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Health Food Recording Guideline (Trial)

保健食品备案工作指南（试行）

Health Food Recording Guideline (Trial)

Health Food Recording refers to the process of health food manufacturing company submit product safety, health function and quality controllability materials base on legal procedure, condition and requirements to food and drugs supervision management department for archive, publicity and records.

1. Applicable Scope
The rules applicable for the health food which need to be recorded according to the <Measures for Health Food Registration and Recording>.

2 Recording Subject
2.1 Domestic Health Food
The domestic health food applicant shall be health food manufacturing company. Health food original registrant can be the recording applicant.

2.2 Imported Health Food
The imported health food applicant shall be oversea manufacturer and trader of marketed health food. Oversea manufacturer and trader (the applicant) shall be the legal person or other organization which conform to the requirement of its country. The product country of origin refers to the country where the imported health food has been marketed and sold.

3 Recording Procedure and Requirements
3.1 Obtain Recording Login Account Number

3.1.1 Domestic Health Food

Domestic health food recording applicant shall submit application to its provincial, autonomous, direct-controlled municipal FDA to achieve recording management information system login account. The specific procedure shall be established by each provincial, autonomous, direct-controlled municipal FDA.

3.1.2 Imported Health Food

The Imported health food recording applicant shall bring the qualification proof document issued by the government competent authority or legal service institute of the country of origin, which show that the applicant is the oversea manufacturer and trader of marketed health food, and the contact person authorization letter etc. to CFDA administrative acceptance service department. And file the application to achieve the recording management information system login account onsite. The acceptance department will issue the login account to the applicant after approve the application.

3.1.3 Original Registrant Record Health Food

For the original registrant product transfer to recording system, shall submit application to CFDA technical review institute. CFDA technical review institute will review the application materials. If it is qualify, they will deliver the electronic product registration information to the recording management department and issue a written notice to inform the applicant to submit the recording application.

The original registrant includes: 1) The accepted health food registration application submitted before established the <Health Food Raw Materials List>. Product ingredients are included in the <Health Food Raw Materials List> and conform to the related technical requirements of recording system; 2) The health food which has gained the registration. Product ingredients are included in the <Health Food Raw Materials List> and compliance with the related technical requirements of recording system.

For the accepted health food registration application submitted before establish the <Health Food Raw Materials List> and the health food which has gained the registration, if any ingredient or its usage amount fail compliance with <Health Food Raw Materials List>, but the registrant or registration applicant agree to adjust product ingredient and technical requirements base on <Health Food Raw Materials List>, then they can be the original registrant as well.

For the accepted health food registration application submitted after established <Health Food Raw Materials List>, its ingredients are included in the <Health Food Raw Materials List> and conform to the related technical requirements of recording system, the original registration applicant cannot be the original registrant apply for the recording.

3.2 Product Recording Information Filing and Submission

3.2.1 Domestic Health Food

The recording applicant can enter the system through http://bjba.zybh.gov.cn after achieve the recording management information system login account. The applicant shall carefully read the related requirement and file the information about the applicant itself and recording product one by

one. Print out the recording application form attached with barcode and Check digit which are automatically generated by the system, product formulation, label and instruction book, product technical requirements etc. Along with other recording application materials, those are all need to be stamped with the applicant's seal at the text area (Except test reports issued by testing agency, notarial certificate and proof documents).

The applicant shall clearly color scan all paper materials and save in PDF file. And then upload those files to health food recording management information system and confirm the submission.

For the original registrant transfer the registered product (or ongoing registration application) to recording system, they can change and complete related information base on the <Health Food Raw Materials List> and related requirements after enter the system, also make notes of the changing content and reasons.

3.2.2 Imported Health Food

After receive the recording login account number, the recording applicant can get into the health food recording management information system through the following link: http://bjba.zybh.gov.cn . Carefully read through the instruction and following the requirements to file out the recording information. Print out the recording application form attached with barcode and Check digit which are automatically generated by the system, product formulation, label and instruction book, product technical requirements etc. Along with other recording application materials (Article 6), those are all need to be stamped with the applicant's seal at the text area (Except test reports issued by testing agency, notarial certificate and proof documents). If the applicant doesn't have seal, replace with the legal person's signature.

The applicant shall clearly color scan all paper materials and save in PDF file. And then upload those files to health food recording management information system and confirm the submission. The applicant shall also submit the whole original application package to CFDA administrative acceptance service department.

3.3 Issue Recording Number, Archive and Publicity

If the recording materials compliance with related requirements, FDA shall grant recording number immediately. If not, FDA shall inform the applicant all needed supplementary materials at a time.

Food and Drugs Supervision Management Department shall conduct health food recording work and supervision management base on <Measures of Health Food Registration and Recording Management> and <Health Food Raw Materials List>. The recording applicant shall keep an integrated application package for future reference.

4. Requirements of the Recording Materials Format

4.1 The content of those materials shall conform to <Measures for Health Food Registration and Recording> <Measures for Health Food Registration Test and Retest> <Technical Guideline for Health Food Test and Evaluation> <Food Safety National Standard - Health Food GB16740> etc. regulations, guidelines and national standards.

4.2 Health food recording materials shall be filed strictly base on the requirements of recording management information system.

4.3 The first page of the recording materials shall be the 'Table of Content' and page number. Separator page shall be added for each material. Separator page shall indicate material name, serial number of the material in the table of content and page number.

4.4 The content of recording materials (such as product name, recording applicant's name, address etc.) shall be consistent with each other. Provide written explanation, reason and basis for inconsistent content.

4.5 Recording materials shall be printed by A4 paper. Chinese character shall not smaller than Song Typeface 4 font. English character shall not smaller than 12 font. The content shall be completed, clear and no changes.

