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Health Food Registration Review Rules

保健食品注册审评细则
2016 版

Regulation's Main Points

Health Food Registration Review Rules

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1 General Rules

1.1 Establishment Basis

The Health Food Registration Review Rules are promulgated in accordance with the Food Safety Law of the People's Republic of China, Measures for Health Food Registration and Recording (hereinafter referred to as "the Measures") aim to regulate the health food registration review process.

1.2 Applicable Scope

This rules can be used to regulate the review process of new product registration, registration alteration, technology transfer, registration renewal, certificate reissue of the health food, which contains ingredients are not on the 'Health Food Raw Material List', and first-time imported health food (except vitamins, minerals supplements).

1.3 Work Principles

The health food registration review rules shall insist on legal, scientific, fair and efficient principles.

2 Application Acceptance

2.1 Application Materials Review

For those applications belong to health food registration and have completed fill the health food registration application system, the acceptance institute shall issue <Application Material Receipt> to the registration applicant. The acceptance institute shall also review the integrity and consistency of the application materials according to application material list within 5 business days.

2.1.1 Domestic New Product Registration Application Materials

2.1.1.1 Proof Documents

(1) Health food registration application form, the legal liability commitment signed by the applicant who shall take responsibility of the authenticity of the application materials.
(2) Copy of the applicant registered body certificate documents.

2.1.1.2 Product Research and Development Report

2.1.1.2.1 Safety Demonstration Report

(1) Usage basis of raw materials and excipients;
(2) Safety scientific basis of product formula, compatibility and dosage;
(3) Analysis of safety evaluation testing materials;
(4) Description of product formula, applicable population, not applicable population, suggested use, intake amount, warnings etc.

2.1.1.2.2 Health Function Demonstration Report

(1) Scientific basis which can prove the function of the main ingredients of the formula, Necessity of compatibility of other ingredients.
(2) Health function scientific basis of of product formula;

(3) Analysis of product health function evaluation testing material, population consumption evaluation material etc.
(4) Description of product formula, applicable population, not applicable population, suggested use, intake amount, warnings etc.

2.1.1.2.3 Production Process Research Report
(1) Basis of dosage form selection and specification determination;
(2) Basis of excipients and dosage selection;
(3) Research report of the main production process and the key process parameters which will affect product safety, health function etc.
(4) Production verification report and sample self-test report of pilot or above production scale;
(5) For those ingredients without applicable national standard, local standard and industry standard, shall submit detailed preparation technology, technology explanation and technology rationality basis.
(6) Name, standardized number and text of all processing aids are used in the production process of the product and ingredients.
(7) Description of production materials, excipients in the formula, dosage form, specification, applicable population, not applicable population, technical requirements of the production process, direct contact package materials, quality requirements of ingredients and excipients etc.

2.1.1.2.4 Product Technical Requirement Research Report
(1) Research material of identification method;
(2) Determination basis of each physical and chemical index and its testing method;
(3) Determination basis of functional ingredients index and index value, and the research verification material of its testing method;
(4) Determination basis of weight variation (Net weight and allow negative tolerance) index;
(5) Determination basis of the quality requirements of all ingredients and excipients;
(6) Product stability testing conditions, testing items and testing methods etc. Analysis and evaluation of the stability testing results generated by the registration applicant;
(7) Product technical requirements;

2.1.1.3 Product Formula Materials
(1) Product formula list;
(2) Quality standard of ingredients and excipients, production technology, quality verification certificate;
(3) Provide the instruction of the used part and variety verification report etc. if necessary;

2.1.1.4 Production Process Materials
Production process flow chart and its description, key production control point and its description.

2.1.1.5 Safety and Health Function Evaluation Testing Materials
(1) Qualification certificate of food testing agency;
(2) Safety evaluation testing materials issued by legally qualified food testing agency;

(3) Health function evaluation testing materials issued by legally qualified food testing agency;
(4) Population consumption evaluation materials issued by legally qualified food testing agency (refer to human feeding trials);
(5) Functional ingredients, sanitary, stability testing reports of three batches samples (the authorized food testing agency should be legally qualified);
(6) Bacteria strain identification report issued by authority, bacteria strain toxicity testing report issued by legally qualified food testing agency;
(7) Product related stimulants and banned substances testing report issued by legally qualified testing agency;

2.1.1.6 Classification, name and standard of direct contact health food package materials.
Classification, name, standardized number, standard and usage basis of direct contact health food package materials.

2.1.1.7 Product Label and Instruction Book Samples
The content shall include ingredients, excipients, quantity of functional ingredients, applicable population, not applicable population, health function, intake amount, suggested use, specification, storage method, expiration date, warnings.

2.1.1.8 Retrieval data of the product general name is not the same as any registered drug; Retrieval data of the product name is not the same as any approved registered health food.

(1) Retrieval data of the product general name is not the same as any registered drug; Retrieval data of the product name is not the same as any approved registered health food.
(2) Provide naming declaration if use any words (except ingredients name or abbreviation) represent product specialty as product general name.
(3) Provide registered trademark certificate if use any registered trademark.

2.1.1.9 Three Smallest Sales Package Samples

(1) The package shall be completed, unbroken and more than 3 months from the expiration date;
(2) The label content shall conform with the label and instruction book content in the registration application materials, and include manufacture date and manufacturer.
(3) Imported product shall conform with the marketed sales products in its manufacture country.

2.1.1.10 Other Materials Related with Product Registration Review

(1) A copy of the documents which can verify the quality management system of the sample manufacturer conform with health food production permission requirements.
(2) If the sample was produced by original equipment manufacturer, shall provide OEM agreement original copy.
(3) Scientific references copy include source, author, year, volume No., issue No., page No. etc.

2.1.1.11 Domestic Product Registration Materials for the product belong to vitamins, minerals supplements.

(1) Supplementary vitamins and minerals have identified China Resident Dietary Nutrients Recommend Nutrient Intake (RNI) or Adequate Intake (AI);
(2) The ingredients quality standard shall have food safety national standard or other applicable standard verified by the health administrative department. For those ingredients only have China drug standard or Chinese Pharmacopoeia, shall be applicable to GB 14880 standard or nutrition enhancer announced by the health administrative department;
(3) Shall follow new product registration application requirements, health food raw materials list requirements and other related regulations to submit registration application materials. Safety evaluation testing materials and health function testing materials are exempted from those application materials.

2.1.2 Domestic Product Registration Renewal Application Materials

2.1.2.1 Proof Documents

(1) Registration renewal application form, the legal liability commitment signed by the applicant who shall take responsibility of the authenticity of the application materials.
(2) Copy of the applicant registered body certificate documents.
(3) Copy of Health food registration certificate and its attachments

2.1.2.2 Health Food Manufacture and sales status verified by provincial FDA department within the effective date of the registration certificate.

Demonstration documents of health food manufacture and sales status issued by provincial FDA department within the effective date of the registration certificate.

2.1.2.3 Analysis Report of Population Consumption Status

Issued by the registration applicant which included edible safety and health function information, consumer complains and corrective actions.

2.1.2.4 Manufacture Quality Management System Operation Status Self-Inspection Report

Self-inspection report issued by the registration applicant to determine if there any violations existed in production and sales within the registration certificate effective date.

2.1.2.5 Product Technology Requirements Whole-project Inspection Report

One batch product technology requirements whole-project inspection report Issued by legally qualified food testing agency within the registration certificate effective date.

2.1.3 Domestic Product Registration Alternation

2.1.3.1 Proof Documents

(1) Registration Alteration Application Form, the legal liability commitment signed by the applicant who shall take responsibility of the authenticity of the application materials.
(2) Copy of the applicant registered body certificate documents.

(3) Copy of Health food registration certificate and its attachments

2.1.3.2 Alteration Items, Reasons and Basis

List all items before and after the alteration, and the analysis report which indicate the alteration application items will not cause substantive changes for product safety, health functions and quality controllability. Includes the necessity of alteration, rationality basis, comparative analysis with the original application materials, related testing date and scientific references etc.

Shall provide revised information refer to any changes of product formula, label and instruction book samples, product technical requirements, production materials.

2.1.3.3 Alteration Application of registrant name and address

Demonstration document issued by the local industry and commerce administrative department which indicate the registrant name and address have been changed.

2.1.3.4 Alteration Application involve Company Merge or Newly Established Merge

(1) Copy of the registrant business licenses before and after the merge;

(2) Merge or Written-off certificate issued by the local industry and commerce administrative department;

(3) Declaration and its notarial documents about the applicant and related companies have no objection to the product registration certificate proprietary rights.

2.1.3.5 Alteration Application Involve Company Founded Wholly-owned Subsidiary

(1) Copy of the applicant and its wholly-owned subsidiary business license;
(2) Supporting document issued by the local industry and commerce administrative department which prove that the applicant founded the wholly-owned subsidiary;
(3) Capital verification supporting documents issued by the capital verification agency which indicate that all health food related production shop, equipment and facilities, manufacturing staffs and product registration certificate etc. belong to the wholly-owned subsidiary;
(4) Decision letter and approval documents issued the Board of directors or related department which state that the applicant agrees to assign all health food related production shop, equipment and facilities, manufacturing staffs and product registration etc. to the wholly-owned subsidiary.
(5) Commitment letter which promise that there will be no substantial changes happen in production shop, equipment and facilities, manufacturing staffs and product registration etc. related with the product quality safety requirements before or after the transition.

2.1.3.6 Alternation Application of Change Product Name

Retrieval data of the proposed new product general name is not the same as any registered drug; Retrieval data of the product name is not the same as any approved registered health food. Use the word which present product characteristic other than ingredient name or ingredient abbreviation as the product general name, and the naming explanation shall be provided as well. Provide trademark registration proof documents if use any registered trademark.

2.1.3.7 Alternation Application of Add Health Function

(1) Demonstration report of proposed add health function;
(2) Test evaluation materials of proposed add health function, provide population consumption evaluation materials if human feeding trial is needed.
(3) Hygiene test report of the testing samples which proposed add health function.

2.1.3.8 Alternation Application of Change Product Specification, Storage Method, Expiration Date, Excipients, Production Process and Product Technical Requirements.

Functional component test report, hygiene test report and stability test report of samples from three batches. Those tests reports can be exempt if there is no substantial changes happen to the standard content even though the reference standard of the product technical requirements is updated or replaced.

Provide reference basis, test data, comparative analysis of before/after production process change if the production process changed to prove the product safety, health function, quality controllability are substantial equivalence with the original registered product.

2.1.3.9 Alternation Application of Change applicable population, non-applicable population, warning, suggested use or intake amount.

(1) For the alternation application of change applicable population, non-applicable population, suggested use and warning, shall supplement safety, health function evaluation test or hygiene, stability test if the previous safety, health function evaluation and hygiene, stability test attached to the original registration application cannot support the altered applicable population, non-applicable population, suggested use and warning.
(2) For alternation application of reduce intake amount, shall provide health function evaluation test report base on the proposed altered intake amount;
(3) For alternation application of increase intake amount, shall provide safety evaluation test report base on the altered intake amount, and the comparative analysis of health function evaluation test before/after change the intake amount;
(4) Provide the hygiene test report issued by legally qualified food testing agency if need to conduct safety and health function evaluation test. Provide ethic review documents and population consumption evaluation materials if need to conduct human feeding trial.

2.1.4 Domestic Product Technology Transfer Registration Application Material

2.1.4.1 Demonstration Documents

(1) Health food technology transfer registration application form, the legal liability commitment signed by the applicant who shall take responsibility of the authenticity of the application materials.
(2) Copy of transferor and transferee registered body certificate documents;
(3) Copy of original registration certificate and its attachment;
(4) Notarial transfer agreement and application for write-off original registration certificate issued by transferor;

(5) Copy of demonstration documents which prove that the sample manufacturer quality management system comfort to health food production permit requirements, original copy of manufacturing consignment agreement.

2.1.4.2 Technical Materials

(1) According to the new product registration application material requirements, provide product formula materials, production process materials, direct-contact product package materials, functional component of three batches samples, hygiene and stability test report, label and instruction book samples, 3 smallest sales package samples etc.;

(2) For transferee apply for change product name, shall provide Retrieval data of the product general name is not the same as any registered drug; Retrieval data of the product name is not the same as any approved registered health food. Use the word which present product characteristic other than ingredient name or ingredient abbreviation as the product general name, and the naming explanation shall be provided as well. Provide trademark registration proof documents if use any registered trademark.

(3) Explanation of if the sample manufacturing location and condition has been changed compare with the original registration.

2.1.5 Reissue Certificate Application Materials

(1) Reissue certificate application form, the legal liability commitment signed by the applicant who shall take responsibility of the authenticity of the application materials.

(2) Copy of registrant registered body certificate documents;

(3) Lost Declaration printed copy (domestic product registrant announced on the local provincial, autonomous region or direct-controlled municipality FDA website; imported product registrant announced on CFDA website) or damaged original health food registration certificate.

2.1.6 Imported Product Registration Application Materials

For new imported product registration application, registration renewal application, registration alternation application, technology transfer application, except domestic product application related materials, shall submit the below:

(1) Qualification proof documents issued by the manufacturing country government authorities or legal service agency to show that the registration applicant is public health food oversea manufacturer or trader;

(2) The certificate issued by the manufacturing government authorities or legal service agency to show that the product has been marketed at least one year; Or its oversea sales report and the population consumption safety report;

(3) Health food related technology regulation and (or) standard master copies from the manufacturing country or international organization;

(4) Samples of marketed product package, label and instruction book from the manufacturing country.

(5) If the China representative office of the oversea registration applicant conduct the registration, shall submit a copy of ‘The Foreign Company Resident Representative China office Registration Certificate’.

If the oversea registration applicant authorize a domestic agency conduct the registration, shall submit the notarial authorization letter master copy and a copy of the authorized agency's business license.

