门应当将保健食品注册和备案的事项、依据、条件、程序、期限以及需要提交的全部材料的目录和申请书示范文本等在行政机关的网站和办公场所公示。

第十一条［遵循原则］保健食品的注册与备案工作，应当遵循科学、公正、公开、高效、便民的原则。对于保健食品注册和备案的依据和结果，食品药品监督管理部门应当公开。

第十二条［保密义务］食品药品监督管理部门、技术审评机构、检验机构以及其他参与保健食品注册与备案工作的单位和个人，应当对注册或者备案中获知的企业商业秘密予以保密。

第十三条［社会监督］任何单位和个人对保健食品产品研制、注册检验、受理、技术审评、行政审批等工作中发现的违法违规行为，有权向食品药品监督管理部门举报。食品药品监督管理部门应当及时核实处理。

第二章 保健食品注册

第一节 注册要求

第十四条［注册范围］保健食品注册申请范围包括：

（一）使用保健食品原料目录以外的原料生产经营保健食品的；

（二）首次进口的保健食品。

第十五条［申请人资质］保健食品注册，申请人应当具备以下条件：

（一）申请注册国产保健食品的，应当是中国境内合法登记的法人或者其他组织；申请注册进口保健食品的，应当是上市产品的合法持有人；

（二）两个以上单位共同研发的保健食品，应当由其中的一个单位申请注册。

第十六条［注册申请材料要求］保健食品注册应当提交以下材料：

（一）保健食品注册申请表；

（二）申请人有效的合法登记证明文件及其复印件；

（三）申请注册保健食品的通用名称与已经批准注册的药品名称不重名的检索材料；

（四）产品研发材料，内容主要包括研发时间、研发过程、研发依据、研发数据及研发人信息，申请人生产研发行为及申请材料不构成侵权的法律责任承诺书；

（五）产品配方材料，内容主要包括配方及配伍用量依据，原料和辅料的合法来源、使用依据、检验合格证明以及原料鉴定报告等；

（六）产品工艺材料，内容主要包括生产工艺流程简图及说明，关键工艺控制点及说明。直接接触产品的包装材料的种类、名称、质量标准及选择依据等；

（七）产品安全性和保健功能评价材料，内容主要包括安全性和保健功能试验评价材料，人群食用评价材料，功效成分或标志性成分试验报告，卫生学试验报告，稳定性试验报告、菌种毒力试验报告以及涉及兴奋剂、违禁药物成分的检测报告等；产品安全性、保健功能复核性检验的具体试验方法（明确样品前处理方法和检验周期）以及详细说明和相关研究材料等内容；

（八）产品技术要求材料，内容主要包括感官要求，鉴别，理化指标、微生物指标、功效成分或标志性成分含量及测定方法（明确样品前处理方法及检验周期），生产工艺流程、关键工艺控制点，原辅料标准和来源等，以及详细说明和相关研究材料等内容；

（九）产品标签、说明书样稿材料，主要包括原料、辅料、功效成分或标志性成分及含量、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；

（十）全面分析产品安全性、保健功能及质量可控性的综述报告及相关科学依据；

（十一）三个未启封的保质期内的最小销售包装样品；

（十二）其他有助于产品审评的材料。

第十七条［首次进口产品注册材料要求］申请首次进口保健食品注册的，应当提交本办法第十六条（二）项外的材料，并补充提交以下材料：

（一）所在国家（地区）主管部门出具的申请人为上市产品合法持有人的资质证明文件及有效期；

（二）生产国（地区）有关机构出具的该产品生产企业符合当地相应生产质量管理规范的证明文件及有效期；

（三）由境外厂商常驻中国代表机构代理注册事务的，应当提交《外国企业常驻中国代表机构登记证》及复印件；

（四）产品生产国（地区）主管部门出具该产品上市销售一年以上的证明文件；

（五）境外销售及人群食用情况的分析说明报告；

（六）生产国（地区）或国际组织与产品相关的标准；

（七）产品在生产国（地区）上市使用的包装、标签、说明书实样；

（八）复核性检验时所需的连续三个批号的上市销售产品或因检验特需处理的样品，其数量为检验所需量三倍。

上述申请材料必须使用中文并附原文，外文的资料可附后作为参考。中文译文应当由境内公证机关进行公证，确保与原文内容一致；境外机构出具的证明文件应当经生产国（地区）的公证机关公证和驻所在国中国使领馆确认。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。