5 Domestic Health Food Recording Materials and its Requirements
5.1 Health Food Recording Register Form, and Letter of commitment that recording applicant take legal responsibility for the authenticity of the submitted materials.
The recording register form and letter of commitment will be automatically generated after the recording applicant complete applicant's information and product information in health food recording management information system. The recording applicant shall print and stamp base on Article 3.2 and then upload to the system.

5.2 Registration proof document of the recording applicant body
The recording applicant shall provide scanned copy of business license, uniform social credit code/organization code and other legal proof document, and scanned copy of production permit proof document contain health food category.

The original registrant shall provide scanned copy of health food registration proof document. If the original registrant doesn't have a production permit proof document contain health food category, can be exempted.

5.3 Product Formulation Materials
5.3.1 Product formulation will be automatically generated base on the information that the applicant filed, include name and usage amount of raw materials and excipients.

Raw materials shall conform to <Health Food Raw Materials List>; excipients shall conform to excipients list of health food recording product and its requirements.

Raw materials and excipients usage amount refer to the usage amount of produce 1000 smallest dosage form unit.

5.3.2 Pretreated raw material/excipient shall conform to <Health Food Raw Materials List>, excipients list of health food recording product and its requirements.

When file the recording information, shall list the name and usage amount of raw materials and excipients which are used to pretreated raw materials and excipients. If those raw materials and excipients are the same as other raw materials and excipients of the recording product, no need to list those again, and its usage amount is total amount which cannot exceed the maximum usage amount of excipients.

5.3.3 When the original registrant apply for product recording, if the raw materials and excipients are not conform to <Health Food Raw Materials List> and related technical requirements, the recording applicant shall adjust product formulation and related technical requirement and provide explanation, but cannot add raw material category.

5.4 Production Process Material

5.4.1 Provide production process flow chart and its instruction. Production process flow chart use graphical symbols to indicate the production process of make raw materials into finish product, include master operation, key control points etc. Provide pretreatment process if raw materials go through premix, encapsulation, microencapsulation. The production process content in the production process flow chart, production instruction shall be consistent with product technical requirements.

If any raw materials and excipients have been pretreated, mark those in the production process flow chart and its instruction.

5.4.2 Chemical structure, component etc. of the raw material which listed in <Health Food Raw Materials List> cannot be changed by technologies such as extraction, synthesis etc.

5.4.3 Dosage form selection shall be reasonable. The dosage form of recording product shall be determined by product's applicable population etc. to avoid any edible safety risks caused by dosage form selection.

5.5 Safety and Health Function Evaluation Material

5.5.1 Provide functional component, hygiene, stability etc. test reports of three batches products which are produces through pilot or up scale production process.

The recording applicant shall make sure the source of the test sample is clear and traceable. Domestic recording product shall be the sample which is produced through pilot or up scale production process.

The recording applicant shall have the self-test ability to conduce self-test for the product. If not, the recording applicant shall authorize legal qualified testing agency to conduct tests.

5.5.2 Provide the instruction of raw material and excipient reasonable usage, instruction of product label instruction book and technical requirements compliance with related regulations.

5.5.3 If the original registrant adjusts product formulation or technical requirement for recording application, provide related materials base on Article 5.5.1; If no adjustments have been made, provide test reports which were submitted for the original submission and the explanation.

5.6 Classification, name and related standard of direct-contact health food package material.
List the classification, name, standard number, standard content etc. of direct-contact health food package material.

5.7 Samples of product label and instruction book.
Product label shall compliance with the related law, regulation and other related rules. If it contains any content of the instruction book, keep consistent with the instruction book.

The product instruction book sample will be automatically generated after the applicant filed up the recording information in the health food recording management information system. The content of the instruction book shall the below requirements:

[Product Name] Shall conform to <Measures for Health Food Registration and Recording Management> and related law/regulations.

1) Product name is made up of brand name, general name and attribute name. The product name can be selected after the recording system automatically generate by input trade name, raw materials name and dosage form.

2) If use registered trademark, shall provide trademark registration certificate or authorization letter of registered trademark usage.

3) The same company cannot use the same formulation record health food in different names. The same company cannot use the same name record health food in different formulations.

Same formulation refers to the category and usage amount of raw materials and excipients are consistent.

Same name refers to the trade name, general name and attribute name are consistent.

[Raw Materials] List all raw materials according to Article 5.3

[Excipients] List all excipients according to Article 5.3

[Functional Component and its content] Shall include name and content of the functional component. The name of each functional component shall be consistent with the product technical requirements.

The functional component content (listed value) of non-nutrient supplements shall in accordance with the minimum usage amount of product technical requirement and the daily intake amount for the applicable population in the <Health Food Raw Materials List>.

Nutrients supplement shall list name and content (listed value) for all functional components, the functional component name shall be the nutrient for each raw material. The rank of functional components shall be the same as nutrients' order in <Health Food Raw Materials List>. The listed value shall be the certain theoretical value of any nutrient contain in the smallest unit, which calculated by the product formulation. The listed value shall in accordance with the index range of product technical requirement and the daily intake amount for the applicable population in the <Health Food Raw Materials List>. Marked as 'Per tablet contains', 'Per granule contains', 'Per bottle contains' etc.

[Applicable Population] In accordance with <Health Food Raw Materials List> and requirements of recording management information system; safe to consume, with specific function requirements and specific population which is applicable for this recording product.

The applicable population of nutrient supplements shall conform to the population classification in <Health Food Raw Materials List>. Marked as "need supplement xx (nutrient) + age + population" or "Adults, pregnant woman, breastfeeding woman need supplement xx (nutrient)". Shall also conform to the following requirements:

1) If select two or more continual age groups as applicable population, shall combine those age groups together to mark. For example, if the product applicable for both 7-10 years old (include 7 years old and 10 years old population, same below) and 11-13 years old, marked as 7-13 years old.

