Regulatory Insights

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China FDA

国家食品药品监督管理总局关于印发保健食品备案工作指南（试行）的通知

China FDA Notification of Releasing Health Food Recording Guide(Trial)

Health food recording refers to the procedure that health food manufacturers submitting materials about the product's safety, function and quality controllability to CFDA for archiving, publicity and future reference.

1. Scope of Application

Health food recording work stipulated in <Measures for the Registration and Recording of Health Food>.

2. Recording Subject

2.1 Domestic Health Food

The recording subject should be the manufacturer of health food. The previous registration subject(hereinafter referred to as previous registrant) could be the recording subject.

2.2 Imported Health Food

The recording subject should be the foreign manufacturer of health food. Foreign manufacturer refers to business body or other organizations who are in conformity with legal requirements on products' launching in the country of origin. Country of origin refers to the country that the products has been sold in.

3. Recording Procedure and Requirements.

3.1 Apply for the account of recording system.

3.1.1 Domestic Health Food

The domestic recorder should apply for the account to provincial or municipal FDA. The details shall be released by the management department of local FDA.

3.1.2 Imported Health Food

Recorder of imported health food should submit certificates and letter of authorization from government authorities or legal services corporation indicating the recorder is a foreign health food

manufacturer to CFDA acceptance department for the account. The CFDA shall issue the account after audit.

3.1.3 Previous Registrant
The registrant who wants to transfer the product to recording, should apply to CFDA technical evaluation department. After review, registration information of qualified cases will be transferred to recording management department. At the same time, applicants shall get written notification that they are allowed to submit recording application to recording management department.

Previous registrant refers to: 1. Health food registration issued before the releasing of <Health Food Ingredients List>, and is in conformity with recording technical requirements. The applicant could be the previous registrant. 2. Registered health food, which ingredients have been listed in <Health Food Ingredients List>, and is in conformity with recording technical requirements. The registrant could be the previous registrant.

Issued health food registration or registered health food before releasing of <Health Food Ingredients List>, which ingredients or dosage partly not in conformity with recording technical requirements, could become the previous registrant only after agreeing to adjust the formula according to <Health Food Ingredients List>.

For health food registration issued after the releasing of <Health Food Ingredients List>, which ingredients are listed in <Health Food Ingredients List> and the dosage is in conformity with relevant technical requirements, the registrant can't apply for product recording as the Previous Registrant.

3.2 Product Recording Information Completing and Submitting.
3.2.1 Domestic Health Food
With recording system account, enter system through <http://bjba.zybh.gov.cn/>bjba.zybh.gov.cn <http://bjba.zybh.gov.cn/>, fill relevant information and download materials with shape code including recording application chart, formula chart, label instruction book, product technical requirements etc. Get them stamped page by page (Except for test reports, notary documents or documentary evidences).

Scan all paper materials into chromatic PDF and upload them to recording management system. Submit after confirmation.

For the transition of health food from registration to recording, enter recording management system and modify product information according to <Health Food Ingredients List> and other relevant requirements with explanations and reasons.

3.2.2 Imported Health Food
With recording system account, enter system through <http://bjba.zybh.gov.cn/>bjba.zybh.gov.cn, fill relevant information and download materials with shape code including recording application chart, formula chart, label instruction book, product technical requirements and other recording materials(Refer to Article 6). Get them stamped page by page (Except for test reports, notary

documents or documentary evidences). Signature or seal of legal representative could be the alternative it there is no stamp.

Scan all paper materials into chromatic PDF and upload them to recording management system. Submit after confirmation and submit whole materials to CFDA acceptance department.

3.3 Issue, Archive and Publish of the Recording Number.
The recording number should be issued on the spot if all materials are in conformity with requirements and the recording certificate should be granted. For cases not in conformity with requirements, should notice to recorder for one time to supplement materials.

After issuing recording number to previous registered products, the recording department should notice CFDA technical evaluation department in written form to cancel registration certificate and approval number, or cancel previous application.