第二节 注册变更与延续的基本要求

第十八条［注册变更范围］保健食品注册变更申请范围包括：

（一）变更保健食品批准证书及其附件所载明内容的；

（二）改变保健食品注册证书持有人自身名称、地址和中国境内代理机构的；

（三）改变保健食品注册证书持有人的。

第十九条［申请人资质］申请保健食品注册变更与延续的，应当是保健食品批准证书持有人。

申请改变保健食品证书持有人的，应当是公司吸收合并或新设合并后的证书持有者、公司分立成立全资子公司前的证书持有者或拟转让的保健食品注册持有人和受让人。

进口保健食品或国产保健食品在境内转让的，受让人应当是中国境内合法登记的法人或其他组织。进口保健食品在境外转让的，境外受让人应当是符合当地相应的生产质量管理规范的保健食品生产企业。

第二十条［注册延续］已生产销售的保健食品批准证书有效期届满需要延长有效期的，申请人应当在有效期届满 3 个月前申请延续。

第二十一条［注册变更与延续的材料要求］申请国产保健食品注册变更与延续的，应当提交以下材料：

（一）保健食品注册变更申请表或保健食品注册延续申请表；

（二）申请人有效的合法登记证明文件及其复印件；

（三）保健食品批准证明文件及其附件的复印件；

（四）变更具体事项的名称、内容、理由及依据，包括变更后对产品安全性、保健功能及质量可控性的研究分析报告（包括与原申请材料的对比分析）以及其他相关试验数据等；

（五）拟变更的保健食品批准证书及附件相关内容样稿，并附详细的修订说明；

（六）改变食用量的变更申请，还应当提供按照拟变更的食用量进行功能学评价的试验报告。增加食用量的变更申请，还应当提供按照拟变更的食用量进行毒理学评价试验报告，以及拟变更的食用量与原食用量相比较的功能学评价试验报告；

（七）改变产品规格、保质期、生产工艺、辅料等产品技术要求的变更申请，还应当提供拟变更的三批产品全项目检验报告；

（八）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；

（九）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称与已经批准注册的药品名称不重名的检索材料；已生产销售的产品还应当提供两年内无违法违规的承诺书；

（十）申请延长已生产销售保健食品注册证书有效期的，还应当提交有效期内保健食品的生产销售记录、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保健食品检验机构出具的拟延长注册有效期的保健食品的全项目检验报告；

（十一）申请改变证书持有人的变更注册，还应当提交：

1. 技术转让：拟转让注册的保健食品证书持有人和受让人有效的合法登记证明文件以及经公证机关依法公证的双方联合署名签订的转让合同书；产品批准证书及其附件的复印件。

2. 公司吸收合并或新设合并：申请人合并前后营业执照的复印件；当地工商行政管理部门出具的合并、注销的证明文件；产品批准证书及其附件的复印件；申请人与相关公司对产品批准证书所有权归属无异议的声明及其公证文件。

3. 公司分立成立全资子公司：申请人及其全资子公司营业执照的复印件；当地工商行政管理部门出具的该申请人成立全资子公司的证明文件；申请人同意将所有涉及保健食品的生产车间、设备设施、生产人员和产品批准证书等一并划入其全资子公司的董事会或有关单位的决议及批准文件；划转前后，生产车间、设备设施、生产工艺、质量标准、生产人员等与产品质量安全相关条件要求未发生改变的承诺书；产品批准证明文件及其附件的复印件。