2)If the product contains three or more vitamins, marked as 'xx population need supplement multivitamins'. If the product contains three or more minerals, marked as 'xx population need supplement multi-minerals' If the product contains three or more vitamins and minerals, marked as 'xx population need supplement multiple vitamins and minerals'.

3) If the product contains three or more vitamin B (vitamin B1, B2, B6, B12, niacin, pantothenic acid, folic acid etc.), marked as 'xx population need supplement vitamin B'.

[Non-applicable population] Shall conform to the population classification in <Health Food Raw Materials List>. Include specific population not include in the applicable population, specific population which the current scientific basis is not enough to support that the product applicability such as infant, pregnant woman, breastfeeding woman etc. Shall also conform to the following requirements:

1) If select tablet, capsule as the product dosage form, shall exclude the population who may exist edible safety risks caused by edible method;

2) Determine the non-applicable population by the applicable range of each raw materials and excipients. If the applicable range of the selected compound is '4 years old and older population', the non-applicable population shall include '3 years old and younger population'.

3) Non-applicable population of nutrient supplements shall include 1 years old and younger population; If select two or more continual age groups as non-applicable population, shall combine and mark those age groups.

[Health Function] Mark health function base on <Health Food Raw Materials List>.
Nutrients supplement shall list all supplement vitamins or minerals, described as 'supplement xx, xx';

For the product contains three or more vitamins, marked as 'supplement multivitamins'; For the product contains three or more minerals, marked as 'supplement multi-minerals'; For the product contains three or more vitamins or minerals, marked as 'supplement multiple vitamins or minerals', but cannot marked as 'supplement xx, xx and multiple vitamins or minerals';

For the product contains three or more vitamin B, described as 'supplement vitamin B'.

[Intake amount and edible method] Shall be consistent with the scientific basis and safety information of product formulation/compatibility and usage amount, health function evaluation materials. The description of edible amount and edible method shall be standardized and detailed. Description sequence is intake amount (list serving per day and intake amount per serving), edible method. If different applicable population need follow different intake amount, shall mark separately for each applicable population.

For nutrients supplements product, the total daily intake amount of solid product shall not exceed 20 grams; the total daily intake amount of liquid product shall not exceed 30 ml.

[Specification] Weight or volume (exclude package materials) shall be the smallest dosage form unit (smallest edible unit). Such as: for capsule, it's content weight; for sugar coated tablet, it's tablet weight before add sugarcoat; for membrane tablet, it's the tablet weight before add membrane); Product specification shall in accordance with the edible method and edible amount. Marked as tablet: X g/tablet; capsule: X g/capsule; oral liquid: X ml/bottle; granules: X g/bag.

One recording application shall only address one product specification. If need multiple specifications, shall apply for the recording alternation procedure. If compliance with alternation requirements, list all specifications need to be added in the Note column of the recording voucher. The same product cannot gain multiple recording voucher by different specification.

For the original registrant product recording, if the original approved certificate or registered product contain multiple specification, edible amount and edible method, recording application shall declare one specification, then list other specifications, edible amount and edible method in the Note column of the recording voucher.

[Storage method] The recording applicant shall identify the storage method by product characteristics, stability test etc. For any specific storage method such as cold storage etc., list specific condition.

[Shelf life] The recording applicant shall identify the shelf life by stability test. Mark as 'xx days' if not enough one month. For the product go through accelerated stability test, the shelf life cannot exceed 24 months.

[Warnings] Indicate 'This product is not a substitute for drugs. Not recommend for people who out of applicable population range'. For nutrients supplements, shall add 'Should not exceed the recommended amount or take the same kind of nutrients at the same time'. Add more contents according to R&D, scientific consensus and product feature if necessary. For example, if excipients contain Aspartame, indicate people who have phenylketonuria shall cautiously use the product; effervescent tablet cannot be chewed, sub-lingual or swallowed.

5.8 Product Technical Requirement Material

The content of product technical requirement shall complete and in accordance with the test report results, also compliance with the current regulation, technical guidelines, food safety national standard, <Health Food Raw Materials List>.

The product technical requirements will be automatically generated after the applicant filed out the recording information in the health food recording management information system.

[Product Name] Automatically generated once the applicant filed out the recording information in the system.

[Raw Materials] List all raw materials and usage amount according to Article 5.3

[Excipients] List all excipients and usage amount according to Article 5.3

[Production Process] Select master operation, key control parameters one by one according to the real production operation procedure; Master operation with the same description can be re-selected.

[Classification, name and related standard of direct-contact health food package material] Consistent with Article 5.6.

[Sensor Requirements] Describe the appearance (color, form etc.) and content (color, taste, odor, form etc.). Do not describe the appearance of the direct-contact package material and the color of hard capsule etc.

[Identification] Determine the identification method according to the product formulation and related research results. Make accurate description of it. Provide reasons for not created identification items.

[Physical and Chemical Index] Identify the name, value, testing method of physical and chemical index. If take national standard, local standard or guidelines as the testing method, provide the standard number or the title of the guideline; if take the revised national standard, local standard as the testing method, provide the standard number or the title of guideline, also detailed list revised content; If the testing method is created by the applicant, provide the whole content and the testing method's applicability for the product.

[Microorganism Index] Indicate the name, value and testing method of the microorganism index.

[Functional Component] Indicate the name, index range and testing method of the functional component.

Nutrients supplements' functional component shall be the functional component index of the smallest edible unit (such as per tablet, per pill, per bag, per bottle), include all supplement nutrients. The content range of vitamins shall be 80%-180% of the listed value, the content range of minerals shall be 75%-125% of the list value. The range of functional component index shall conform to the daily intake amount for the applicable population stipulated in <Health Food Raw Materials List>.

If take national standard, local standard or guidelines as the testing method, provide the standard number or the title of the guideline; if take the revised national standard, local standard as the testing method, provide the standard number or the title of guideline, also detailed list revised content; If the testing method is created by the applicant, provide the whole content and the testing method's applicability for the product.