For imported product registration alternation application, shall submit the below:

(1) Altered product package, label and instruction book samples, demonstration documents issued by the manufacturing country government authorities or legal service agency to proof those items has been altered;
(2) For alternation application of change the registrant name and location, shall provide demonstration documents issued by the manufacturing country governmental authorities or legal service agency to prove that the production location has not changed;
(3) For alternation application of change oversea production location but not in the manufacturing country or region, shall provide the demonstration documents issued by the new production location country government authorities or legal service agency to prove that the product can be manufactured and sold in that country; product package and label instruction book samples in the new production location country; functional component test report, hygiene test and stability test reports of three batches samples manufactured in new production location issued by legally qualified food testing agency. If change the manufacturing country or region, shall provide additional materials base on the technology transfer requirements.

2.2 Application Material Supplements and Corrections

The acceptance institution shall issue <Application Material Supplements and Corrections Notice Letter> and inform the registration applicant all needed supplements and correction at a time if the application materials are incomplete or not match the legal format.

2.3 Application Materials Acceptance

(1) The acceptance institution shall accept the application and issue the dated <Acceptance Notice Letter> stamp with CFDA administrative permit acceptance seal if the application materials are completed and match the legal format.
(2) Domestic health food new product registration application, registration renewal application, registration alternation application, technology transfer application, reissue registration application acceptance number are: 国食健申 G + Year(xxxx) + Sequence number (xxxx), 国食健续 G +Year (xxxx) + Sequence number (xxxx), 国食健更 G + Year (xxxx) + Sequence number (xxxx), 国食健转 G + Year (xxxx) + Sequence number (xxxx), 国食健补 G + Year (xxxx) + Sequence number (xxxx).
(3) Imported health food new product registration application, registration renewal application, registration alternation application, technology transfer application, reissue registration application acceptance number are: 国食健申 J + Year(xxxx) + Sequence number (xxxx), 国食健续 J +Year (xxxx) + Sequence number (xxxx), 国食健更 J + Year (xxxx) + Sequence number (xxxx), 国食健转 J + Year (xxxx) + Sequence number (xxxx), 国食健补 J + Year (xxxx) + Sequence number (xxxx).

2.4 Application Materials Transfer

(1) The acceptance institution shall send the application materials to the CFDA health food review center with in 3 business days after accept the application materials.
(2) The review center shall verify the application materials and file the <Health Food Registration Application Materials Transfer Form>.

3 Technical Review

3.1 Review Expert Panel

The review center shall randomly extract review experts from the review expert database and organize expert review panel to review the application materials.

3.1.1 Consist of Expert Panel

(1) Expert panel include safety expert review group, health function expert review group, technology expert review group, product technical requirements expert review group.
(2) Number of member of each expert review group shall be odd, set up one person as group leader;
(3) Safety expert review group consist of formula, toxicity, technology experts, the total number no less than 7;
(4) Health function expert review group consist of formula, function, technology experts, the total number no less than 7;
(5) Technology expert review group consist of technology experts, the total number no less than 3;
(6) Product technical requirements expert group consist of physic & chemistry and standard experts, the total number no less than 3.

3.1.2 Operation Mode of Expert Review Panel

(1) The review expert conducts the technical review work according to the expert review panel responsibilities; provide technical review comments according laws and regulations, technical standards and review requirements; responsible for the technical review comments.
(2) The leader of expert review panel is responsible for conclude experts review comments and draft expert review panel review report;
The expert review panel review report includes review contents, review comments, review suggestion and basis, review expert signature and review date etc.
Review suggestion can be divided into qualified application materials, supplement materials, disapprove registration.
If involve in multiple professional technical problems and need related expert review panel joint research, the expert review panel leader shall put forward discussion suggestion and indicate discussion content. The review center responsible for conduct joint discussion conference. Use the joint discussion suggestion as the basis of conclude product review suggestion.
If the review suggestion cannot be provided as expert review comments are inconsistent or technical problems, the review center shall organize another expert discussion meeting and us the expert discussion suggestion as the product review suggestion basis. If the review suggestion cannot be provided involve in the current regulations or national standards, the review center shall consult with the related department and clarify the explanation, also organize the expert review panel restart the review.

3.2 Joint Discussion Panel

3.2.1 Consist of Joint Discussion Panel

Joint discussion panel experts consist of relevant experts from expert review panel on technical issues, set up the expert review panel leader who suggest joint discussion as the leader for joint discussion panel, set up a secretary.

3.2.2 Operation Mode of Joint Discussion Panel

The leader of joint discussion panel hosts the discussion; the secretary collects expert comments. After vote by a show of hands, the joint discussion panel review comments and review suggestion can be drafted with all experts' signatures. Review comments and suggestion confirmed by more than two thirds of experts can be the basis of draft the review report. If not reach more than two thirds of experts, shall record the reason of not able to issue review suggestion in details and suggest to organize expert discussion meeting. The review center shall organize another expert discussion meeting for the issue.

3.3 Expert Demonstration Panel

3.3.1 Consist of expert demonstration panel

Expert demonstration panel consist on relevant experts from expert review panel on controversial issues, set up the main demonstration question related expert as the leader, set up a secretary. The total number of safety and health function expert review group no less than 13. The total number of technology and product technical requirements expert review group no less than 5.

3.3.2 Operation Mode of Expert Demonstration Panel

The leader of expert demonstration panel hosts the discussion; the secretary collects expert comments. After vote by a show of hands, the expert demonstration panel review comments and suggestion can be drafted with all experts' signatures. Review comments and suggestion confirmed by more than four fifths of experts can be the basis of draft the review report. Combine with the previous product review comments, draft the expert review report. If not reach more than four fifths of experts agree on comments, which mean the product safety, health function or quality controllability cannot be determined, then combine with the previous product review comments and draft the expert review report with review suggestion 'Not Grant Registration'.

3.4 Safety Review

3.4.1 Responsibility of Safety Expert Review Panel

3.4.1.1 Responsibility of formula expert in safety expert review panel

(1) Review the ingredients usage basis, health food new ingredients safety evaluation materials, formula compatibility and consumption theory basis, reference basis etc. related contents;
(2) Review the product safety, product formula and label instruction book samples include applicable population, non-applicable population, intake amount and suggested use, warning etc. related contents.

3.4.1.2 Responsibility of toxicity expert in safety expert review panel

(1) Review the safety evaluation materials and toxicity test report of the new ingredient, product safety test materials and its demonstration report;
(2) Review the product safety and label instruction book samples include applicable population, non-applicable population, intake amount and suggested use, warning etc. related contents.
(3) Provide suggestion for the test manufacturing on-site inspection of the not finalized package sample.

3.4.1.3 Responsibility of technology expert in safety expert review panel

(1) Determine if the production process of the ingredient use any irregular technology which may cause significant for the substantial basis;
(2) Determine if the production process of the product use any irregular technology which may cause significant for the substantial basis.

3.4.2 Content of Product Safety Review

3.4.2.1 Product Safety Demonstration Report

(1) Specific the usage basis of the ingredient according to general food (include general food and food additives), new food ingredients, homology of food and medicine, proposed include into health food raw materials list, health food new ingredient etc. categories.
(2) Product formula compatibility and consumption theory basis, reference basis and test data shall support the product safety. Formula shall not exist traditional Incompatibility. Modern medicine pharmacology research shall not find edible safety problems. Varieties, levels, quality, dosage and numbers of formulation ingredients shall comfort to related rules.
(3) Safety evaluation materials, toxicity test report, bacteria strain identification report, bacterial strain toxicity strength test report, product safety evaluation test etc. related with health food new ingredients shall support the product safety.
(4) Determine the rationality of the formula and the content on label instruction book (such as applicable population, non-applicable population, suggested use and intake amount, warning etc.) shall according to ingredient usage basis, product formula compatibility and usage basis, safety evaluation test materials etc.

3.4.2.2 Safety Evaluation of Health Food New Ingredient

3.4.2.2.1 Health food new ingredient include:

(1) Ingredient not belongs to general food, new food ingredient, ‘homology of food and medicine’, health food raw materials list;
(2) Ingredient belongs to general food, new food ingredient, ‘homology of food and medicine’, health food raw materials list but use the production process may cause significant changes on substantial basis.

3.4.2.2.2 Provide health food new ingredient developing and manufacturing report, safety evaluation materials and toxicity test report (such as domestic and oversea research usage status), production process, quality requirements, testing report according to new food ingredient safety review rules.
Developing and manufacturing report shall have sufficient basis, developing and manufacturing process shall be scientific basis; Determine toxicity evaluation test requirement base on safety evaluation materials such as domestic and oversea research usage status; toxicity evaluation report, production process, quality requirements shall conform to food safety standard and related rules; each ingredient content shall not cause any health issues with expected intake level.

3.4.2.3 Product Safety Evaluation Test
Product safety evaluation test sample, test items, design, operation, result, conclusion, report format etc. shall conform to the current rules, technical guidelines and the below requirements:

3.4.2.3.1 Requirements of product safety evaluation test items
(1) If use the ingredient (belongs to general food, new food ingredient, homology food and medicine.) to manufacture health food by traditional food production process (such as water extract etc.); the suggested use is the same as traditional suggested use; the ingredient suggested intake amount is the general dosage or conform to the national food dosage standard, registration applicant shall apply for exempt for provide safety evaluation test materials.
(2) If use any substances conform to health food raw material management rules as ingredient to manufacture health food by regular production process, shall conduct oral acute to toxicity test, three terms of hereditary toxicity test, 28 days' oral toxicity test. Determine if add 90 days oral toxicity test, teratogenicity test, reproductive toxicity test, chronic toxicity and carcinogenicity test and metabolism test;
(3) If the production process includes any irregular technology which may cause significant changes for substances basis, shall conduct product safety evaluation and toxicity evaluation test according to new food ingredient safety review related rules.

3.4.2.3.2 Requirements of product safety evaluation test sample
(1) The name, specification, sensory, dosage form, expiration date, manufacturer of the product, and the test applicant, R&D person, R&D company, R&D time etc. listed in the test report shall consist with the registration application material. The source of samples shall be clear;
(2) In principle, test shall use integrated package samples; If need not finalized samples for the test, shall provide manufacturing and handling process of the not finalized sample, as well as sample preparation requirements and rationality explanation issued by food testing agency;
(3) Strain identification report and strain toxicity test report shall use the strain sourced from ingredients used by test samples, or provide demonstration documents to show that the strain is consist with ingredients used by test samples, which truly reflect the strain and its toxicity ability.

3.4.2.3.3 Start from the issue date of the report, end up at the acceptance date of the registration application. The validity of product evaluation test report is 5 years.

3.4.2.4 Product formula, label instruction book proposed applicable population, non-applicable population, suggested use and intake amount, warning etc. shall consist with safety demonstration report and safety evaluation test materials.

3.5 Health Function Review

3.5.1 Responsibility of Health Function Expert Review Panel

3.5.1.1 Responsibility of formula expert in health function review panel

(1) Review the main ingredient function basis, necessity of other ingredients compatibility, formula compatibility usage and its theory/reference basis etc. related information of health function demonstration report;
(2) Review product functional claim, product formula, brand name, general name and label instruction book proposed ingredients, excipients, applicable population, non-applicable population, suggested use and intake amount.

3.5.1.2 Responsibility of function expert in health function review panel

(1) Review product health function evaluation test materials, population consumption evaluation materials, health function demonstration report and other related contents;
(2) Review label instruction book proposed applicable population, non-applicable population, suggested use and intake amount;
(3) Provide suggestion for on-site inspection of sample trial production. (Health function animal test use not finalized samples; population consumption evaluation test, health function animal test and safety evaluation test use samples from different batches.)

3.5.1.3 Responsibility of technology expert of health function review panel

Determine if the production process, substantial basis, suggested use and intake amount, dosage form specification etc. consist with product function basis.

3.5.2 Content of Product Health Function Review

3.5.2.1 Health function demonstration report

(1) Product formula ingredients shall have specific intended use. The scientific basis of main ingredient function shall be sufficient. The necessity of other ingredients compatibility shall be clarified.
    Use simple processed general food as ingredient, shall provide sufficient domestic and foreign experimental scientific references basis, focus on clarify all ingredients functional component, quantity and does-effect relationship.
(2) The theory of product formulation shall be specified; theory basis and reference basis of product compatibility and its usage level carry out functional claims shall be sufficient; compatibility use shall enhance performance of health function.
(3) Declaration functional materials according to product formula compatibility and usage: scientific basis, health function evaluation test materials, population consumption evaluation materials etc. The necessity of product formula, product label instruction book proposed ingredients,

excipients, applicable population, non-applicable population, health function, suggested use and intake amount etc.

3.5.2.2 Sample source, test items, test operation and conclusion etc. of health function evaluation test material and population consumption evaluation material shall consist with related rules.

Procedures, methods, samples, reports etc. involve in the test/trial shall consist with the below requirements:

(1) Before start the health function human feeding trial, shall accomplish the necessity of safety evaluation test, animal function test, hygiene test first. Achieve the ethics approval letter from the ethics committee which agree to conduct human feeding trial, then process health function human feeding trial according to relate rules. Ethics approval letter includes: approval number, name of the trial, name of the applicant, name of the trial agency, description of the review decision, other suggestion and requirements from ethics committee, date of the review decision, signature of the director of the ethics committee, seal of the ethics committee etc.
(2) Health function evaluation animal test and product safety evaluation test shall be conducted at the same testing agency;
(3) Health function animal test and safety evaluation test shall use the same sample, which is one of those samples for functional component test, hygiene rest, stability test.
Population consumption evaluation test shall use the integrated package samples from the same batches as the health function animal test and safety evaluation test. If population consumption evaluation test sample cannot be from the same batch as health function animal test and safety evaluation test samples, shall explain reasons and provide demonstration documents to show the consistency of production process and quality of samples from different batches, as well as the hygiene test report issued by the testing agency.
(4) Start from the issue date of the report, end up at the acceptance date of the registration application. The validity of health function evaluation animal test report and population consumption evaluation test report are 5 years.

3.5.2.3 The brand name and general name of the product shall conform to the 'Measures of Health Food Registration and Recording' and the below requirements.