第二十二条［进口产品注册变更材料要求］申请进口保健食品注册变更与延续的，应当提交本办法第二十一条第（二）项以外的材料，并补充提交以下材料：

（一）所在国家（地区）主管部门出具的申请人为上市产品合法持有人的资质证明文件及有效期；

（二）生产国（地区）有关机构出具的该产品生产企业符合当地相应生产质量管理规范的证明文件及有效期；

（三）生产国（地区）相关机构出具的允许该产品销售以及相关事项已变更的证明文件及相关材料；

（四）进口保健食品申请人由境外厂商常驻中国代表机构办理变更事务的，应当提交《外国企业常驻中国代表机构登记证》及复印件。境外生产厂商委托境内的代理机构负责办理变更事项的，需提交经过公证的委托书原件以及受委托的代理机构的营业执照复印件；

（五）生产国（地区）相关机构出具的保健食品注册批准证书持有人自身名称、地址已变更的证明文件及相关材料；

（六）经受让方所在国家（地区）公证的境外转让合同；

（七）境外销售及人群食用情况的分析说明报告；

（八）产品在生产国（地区）上市使用的包装、标签、说明书实样；

（九）复核性检验时所需的连续三个批号的上市销售产品或因检验特需处理的样品，其数量为检验所需量三倍。

上述申请材料必须使用中文并附原文，外文的资料可附后作为参考。中文译文应当由境内公证机关进行公证，确保与原文内容一致；境外机构出具的证明文件应当经生产国（地区）的公证机关公证和驻所在国中国使领馆确认。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。

第三节 申请与审批

第二十三条［自主研发］申请人在申请保健食品注册之前，应当对拟申请注册保健食品进行充分的研发试制和研究论证工作，证明产品的安全性、保健功能和质量可控性。

第二十四条［申请提交］申请保健食品注册和进口保健食品注册变更与延续的，申请人应当按照要求向国家食品药品监督管理总局注册受理机构提交申请材料和样品。

申请国内生产保健食品注册变更与延续的，申请人应当按照要求向省、自治区、直辖市食品药品监督管理部门注册受理机构提交申请材料和样品。

第二十五条［受理审查］食品药品监督管理部门注册受理机构收到申请材料后，应当当场或者在 5 日内对申请材料的规范性、完整性进行形式审查：

（一）对于申请事项属于本部门职权范围，申请材料齐全，符合形式审查要求的，予以受理并向申请人发出《受理通知书》；

（二）对于申请材料不符合规范要求或不完整的，应当一次告知申请人需要补正的全部材料，逾期不告知的，自收到申请材料之日起即为受理。申请材料存在可以当场更正的错误的，应当允许申请人当场更正；

（三）对于申请事项不属于本部门职权范围或不符合本办法要求的，不予受理并向申请人发出《不予受理通知书》，并书面说明理由。

第二十六条［材料移送］食品药品监督管理部门注册受理机构应当在受理后 5 日内将注册申请材料和样品一并送达保健食品技术审评机构。

第二十七条［技术审评］保健食品技术审评机构应当在接到申请材料后 60 日内组织专家和技术人员，完成对产品安全性、保健功能以及质量可控性的一次性技术审评工作，并作出综合性技术审评意见和结论。技术审评内容应当包括：

（一）研发报告的科学性、完整性、合理性和真实性；

（二）配方及配伍用量依据的科学性、保健功能以及安全性；

（三）生产工艺的合理性、可行性和质量可控性；

（四）技术要求和检验方法的科学性和复现性；

（五）命名、标签和说明书的规范性以及与产品安全、保健功能的匹配性；

（六）对保健食品安全性、有效性以及质量可控性以及科学依据充足程度的全面综合评价。

第二十八条［审查内容］保健食品技术审评机构在组织产品技术审评时可以调阅原始研究资料，并根据申报资料审查情况，组织对申请人进行与产品研制生产有关的质量管理体系核查。需进行复核性检验的，应当按要求抽取动态生产样品。