4. Form requirements on recording materials.

4.1 Health food recording materials should be in conformity with<Measures for Registration and Recording of Health Food>, <Health Food Ingredients List> and other relevant regulations regarding excipients, testings etc.

4.2 The filling of health food recording should be strictly in accordance with the requirements of the recording management system.

4.3 The first page of recording materials should be the item directory and page numbers. There should be a page between different materials writing material name and item reflecting the first page.

4.4 Relevant contents in materials should stay the same. If not, the recorder should submit written explanation, reason and reference.

4.5 Recording materials should be printed on A4 paper, Chinese size should be smaller than No.4, English shouldn't be smaller than No.12. The content should be complete and clear.

5. Items and Requirements of Domestic Health Food Recording Materials

5.1 Health food recording chart, letter of commitment claiming legal responsibilities for the authenticity of materials.
After filling information of recorder and product in the recording system, recording chart and letter of commitment will be produced automatically. Get them printed, stamped and submitted according to Article 3.2 .

5.2 Business registration document of recording subject
Should provide copies of business license, unified social credit code/ organizing institution bar code and scan of production licence with health food listed in.

Previous registrant should also provide registration certificate. If don't have a health food listed production licence, registrant can be exempt from having to provide the licence.

5.3 Formula Materials
5.3.1 Product Formula Chart including names and dosages of ingredients and excipients will be produced automatically according to the information filled by recorder.
Ingredients should be in conformity with <Health Food Ingredients List> , excipients should be in conformity with relevant requirements of approved excipients.
Dosages of ingredients and excipients refer to the quantity producing 1,000 pcs minimal packages.

5.3.2 Pretreated ingredients should be in conformity with <Health Food Ingredients List> , excipients should be in conformity with relevant requirements of approved excipients.

Ingredients and excipients in the pretreated ingredient should be respectively listed when filling recording chart. Each ingredient should be listed as the accumulated amount and shouldn't exceed the maximum level.

5.3.3 Previous registrant applying for recording, if the ingredients are not in conformity with <Health Food Ingredients List> or other relevant requirements, recorder is allowed to modify formula to meet the requirements but shouldn't add new ingredients.

5.4 Product Production and Technology Materials
5.4.1 Should provide flow chart and explanation. In the chart, the process from ingredients to final products should be marked in icon and symbol form. The chart should be in conformity with the technical requirements.
It should be marked out if pretreated ingredients are used in production.

5.4.2 Shouldn't change the chemical structure or components of ingredients by extraction, synthesis or other processes.

5.4.3 The dosage form should be reasonable to avoid any potential safety risks may caused by wrong dosage form.

5.5 Safety and Function Evaluation Materials
5.5.1 Should provide test reports of characteristic ingredients, hygiene and stability from three batches sampled from pilot trial or above-level production
Recorder should assure the source, traceability of samples. For domestic health food, three batches samples from pilot trial or above-level production should be provided for test.
Capable recorder could test the samples by themselves. Incapable recorder should authorize certified inspection agency to arrange the tests.

5.5.2 Provide a statement indicating ingredients and excipients are used reasonably and the label instruction book and product technical requirements are in conformity with relevant regulations.

5.5.3 Previous registrant should provide materials listed in 5.5.1 if the formula or technical requirements are modified. Otherwise, registrant could provide the previous test reports and make the explanation.

5.6 Packing Materials that Have Direct Contact with Product
Should provide the application reference such as category, name and standard.
5.7 Draft of Label and Instruction Book
The label should be in conformity with relevant laws and regulations. And stay the same with instruction book.
The draft of instruction book shall be produced automatically according to the information filled by recorder, the information should follow the requirements listed below:
【Product Name】 should in conformity with <Measures for Registration and Recording of Health Food> and other relevant regulations.
(1) Product name should consists of trademark, common name and attribute name. After filling trademark, ingredients and dosage form in system, the product name could be selected from category produced automatically.
(2) Using a registered trademark, recorder should provide trademark registration document or trademark authorization.
(3) One manufacturer shouldn't record health foods in different names with the same formula, shouldn't record health foods with different formulas in the same name.
Same formula refers to the same ingredients and excipients in the same dosage.
Same name refers to the same trademark, common name and attribute name.