3.5.2.3.1 Health Food Brand Name

Marked by Chinese characters, add '牌' at the end or ® at the upper-right corner of the brand name if use registered brand; add '牌'at the end of the brand name if use non-registered brand. One product shall only use one brand name.

3.5.2.3.2 Health Food General Name

(1) Use ingredient name as the general name: ingredient name shall consist with the national standard; or consist with the local standard, industry standard if no national standard;
(2) Use ingredient abbreviation as the general name: abbreviation cannot cause any ambiguities, or violate other naming rules;
(3) Single ingredient product shall use the ingredient name or ingredient abbreviation as the general name;

(4) Formulation product use some ingredients name or abbreviation as general name shall select ingredients with applicable classifications and quantities according to the product formulation basis, usage level, function level of each ingredient etc.
(5) Use characters other than ingredient name or abbreviation which represent the product specialty as the product general name, shall conform to the 'Measures of Health Food Registration and Recording' and other rules.

3.5.2.3.3 The same applicant declare for different products, shall not use the same product name. For those need to label specific population or identify other necessary specialties, shall add brackets standardized annotation behind attribute name.

3.5.2.4 Product formula, label instruction book proposed ingredients, excipients, applicable population, non-applicable population, health function, suggested use and intake amount etc. shall consist with health function demonstration report and health function evaluation test materials.

3.6 Production Process Review

3.6.1 Responsibility of Production Expert Review Panel

(1) Review the production research material and the rationality of the production process of ingredient and product, as well as the attribute name of the review sample and product;
(2) Review the production process materials, excipients, specification of label instruction book, production process in product technical requirements, direct-contact product package materials, ingredients and excipients quality requirements related production contents etc.;
(3) Provide review suggestion for on-site inspection.

3.6.2 Content of Production Process Review

3.6.2.1 Production Process Research Materials

The research process and result shall be real and integrated, provide sufficient demonstration for the necessity, scientific, feasibility of each procedure and technology.

Research material shall conform to the below requirements:

(1) Review the rationality of product dosage form and specification according to formula composition, suggested use, compliance of applicable population, physical and chemical characteristics of ingredients/excipients. Disintegration, dissolution and other release model different from regular tablet, capsule, granule, powder, oral liquid etc. special dosage forms. Dosage form selection shall have sufficient and reasonable scientific basis.
(2) Review the rationality of excipients and its usages base on excipients safety, technical necessity, maintain product stability, no chemical changes with direct-contact product package materials, no effect on product test, dosage form creation and stability etc.
(3) Main production procedure and key technical parameters which affect product safety and health function shall be reasonable. Its optimized test design and optimization process shall be clear and reasonable. The necessity of technology shall be identified.
Key technology refers to the process which has direct affect on product quality safety or health function, and no need to adjust parameters if any objective changes exist in technical scale, production facility.

(4) Pilot production verification, research process of pilot production and technical amendments shall be integrated and qualified, and the research result shall be reasonable scientifically.
The production permission certified document of pilot sample production shop and production verification shop, and commission contract shall compliance with the regulation.
Domestic products shall provide production verification data and self-inspection report at least from three batches pilot or above level scales product. Production verification data shall verify production stability is controllable. Self-inspection report of pilot product includes all technical parameters of product requirements; product quality shall conform to the requirements.
(5) If the production research information of lab and pilot scales of the first time imported product is integrated, provide production verification data and self-inspection report at least from three scale-up batches product. If it's not integrated, provide production verification report and self-inspection report at least from ten scale-up batches product issued by oversea manufacturer or trader.
(6) For those ingredient without applicable national standard, local standard or industry standard, provide preparation technology, technology explanation and production reasonability basis.
(7) Processing aid used during product and ingredient manufacturing process shall conform to GB2760 national standard and relate rules.

3.6.2.2 Production Materials
Production flowchart and explanation, includes main procedures, key technical control points and key technical parameters and its explanation, shall conform to production research results.

3.6.2.3 Samples are delivered for review shall be integrated and without damages under the expiration date; shall be labeled the manufacturing date and manufacturer; the quality shall conform to national standard and product technical requirements, and also match with other contents in the application materials.

3.6.2.4 The attribute name of health food shall identify the classification or type of the product
If there is applicable national standard can be referred to, use the product classification attribution name of the national standard as the product attribute name; if there is no applicable national standard can be referred to, use the attribute name in the preparation general rules section of <Chinese Pharmacopoeia> as product attribute name.

3.6.2.5 Technical contents of excipients in product formula, specification, applicable population, non-applicable population of the label instruction book, technical requirements of the production process, direct-contact product package materials, quality requirements of ingredients and excipients shall conform to production related materials.

3.6.2.6 If the application materials are qualified, shall conduct on-site inspection for the authenticity and feasibility of the production process.

3.7 Product Technical Requirement Review

3.7.1 Responsibility of Product Technical Requirement Expert Review Panel

(1) Review product technical requirements research and functional component test report, hygiene test report and stability test report etc.
(2) Review product technical requirements materials and label instruction book proposed functional component and its content, specification, storage method, expiration date etc.
(3) Review the content of product technical requirements.

3.7.2 Content of Product Technical Requirement Review

3.7.2.1 Product Technical Requirement Research Materials shall conform to the below:

(1) The selection of the quality control index shall reflect product attribution and control product quality.
(2) The selection and creation basis of physical and chemical index shall be reasonable and conform to the current rules, technical guidelines and related national standards; shall also conform to formula, technology, product dosage form and other application materials.
Functional component index shall be the specific component of the main ingredient with stable properties and accurate quantity which associate with health function. For multi-ingredients composition product, shall consider the active component, specific component, extract technology, composition feature of each main ingredient of the formula, and select multiple functional component indexes. Functional component index shall conform to the formula, ingredient quality requirements, production process and other related application materials.
(3) The test method of each index in the product technical requirements shall be scientific, applicable and repeatable.
Test of physical and chemical index, microbial index shall conform to national standards, local standards, industry standards or technical guidelines; If sample pretreatment and test conditions are not identified, shall conduct research about those contents; if there is no applicable national standard, local standard, industry standard or technical guideline for test method, the registration applicant shall provide detailed test method and related research materials. Test method shall be scientific, applicable and repeatable.
The registration applicant shall provide detailed research materials about the functional component test method and its applicability and repeatability.
(4) The name, type, standardized number and standardized text of the direct-contact product package materials shall be integrated, the selection basis shall conform to the current rules.
(5) The quality requirements of ingredient and excipients shall be integrated, the creation basis shall be identified. If it has applicable national standards, local standards or industry standards, the quality requirements will not be lower than those standards. If the quality requirement is not needed, shall explain the reason.
(6) Provide comprehensive and accurate description if the product test method can be identified according to the product formula and its research results. All colorful photos and chromatogram generated by microscopic identification, TLC identification, color reaction shall reflect the identification results. Explain reasons if no identification items have been created.
(7) General food type product shall test and create net weight and allow negative tolerance index base on JJF 1070 rules; Weight deviation index shall conform to related rules if product dosage form listed in the preparation general rules section of <Chinese Pharmacopoeia>.

(8) Functional component test report, hygiene test report and stability test report of three batches samples shall conform to the current technical guidelines and national standards.
Test items shall be integrated; test method shall consist with the application materials; test results shall consist with technical requirements of product formula and production process; product quality shall be stable. Applicant shall conduct systematic analysis and determination for the stability test result, as well as analyze and demonstrate the storage method, direct-contact product package materials, expiration date etc.
Start from the issue date of the report, end up at the acceptance date of the registration application. The validity of functional component test report, hygiene test report and stability test report are 5 years.
(9) The content of product technical requirements shall be integrated; the index shall be reasonable and consist with research results.

3.7.2.2 Label instruction book proposed functional components and its content, specification, storage method, expiration date etc. shall consist with the related content of product technical research report, functional component test report, hygiene test report and stability test report.

3.7.2.3 If functional component test, hygiene test and stability test of those three batches samples are done by the registration applicant, shall conduct on-site inspection for the test ability for the applicant and self-test report.

3.8 Objections Handling and Inspection of Expert Review Panel Evaluation Report

3.8.1 After the review meeting, the review center shall verify and collect each expert review panel's review report. Draft review center conclusion according to the current rules, technical guideline and collect comments.

3.8.2 If the review center agrees with review suggestion from expert review panels, handle as below:
(1) Review suggestion is 'the application materials compliance to requirements' - shall send <Health Food On-site Inspection Notice Letter> to CFDA inspection center if need to conduct on-site inspection. The notice letter shall identify items and requirements of the inspection.
(2) Review suggestion is 'supplemental materials' – shall inform the registration applicant all contents need to supplement or correct at a time.
(3) Review suggestion is 'not grant the registration' – shall inform the registration applicant the reason and basis of the decision after get approval by the leader in charge of the review center.
(4) The review center informs the registration applicant to get <Review Suggestion Notice Letter> as below:
Contact number has been verified during the first-time registration. Send a text message to inform the applicant that they can get the <Review Suggestion Notice Letter> by acceptance number and login password; Get the product list of <Review Suggestion Notice Letter>from the review center homepage announcement.

3.8.3 If the review center disagrees with review suggestion from expert review panels, the review center shall conduct expert demonstration meeting to further demonstrate the issue after get approval from the leader in charge of the review center.
The handling process shall be recorded. Use the review center review conclusion as the basis of product comprehensive review suggestion and conclusion.

3.8.4 If the registration applicant has objections about 'not grant the registration' review suggestion, shall submit application for second review within 20 business days and also apply for second review defense at the same time. The content of second review will only focus on the original application items and application materials.

(1) For registration alternation application of new product and add health function, the review center shall organize those review experts who involve in 'not grant the registration' review suggestion to conduct second review and issue decision within 30 business days since the day receive the second review application.
Safety and health function expert review panel which involve in 'not grant the registration' review suggestion shall no less than 13 persons, respectively; Production and technical requirement expert review panel shall no less than 5 persons, respectively. Second review expert panel shall not include expert who used to issue 'not grant the registration' review suggestion.

(2) For other registration application such as supplementary materials, registration renewal, technology transfer, registration alternation (except add health function), safety and health function expert review panel which involve in 'not grant the registration' review suggestion shall no less than 7 persons, respectively; Production and technical requirement expert review panel shall no less than 3 persons, respectively.

(3) If the review center disagrees with the review suggestion issued by the second review expert panel, shall explain the reason and basis of review conclusion. Use Use the review center review conclusion as the basis of product comprehensive review suggestion and conclusion.

3.9 On-site Inspection and Retest

3.9.1 After receive the <Health Food Registration On-site Inspection Notice Letter>, the inspection center shall conduct the on-site inspection according to the requirements of the notice letter and related rules of registration on-site inspection. If use not finalized sample to do function and toxicity tests; or use samples from different batches to do population consumption evaluation test; or the registration applicant take self-test and issue functional component test report, hygiene test report and stability test report, shall inspect the production process of not finalized samples and different batches samples, as well as inspect the authenticity of the self-test report and self-test ability of the registration applicant.

3.9.2 If the on-site inspection conform to the requirement, shall transfer extracted samples, product technical requirements, sample receive receipt and other materials to the retest agency.

3.9.3 The inspection center shall notice and confirm the inspection status with the applicant after finish the on-site inspection. If the applicant has objections about issues founded during the

inspection, shall provide written explanation. The inspection center shall issue the inspection report with identified conclusion and deliver it to the review center according to the inspection status and applicant's explanation.

3.9.4 Retest agency shall conduct the operation strictly according to the test method of the application materials and related explanation; verify the scientific, repeatability, applicability of the test method; retest the product quality; issue retest report with identified conclusion and deliver the report to the review center.

3.10 Review of Supplementary Application Materials, Registration Renewal, Technology Transfer, Registration Alteration, Re-issue Certificate etc.

3.10.1 Registration Alteration – Add Health Function
Registration alternation of add health function shall provide health function demonstration report, health function evaluation test materials, population consumption evaluation materials, hygiene test report, altered label instruction book samples etc. according to new product registration application requirements. The review process will be conducted by health function expert review panel.

3.10.2 Supplementary Application Materials, Registration Renewal, Technology Transfer, Registration Alteration (except add health function), Re-issue Certificate etc.

3.10.2.1 The review center shall identify the reviewer, verifier, issuer and conduct the review after receive the application materials. The review center can organize related expert review panel to start the review if needed.

(1) If the application materials conform to the requirement and on-site inspection is needed, the review center shall issue <Health Food Registration On-site Inspection Notice Letter> to the inspection center; If on-site inspection is not needed, the review center shall draft comprehensive review comments and suggestion, and send those to CFDA;
(2) If suggest 'not grant the registration', shall inform the registration applicant the reason, basis of the decision, other contents need to supplemented or corrected after get approval by the leader in charge of the review center.
(3) If need supplemental materials after review the application of registration renewal, technology transfer, registration alteration (except add health function), re-issue certificate etc., shall inform the registration applicant all contents need to be supplemented or corrected at a time.

3.10.2.2 If the product which apply for technology transfer, registration alternation or registration renewal has been listed into health food raw material catalog and conform to related technical requirements, the review center shall issue terminate review written notice to the registration applicant. Also inform the applicants and original registrants of technology transfer, registration alternation or registration renewal to submit recording application to the recording department.

3.10.2.3 Functional component, hygiene, stability tests reports of technology transfer and alternation registration or product technical requirements whole item test report, test method of registration renewal shall consist with product technical requirement test method and related

explanation. Product quality shall be stable and controllable, the test result shall conform to the current rules, technical guidelines, mandatory national standard and product technical requirements. Also need to meet the following requirements:

(1) Technology Transfer Registration Application
Product formula, production process, label instruction book, technical requirements etc. materials consist with the original approved registration product.
If the transferee applies for change product name, the altered name shall conform to health food name rules;
If the technical review of technology transfer registration application materials is compliance, shall conduct on-site inspection and retest. Provide related proof documents to show that the manufacturing location and conditions are the same as the original registration, which will be exempt for conduct on-site inspection and retest.