[Weight Deviation Index (net weight and allowable negative tolerance index)] Described in text format.

[Quality Requirements of Raw Materials and Excipients] List the specific quality standard for all raw materials and excipients.

Conform to <Health Food Raw Materials List>, excipients for health food recording product. List the standard number. For pre-treated raw material, shall list the source and executive standard, main product technology and key technical parameters etc.

5.9 All-items inspection report (meet product technical requirements) issued by legal qualified testing agency.

5.9.1 The testing agency shall conduct test according to the applicant proposed items and method in the product technical requirements, and then issue technical requirements all-items inspection report of three batches product.

Test report shall include the conclusion of if the test result meet for the current regulation, guideline, mandatory national standard and technical requirements etc.

The product name, test index etc. in the test report shall in accordance with the product recording name, technical requirement etc. The test report cannot be altered once it's been issued by the testing agency.

For those appearance requirements, functional component index which are not certified by the legal testing agency, the agency shall provide text explanation and testing basis.

5.9.2 If this test report is issued by the same testing agency who issued the test report described in Article 5.5, shall for different three batches.

5.9.3 If the original registrant adjusts product formulation or technical requirement for recording application, provide related materials base on Article 5.9.1; If no adjustments have been made, provide test reports which were submitted for the original submission.

5.10 Retrieval Materials of the Product Name
The recording applicant shall provide retrieval materials to show that the product name is not the same as the name of any approved registered or recorded health food. Search in CFDA website and print it out.

5.11 Other materials can show product safety and health function

6 Requirement of Imported Health Food Recording Materials

Submit the domestic product required materials and the below:

6.1 Proof Documents of the Recording Applicant's Registration Body
Qualification proof document issued by government authorities or legal service organization from the country of origin to show that the recording applicant is an oversea manufacturer or trader of marketed health food. The document shall specify the name of the organization which issued the document, name and address of the manufacturer or trader, product name and issue date etc.

6.2 Proof Documents of the Recording Product has been Sold More than One Year
Proof document issued by by government authorities or legal service organization from the country of origin to show that the health food has been available on the market for sales for 1 year or longer. Or safety report of product oversea sales and human consumption.

The proof document is to show that the product has been available on the country of origin for sales for one year or longer as health food, dietary supplements or other similar types of products. The document shall specify the name of the organization which issued the document, recording applicant's name, manufacturer's name, product name and issue date. The document shall clearly state that the product in accordance with the law, related technical regulations, standards of the country of origin and the product has been allowed to manufactured and sold in the country of origin. Meanwhile, provide related materials which make sure the product function, consumption population are consistent with each other, and make sure the product is safe.

If it's implemented and approved by the product exporting country, shall provide the proof document issued by the government authorities from the exporting country to show the product has been approved to sale on the market.

6.3 Health food related technical regulations and (or) standard from the country of origin or international organization. Explanation issued by oversea manufacturer to guarantee the product they export to China in accordance with Chinese laws, administrative regulations and food safety national standard. Self-inspection report to guarantee the manufacture quality management system will be operating effectively.

If the application materials contain product manufacturer quality management system proof document, the document shall be issued by either government authorities of the country of origin or government authorities designated relevant department which take legal responsibilities. The proof document shall in accordance with Good Manufacturing Practice (GMP) and specify the name of the organization which issued the document, manufacturer's name, product name and issue date.

6.4 The recording applicant shall make sure the source of test samples is clear and traceable. Imported recording product shall be any product sold in its country of origin.

6.5 Package, label, instruction book samples of the product which on the market of country of origin. Provide the label and instruction book sample of the marked product in the country of origin, notarized by domestic notary authority in China. Provide the Chinese version which the content in accordance with original language.

6.6 Where recording matters are to be handled by the resident representative office of an overseas recording applicant in China, the copy of <Registration Certificate of the Resident Representative Offices of Foreign Enterprises in China> shall be submitted.

Where an overseas recording applicant authorizes an agency within China to handle recording matters, the original copay of notarized authorization letter and the photocopy of the business license of the authorized agency shall be submitted. The authorization letter shall identify recording applicant, authorized agency name, product name, authorized matters and issue date of authorization letter.

6.7 The recording materials shall be in Chinese. All foreign language materials attached on the back. Chinese translation shall be notarized by domestic notary authority in China and in accordance with the original content.

6.8 Proof documents, authorization letter (agreement) issued by oversea entity shall be original version; in official language of its country of origin; with recording applicant's seal or legal representative's (or authorized person's) signature; confirmed by the Chinese embassy in the country of origin; notarized by the notarial agency in the country of original. The proof documents, authorization letter (agreement) etc. shall contain expiration date and use before it's expired.

6.9 Manufacturing and sales roof documents, quality management system or Good Manufacturing Practice proof documents, manufacturing consignment proof documents etc. can list multiple products. When all products in-processing of recording application at the same time, one of those product use original version and others can use printed copy, also provide a written explanation to point out the product name which has original version. When all products are not in-processing of recording application at the same time, one of those product use original version, other product can use the notarized printed copy, also provide a written explanation to point out the product name which has original version.

7 Health Food Recording Alternation

The recording applicant shall provide alternation explanation and its proof documents to the original recording government entity. If the recording materials meet requirements, FDA shall insert the alternation information to the recording materials for future reference.

If any changes happen to the contact person, contact information etc. of the recording product, the recording applicant shall submit the stamped (recording applicant's seal) alternation application to the recording institute immediately. The recording institute shall update the related information immediately.

For recorded health food, if the product name (trade name) is not qualify and asked for rectification by the supervision department, shall follow the recording alternation procedure.

8 Supplementary Article

This guideline is a trial version. Will be revised according to <Health Food Raw Materials List> and recording procedures.