【Ingredients】 List all ingredients as per Article 5.3
【Excipients】 List all excipients as per Article 5.3
【Active ingredient or Characteristic Component】Should include name and dosage, should stay the same with relevant names in technical requirements.
For products not belonging to nutrients supplement, the active ingredients or characteristic components should be in conformity with the minimum value in technical requirements and daily intake in <Health Food Ingredients List>.
For products belonging to nutrients supplement, the active ingredients' name should be the nutrients in all ingredients(in case of premix or brand ingredient). All nutrients should be ranked in the same order as listed in <Health Food Ingredients List>. Listed value of active ingredient refers to the certain value in the minimum consumption unit per formula and technical requirements. The value should be in conformity with the scope in technical requirements and daily intake in <Health Food Ingredients List>. The value should be marked as "Each tablet contains", "Each pill contains", "Each bag contains", "Each bottle contains" etc.

【Target Users】Meeting requirements of <Health Food Ingredients List> and recording management system, the crowd should have specific demand of certain safe and functional product.

Target users of nutrients supplement should meet the population division in <Health Food Ingredients List> which marked as "need to supplement XX + Age + population division" or "Adult, pregnant, wet nurse who need to supplement XX". And should follow the requirements listed below:

(1) Conjoint age groups should be marked together, for example if the target users include age 7-10 and 11-13, then it should be marked as age 7-13.

(2) For products with 3 or more than 3 vitamins, the Target Users could be marked as “need to supplement multivitamin”. For products with 3 or more than 3 minerals, the Target Users could be marked as “need to supplement multimineral”. For products with 3 or more than 3 vitamins and minerals, the Target Users could be marked as “need to supplement multivitamin and multimineral”.

(3) For products with 3 or more than 3 vitamin B(VB1,VB2,VB3 etc), the Target Users could be marked as “need to supplement multivitamin B”

【Unsuitable Crowds】Should be in conformity with the population division in <Health Food Ingredients List> include: Population excluded from Target Users, products without enough scientific evidence proving the rationality for kids under 3, pregnant, wet nurse or specific population particularly marked out by current regulations. Also should follow the requirements listed below:

(1) For products in forms of tablets or capsules etc, the risks caused by edible methods should be avoided.
(2) Unsuitable crowds should be determined considering application range of ingredients.
(3) Unsuitable crowds of nutrients supplement should include kids under 1 year old(include 1 year old).

【Health Functions】Should claim health functions according to <Health Food Ingredients List>.

For nutrients supplements, the functions should list all vitamins and minerals and be described as “Supplement XX”.

For products with 3 or more than 3 vitamins, the Health Functions could be marked as “Supplement multivitamin”. For products with 3 or more than 3 minerals, the Health Functions could be marked as “Supplement multimineral”. But the Health Functions shouldn’t be marked as “Supplement XX and multimineral”

For products with 3 or more than 3 vitamin B(VB1,VB2,VB3 etc), the Health Functions could be marked as “Supplement multivitamin B”

【Consumption and Edible Methods】Should be in conformity with formula scientific evidence and function evaluation material. The description should be formal and clear in order that consumption first and edible methods follows. If different population requires different dosage, the consumption should be marked separately.

For nutrients supplement, the total consumption shouldn’t exceed 20g solid or 30ml liquid.

【Specification】 Should be the weight or volume of the minimum packing unit. For example, the weight of capsule refers to the content, sugarcoated tablets refers to the tablet core before coating, film-coated tablet refers to the weight after coating. The specification should match consumption and edible methods such as Xg/tablet, Xml/bottle or Xg/bag.

One application could only record one specification, the recorder should apply for modification if need other specifications. The added specifications shall be marked in the recording certificate. One product couldn't apply for several recording certificates with different specifications.

If previous registrant has several specifications in previous approval certificate, one specification should be recorded and other specifications should be listed under item "MARK" in recording certificate.

【Storage】 Should be determined according to product's characteristics and stability test. Specific storage condition should be marked if it requires a cold storage.