(2) Alternation Registration Application (Except Add Health Function)
The necessity and reasonability basis of alternation is sufficient. Altered items will not cause any substantial changes for product safety, health function and quality controllability.
If the application materials of change specification, excipients, production process and technical requirements is compliance after the review, shall conduct on-site inspection and extract samples for retest. Although the reference standard of the technical requirements has been updated or replaced, still can be exempt from onsite-inspection and retest if there are no substantial changes happen to the standard.

(3) Registration Renewal Application
Production safety, health function and quality controllability are compliance.
Conduct manufacture before the expiration date of the registration certificate.

3.10.2.4 The review center shall verify the conclusion of on-site inspection and retest after receive those reports.

(1) If the on-site inspection conclusion and retest conclusion are compliance, the review center shall issue 'Approve Registration' review conclusion and suggestion.
(2) If the on-site inspection conclusion and retest conclusion are non-compliance, the review center shall issue 'disapprove Registration' written notice to the registration applicant.

3.11 Summarize technical review conclusions and suggestions

After finish the technical review, the review center shall collect review suggestions from joint discussion meeting and expert demonstration meeting, expert review panel report, on-site inspection report, retest report to create review center review report. The review center will have to issue 'Approve Registration' or 'Disapprove Registration' as comprehensive technical review conclusion and suggestion after it's been approved by the review center leader. Then deliver the decision to CFDA within 5 business days.

3.11.1 If the application materials review suggestion is 'conform to the requirements' and no need to conduct on-site inspection and retest or the on-site inspection and retest conclusions are qualified, the comprehensive review conclusion and suggestion shall be 'Approve Registration'. The review center shall draft the sample of health food approval certificate and its appendix, inform the applicant to verify the content by log into health food registration system online within 5 business

days. If the applicant didn't verify the content within 5 business days, it means that the applicant has no objections.

3.11.2 If the applicant didn't submit a second review application within required time limit, or maintain disapprove registration as review suggestion after the second review, the comprehensive review conclusion and suggestion shall be 'Disapprove Registration'.

3.12 Suggested Decision Principles of Technical Review

3.12.1 Meet the following requirements If the review suggestion is 'Application Materials Conform to the Requirements'

(1) The application materials are integrated;
(2) Product test data and reference basis support the product safety and the controllability of health function and quality;
(3) Ingredients and production process are reasonable, product technical requirements are applicable and repeatable, also conform to technical guidelines and mandatory national standards etc. current rules.
(4) Product name, formula, label instruction book contents, product technical requirements etc. materials shall be complete and compliance;
(5) The alternation reason and basis are reasonable which will not cause any substantial changes for product safety, health function and quality controllability.
(6) Safety, health function and quality controllability of registration renewal product conform to related rules and has been manufactured before the expiration date of the registration certificate.

3.12.2 If the scientific basis of product safety, health function and quality controllability are sufficient and meet one of the following situations, review suggestion shall be 'Supplementary Materials':

(1) Need supplementary research for the product instability key parameters;
(2) Need further explain about the determination basis of the content of label instruction book.
(3) Need further improve the application materials which not related the review suggestions of safety, health function quality controllability.

3.12.3 Review suggestion shall be 'Disapprove Registration' if meet one of the following situation:

(1) The content of application materials is contradictive, false or incomplete, which cannot proof the product safety, health function or quality controllability;
(2) Scientific basis is insufficient or application materials cannot support the product safety, health function or quality controllability;
(3) The Safety, health function evaluation materials of the product or ingredients do not conform to the current rules such as technical guidelines or national standard. Or the test result cannot fully support the product safety or health function;
(4) Product functional component test report, hygiene test report, stability test report, retest report or ingredients and excipients quality test report do not conform to the current rules and national standards, the product quality safety is hard to proof;

(5) Functional component test method is unreasonable, non-applicable or non-repeatable. Or research materials cannot fully proof the rationality, applicability and repeatability of the test method;
(6) Product stability test is unreasonable or non-compliance;
(7) Production process of the product and ingredients are unreasonable;
(8) Samples not conform to the application materials; the authenticity of the sample is hard to proof or the quality of sample is not qualified;
(9) New declared domestic product belong to supplements vitamins and minerals not conform to ingredient catalog inclusion standard and other related management rules;
(10) After supplementary materials, still cannot give a reasonable explanation of the content of label instruction book;
(11) The product formula, production process and other contents of the technology transfer application not consist with the original approval registration contents. Label instruction book and product technical requirements not conform to the current rules; or product safety, health function, quality controllability are non-compliance;
(12) The alternation registration application items caused substantial changes for the product quality, or the reasonability of the application items cannot be proved;
(13) The registration renewal product safety, health function and quality controllability basis is insufficient or non-compliance. Did not manufacture or sell within the expiration date of the registration certificate, or did not submit the registration renewal application on time;
(14) Resubmit the application after receiving the 'Disapprove Registration' decision but did not identify the reasons of the resubmission, or the reasons and basis of the resubmission are insufficient;
(15) Did not product supplementary materials or did not finish supplementary materials exceed the time limit;
(16) No more than four fifths experts in the expert demonstration panel share the same suggestion, cannot determine the product safety, health function or quality controllability;
(17) Conclusion of on-site-inspection or retest are non-compliance;
(18) Product belong to recording management system.

3.13 Review Time Limit

(1) The review center shall finish reviewing application materials within 60 business days. If necessary, another 20 days can be extended after it's been approved by the review center leader. If need supplementary materials from the applicant, the review time limit will be recalculated after the review center receive the supplementary materials.

(2) The review stagnate phase include wait for the applicant pick up review comments notice letter, wait for the applicant verify approval certificate sample, wait for the applicant submit supplementary materials, on-site inspection, retest, verification period, which are not calculated into the review time limit.

3.14 Communications

The review center shall build up communication rules which indicate the communication procedure and time arrangement about technical review suggestions between the registration applicant and the review center, also control the honest government risk during the communication.

The review center can be proactive to use phone, internet and other consultation ways to communicate with the registration applicant during the review process, which will promote the review quality and speed.

4 Administrative Inspection, Certificate Creation and Information Disclosure

4.1 Administrative Inspection

CFDA shall examine the validity, normativity and integrity of the review process and conclusion within 20 business days since sign after receiving comprehensive review conclusion and suggestion from the review center. CFDA also shall make a decision of 'Approve Registration' or 'Disapprove Registration'.

4.2 Certificate Creation

CFDA shall transfer the application materials to the acceptance institute within 3 business days since the decision date after making a decision of 'Approve Registration' or 'Disapprove Registration'.

The acceptance institute shall issue the health food registration certificate or 'Disapprove Registration' decision to the registration applicant within 10 business days. The acceptance institute shall take the original registration certificate back if alternation registration or registration renewal or technology transfer registration has been approved.

If the technology transfer has been approved, the acceptance institute shall grant new registration number and issue the new health food registration certificate, annul the original health food registration certificate.

If the registration renewal or alternation registration or re-issue certificate has been approved, keep the original registration number and grant a new health food registration certificate. For approved registration renewal and alternation registration, the original health food registration certificate has to be withdrawn.

The expiration date on the registration certificate of technology transfer, alternation registration or re-issue certificate shall be the same as the expiration date on the original certificate.

4.3 Information Disclosure

After the acceptance institute issue the health food registration certificate or 'Disapprove Registration' decision to the registration applicant, the review center shall submit the related product registration electronic information to CFDA information center through informatics system.

CFDA shall disclose the product registration certificate and its appendix, withdrawal or disapprove renewal etc. registration related information on time except any involving national secrets or trade secrets.

Appendix

CFDA Domestic Health Food

Registration Certificate（ Sample ）

Product Name			
Registrant			
Address of Registrant			
Approval Conclusion	According to the review, the product conform to the <Food Safety Law> and <Measures of Health Food Registration and Recording> , which can be approve to be registered.		
Registration Number	国食健注 G	Expiration Date	Y M D
Appendix	• Product instruction book • Product technical requirements		
Note	1. Alternation registration shall indicate: ****年**月**日，批准该产品“****”中 “****”变更为“****”。 2. Technology transfer shall indicate: ****年**月**日，批准该产品转让技术。转让方为****，产品名称****（注册号****）同时注销。 3.Re-issue certificate shall indicate: ****年**月**日，批准该产品补发证书。		

（Stamp with CFDA seal）

Y M D

CFDA Imported Health Food

Registration Certificate（ Sample ）

Product Name	Chinese name		
	English name		
Registrant	Chinese name		
	English name		
Address of Registrant			
Manufacturer	Chinese name		
	English name		
Country of Origin		Address	
Approval Conclusion	According to the review, the product conform to the <Food Safety Law> and <Measures of Health Food Registration and Recording> , which can be approve to be registered.		
Registration Number	国食健注 J	Expiration Date	Y M D
Appendix	• Product instruction book • Product technical requirements		
Note	1、Alternation registration shall indicate：****年**月**日，批准该产品“****”中 “****”变更为“****”。 2、Technology transfer shall indicate：****年**月**日，批准该产品转让技术。转让方为****，产品名称****（注册号****）同时注销。 3、Re-issue certificate shall indicate：****年**月**日，批准该产品补发证书。 (Attachment is allowed is no enough space)		

（Stamp with CFDA seal）

Y M D

附 1

CFDA

Health Food Product Instruction Book（Template）

国食健注

××××牌××××（Chinese Name）

【Ingredients】
【Excipients】
【Content of Functional Component】
【Applicable Population】
【Non-applicable Population】
【Health Function】
【Intake Amount and Suggested Use】
【Specification】
【Storage Method】
【Expiration Date】
【Warning】

附 2

CFDA

Health Food Product Technical Requirements（Template）

国食健注

××××××××（Product Chinese Name）

【Ingredients】

【Excipients】

【Production Process】本品经××、××、××、××、××、××等主要工艺加工制成。（其中，关键工艺应标注参数或参数合理范围）

【Type, name and standard of direct-contact product package materials】

【Sensory Requirements】应符合表 1 的规定。

表1 感官要求

项　　目	指　标
色 泽	
滋味、气味	
状 态	

【Identification】

1 microscopic identification ××××××××××××××。

2 TCL identification ××××××××××××。

3 chromatographic identification ××××××××××××。

【Physical and chemical index】应符合表 2 的规定。

表2 理化指标

项　　目	指　标	检测方法
×××，××	≤××	GB/T ××××
×××，××	≤××	GB/T ××××
×××，××	≤××	GB ××××
×××，××	≥××	GB ××××
×××，××	××～××	1 ×××的测定

1 ×××的测定

1.1 Equipment

1.1.1 ××××

1.1.2 ×××××

1.2 Reagent

1.2.1 ××××××××

1.2.2 ××××××××

1.2.3 Source and Purity of Standard Substance：××××

1.3 Chromatographic condition

1.3.1 ×××××××××

1.3.2 ××××××××××××××××××

1.3.3 ×××××××××

1.4 Preparation of Standard Substance Solution：××××××××××××××××××××××××××××××××××

1.5 Preparation of Sample Solution：××××××××××××××××××××××××

1.6 Test：××××××××××××××××××××××××××××××××××××

1.7 Result Calculation

$$X = \frac{A \times Cs \times V \times 100}{As \times m}$$

式中：

X—样品中××××××的含量，mg/100g；

A—样品中×××的峰面积；

Cs—标准溶液中×××××标准品的浓度，mg/mL；

As—标准溶液中×××××标准品的峰面积；

m—样品质量，g；

V—样品定容体积，mL。

【Microbe Index】应符合表 3 的规定。

表3 微生物指标

项　　目	指　标	检测方法
菌落总数，CFU/×	≤××	××××
大肠菌群，MPN/××	≤××	××××
霉菌和酵母，CFU/×	≤××	××××
金黄色葡萄球菌	≤0/25g	××××
沙门氏菌	≤0/25g	××××
××××	××××	××××

【Functional Component Index】应符合表 4 的规定。

表4 标志性成分指标

项　　目	指　标	检测方法
×××，××	≥××	GB/T ××××
×××，××	××～××	1 ×××的测定

1 ×××的测定

1.1 Theory：××

1.2 Reagent

1.2.1 ××××××××××××

1.2.2 ××××××××××××××××××××××××××

1.2.3 ××××××××××××××××××××××××××××

1.2.4 ××××××××××××××××××××××

1.2.5 Source and Purity of Standard Substance：×××××

1.3 Equipment

1.3.1 ××××××

1.3.2 ×××

1.3.3 ××××××××××

1.4 Preparation of Standard Curve：××××××××××××××××××××

1.5 Sample Preparation

1.5.1 ××

1.5.2 ××

1.6 Test：××

1.7 Result Calculation

$$X = \frac{W_1 - W_2}{M \times V_2/V_1 \times V_4/V_3}$$

式中：

X—样品中×××的含量，mg/mL；

W_1—样品测定液中×××的质量，mg；

W_2—样品空白液中×××的质量，mg；

M—取样量，mL；

V_1—××××，mL；

V_2—×××，mL；

V_3—××××××，mL；

V_4—×××，mL。

【Weight Deviation Index/Net Weight and Allow Negative Tolerance Index】

【Quality Requirement of Ingredients and Excipients】

1.×××××：应符合 GB ××××的要求。

2.×××：应符合 GB ×××××的要求。

3.×××：应符合 GB/T ××××的要求，且××××含量不得少于××，××含量不得多于××。

4.×××××：应符合 SB/T ×××××中一级品的要求。

5.××××××××：应符合 QB/T ××××的要求。

6.××××××

项　　目	指　标
感官要求	主要包括色泽、滋味、气味、性状、粒度（如需要）等等
含量	≥××
××	≤××
××××	≤××
×××××	≤××

7.×××提取物

项　　目	指　标
原料来源	××××××
制法	××、××、×××、×××（（应标注关键工艺参数或参数合理范围）
提取率（或得率）	××～××
感官要求	主要包括色泽、滋味、气味、状态等
××含量	≥××（或××～××）
水分	≤××
灰分	≤××
粒度	××××××××
铅	≤××
总砷	≤××
总汞	≤××
溶剂残留	≤××
农药残留	≤××
菌落总数	≤××
大肠菌群	≤××
霉菌和酵母	≤××
金黄色葡萄球菌	≤××
沙门氏菌	≤××