第二十九条［管理体系核查］境内质量管理体系核查，由国家食品药品监督管理总局技术审评机构通知相应省、自治区、直辖市食品药品监督管理部门开展核查，必要时参与核查。

第三十条［现场核查］省、自治区、直辖市食品药品监督管理部门应当在 30 日内根据相关要求完成现场核查。需要进行复核性检验的，由核查人员按要求抽取样品，送技术审评机构指定的检验机构进行复核性检验。

第三十一条［境外现场核查］境外质量管理体系现场核查，由国家食品药品监督管理总局技术审评机构组织开展。需要进行复核性检验的，由核查人员按要求抽取样品，送技术审评机构指定的检验机构进行复核性检验。

第三十二条［复核性检验］复核性检验应当由国家食品药品监督管理总局遴选的保健食品检验机构承担。检验机构应当严格按照申请材料中申请人研究确定的试验方法、样品前处理方法、试验周期以及相关说明进行操作，对检验方法科学性、复现性以及产品安全性、保健功能及质量稳定性进行复核性检验，并出具复核性检验报告和结论。

第三十三条［技术审查时限］质量管理体系现场核查、复核性检验所需时间以及申请人原因延误的时间，不计算在本办法规定的审评时限内。

第三十四条［现场核查和复核性检验要求］质量管理体系现场核查和复核性检验的原因、内容应当明确，具有充足的依据，程序符合有关规定。

第三十五条［资料审查与现场核查及复核性检验］申请材料不符合要求，未通过技术审评的，不再对该申请开展质量管理体系现场核查和复核性检验；质量管理体系现场核查不符合要求的，不再对该申请开展动态抽样和复核性检验。

第三十六条［审核意见］保健食品技术审评机构应当对专家技术审评意见进行审核，并向国家食品药品监督管理总局提交最终综合性技术审评意见和结论：

（一）申请人的申请真实、科学、安全、具有明确的保健功能，生产工艺合理、可行和质量可控，技术要求和检验方法科学、可复现的；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，建议予以注册；

（二）申请人的申请虚假，科学依据不充足，安全性或保健功能尚待论证，生产工艺不合理、不可行或不可控，技术要求或检验方法不科学、不具有复现性的；变更申请理由依据不充分不合理，拟变更事项可能影响产品安全性、保健功能和质量可控性的，建议不予注册。

第三十七条［审查决定］国家食品药品监督管理总局接到保健食品技术审评机构的综合性技术审评意见和结论后，应当于 10 日内对技术审评程序、技术审评意见和结论的合法性、规范性以及完整性进行审查，并作出审查决定。

不符合要求的，退回保健食品技术审评机构，重新在规定的时间内补正并出具技术审评意见和结论。

第三十八条［证书送达］食品药品监督管理部门作出准予注册或不予注册的决定后，应当自作出决定之日起 10 日内，向申请人颁发并送达《保健食品注册证书》或《不予批准注册通知书》。准予注册变更或延续的，颁发新的《保健食品注册证书》，同时收回原《保健食品注册证书》。

第三十九条［复审申请］申请人对食品药品监督管理部门作出的不予注册的决定有异议的，应当在收到《不予批准注册通知书》之日起 10 日内向食品药品监督管理部门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原申报资料。

第四十条［复审决定］食品药品监督管理部门收到复审申请后，应当按照原申请事项的审查时限和要求进行复审，并作出复审决定。撤销不予注册决定的，向申请人颁发相应的保健食品批准证明文件；维持原决定的，不再受理再次的复审申请。

申请人可按照有关法律规定，向国家食品药品监督管理总局申请行政复议或者向人民法院提起行政诉讼。

第四十一条［证书有效期］《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》的有效期与原保健食品批准证书的有效期相同。