保健食品备案工作指南（试行）

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

1 适用范围

本指南适用于《保健食品注册与备案管理办法》规定的保健食品备案工作。

2 备案主体

2.1 国产保健食品

国产保健食品备案人应当是保健食品生产企业。保健食品原注册人（以下简称原注册人）可以作为备案人。

2.2 进口保健食品

进口保健食品备案人应当是上市保健食品境外生产厂商。境外生产厂商（备案人）是指符合其所在国（地区）上市要求的法人或其他组织。产品生产国（地区）是指进口保健食品上市销售的国家（地区）。

3 备案流程及要求

3.1 获取备案系统登录账号

3.1.1 国产保健食品

国产保健食品备案人应向所在地省、自治区、直辖市食品药品监督管理部门提出获取备案管理信息系统登录账号的申请。申请登录账号的具体方式由各省、自治区、直辖市食品药品监督管理部门自行发布。

3.1.2 进口保健食品

进口保健食品备案人携带产品生产国（地区）政府主管部门或法律服务机构出具的备案人为上市保健食品境外生产厂商的资质证明文件和联系人授权委托书等，向国家食品药品监督管理总局行政受理服务部门现场提出获取备案管理信息系统登录账号的申请，由受理部门审核通过后向备案人发放登录账号。

3.1.3 原注册人备案保健食品

原注册人产品转备案的，应当向总局技术审评机构提出申请。总局技术审评机构对转备案申请相关信息进行审核，符合要求的，将产品相关电子注册信息转送备案管理部门，同时书面告知申请人可向备案管理部门提交备案申请。

原注册人包括：（1）《保健食品原料目录》发布前受理的保健食品注册申请，其原料已列入《保健食品原料目录》，且符合备案相关技术要求的，申请该产品备案的原注册申请人；（2）获得注册的保健食品，其原料已列入《保健食品原料目录》，且符合备案相关技术要求的，申请该产品备案的原保健食品注册人。

《保健食品原料目录》发布前受理的保健食品注册申请，以及获得注册的保健食品，其部分原料或用量不符合《保健食品原料目录》以及备案技术要求的，注册申请人或证书持有人同意按照《保健食品原料目录》调整产品原料和产品技术要求，也可以作为原注册人。

《保健食品原料目录》发布后受理的注册申请保健食品，其原料已列入《保健食品原料目录》，且产品符合相关技术要求，原注册申请人不可以作为原注册人申请该产品备案。

3.2 产品备案信息填报、提交

3.2.1 国产保健食品

备案人获得备案管理信息系统登录账号后，通过 http://bjba.zybh.gov.cn 网址进入系统，认真阅读并按照相关要求逐项填写备案人及申请备案产品相关信息，逐项打印系统自动生成的附带条形码、校验码的备案申请表、产品配方、标签说明书、产品技术要求等，连同其他备案材料，逐页在文字处加盖备案人公章（检验机构出具的检验报告、公证文书、证明文件除外）。备案人将所有备案纸质材料清晰扫描成彩色电子版（PDF 格式）上传至保健食品备案管理信息系统，确认后提交。

原注册人已注册（或申请注册）产品转备案的，进入保健食品备案管理信息系统后，可依据《保健食品原料目录》及相关备案管理要求，修改和完善原注册产品相关信息，并注明修改的内容和理由。

3.2.2 进口保健食品

备案人获得备案管理信息系统登录账号后，通过 http://bjba.zybh.gov.cn 网址进入系统，认真阅读并按照相关要求逐项填写备案人及申请备案产品相关信息，逐项打印系统自动生成的附带条形码、校验码的备案申请表、产品配方、标签说明书、产品技术要求等，连同其他备案材料（具体见 6 进口保健食品备案材料项目及要求），逐页在文字处加盖备案人公章（检验机构出具的检验报告、公证文书、证明文件除外）。备案人若无印章，可以法人代表签字或签名章代替。

备案人将所有备案纸质材料清晰扫描成彩色电子版（PDF 格式）上传至保健食品备案管理信息系统，确认后提交，并应当向国家食品药品监督管理总局行政受理服务部门提交全套备案材料原件 1 份。