保健食品注册审评审批工作细则（2016 年版）

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保健食品注册审评审批工作细则（2016 年版）

1.总则

1.1 制定依据

为规范保健食品注册审评审批工作，根据《中华人民共和国食品安全法》、《保健食品注册与备案管理办法》（以下简称《办法》）等法律、法规和规章，制定本细则。

1.2 适用范围

本细则适用于使用保健食品原料目录以外原料的保健食品和首次进口的保健食品（不包括补充维生素、矿物质等营养物质的保健食品）新产品注册、延续注册、转让技术、变更注册、证书补发等的审评审批工作。

1.3 工作原则

保健食品注册审评审批工作应当坚持依法、科学、公正、高效的原则。

2.注册受理

2.1 材料审查

对申请事项属于保健食品注册范围并已完成保健食品注册申请系统填报的，受理机构收到申请材料后，应向注册申请人出具《申请材料签收单》，并在 5 个工作日内按照注册申请表注明的申请材料清单，逐项对申请材料的完整性和一致性进行审查。

2.1.1 国产新产品注册申请材料

2.1.1.1 证明性文件

（1）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；

（2）注册申请人主体登记证明文件复印件。

2.1.1.2 产品研发报告

2.1.1.2.1 安全性论证报告

（1）原料和辅料的使用依据；

（2）产品配方配伍及用量的安全性科学依据；

（3）对安全性评价试验材料的分析评价；

（4）对配方以及适宜人群、不适宜人群、食用方法和食用量、注意事项等的综述。

2.1.1.2.2 保健功能论证报告

（1）配方主要原料具有功能作用的科学依据，其余原料的配伍必要性；

（2）产品配方配伍及用量具有保健功能的科学依据；

（3）对产品保健功能评价试验材料、人群食用评价材料等的分析评价；

（4）对配方以及适宜人群、不适宜人群、食用方法和食用量等的综述。

2.1.1.2.3 生产工艺研究报告

（1）剂型选择和规格确定的依据；

（2）辅料及用量选择的依据；

（3）影响产品安全性、保健功能等的主要生产工艺和关键工艺参数的研究报告；

（4）中试以上生产规模的工艺验证报告及样品自检报告；

（5）无适用的国家标准、地方标准、行业标准的原料，应提供详细的制备工艺、工艺说明及工艺合理性依据；

（6）产品及原料工艺过程中使用的全部加工助剂的名称、标准号及标准文本；

（7）对产品生产工艺材料、配方中辅料、标签说明书的剂型、规格、适宜人群、不适宜人群项以及产品技术要求的生产工艺、直接接触产品的包装材料、原辅料质量要求项中的工艺内容等的综述。

2.1.1.2.4 产品技术要求研究报告

（1）鉴别方法的研究材料；

（2）各项理化指标及其检测方法的确定依据；

（3）功效成分或标志性成分指标及指标值的确定依据及其检测方法的研究验证材料；

（4）装量差异或重量差异（净含量及允许负偏差）指标的确定依据；

（5）全部原辅料质量要求的确定依据；

（6）产品稳定性试验条件、检测项目及检测方法等，以及注册申请人对稳定性试验结果进行的系统分析和评价；

（7）产品技术要求文本。

2.1.1.3 产品配方材料

（1）产品配方表；

（2）原辅料的质量标准、生产工艺、质量检验合格证明；

（3）必要时还应按规定提供使用部位的说明、品种鉴定报告等。

2.1.1.4 生产工艺材料

生产工艺流程简图及说明，关键工艺控制点及说明。

2.1.1.5 安全性和保健功能评价试验材料

（1）食品检验机构的资质证明文件；

（2）具有法定资质的食品检验机构出具的安全性评价试验材料；

（3）具有法定资质的食品检验机构出具的保健功能评价试验材料；

（4）具有法定资质的食品检验机构出具的人群食用评价材料（涉及人体试食试验的）；

（5）三批样品的功效成分或标志性成分、卫生学、稳定性试验报告（委托检验的，被委托单位应为具有法定资质的食品检验机构）；

（6）权威机构出具的菌种鉴定报告、具有法定资质的食品检验机构出具的菌种毒力试验报告等；

（7）具有法定资质的食品检验机构出具的涉及产品的兴奋剂、违禁药物成分等检测报告。

2.1.1.6 直接接触保健食品的包装材料的种类、名称和标准

直接接触保健食品的包装材料的种类、名称、标准号、标准全文、使用依据。

2.1.1.7 产品标签说明书样稿

应包括原料、辅料、功效成分或标志性成分含量、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。

2.1.1.8 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、产品名称与批准注册的保健食品名

称不重名的检索材料

（1）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、产品名称与批准注册的保健食品名称不重名的检索材料，应从国家食品药品监督管理总局网站数据库中检索后打印；

（2）以原料或原料简称以外的表明产品特性的文字，作为产品通用名的，应提供命名说明；

（3）使用注册商标的，应提供商标注册证明文件。

2.1.1.9 3 个最小销售包装样品

（1）包装应完整、无破损且距保质期届满不少于 3 个月；

（2）标签主要内容应与注册申请材料中标签说明书内容一致，并标注样品的生产日期、生产单位；

（3）进口产品应与生产国（地区）上市销售产品一致。

2.1.1.10 其他与产品注册审评相关的材料

（1）样品生产企业质量管理体系符合保健食品生产许可要求的证明文件复印件；

（2）样品为委托加工的，应提供委托加工协议原件；

（3）载明来源、作者、年代、卷、期、页码等的科学文献全文复印件。

2.1.1.11 属于补充维生素、矿物质等营养物质的国产产品注册申请材料

（1）补充的维生素、矿物质等营养物质，具有明确的中国居民膳食营养素推荐摄入量（RNI）或适宜摄入量（AI）；

（2）产品使用的原料质量标准应有适用的食品安全国家标准或卫生行政部门认可的适用标准。仅有《中华人民共和国药典》（以下简称《中国药典》）或中国药品标准的，原料应属已列入《食品安全国家标准 食品营养强化剂使用标准》（GB 14880）或卫生行政部门公告的营养强化剂；

（3）应按新产品注册申请要求，以及保健食品原料目录的纳入要求等有关规定，提交注册申请材料。其中，安全性评价试验材料和保健功能评价试验材料可以免于提供。

2.1.2 国产产品延续注册申请材料

2.1.2.1 证明性文件

（1）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；

（2）注册申请人主体登记证明文件复印件；

（3）保健食品注册证书及其附件复印件。

2.1.2.2 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

省级食品药品监督管理部门出具的注册证书有效期内保健食品生产销售情况的证明文件。

2.1.2.3 人群食用情况分析报告

注册申请人出具的反映产品食用安全性和保健功能的信息、消费者投诉及采取的措施等处理情况。

2.1.2.4 生产质量管理体系运行情况的自查报告

注册申请人出具的注册证书有效期内产品的生产、经营等行为是否违反相关法规的自查报告。

2.1.2.5 产品技术要求全项目检验报告

注册证书有效期内，具有法定资质的食品检验机构出具的一批次产品技术要求全项目检验报告。

2.1.3 国产产品变更注册申请材料

2.1.3.1 证明性文件

（1）变更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；

（2）注册申请人主体登记证明文件复印件；

（3）保健食品注册证书及其附件复印件。

2.1.3.2 变更的具体事项、理由和依据

分别列出变更前和变更后的具体事项，以及变更申请事项不导致产品安全性、保健功能、质量可控性发生实质性改变的研究分析报告，包括变更的必要性、合理性依据，与原申请材料的对比分析、相关试验数据以及科学文献依据等。

涉及更改产品配方表、标签说明书样稿、产品技术要求、生产工艺材料的，应提供修订后的相关材料。

根据具体变更事项，还应提供以下材料：

2.1.3.3 改变注册人自身名称、地址的变更申请

当地工商行政管理部门出具的注册人名称、地址已经变更的证明文件。

2.1.3.4 涉及公司吸收合并或新设合并的变更申请

（1）申请人合并前后营业执照的复印件；

（2）当地工商行政管理部门出具的合并、注销的证明文件；

（3）申请人与相关公司对产品注册证书所有权归属无异议的声明及其公证文件。

2.1.3.5 涉及公司分立成立全资子公司的变更申请

（1）申请人及其全资子公司营业执照的复印件；

（2）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；

（3）验资机构出具的将所有涉及保健食品的生产车间、设备设施、生产人员和产品注册证书等一并划入分立后全资子公司的验资证明文件；

（4）申请人同意将所有涉及保健食品的生产车间、设备设施、生产人员和产品注册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；

（5）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。

2.1.3.6 改变产品名称的变更申请

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、产品名称与批准注册的保健食品名称不重名的检索材料。以原料或原料简称以外的表明产品特性的文字，作为产品通用名的，还应提供命名说明。使用注册商标的，还应提供商标注册证明文件。

2.1.3.7 增加保健功能的变更申请

（1）拟增加保健功能的论证报告；

（2）拟增加保健功能的试验评价材料。需进行人体试食试验的，还应提供人群食用评价材料；

（3）拟增加保健功能试验用样品的卫生学试验报告。

2.1.3.8 改变产品规格、贮存方法、保质期、辅料、生产工艺以及产品技术要求其他内容的变更申请

三批样品的功效成分或标志性成分、卫生学、稳定性试验报告。产品技术要求中引用标准被更新、替代，标准内容未发生实质性更改的，可以免于提供三批样品的功效成分或标志性成分、卫生学、稳定性试验报告。

变更生产工艺的，还应提供文献依据、试验数据，对变更前后的工艺过程进行对比分析，证实工艺变更后产品的安全性、保健功能、质量可控性与原注册产品实质等同。

2.1.3.9 更改适宜人群范围、不适宜人群范围、注意事项或食用方法、食用量的变更申请

（1）改变适宜人群范围、不适宜人群范围、食用方法以及注意事项的变更申请，原注册申请时开展的安全性、保健功能评价试验以及卫生学、稳定性试验，不能充分支持更改后的适宜人群范围、不适宜人群范围、食用方法或注意事项等的，应补充开展安全性、保健功能评价试验或卫生学、稳定性试验；

（2）减少食用量的变更申请，应提供按照拟变更的食用量进行保健功能评价试验的试验报告；

（3）增加食用量的变更申请，应提供按照拟变更的食用量进行安全性评价试验的试验报告，以及拟变更的食用量与原食用量的保健功能评价试验比较分析报告；

（4）开展安全性、保健功能评价试验的，应同时提供具有法定资质的食品检验机构出具的试验用样品的卫生学试验报告。需进行人体试食试验的，还应提供伦理审查批件以及人群食用评价材料。

2.1.4 国产产品转让技术注册申请材料

2.1.4.1 证明性文件

（1）保健食品转让技术注册申请表，以及申请人对申请材料真实性负责的法律责任承诺书；

（2）转让方和受让方主体登记证明文件复印件；

（3）原注册证书及其附件复印件；

（4）经公证的转让合同以及转让方出具的注销原注册证书申请；

（5）样品生产企业质量管理体系符合保健食品生产许可要求的证明文件复印件、委托加工协议原件。

2.1.4.2 技术材料

（1）应按照新产品注册申请材料要求，提供产品配方材料、生产工艺材料、直接接触产品的包装材料、三批样品的功效成分或标志性成分、卫生学和稳定性试验报告、标签说明书样稿、3 个最小销售包装样品等材料；

（2）受让方申请改变产品名称的，应提交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、产品名称与批准注册的保健食品名称不重名的检索材料；以原料或原料简称以外的表明产品特性的文字，作为产品通用名的，还应提供命名说明。使用注册商标的，应提供商标注册证明文件；

（3）样品试制场地和条件与原注册时是否发生变化的说明。

2.1.5 证书补发申请材料

（1）证书补发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；

（2）注册申请人主体登记证明文件复印件；

（3）国产产品在注册人所在地的省、自治区、直辖市食品药品监督管理部门网站，进口产品在国家食品药品监督管理总局网站上发布的遗失声明的打印件，或损坏的保健食品注册证书原件。

2.1.6 进口产品注册申请材料

进口新产品、延续注册、变更注册、转让技术申请，除按国产产品提交相关材料外，还应提交：

（1）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；

（2）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；

（3）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和（或）标准原文；

（4）产品在生产国（地区）上市的包装、标签、说明书实样；

（5）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》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。

进口产品变更注册申请另需提供以下材料：

（1）变更后的产品包装和标签说明书实样、产品生产国（地区）政府主管部门或者法律服务机构出具的申请事项已变更的证明文件；

（2）进口产品改变注册人自身名称、地址的变更申请，还应提供产品生产国（地区）政府主管部门或者法律服务机构出具的该产品生产场地未变更的证明文件；

（3）进口产品注册人改变在中国境外生产场地的变更申请，不改变生产国或地区的，还应提供新生产场地所在国（地区）政府主管部门或者法律服务机构出具的允许该产品在该国（地区）生产销售的证明文件、产品在新生产场地所在国（地区）上市的包装和标签说明书实样、具有法定资质的食品检验机构出具的新生产场地生产的三批样品功效成分或标志性成分、卫生学、稳定性试验报告；同时改变生产国或地区的，另需按照转让技术注册提供相关材料。

2.2 材料补正

申请材料不齐全或者不符合法定形式的，受理机构应出具《申请材料补正通知书》，一次告知注册申请人需要补正的全部内容。

2.3 材料受理

（1）申请材料齐全、符合法定形式要求的，受理机构应当予以受理，并向注册申请人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《受理通知书》。

（2）国产保健食品新产品、延续注册、变更注册、转让技术、证书补发注册申请的受理编号分别为：国食健申 G+4 位年代号+4 位顺序号、国食健续 G+4 位年代号+4 位顺序号、国食健更 G+4 位年代号+4 位顺序号、国食健转 G+4 位年代号+4 位顺序号、国食健补 G+4 位年代号+4 位顺序号。