第四十二条［证书批准文号］国内生产保健食品批准文号格式为：国食健字 G+4 位年代号+4 位顺序号；进口保健食品批准文号格式为：国食健字 J+4 位年代号+4 位顺序号。

第四十三条［证明文件补发］保健食品注册有效期内，《保健食品注册证书》丢失的，保健食品注册持有人应当向食品药品监督管理部门提出书面申请并说明理由。因遗失申请补发的，应当在主管部门指定的网站上发布遗失声明；因损毁申请补发的，应当交回保健食品批准证明文件原件。

食品药品监督管理部门应当在受理后 20 日内予以补发。补发的批准证明文件应当标注原批准日期，并注明“补发”字样。

第三章　　保健食品备案

第一节　　备案要求

第四十四条［备案范围］保健食品备案范围包括：

（一）拟使用保健食品原料目录内的原料生产经营保健食品的；

（二）首次进口的保健食品中属于补充维生素、矿物质等营养物质的；

（三）已备案信息发生变化，重新备案的。

第四十五条［备案人资质］保健食品备案人应当具备以下条件：

（一）使用保健食品原料目录内的原料生产经营国产保健食品的，应当具有生产企业资质；

（二）备案进口保健食品的，应当是上市产品的合法持有人。

第四十六条［备案材料］申请保健食品备案，应当提交以下材料：

（一）保健食品备案登记表；

（二）备案人有效的资质证明文件复印件；

（三）产品配方、生产工艺、标签、说明书、质量标准以及表明产品安全性和保健功能的材料。

第四十七条［进口产品备案材料要求］申请进口保健食品备案的，应当提交本办法第四十六条（二）项外的材料，并补充提交以下材料：

（一）所在国家（地区）主管部门出具的申请人为上市产品合法持有人的资质证明文件及有效期；

（二）生产国（地区）有关机构出具的该产品生产企业符合当地相应生产质量管理规范的证明文件及有效期；

（三）由境外厂商常驻中国代表机构代理注册事务的，应当提交《外国企业常驻中国代表机构登记证》及复印件；

（四）产品生产国（地区）主管部门出具该产品上市销售一年以上的证明文件；

（五）境外销售及人群食用情况的分析说明报告；

（六）生产国（地区）或国际组织与产品相关的标准；

（七）保健食品检验机构出具的三批产品符合质量标准要求的全项目检验报告。

（八）产品在生产国（地区）上市使用的包装、标签、说明书实样。

上述登记材料必须使用中文并附原文，外文的资料可附后作为参考。中文译文应当由境内公证机关进行公证，确保与原文内容一致；境外机构出具的证明文件应当经生产国（地区）的公证机关公证和驻所在国中国使领馆确认。登记备案的产品质量标准（中文本），必须符合中国保健食品质量标准的格式。

第二节　　产品备案

第四十八条［备案申请］进口保健食品备案应当向国家食品药品监督管理总局提出；国内生产的保健食品备案应当向申请人所在地省级食品药品监督管理部门提出。

第四十九条［受理与备案］办理保健食品备案，备案人应当按照备案要求提交备案资料。备案资料符合要求的，食品药品监督管理部门应当当场备案，备案资料不齐全或者不符合规定形式的，应当一次告知需要补正的全部内容，由备案人补正后备案。

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予以公布。

第五十条［备案变更］已备案的保健食品，备案信息表中登载内容及备案的产品技术要求发生变化的，备案人应当提交变化情况的说明及相关证明文件，向原备案部门提出变更备案信息。备案资料符合形式要求的，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，将备案资料存档。

第四章　　法律责任

第五十一条［许可处罚］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，可以在核实后依照《行政许可法》第六十九条的规定进行处理：