3.3 发放备案号、存档和公开

备案材料符合要求的，备案管理部门当场备案，发放备案号，并按照相关格式要求制作备案凭证；不符合要求的，应当一次告知备案人补正相关材料。

食品药品监督管理部门应当按照《保健食品注册与备案管理办法》《保健食品原料目录》的要求开展保健食品备案和监督管理工作。备案人应当保留一份完整的备案材料存档备查。

备案管理部门对原注册产品发放备案号后，应当书面告知总局技术审评机构注销原注册证书和批准文号，或终止原注册申请。

4 备案材料形式要求

4.1 保健食品备案材料应符合《保健食品注册与备案管理办法》《保健食品原料目录》以及辅料、检验与评价等规章、规范性文件、强制性标准的规定。

4.2 保健食品备案材料应当严格按照备案管理信息系统的要求填报。

4.3 备案材料首页为申请材料项目目录和页码。每项材料应加隔页，隔页上注明材料名称及该材料在目录中的序号和页码。

4.4 备案材料中对应内容（如产品名称、备案人名称、地址等）应保持一致。不一致的应当提交书面说明、理由和依据。

4.5 备案材料使用 A4 规格纸张打印，中文不得小于宋体 4 号字，英文不得小于 12 号字，内容应完整、清晰。

5 国产保健食品备案材料项目及要求

5.1 保健食品备案登记表，以及备案人对提交材料真实性负责的法律责任承诺书

备案人通过保健食品备案管理信息系统完善备案人信息、产品信息后，备案登记表和法律责任承诺书将自动生成。备案人应当按照 3.2 项要求打印、盖章后上传。

5.2 备案人主体登记证明文件

应当提供营业执照、统一社会信用代码/组织机构代码等符合法律规定的法人组织证明文件扫描件，以及载有保健食品类别的生产许可证明文件扫描件。

原注册人还应当提供保健食品注册证明文件扫描件。原注册人没有载有保健食品类别的生产许可证明文件的，可免于提供。

5.3 产品配方材料

5.3.1 产品配方表根据备案人填报信息自动生成，包括原料和辅料的名称和用量。

原料应当符合《保健食品原料目录》的规定，辅料应符合保健食品备案产品可用辅料相关要求。

原料、辅料用量是指生产 1000 个最小制剂单位的用量。

5.3.2 使用经预处理原辅料的，预处理原辅料所用原料应当符合《保健食品原料目录》的规定，所用辅料应符合保健食品备案产品可用辅料相关要求。

备案信息填报时，应当分别列出预处理原辅料所使用的原料、辅料名称和用量，并明确标注该预处理原料的信息。如果预处理原辅料所用原料和辅料与备案产品中其他原辅料相同，则该原辅料不重复列出，其使用量应为累积用量，且不得超过可用辅料范围及允许的最大使用量。

5.3.3 原注册人申请产品备案时，如果原辅料不符合《保健食品原料目录》或相关技术要求的，备案人应调整产品配方和相关技术要求至符合要求，并予以说明，但不能增加原料种类。

5.4 产品生产工艺材料

5.4.1 应提供生产工艺流程简图及说明。工艺流程简图以图表符号形式标示出原料和辅料通过生产加工得到最终产品的过程，应包括主要工序、关键工艺控制点等。工艺流程图、工艺说明应当与产品技术要求中生产工艺描述内容相符。

使用预处理原辅料的，应在工艺流程简图及说明中进行标注。

5.4.2 不得通过提取、合成等工艺改变《保健食品原料目录》内原料的化学结构、成分等。

5.4.3 剂型选择应合理。备案产品剂型应根据产品的适宜人群等综合确定，避免因剂型选择不合理引发食用安全隐患。

5.5 安全性和保健功能评价材料

5.5.1 应提供经中试及以上规模的工艺生产的三批产品功效成分或标志性成分、卫生学、稳定性等检验报告。

备案人应确保检验用样品的来源清晰、可溯源。国产备案产品应为经中试及以上生产规模工艺生产的样品。

备案人具备自检能力的可以对产品进行自检；备案人不具备检验能力的，应当委托具有合法资质的检验机构进行检验。

5.5.2 提供产品原料、辅料合理使用的说明，及产品标签说明书、产品技术要求制定符合相关法规的说明。

5.5.3 原注册人调整产品配方或产品技术要求申请备案的，应按 5.5.1 提供相关资料；未调整产品配方和产品技术要求的，可以提供原申报时提交的检验报告，并予以说明。

5.6 直接接触产品的包装材料的种类、名称及标准

应提供直接接触产品的包装材料的种类、名称、标准号等使用依据。

5.7 产品标签、说明书样稿

产品标签应该符合相关法律、法规等有关规定，涉及说明书内容的，应当与说明书有关内容保持一致。

产品说明书样稿根据备案人填报信息自动生成，应符合以下要求：

【产品名称】应符合《保健食品注册与备案管理办法》等相关法律法规。

（1）产品名称由商标名、通用名和属性名组成。备案人输入商标名、原料名称及产品剂型后，可在备案系统自动生成的产品名称中自主选择。

（2）使用注册商标的，应提供商标注册证明文件或注册商标使用授权书。

（3）同一企业不得使用同一配方备案不同名称的保健食品。不得使用同一名称备案不同配方的保健食品。

同一配方，是指产品的原料、辅料的种类及用量均一致的情形。

同一名称，是指产品商标名、通用名、属性名（包括特定人群、口味等）均一致的情形。

【原料】按 5.3 产品配方材料列出全部原料。

【辅料】按 5.3 产品配方材料列出全部辅料。

【功效成分或标志性成分及含量】应包括功效成分或标志性成分名称及含量。功效成分或标志性成分名称应与产品技术要求中相应指标名称一致。

非营养素补充剂产品功效成分或标志性成分含量（标示值）与产品技术要求中指标最低值一致，并符合《保健食品原料目录》规定的适宜人群对应的每日摄入量。

营养素补充剂产品应标示功效成分名称及含量（标示值），其功效成分名称为所有原料对应的营养素，排列顺序与《保健食品原料目录》中营养素的排列顺序相同；功效成分标示值是根据配方、生产工艺等产品技术要求综合确定的最小食用单元中某种营养素含量的确定数值，标示值应符合产品技术要求的功效成分指标范围以及《保健食品原料目录》规定的适宜人群对应的每日摄入量。标注方式为“每片含”“每粒含”“每袋含”“每瓶含”等。

【适宜人群】符合《保健食品原料目录》规定以及备案管理信息系统填报要求，食用安全、有明确保健功能需求且适合该备案产品的特定人群。

营养素补充剂的适宜人群应符合《保健食品原料目录》中人群分类，标注为“需要补充 XX，XX（营养素）的+年龄段+人群”或“需要补充 XX，XX（营养素）的成人、孕妇、乳母”，并应当符合以下要求：

（1）当适宜人群选择两个或以上连续的年龄段时，应当将年龄段合并标注，如适宜人群同时适用于 7—10 岁（含 7 岁和 10 岁人群，下同）、11—13 岁时，则标注为 7—13 岁。

（2）含有三种及以上维生素的产品可以标注为“需要补充多种维生素的 XX 人群”；含有三种及以上矿物质的产品可以标注为“需要补充多种矿物质的 XX 人群”；当维生素和矿物质的种类均超过三种（含三种）时，可以标注为“需要补充多种维生素矿物质的 XX 人群”。