（3）进口保健食品新产品、延续注册、变更注册、转让技术、证书补发注册申请的受理编号分别为：国食健申 J+4 位年代号+4 位顺序号、国食健续 J+4 位年代号+4 位顺序号、国食健更 J+4 位年代号+4 位顺序号、国食健转 J+4 位年代号+4 位顺序号、国食健补 J+4 位年代号+4 位顺序号。

2.4 材料移交

（1）受理机构受理申请材料后，应在 3 个工作日内将申请材料一并送交国家食品药品监督管理总局保健食品审评中心（以下简称审评中心）。

（2）审评中心应在移交当日核实并填写《保健食品注册申请材料移交单》，签收申请材料。

3.技术审评

3.1 组织专家审查组

收到申请材料后，审评中心应当从审评专家库中随机抽取审评专家，组建专家审查组对申请材料进行审评。

3.1.1 专家审查组的组成

（1）专家审查组包括安全性专家审查组、保健功能专家审查组、工艺专家审查组、产品技术要求专家审查组。

（2）各专家审查组成员人数应为单数，设组长 1 人。

（3）安全性专家审查组由配方、毒理、工艺专家组成，专家人数不少于 7 人。

（4）保健功能专家审查组由配方、功能、工艺专家组成，专家人数不少于 7 人。

（5）工艺专家审查组由工艺专家组成，专家人数不少于 3 人。

（6）产品技术要求专家审查组由理化和标准专家组成，专家人数不少于 3 人。

3.1.2 专家审查组工作模式

（1）审评专家按专家审查组职责开展技术审评工作，根据法律法规、技术标准和审评要求提出技术审评意见，并对技术审评意见负责。

（2）专家审查组组长负责组织汇总组内专家审评意见，形成专家审查组审评报告，并对审评报告负责。

专家审查组审评报告，应当包括审评内容、审评意见、审评建议及依据、审评专家签字和审评日期等。

审评建议分为申请材料符合要求、补充材料、不予注册。

涉及多个专业的技术问题，需相关专家审查组共同研究讨论的，专家审查组组长提出讨论建议，明确讨论内容，审评中心负责组织召开合组讨论会，以合组讨论会意见作为提出产品审评建议的依据。

专家审评意见不一致或因技术争议问题无法提出审评建议的，由审评中心另行组织召开专家论证会，以专家论证会意见作为提出产品审评建议的依据。涉及对现行规定、国家标准等的解释，无法提出审评建议的，审评中心及时向有关部门协商明确相关解释后，重新组织专家审查组审评。

3.2 组织合组讨论会

3.2.1 合组讨论会的组成

合组讨论会专家由技术问题涉及的相关专家审查组专家组成，组长由建议合组讨论的专家审查组组长担任，设秘书 1 人。

3.2.2 合组讨论会工作模式

合组讨论会组长负责主持讨论，秘书负责汇总整理专家意见，经举手表决，全体专家签字，形成合组讨论会意见和审评建议。三分之二以上专家意见一致的审评意见和建议，作为形成各专家审查组审评报告的依据。未形成三分之二以上专家一致意见的，应详细记录无法作出审评建议的原因，提出组织专家论证会的建议，审评中心另行组织专家论证会对争议问题进行论证。

3.3 组织专家论证会

3.3.1 专家论证会的组成

专家论证会由争议问题涉及的相关专家审查组专家组成，组长由主要论证问题相关专业的专家担任，设秘书 1 人。安全性、保健功能专家审查组人数分别不少于 13 人，工艺、产品技术要求专家审查组人数分别不少于 5 人。

3.3.2 专家论证会工作模式

专家论证会组长负责主持讨论，秘书负责汇总专家意见，经举手表决，全体专家签字，形成专家论证会审评意见和建议。五分之四以上专家意见一致的审评意见和建议，作为形成专家审查组审评报告的依据，合并前次产品审评意见，形成专家审查组审评报告。未形成五分之四以上专家一致意见，无法对产品安

全性、保健功能或质量可控性作出判断的，合并前次产品审评意见，形成专家审查组审评报告，审评建议为不予注册。

3.4 安全性审评

3.4.1 安全性专家审查组审评职责

3.4.1.1 安全性审查组配方专家审评职责

（1）对原料的使用依据、保健食品新原料的安全性评估材料、配方配伍和用量的理论依据和文献依据等安全性论证报告相关内容进行审评；

（2）对产品安全性、产品配方以及标签说明书样稿拟定的适宜人群、不适宜人群、食用量和食用方法、注意事项等相关内容进行审评。

3.4.1.2 安全性审查组毒理专家审评职责

（1）对新原料的安全性评估材料和毒理学试验报告，产品安全性试验评价材料及其论证报告相关内容进行审评；

（2）对产品安全性及产品标签说明书样稿拟定的适宜人群、不适宜人群、食用量和食用方法、注意事项等相关内容进行审评；

（3）对非定型包装样品的试制现场核查提出建议。

3.4.1.3 安全性审查组工艺专家审评职责

（1）研判原料的生产工艺是否采用可能导致物质基础发生重大改变的非常规工艺；

（2）研判产品的生产工艺是否采用可能导致物质基础发生重大改变的非常规工艺。

3.4.2 产品安全性审评内容

3.4.2.1 产品安全性论证报告

（1）应按照普通食品（包括可用于普通食品的物品、食品添加剂，下同）、新食品原料、“按照传统既是食品又是中药材的物质”、“拟纳入保健食品原料目录”以及保健食品新原料等类别，明确原料的使用依据。

（2）产品配方配伍及用量理论依据、文献依据和试验数据应支持产品的安全性。配伍使用应无传统配伍禁忌，现代医学药理学研究应未发现食用安全性问题。配方原料的品种、等级、质量、用量及个数应符合有关规定。

（3）涉及的保健食品新原料安全性评估材料和毒理学试验报告以及菌种鉴定报告和菌种毒力试验报告、产品的安全性评价试验等，应充分支持产品的安全性。

（4）应根据原料的使用依据、产品配方配伍及用量的科学依据、安全性评价试验材料等，确定配方以及标签说明书拟定的适宜人群、不适宜人群、食用方法和食用量、注意事项等的合理性。

3.4.2.2 保健食品新原料的安全性评价

3.4.2.2.1 保健食品新原料包括：

（1）普通食品、新食品原料、“按照传统既是食品又是中药材的物质”和“拟纳入保健食品原料目录”以外的原料；

（2）普通食品、新食品原料、“按照传统既是食品又是中药材的物质”和“拟纳入保健食品原料目录”中的物品，采用导致物质基础发生重大改变的工艺生产的原料。

3.4.2.2.2 应参照新食品原料安全性审查的有关规定，提供保健食品新原料的研制报告、国内外的研究利用情况等安全性评估材料和毒理学试验报告、生产工艺、质量要求、检验报告。

研制报告应依据充分，研制过程科学；应依据国内外的研究利用情况等安全性评估材料，确定毒理学评价试验要求；毒理学评价报告、生产工艺、质量要求应符合食品安全标准和有关规定；各成分含量应当在预期摄入水平下对健康不产生危害。

3.4.2.3 产品的安全性评价试验

产品安全性评价试验的样品以及试验项目、设计、操作、结果、结论、报告格式等，应符合现行规定、技术规范及以下要求：

3.4.2.3.1 产品的安全性评价试验项目要求

（1）以普通食品、新食品原料、按照传统既是食品又是中药材的物质为原料，采用水提等传统食品生产工艺生产、食用方法与传统食用方法相同，且原料推荐食用量为常规用量或符合国家相关食品用量规定的保健食品，注册申请人可以申请免于提供产品的安全性评价试验材料；

（2）以使用依据符合保健食品原料管理有关规定的物品为原料，采用常规工艺生产的保健食品，应当至少进行急性经口毒性试验、三项遗传毒性试验、28 天经口毒性试验。根据试验结果决定是否增加 90 天经口毒性试验、致畸试验和生殖毒性试验、慢性毒性和致癌试验及代谢试验；

（3）产品的生产工艺采用导致物质基础发生重大改变的非常规工艺的，应参照新食品原料安全性审查的有关要求开展产品的安全性评估和毒理学评价试验。

3.4.2.3.2 产品的安全性评价试验用样品要求

（1）样品的名称、规格、感官、剂型、保质期、生产企业，以及试验报告的试验申请人、研发人、研发单位、研发时间等信息，应与注册申请材料的相应内容一致，样品的来源应清晰；

（2）原则上，试验应使用完整包装的样品；因检验工作需要确需使用非定型样品的，应提供非定型样品的生产和处理过程，以及食品检验机构出具样品处理的具体要求及必要性和合理性说明；

（3）菌种鉴定报告以及菌种毒力试验报告用菌种，应源自试验样品使用的原料，或提供与试验样品使用的原料具有明确一致性的证明材料，真实反映试验样品使用原料的菌种和产毒能力。

3.4.2.3.3 自报告签发之日起至注册申请受理之日止，产品的安全性评价试验报告有效期为 5 年。

3.4.2.4 产品配方、标签说明书样稿拟定的适宜人群、不适宜人群、食用方法和食用量、注意事项等应与安全性论证报告、安全性评价试验材料相符。

3.5 保健功能审评

3.5.1 保健功能专家审查组审评职责

3.5.1.1 保健功能审查组配方专家审评职责

（1）对配方主要原料功能依据、其他原料的配伍必要性、配方配伍用量及其理论依据和文献依据等保健功能论证报告相关内容进行审评；

（2）对产品功能声称、产品配方、商标名、通用名以及标签说明书样稿拟定的原料、辅料、适宜人群、不适宜人群、食用方法和食用量等进行审评。

3.5.1.2 保健功能审查组功能专家审评职责

（1）对产品的保健功能评价试验材料、人群食用评价材料、保健功能论证报告等相关内容进行审评；

（2）对标签说明书样稿拟定的适宜人群、不适宜人群、食用方法和食用量等进行审评；

（3）保健功能动物试验使用非定型样品，人群食用评价试验使用与保健功能动物试验、安全性评价试验不同批次样品的，对样品的试制现场核查提出建议。

3.5.1.3 保健功能审查组工艺专家审评职责

研判产品和原料的生产工艺、物质基础、食用方法和食用量、剂型、规格等与产品的功能依据是否相符。

3.5.2 产品保健功能审评内容

3.5.2.1 保健功能论证报告

（1）产品配方原料应具有明确的使用目的。配方主要原料具有功能作用的科学依据应充足，其余原料的配伍必要性应明确。

以经简单加工的普通食品为原料的，应提供充足的国内外实验性科学文献依据，重点明确所用原料的功效成分和含量以及量效关系。

（2）产品组方原理应明确清晰，产品配伍及用量具有声称功能的理论依据及文献依据应充足，配伍使用应有助于协同发挥保健功能。

（3）根据产品配方配伍及用量具有申报功能的科学依据、保健功能评价试验材料、人群食用评价材料等，确定产品配方、产品标签说明书拟定的原料、辅料、适宜人群、不适宜人群、保健功能、食用方法和食用量等的合理性。

3.5.2.2 保健功能评价试验材料和人群食用评价材料的样品来源、检测项目、试验操作和结论等，应符合相关规定。

试验或检验涉及的程序、方法、样品、报告等，应符合以下要求：

（1）进行保健功能人体试食试验之前，应当先完成必要的安全性评价试验、动物功能试验、卫生学试验。取得试验机构伦理委员会的伦理审查批件，同意开展人体试食试验的，方可按照人体试食试验规程等有关规定进行保健功能人体试食试验。伦理审查批件内容应包括：批件号、审查试验项目名称、申请人名称、试验机构名称、审查决定的明确阐述、伦理委员会的其他建议和要求、审查决定的日期、主任委员（或授权者）签名、伦理委员会盖章等。

（2）保健功能评价动物试验、产品安全性评价试验应在同一家试验机构进行。

（3）保健功能动物试验、安全性评价试验应该使用同一样品，并为功效成分或标志性成分试验、卫生学试验、稳定性试验用样品之一。

人群食用评价试验应使用与保健功能动物试验、安全性评价试验同批次的完整包装样品。特殊情况，人群食用评价试验用样品不能使用保健功能动物试验、安全性评价试验同批次样品的，应说明理由并提供不同批次样品的生产工艺和样品质量一致性证明材料以及该试验机构出具的卫生学试验报告。

（4）自报告签发之日起至注册申请受理之日止，保健功能评价动物试验、人群食用评价试验报告有效期为 5 年。

3.5.2.3 产品商标名和通用名应符合《办法》等规定及以下要求。

3.5.2.3.1 保健食品商标名

应以文字标示，使用注册商标的，在商标名后加“牌”或在商标名右上角加“®”；使用非注册商标的，在商标名后加“牌”，使用的非注册商标名应符合《办法》等命名有关规定。一个产品只允许使用一个商标名。

3.5.2.3.2 保健食品通用名

（1）以原料名称命名的，使用的原料名称应规范。原料名称应与国家标准规定的内容一致；没有国家标准的，应与地方标准、行业标准等规定的内容一致；

（2）以原料简称命名的，其简称不能产生歧义，或组合成违反其他命名规定的含义；

（3）单一原料产品应以原料或原料简称命名；

（4）复配产品以部分原料的名称或简称命名的，应结合产品配方依据、各原料功效主次、用量高低等，选用适宜种类和数量的原料名称或简称命名；

（5）以原料或原料简称以外的表明产品特性的文字，作为产品通用名的，产品通用名应符合《办法》等的命名规定。

3.5.2.3.3 同一申请人申报的不同产品，不得使用相同的产品名称。必须标注特定人群或区分其他必要特性的，应在属性名后加括号规范标注。标注的特定人群或其他必要特性应有充足的依据。