（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）超越法定职权作出准予注册决定的；

（三）违反法定程序作出准予注册决定的；

（四）对不具备申请资格或者不符合法定条件的申请人准予注册的；

（五）依法可以撤销保健食品批准证明文件的其他情形。

第五十二条［许可处罚］食品药品监督管理部门及其工作人员违反本办法规定，有下列情形之一的，依照《行政许可法》第七十二条、七十三条、七十四条、七十五条的规定处理：

（一）对符合法定条件的保健食品注册申请不予受理的；

（二）不在受理场所公示保健食品注册与备案申报资料项目的；

（三）在保健食品受理、审查或备案过程中，未向申请人履行法定告知义务的；

（四）申请人提交的保健食品申报材料不齐全、不符合法定形式，不一次告知申请人必须补正的全部内容的；

（五）未依法说明不受理或者不批准保健食品注册申请理由的；

（六）对不符合本办法规定条件的保健食品注册申请作出准予注册决定或者超越法定职权作出准予注册决定的；

（七）未按要求全部移交、登记和保存申请材料的；

（八）对符合本办法规定的申请作出不予注册决定或者不在本办法规定期限内作出准予注册决定的；

（九）擅自收费或者不按照法定项目的标准收费的；

（十）索取或者收受他人财物或者谋取其他利益的。

第五十三条［申请人处罚］保健食品注册申请人隐瞒、谎报、提供虚假材料的，国家食品药品监督管理总局对该项申请不予受理或者不予注册，对申请人给予警告，申请人在一年内不得再次提出该保健食品的注册申请。

第五十四条［注销手续］有下列情形之一的，食品药品监督管理部门应当办理保健食品备案登记的注销手续：

（一） 备案人申请注销的；

（二）未在规定时间内申请生产许可的；

（三）备案产品存在安全性问题的；

（四）未按备案的产品配方、生产工艺等技术要求组织生产的；

（五）保健食品生产许可失效或被撤销的；

（六）依法应当注销的其他情形。

第五十五条［注销注册］有下列情形之一的，国家食品药品监督管理总局应当注销保健食品批准文号：

（一）保健食品注册证书有效期内未生产销售的；

（二）保健食品注册证书有效期届满未申请延续的；

（三）保健食品注册持有者申请注销的；

（四）确认已注册的保健食品存在安全性问题的；

（五）违反法律法规规定，应当撤销其保健食品批准证书的；

（六）依法应当注销的其他情形。

第五十六条［撤销注册］有下列情形之一的，国家食品药品监督管理总局应当撤销保健食品批准证书：

（一）违反规定取得保健食品批准证书的；

（二）擅自转让保健食品批准证书的；

（三）违法使用保健食品批准证书；

（四）变造、涂改、倒卖、出租、出借保健食品批准证书。

第五十七条 [欺瞒处罚] 申请人以欺骗、贿赂等不正当手段取得保健食品批准证书的，食品药品监督管理部门应当撤销其保健食品批准证书，申请人在三年内不得再次提出该保健食品的注册申请。

第五十八条 [检验机构处罚] 遴选的保健食品检验机构及检验人员违反相关规定的，国家食品药品监督管理总局应当责令限期改正，涉及违法收取费用的，由国家食品药品监督管理总局或者政府有关部门责令退还；情节严重的，撤销保健食品检验机构遴选资质。检验机构、检验人员出具虚假检验报告的，依据《食品安全法》第一百三十八条追究相关责任。

第五章 附 则

第五十九条 [工作日计算] 本办法工作期限以工作日计算，不含法定节假日。

第六十条 [定义] 保健食品，是指声称具有保健功能或者以补充维生素、矿物质等营养物质为目的的食品。能够调节人体机能，不以治疗疾病为目的，含有特定功能成分，适宜于特定人群食用，有规定食用量。

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。

第六十一条 [港澳台产品] 香港、澳门、台湾地区保健食品的注册、备案，参照进口保健食品办理。

第六十二条［注册收费］申请保健食品注册的，申请人应当按照规定缴纳注册费用。保健食品产品注册收费项目、收费标准按照国务院财政部门、价格主管部门的有关规定执行。

第六十三条［实施日期］本办法自 年 月 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。