（3）含有三种及以上 B 族维生素（维生素 B1，维生素 B2，维生素 B6、维生素 B12、烟酸、泛酸、叶酸等）的产品可标注为“需要补充多种 B 族维生素的 XX 人群”。

【不适宜人群】应符合《保健食品原料目录》中人群分类。包括：适宜人群中应当除外的特定人群，现有科学依据不足以支持该产品适宜的 3 岁以下人群、孕妇、乳母等特定人群，以及现行规定明确应当标注的特定人群。还应当符合以下要求：

（1）产品剂型选择了片剂、胶囊剂等的，应排除可能因食用方法会引起食用安全隐患的人群；

（2）根据产品使用的原料、辅料所对应的适用范围确定不适宜人群。如所选用的化合物使用范围为“4 岁以上人群（含 4 岁人群）”，不适宜人群应包括“3 岁以下人群（含 3 岁人群）”。

（3）营养素补充剂的不适宜人群应当包括 1 岁以下人群（含 1 岁人群）；当不适宜人群选择两个或以上连续的年龄段时，应将年龄段合并标注。

【保健功能】应按《保健食品原料目录》的规定标注保健功能。

营养素补充剂应列出所有要补充的维生素和矿物质，表述为“补充 XX，XX”。

含有三种及以上维生素的产品可以标注为“补充多种维生素”；含有三种及以上矿物质的产品可以标注为“补充多种矿物质”；含有维生素和矿物质的种类均超过三种（含三种）时，可以标注为“补充多种维生素矿物质”，但不得以“补充其中一种或几种原料名称+多种维生素矿物质”形式表述。

含有三种及以上 B 族维生素的产品可以表述为“补充多种 B 族维生素”。

【食用量及食用方法】应与产品配方配伍及用量的科学依据、安全性和保健功能评价材料等相符。食用量及食用方法的表述应规范、详细，描述顺序为：食用量（应标示每日食用次数和每次食用量），食用方法。如不同的适宜人群需按不同食用量摄入时，食用量应按适宜人群分别标示。

营养素补充剂产品中，固体形态产品每日食用总量不得超过 20 克，液体形态产品每日食用总量不得超过 30 毫升。

【规格】应为最小制剂单元（最小食用单元）的重量或者体积（不包括包装材料）。如：胶囊剂指内容物重量；糖衣片指包糖衣前的片芯重量；薄膜衣片应在包薄膜衣后检查重量。产品规格还应与产品食用方法、食用量相匹配。表示为：片剂为 Xg/片，胶囊剂为 Xg/粒；口服液为 Xml/瓶（或支）；颗粒为 Xg/袋。

一次备案申请仅可备案一种产品规格，如需要备案多个规格时，应按备案变更程序申请，符合变更要求后，在备案凭证的备注部分列出所要增加的规格。同一个产品不得以不同规格获得多个备案凭证。

原注册人产品备案，如果原批准证书或已申请注册的产品中有多个规格和食用量、食用方法的，备案时应填报一种规格，其他规格和食用量、食用方法在备案凭证中备注项下列出。

【贮藏方法】应根据产品特性、稳定性试验等综合确定。贮藏方法为冷藏等特殊条件的，应列出具体贮藏条件。

【保质期】应根据稳定性试验考察结果综合确定，以“XX 月”表示，不足月的以“XX 天”表示。采用加速稳定性试验的产品，保质期不超过 24 个月。

【注意事项】应注明“本品不能代替药物。适宜人群外的人群不推荐食用本产品”。营养素补充剂产品还应增加“不宜超过推荐量或与同类营养素同时食用”。必要时还应根据研发情况、科学共识以及产品特性增加相应内容。如：辅料中含有阿斯巴甜，应标明苯丙酮尿患者慎用；泡腾片不可咀嚼、含服或吞服等。

5.8 产品技术要求材料

备案人应确保产品技术要求内容完整，与检验报告检测结果相符，并符合现行法规、技术规范、食品安全国家标准、《保健食品原料目录》的规定。

备案人在保健食品备案管理信息系统中填报备案信息后自动生成产品技术要求。

【产品名称】备案人在保健食品备案管理信息系统中填报备案信息后自动生成。

【原料】按照 5.3 产品配方材料列出全部原料及用量

【辅料】按照 5.3 产品配方材料列出全部辅料及用量。

【生产工艺】应根据实际工艺操作步骤依次选择主要工序、关键工艺参数；同一描述的主要工序可以根据实际生产操作规程重复选择。

【直接接触产品包装材料的种类、名称及标准】与 5.6 项下材料要求一致。

【感官要求】应描述产品的外观（色泽、状态等）和内容物的色泽、滋味、气味、状态等项目。不对直接接触产品的包装材料的外观、硬胶囊剂的囊壳色泽等进行描述。

【鉴别】根据产品配方及相关研究结果等可以确定产品鉴别方法的，应予以准确阐述。未制定鉴别项的，应提供未制定的理由。

【理化指标】应标明理化指标名称、指标值和检测方法。检测方法为国家标准、地方标准或规范性文件的，应列出标准号或规范性文件的文题文号；检测方法为备案人在国家标准、地方标准或规范性文件基础上进行修订的，应列出标准号或规范性文件的文题文号，同时详细列出修

订内容；检测方法为备案人研究制定的，应列出检测方法全文，并提供该检测方法对本产品适用性相关资料。

【微生物指标】应标明微生物指标名称、指标值和检测方法。

【功效成分或标志性成分指标】应标明功效成分或标志性成分名称、指标范围和检测方法。

营养素补充剂产品功效成分应为产品食用最小单元（如每片、每粒、每袋、每瓶）的功效成分指标，包括补充的全部营养素。维生素含量范围应为标示值的 80%—180%，矿物质含量范围应为标示值的 75%—125%。功效成分指标范围应符合《保健食品原料目录》规定的产品适宜人群对应的每日摄入量。