3.5.2.4 产品配方、标签说明书样稿拟定的原料、辅料、适宜人群、不适宜人群、保健功能、食用方法和食用量等内容应与保健功能论证报告、保健功能评价试验材料相符。

3.6 生产工艺审评

3.6.1 工艺专家审查组审评职责

（1）对生产工艺研究材料以及原料和产品生产工艺的合理性、送审样品、产品属性名进行审评；

（2）对生产工艺材料、产品配方中辅料、标签说明书的规格、适宜人群、不适宜人群项以及产品技术要求中生产工艺、直接接触产品的包装材料、原辅料质量要求项中涉及的工艺内容等进行审核确定；

（3）对现场核查提出审评建议。

3.6.2 生产工艺审评内容

3.6.2.1 生产工艺研究材料

研究过程和结果应真实完整，应提供依据对各工序和使用技术的必要性、科学性、可行性进行充分论证。

研究材料应符合以下要求：

（1）应根据配方组成、食用方法、适宜人群食用的依从性、原辅料的理化性质等方面，对产品的剂型和规格的合理性进行审评。崩解、溶散等物质释放方式异于一般片剂、胶囊、颗粒、粉剂、口服液等的特殊剂型，剂型选择的科学依据应充足、合理。

（2）从辅料的安全性、工艺必要性、保持产品稳定、与直接接触产品的包装材料不发生化学变化、不影响产品的检测、制剂成型性和稳定性等方面，对辅料及用量的合理性进行审评。

（3）影响产品安全性、保健功能的主要生产工序和关键工艺参数应合理，其优选试验设计和优选过程应清晰、合理，工艺的必要性应明确。

关键工艺是指产品生产过程中，对产品质量安全或保健功能有直接影响，不随着工艺规模、生产设备等客观变化必须进行参数调整的工艺。

（4）中试生产工艺验证、中试生产工艺流程及工艺修正的研究过程应完整、规范，研究结果应科学合理。

中试样品生产车间和工艺验证车间的生产许可证明文件、委托合同等相关材料应合规、完整。

国产产品应提供至少 3 批中试及以上规模产品的生产验证数据及自检报告。生产验证相关数据应能验证产品工艺稳定可控。中试产品自检报告应包括产品技术要求全部技术指标，产品质量应符合产品技术要求。

（5）首次进口产品的小试、中试工艺研究资料完整的，应提供至少 3 批规模化产品生产验证数据及自检报告；小试、中试工艺研究资料缺失或不完整的，应提供国外生产厂商出具的 10 批次以上规模化产品生产验证报告及自检报告。

（6）无适用的国家标准、地方标准、行业标准的原料，应提供详细的制备工艺、工艺说明及工艺合理性依据。

（7）产品及原料生产过程中使用的加工助剂应符合 GB 2760 及相关规定。

3.6.2.2 生产工艺材料

生产工艺流程简图及说明，应包括主要工序、关键工艺控制点及关键工艺参数等及其说明，应与生产工艺研究结果相符。

3.6.2.3 送审样品包装应完整、无破损且在保质期内，应标注样品的生产日期、生产单位，样品质量应符合国家相关标准及产品技术要求的规定,并与申请材料其他内容相符。

3.6.2.4 保健食品的属性名应表明产品的类别或形态

产品属性名有适用的国家标准的，应按照国家标准的产品分类属性名命名；产品属性名无适用的国家标准的，应按照《中国药典》制剂通则规定的属性名命名。

3.6.2.5 产品配方中辅料、标签说明书的规格、适宜人群、不适宜人群项以及产品技术要求的生产工艺、直接接触产品的包装材料、原辅料质量要求项中涉及的工艺内容等应与生产工艺相关材料相符。

3.6.2.6 申请材料符合要求后，应对产品生产工艺的真实性、可行性进行现场核查。

3.7 产品技术要求审评

3.7.1 产品技术要求专家审查组审评职责

（1）对产品技术要求研究以及功效成分或标志性成分、卫生学、稳定性试验报告等进行审评；

（2）对产品技术要求材料以及标签说明书样稿拟定的功效成分或标志性成分及含量、规格、贮藏方法、保质期等进行审评；

（3）审核确定对产品技术要求内容。

3.7.2 产品技术要求审评内容

3.7.2.1 产品技术要求研究材料应符合以下要求：

（1）产品技术要求中质量控制指标的选择应反映产品的真实属性，达到控制产品质量的目的。

（2）理化指标及指标值的选择和制定依据应合理，符合现行规定、技术规范和国家相关标准等的规定，并与配方、工艺、产品剂型（形态）等申请材料相关内容相符。

功效成分或标志性成分指标应为主要原料含有的性质稳定、能够准确定量、与产品保健功能具有明确相关性的特征成分。多原料组方产品，应综合考虑配方各主要原料所含的活性成分、特征成分、提取工艺、组方特点等情况，选择制定多个功效成分或标志性成分指标。功效成分或标志性成分指标值应与配方、原料质量要求、生产工艺等申请材料相关内容相符。

（3）产品技术要求中各指标检测方法应符合科学性、适用性和重现性的要求。

理化指标、微生物指标等的检测，应采用适用的国家标准、地方标准、行业标准或技术规范等检测方法；引用的国家标准、地方标准、行业标准或技术规范等检测方法中，样品前处理、检测条件等未明确的，应重点对未明确的内容进行研究明确；无适用的国家标准、地方标准、行业标准或技术规范等检测方法的，注册申请人应提供详细的检测方法以及检测方法的适用性、重现性等方法学研究材料，检测方法应科学、适用、重现。

注册申请人应提供详细的功效成分或标志性成分检测方法以及检测方法的适用性、重现性等方法学研究材料，检测方法应科学、适用、重现。

（4）直接接触产品的包装材料的名称、种类、标准号和标准文本应完整，选择依据应符合现行规定。

（5）原辅料的质量要求应完整，制定依据应明确。有适用的国家相关标准、地方标准、行业标准等的，其质量要求不得低于国家相关标准、地方标准、行业标准等的规定。原辅料质量要求内容有缺项难以或无需制定的，应说明原因。

（6）根据产品配方及相关研究结果等可以确定产品的鉴别方法的，应予以全面、准确地阐述。采用显微鉴别、色谱鉴别、颜色反应等的，提供的彩色照片、色谱图等，应能真实反映鉴别结果。未制定鉴别项的，应说明未制定的理由。

（7）普通食品形态产品应检测并制定净含量及允许负偏差指标，指标应符合《定量包装商品净含量计量检验规则》（JJF 1070）规定；《中国药典》“制剂通则”项下有相应要求的产品剂型，装量差异或重量差异指标应符合要求。

（8）三批样品的功效成分或标志性成分、卫生学、稳定性试验报告应符合技术规范及国家标准等现行规定。

检测项目应完整，检验方法应与申请材料中的测定方法以及相关说明一致，检测结果应与产品配方、生产工艺等技术要求相关内容相符，产品质量应稳定。申请人对稳定性试验结果进行的系统分析和判断，以及对贮藏方法、直接接触产品的包装材料、保质期等进行的综合分析论证应科学合理。

自报告签发之日起至注册申请受理之日止，功效成分或标志性成分、卫生学、稳定性试验报告有效期为 5 年。

（9）产品技术要求内容应完整，指标及指标值的设定应合理并与研究结果一致。

3.7.2.2 标签说明书样稿拟定的功效成分或标志性成分及含量、规格、贮藏方法、保质期等，应与产品技术研究、功效成分或标志性成分、卫生学、稳定性试验报告等相关内容相符。

3.7.2.3 三批样品的功效成分或标志性成分、卫生学、稳定性试验为注册申请人自检的，应对注册申请人检测能力以及自检报告真实性现场核查提出建议。

3.8 专家审查组审评报告审核及异议处理

3.8.1 审评会议结束后，审评中心应对各专家审查组审评报告进行审核和汇总，根据现行规定、技术规范和汇总意见，形成审评中心审核结论。

3.8.2 审评中心同意专家审查组审评建议的，应按以下要求处理：

（1）审评建议为申请材料符合要求，按规定需要开展现场核查的，应向国家食品药品监督管理总局食品药品审核查验中心（以下简称核查中心）发出《保健食品现场核查通知书》，核查通知中应当明确核查的具体事项和要求。

（2）审评建议为补充材料的，应一次告知注册申请人需要补正的全部内容。

（3）审评建议为拟不予注册的，经审评中心主管领导批准后，告知注册申请人拟不予注册的理由、依据以及需要补正的其他内容。

（4）审评中心通过以下方式告知注册申请人领取《审评意见通知书》电子审评意见：

通过首次注册时验证的联系方式，以短信形式告知申请人凭受理编号及登录密码领取《审评意见通知书》电子审评意见；在审评中心主页公告领取《审评意见通知书》电子审评意见的产品名单。

3.8.3 审评中心不同意专家审查组审评建议的，经审评中心主管领导批准后，审评中心应组织召开专家论证会，对争议问题进一步论证。

审评中心不同意专家论证会审评建议的，应详细记述争议问题的处理过程，以审评中心审核结论作为作出产品综合审评结论和建议的依据。

3.8.4 注册申请人对拟不予注册的审评建议有异议的，应在 20 个工作日内提出复审申请，可以同时申请复审答辩。复审的内容仅限于原申请事项及申请材料。

（1）新产品、增加保健功能的变更注册申请，自受理复审申请之日起 30 个工作日内，审评中心应当组织拟不予注册审评建议涉及的复审专家审查组进行审评并作出复审决定。

拟不予注册审评建议涉及的安全性、保健功能专家审查组人数分别不少于 13 人，工艺、产品技术要求专家审查组人数分别不少于 5 人。复审专家审查组应不包括原作出不予注册审评建议的专家。

（2）补充材料、延续注册、转让技术、增加保健功能以外的其他变更注册等注册申请，复审专家审查组中拟不予注册审评建议涉及的安全性、保健功能专家审查组人数分别不少于 7 人，工艺、产品技术要求专家审查组人数分别不少于 3 人。

（3）审评中心不同意复审专家审查组审评建议的，应详细说明作出审核结论的理由和依据，以审评中心审核结论作为作出产品综合审评结论和建议的依据。

3.9 现场核查和复核检验

3.9.1 收到《保健食品注册现场核查通知书》后，核查中心应按照核查通知的要求及注册现场核查有关规定开展现场核查。涉及功能、毒理试验使用非定型样品、人群食用评价试验使用不同批次样品以及功效成分或标志性成分、卫生学、稳定性试验报告为注册申请人自检的，还应分别对使用的非定型样品和不同批次样品的工艺过程，自检报告真实性和注册申请人自检能力等进行核查。

3.9.2 现场核查符合要求的，应抽取下线样品，向复核检验机构移交样品、产品技术要求及样品接收单等材料。

3.9.3 现场核查结束后，核查中心应当应将核查情况向申请人通报并确认。申请人对于核查中发现的问题有异议的，应当提供书面说明。核查中心应当根据核查情况及申请人的说明，出具结论明确的核查报告，报送审评中心。

3.9.4 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，对产品质量进行复核检验，出具结论明确的复检报告，报送审评中心。

3.10 补充材料、延续注册、转让技术、变更注册、证书补发等申请的审评

3.10.1 增加保健功能变更注册

增加保健功能的变更申请，应按照新产品注册申请的要求，提供保健功能论证报告、保健功能评价试验材料、人群食用评价材料、卫生学试验报告、变更后的标签说明书样稿等材料。增加保健功能的变更申请应当由保健功能专家审查组进行审评。

3.10.2 补充材料、延续注册、转让技术、变更注册（增加保健功能除外）、证书补发等申请

3.10.2.1 收到申请材料后，审评中心应明确审评人、复核人、签发人，组织进行审评。需要提交专家审查组审查的，审评中心可以组织相关领域专家审查组进行审查。

（1）申请材料符合要求，涉及现场核查的，应当向核查中心发出《保健食品注册现场核查通知书》；不涉及现场核查的，应形成综合审评意见和建议，报送国家食品药品监督管理总局；

（2）建议不予注册的，经审评中心主管领导批准后，应当告知注册申请人拟不予注册的理由、依据以及需要补正的其他内容；

（3）延续注册、转让技术、变更注册（增加保健功能除外）、证书补发审评后需要补充材料的，应一次告知注册申请人需要补正的全部内容。

3.10.2.2 转让技术、变更注册、延续注册申请产品已经列入保健食品原料目录，并符合相关技术要求的，审评中心应向注册申请人发出中止审评的书面通知，并告知转让技术、变更注册、延续注册申请人以原注册人为备案申请人按程序向备案部门提出备案申请。

3.10.2.3 转让技术、变更注册的功效成分或标志性成分、卫生学、稳定性试验报告或延续注册的产品技术要求全项目检验报告，检验方法应与产品技术要求的测定方法以及相关说明一致，产品质量应稳定可控，检验结果应符合现行规定、技术规范、强制性国家标准和产品技术要求的规定。还应符合以下要求：

（1）转让技术注册申请

产品配方、生产工艺、标签说明书、产品技术要求等材料，应与原批准注册产品一致。

受让方申请改变产品名称的，变更后产品名称应符合保健食品命名规定。

转让技术注册申请材料经技术审评符合要求后，应开展试制现场核查及复核检验。样品试制场地和条件与原注册时未发生变化的，提供相关证明文件，可以免于进行试制现场核查及抽样复检。

（2）变更注册申请（增加保健功能除外）

变更的必要性、合理性依据充足，变更事项不导致产品安全性、保健功能和质量可控性发生实质性更改。

变更规格、辅料、生产工艺以及产品技术要求其他内容的申请材料经审评符合要求后，应开展现场核查并抽取下线样品封样送复核检验。产品技术要求中引用标准被更新、替代，标准内容未发生实质性更改的，可以免于开展现场核查及抽样复检。

（3）延续注册申请

产品的安全性、保健功能和质量可控性符合要求。

注册证书有效期内进行过生产销售。

3.10.2.4 收到现场核查报告、复核检验报告后，审评中心应对现场核查结论和复核检验结论进行审核。

（1）现场核查结论、复核检验结论均为“符合要求”的，应作出“予以注册”的综合审评结论及建议。

（2）现场核查结论或复核检验结论为“不符合要求”的，应当向注册申请人发出拟不予注册的书面通知。

3.11 综合技术审评结论及建议

技术审评结束后，审评中心应汇总合组讨论会和专家论证会审评建议、专家审查组审评报告、现场核查报告、复核检验报告，形成审评中心审评报告，报审评中心主管领导批准后，作出“予以注册”或“不予注册”的综合技术审评结论和建议，在 5 个工作日内报送国家食品药品监督管理总局。

3.11.1 申请材料审评建议为符合要求，按规定无需开展现场核查及复核检验，或现场核查结论及复核检验结论均为符合要求的，综合审评结论及建议应为“予以注册”。审评中心应拟定保健食品批准证明文件及附件样稿，通知申请人在 5 个工作日内登录保健食品注册系统进行校核确认。未在 5 个工作日内校核确定的，视为申请人对拟定的保健食品批准证明文件及附件样稿无异议。

3.11.2 申请人未在规定时限内提出复审申请，或经复审维持不予注册建议的，综合审评结论及建议应为“不予注册”。

3.12 技术审评建议判定原则

3.12.1 审评建议为“申请材料符合要求”的，应符合以下要求：

（1）申请材料完整；

（2）产品试验数据和文献依据充分支持产品的安全性、保健功能和质量可控性；

（3）原料及产品的生产工艺合理可行，产品技术要求适用、可复现并符合技术规范、强制性国家标准等现行规定；

（4）产品名称、配方、标签说明书样稿主要内容、产品技术要求等材料规范完善并符合规定；

（5）变更注册产品的变更理由和依据充分合理，不导致产品安全性、保健功能和质量可控性发生实质性改变；

（6）延续注册产品的安全性、保健功能和质量可控性符合要求，在注册证书有效期内进行过生产销售。

3.12.2 产品安全性、保健功能和质量可控性科学依据应充足，并符合以下情况之一的，审评建议应为“补充材料”：

（1）需要对产品的非稳定性重点考察指标进行补充研究的；

（2）需要对标签说明书中适宜人群范围、不适宜人群范围等内容的确定依据进一步说明的；

（3）需要对不涉及安全性、保健功能、质量可控性审评建议的申请材料进一步规范完善的。

3.12.3 符合下列情况之一的，审评建议应为“不予注册”：

（1）申请材料内容矛盾、不符，真实性难以保证或者内容不完整，无法证实产品安全性、保健功能或质量可控性的；

（2）科学依据不充足或申请材料无法保证产品安全性、保健功能或质量可控性的；

（3）产品或原料的安全性、保健功能评价试验材料不符合技术规范、国家标准等现行规定，或者试验结果不能充分支持产品的安全性或保健功能的；

（4）产品功效成分或标志性成分、卫生学、稳定性试验报告、复核检验报告或原辅料质量检验报告不符合现行规定、国家相关标准，产品质量安全难以保证的；

（5）功效成分或标志性成分检测方法不合理、不适用、不能复现或方法学研究资料不能充分证明检测方法合理性、适用性和重现性的；

（6）产品稳定性试验不合理或不符合规定的；

（7）产品或原料的生产工艺不合理的；

（8）送审样品与申请材料明显不符，样品真实性难以保证，或样品质量不合格的；

（9）属补充维生素、矿物质等营养物质的新申报国产产品，不符合原料目录纳入标准等相关管理规定的；

（10）经补充材料，仍未对标签说明书中适宜人群范围、不适宜人群范围等内容的确定依据作出合理解释的；

（11）转让技术申请产品的配方、工艺等内容与原批准注册内容不一致，标签说明书和产品技术要求等不符合现行规定或产品安全性、保健功能、质量可控性不符合要求的；

（12）变更注册申请事项导致产品质量发生实质性改变，或不能充分证明变更申请事项合理性的；

（13）延续注册产品的安全性、保健功能和质量可控性依据不足或者不符合现行规定，注册证书有效期内未生产销售，或未在规定时限内提交延续申请的；

（14）收到不予注册的决定后重新提出的注册申请，未针对不予注册的原因提供重新注册申请的理由，或重新注册申请的理由和依据不充足的；

（15）逾期未提供补充材料或者未完成补正的；

（16）专家论证会未形成五分之四以上专家一致意见，无法对产品安全性、保健功能或质量可控性作出判断的；

（17）现场核查或复核检验结论为“不符合要求”的；

（18）产品依法属于备案管理的。

3.13 审评时限

（1）审评中心应在 60 个工作日内完成申请材料的审查。必要时，经审评中心主管领导批准，审评时限可延长 20 个工作日。涉及注册申请人补充材料的，审评中心收到补充材料后，审评时间重新计算。

（2）等待注册申请人领取审评意见通知书、等待注册申请人校核批准证明文件样稿、等待注册申请人提交补充材料、现场核查、复核检验、复审的时间，为技术审评停滞时间，不计入审评时限。

3.14 沟通交流

审评中心应建立沟通交流制度，明确注册申请人与审评中心就技术审评意见问题的沟通交流程序和时间安排，管控沟通交流的廉政风险。

审评中心在技术审评过程中，为提升审评质量和效率，也可采用电话、网络等咨询方式，与注册申请人主动进行沟通交流。

4.行政审查、证书制作及信息公开

4.1 行政审查

国家食品药品监督管理总局应当自签收审评中心提交的综合审评结论和建议后 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。

4.2 证书制作

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 3 个工作日内，将审批材料移交受理机构。

受理机构应在 10 个工作日内，向注册申请人发出保健食品注册证书或不予注册决定。延续注册、变更注册或转让技术注册申请获得批准后，受理机构应同时收回原注册证书。

准予转让技术的，应给予新的注册号，颁发新的保健食品注册证书，同时注销原保健食品原注册证书。

准予延续注册、变更注册或证书补发的，仍沿用原注册号，颁发新的保健食品注册证书。准予延续注册、变更注册的，应同时收回原保健食品原注册证书。

转让技术、变更注册或补发的注册证书有效期，应与原注册证书有效期一致。

4.3 信息公开

受理机构向注册申请人发出保健食品注册证书或不予注册决定后，审评中心应通过信息系统将相关产品注册电子信息提交国家食品药品监督管理总局信息中心。

除涉及国家秘密、商业秘密外，国家食品药品监督管理总局信息中心应按要求及时公开产品注册证书及附件，注销或不予延续信息等产品注册相关信息。

附件：保健食品注册证书式样

附件

国家食品药品监督管理总局国产保健食品

注册证书（式样）

<table>
<tr><td>产品名称</td><td colspan="3"></td></tr>
<tr><td>注册人</td><td colspan="3"></td></tr>
<tr><td>注册人地址</td><td colspan="3"></td></tr>
<tr><td>审批结论</td><td colspan="3">经审核，该产品符合《中华人民共和国食品安全法》和《保健食品注册与备案管理办法》的规定，现予批准注册。</td></tr>
<tr><td>注册号</td><td>国食健注 G</td><td>有效期至</td><td>年 月 日</td></tr>
<tr><td>附 件</td><td colspan="3">附 1 产品说明书、附 2 产品技术要求</td></tr>
<tr><td>备 注</td><td colspan="3">1.变更注册应注明：****年**月**日，批准该产品“****”中 “****”变更为“****”。
2.转让技术应注明：****年**月**日，批准该产品转让技术。转让方为****，产品名称****（注册号****）同时注销。
3.证书补发应注明：****年**月**日，批准该产品补发证书。
（以上内容，如表格空间不足，可另附附件）</td></tr>
</table>

（加盖国家食品药品监督管理总局印）

年 月 日

国家食品药品监督管理总局进口保健食品

注册证书（式样）

<table>
<tr><td rowspan="2">产品名称</td><td>中文名</td><td colspan="3"></td></tr>
<tr><td>英文名</td><td colspan="3"></td></tr>
<tr><td rowspan="2">注册人</td><td>中文名</td><td colspan="3"></td></tr>
<tr><td>英文名</td><td colspan="3"></td></tr>
<tr><td>注册人地址</td><td colspan="4"></td></tr>
<tr><td rowspan="2">生产企业</td><td>中文名</td><td colspan="3"></td></tr>
<tr><td>英文名</td><td colspan="3"></td></tr>
<tr><td>生产国（地区）</td><td></td><td>地址</td><td colspan="2"></td></tr>
<tr><td>审批结论</td><td colspan="4">经审核，该产品符合《中华人民共和国食品安全法》和《保健食品注册与备案管理办法》的规定，现予批准注册。</td></tr>
<tr><td>注册号</td><td colspan="2">国食健注 J</td><td>有效期至</td><td>年 月 日</td></tr>
<tr><td>附 件</td><td colspan="4">附 1 产品说明书、附 2 产品技术要求</td></tr>
<tr><td>备 注</td><td colspan="4">1、变更注册应注明：****年**月**日，批准该产品“****”中“****”变更为“****”。
2、转让技术应注明：****年**月**日，批准该产品转让技术。转让方为****，产品名称****（注册号****）同时注销。
3、证书补发应注明：****年**月**日，批准该产品补发证书。
（以上内容，如表格空间不足，可另附附件）</td></tr>
</table>

（加盖国家食品药品监督管理总局印）

年 月 日

附 1

国家食品药品监督管理总局
保健食品产品说明书（范本）

国食健注

××××牌××××（中文名）

【原料】
【辅料】
【功效成分或标志性成分含量】
【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】

附 2

国家食品药品监督管理总局
保健食品产品技术要求（范本）

国食健注

××××××××（产品中文名）

【原料】

【辅料】

【生产工艺】本品经××、××、××、××、××、××等主要工艺加工制成。（其中，关键工艺应标注参数或参数合理范围）

【直接接触产品包装材料的种类、名称及标准】

【感官要求】应符合表 1 的规定。

表 1 感官要求

项　　目	指　　标
色　泽	
滋味、气味	
状　态	

【鉴别】

1 显微鉴别 ××××××××××××××。

2 薄层鉴别 ××××××××××××。

3 色谱鉴别 ××××××××××××。

【理化指标】应符合表 2 的规定。

表2 理化指标

项　　目	指　　标	检测方法
×××，××	≤××	GB/T ××××
×××，××	≤××	GB/T ××××
×××，××	≤××	GB ××××
×××，××	≥××	GB ××××
×××，××	××～××	1 ×××的测定

1 ×××的测定

1.1 仪器

1.1.1 ××××

1.1.2 ×××××

1.2 试剂

1.2.1 ××××××××

1.2.2 ××××××××

1.2.3 标准品来源纯度：××××

1.3 色谱条件

1.3.1 ××××××××××

1.3.2 ××××××××××××××××××××

1.3.3 ××××××××××

1.4 标准品溶液制备：××××××××××××××××××××××××××××××××××××××

1.5 样品溶液制备：××××××××××××××××××××××××××××××

1.6 测定：××

1.7 结果计算

$$X = \frac{A \times Cs \times V \times 100}{As \times m}$$

式中：

X—样品中××××××的含量，mg/100g；

A—样品中×××的峰面积；

Cs—标准溶液中×××××标准品的浓度，mg/mL；

As—标准溶液中×××××标准品的峰面积；

m—样品质量，g；

V—样品定容体积，mL。

【微生物指标】应符合表 3 的规定。

表3 微生物指标

项　　目	指　　标	检测方法
菌落总数，CFU/×	≤××	××××
大肠菌群，MPN/××	≤××	××××
霉菌和酵母，CFU/×	≤××	××××
金黄色葡萄球菌	≤0/25g	××××
沙门氏菌	≤0/25g	××××
××××	××××	××××

【标志性成分指标】应符合表 4 的规定。

表4 标志性成分指标

项　　目	指　　标	检测方法

×××，××	≥××	GB/T ××××
×××，××	××～××	1 ×××的测定

1 ×××的测定

1.1 原理：×××

1.2 试剂

1.2.1 ×××××××××××

1.2.2 ×××××××××××××××××××××××××××

1.2.3 ××××××××××××××××××××××××××××××

1.2.4 ××××××××××××××××××××××××

1.2.5 标准品来源纯度：×××××

1.3 仪器

1.3.1 ××××××

1.3.2 ×××

1.3.3 ×××××××××

1.4 标准曲线的制备：××××××××××××××××××××××

1.5 样品处理

1.5.1 ×××××××××××××××××××××××××××××××××××××××

1.5.2 ××

1.6 样品测定：××

1.7 结果计算

$$X = \frac{W_1 - W_2}{M \times V_2/V_1 \times V_4/V_3}$$

式中：

X—样品中×××的含量，mg/mL；

W_1—样品测定液中×××的质量，mg；

W_2—样品空白液中×××的质量，mg；

M—取样量，mL；

V_1—××××，mL；

V_2—×××，mL；

V_3—××××××，mL；

V_4—×××，mL。

【装量或重量差异指标/净含量及允许负偏差指标】

【原辅料质量要求】

1.××××××：应符合 GB ××××的要求。

2.×××：应符合 GB ××××××的要求。

3.×××：应符合 GB/T ××××的要求，且××××含量不得少于××，××含量不得多于××。

4.××××××：应符合 SB/T ××××××中一级品的要求。

5.××××××××××：应符合 QB/T ××××的要求。

6.××××××

项　　目	指　　标
感官要求	主要包括色泽、滋味、气味、性状、粒度（如需要）等等
含量	≥××
××	≤××
××××	≤××
×××××	≤××

7.×××提取物

项　　目	指　　标
原料来源	××××××
制法	××、××、×××、×××（（应标注关键工艺参数或参数
提取率（或得率）	××～××
感官要求	主要包括色泽、滋味、气味、状态等
××含量	≥××（或××～××）
水分	≤××
灰分	≤××
粒度	×××××××××
铅	≤××
总砷	≤××
总汞	≤××
溶剂残留	≤××
农药残留	≤××
菌落总数	≤××
大肠菌群	≤××
霉菌和酵母	≤××
金黄色葡萄球菌	≤××
沙门氏菌	≤××