功效成分或标志性成分的检测方法为国家标准、地方标准或规范性文件的，应列出标准号或规范性文件的文题文号；检测方法为备案人在国家标准、地方标准或规范性文件基础上进行修订的，应列出标准号或规范性文件的文题文号，同时详细列出修订内容；检测方法为备案人研究制定的，应列出检测方法全文，并提供该检测方法对本产品适用性相关资料。

【装量或重量差异指标（净含量及允许负偏差指标）】应以文字形式描述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】逐项列明所用原辅料具体质量标准。

符合《保健食品原料目录》、保健食品备案产品可用辅料相关要求的，列出标准号。对预处理原料，还应该列出原料来源和执行标准、主要生产工序及关键工艺参数等。

5.9 具有合法资质的检验机构出具的符合产品技术要求全项目检验报告

5.9.1 检验机构应按照备案人拟定的产品技术要求规定的项目、方法等进行检测，出具三批产品技术要求全项目检验报告。

检验报告应包括检测结果是否符合现行法规、规范性文件、强制性国家标准和产品技术要求等的结论。

保健食品备案检验申请表、备案检验受理通知书与检验报告中的产品名称、检测指标等内容应保持一致。检验机构出具检验报告后，不得变更。

对于具有合法资质的检验机构未认证的感官要求、功效成分或标志性成分指标，检验机构应以文字说明其检测依据。

5.9.2 该项检验报告与 5.5 项的检验报告为同一检验机构出具，则应为不同的三个批次产品的检验报告。

5.9.3 原注册人调整产品配方或产品技术要求申请备案的，应按 5.9.1 提供相关资料；未调整产品配方和产品技术要求的，可以提供原申报时提交的检验报告。

5.10 产品名称相关检索材料

备案人应从国家食品药品监督管理总局政府网站数据库中检索并打印，提供产品名称（包括商标名、通用名和属性名）与已批准注册或备案的保健食品名称不重名的检索材料。

5.11 其他表明产品安全性和保健功能的材料

6 进口保健食品备案材料项目及要求

除应按国产产品提交相关材料外，还应提交：

6.1 备案人主体登记证明文件

产品生产国（地区）政府主管部门或者法律服务机构出具的备案人为上市保健食品境外生产厂商的资质证明文件。应载明出具文件机构名称、生产厂商名称地址、产品名称和出具文件的日期等。

6.2 备案产品上市销售一年以上证明文件

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类似产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。

上市销售一年以上的证明文件，应为在产品生产国（地区）作为保健食品类似产品销售一年以上的证明文件，应载明文件出具机构的名称、备案人名称地址、生产企业名称地址、产品名称和出具文件的日期，应明确标明该产品符合产品生产国（地区）法律和相关技术法规、标准，允许在该国（地区）生产销售。同时提供产品功能作用、食用人群等与申请备案产品声称相对应，保证食用安全的相关材料。

产品出口国（地区）实施批准的，还应当出具出口国（地区）主管部门准许上市销售的证明文件。

6.3 产品生产国（地区）或者国际组织与备案保健食品相关的技术法规或者标准原文。境外生产厂商保证向我国出口的保健食品符合我国有关法律、行政法规的规定和食品安全国家标准的要求的说明，以及保证生产质量管理体系有效运行的自查报告。

申请材料涉及提交产品生产企业质量管理体系文件的，应当提交产品生产国（地区）政府主管部门或者政府主管部门指定的承担法律责任的有关部门出具的，符合良好生产质量管理规范的证明文件，应载明出具文件机构名称、产品名称、生产企业名称和出具文件的日期。

6.4 备案人应确保检验用样品的来源清晰、可溯源，进口备案产品应为产品生产国（地区）上市销售的产品。

6.5 产品在产品生产国（地区）上市的包装、标签说明书实样

应提供与产品生产国（地区）上市销售的产品一致的标签说明书实样及照片，以及经境内公证机构公证、与原文内容一致的中文译本。

6.6 由境外备案人常驻中国代表机构办理备案事务的，应当提交《外国企业常驻中国代表机构登记证》扫描件

境外备案人委托境内的代理机构办理备案事项的，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扫描件。委托书应载明备案人、被委托单位名称、产品名称、委托事项及委托书出具日期。

6.7 备案材料应使用中文，外文材料附后。外文证明性文件、外文标签说明书等中文译本应当由中国境内公证机构进行公证，与原文内容一致。

6.8 境外机构出具的证明文件、委托书（协议）等应为原件，应使用产品生产国（地区）的官方文字，备案人盖章或法人代表（或其授权人）签字，需经所在国（地区）的公证机构公证和中国驻所在国使领馆确认。证明文件、委托书（协议）等载明有效期的，应在有效期内使用。

6.9 提供生产和销售证明文件、质量管理体系或良好生产规范的证明文件、委托加工协议等证明文件可以同时列明多个产品。这些产品同时备案时，允许一个产品使用原件，其他产品使用复印件，并书面说明原件所在的备案产品名称；这些产品不同时备案时，一个产品使用原件，其他产品需使用经公证后的复印件，并书面说明原件所在的备案产品名称。

7 备案变更

对于已经备案的保健食品，需要变更备案凭证及附件中内容的，备案人应按申请备案的程序，向原备案机关按备案申请提交相关资料及证明文件。备案资料符合要求的，准予变更。食品药品监督管理部门应当将变更情况登载于变更信息中，将备案材料存档备查。

备案人的联系人、联系方式等发生变化的，应及时向备案受理机构提交加盖备案人公章的更改申请，受理机构及时对相关信息进行更新。

已备案的保健食品，因产品名称（商标名）不符合要求，被监管部门责令整改的，可以按照备案变更程序办理。

8 附则

本指南为试行版，涉及《保健食品原料目录》以及备案工作程序调整的，将及时修订。