【Attention】 Should mark "This product couldn't replace medicines, this product isn't recommended to population except for target users". Nutrients supplement also should mark "This product shouldn't be overdosed, this product shouldn't be taken together with other supplements containing the same nutrient". Should add specific explanation if needed, for example, "This product contains Aspartame" or "This product should be used with caution for PKU patients" etc.

5.8 Product Technical Requirements Materials
Recorder should insure the materials submitted are complete and in conformity with test reports, regulations, nation standards and <Health Food Ingredients List>.

The product technical requirements will be produced automatically after recording information filled in the recording management system.

【Product Name】Will be produced automatically after recording information filled in the recording management system.

【Ingredients】 List all ingredients and the dosages as per Article 5.3

【Excipients】 List all excipients and the dosages as per Article 5.3

【Production Process】Select master operations and critical process parameter according to actual production process. Same operations could be selected repeatedly.

【Category, Name and Standards of Materials Touching the Product Directly】Should stay the same as Article 5.6 .

【Sensory Requirements】Should describe the appearance of product and color, odor, taste and state of the content. No need to describe the packing materials or capsule shell.

【Identification】 The identifications should be elaborated if could be determined according to formula and other relevant researches. If the identifications not formulated, should provide the reason.

【Physical and Chemical Index】 Should indicate the name, value and test methods, if the methods are from nation standards, local standards or other normative documents, the document numbers are also required. If the test methods are formulated by revising nation standards, local standards or other normative documents, the document numbers are required at the same time, revised contents should be listed. If the test methods are formulated by recorder, the full text as well as the materials indicating its feasibility should be provided.

【Microbiological Indicator】Should provide the name, indication range and test methods of microbiological indicators.

【Active ingredient or Characteristic Component】Should list the name, indication range and test methods of active ingredient or characteristic component.

For nutrient supplements, the active ingredient should be all nutrients in the minimal edible unit such as each table, each capsule, each bag, each bottle etc. The vitamins should range from 80% to 180% compared with listed value. The minerals should range from 75% to 125% compared with listed value. The range should meet the daily intake regulated in <Health Food Ingredients List>.

If the methods are from nation standards, local standards or other normative documents, the document numbers are also required. If the test methods are formulated by revising nation standards, local standards or other normative documents, the document numbers are required at the same time, revised contents should be listed. If the test methods are formulated by recorder, the full text as well as the materials indicating its feasibility should be provided.

【Loading Quantity and Weight Variation Index(Net Weight and Allowable Bias)】 Should be listed in text.

【Quality Requirements of Ingredients and Excipients】 The specific quality standards should be listed item by item.

Standard numbers should be listed if ingredients and excipients are in conformity with <Health Food Ingredients List> or other relevant requirements. For pretreated ingredients, the executive standard, production process and critical process parameter are required.

5.9 Test Reports Issued by Certified Inspection Body Indicating All Projects Are in Conformity with Items listed in Product Technical Requirements

5.9.1 The inspection body should provide test reports of three batches using the methods listed in the product technical requirements.

The test reports should indicate the consistency with current regulations, nation standards and other normative documents.

The product name and test items should keep the same with application chart. The reports can't be modified after being issued.

For unauthorized sensory requirements, active ingredients or characteristic components, the inspection body should explain the test basis in text.

5.9.2 If these reports are issued by the same body as Article 5.5, the samples have to be from three different batches.

5.9.3 The previous registrant applying for recording of formula-adjusted products, should provide materials listed in Article 5.9.1. If the formula keeps unadjusted, could provide previous test reports.

5.10 Search Fields Related to Product Name
Recorder should search and print the results page from CFDA database using the product name to avoid the name duplication with existing products.

5.11 Other materials indicating product's safety and function.

6. Items and Requirements of Imported Health Food Recording Materials

Should submit all materials listed in Article 5 and additional materials are:

6.1 The Documentary Evidence of Recorder's Business Body Registration

Documentary evidence issued by government departments or legal services from the country of origin indicating the recorder is a foreign health food manufacturer. The evidence should specify the organization that issues the evidence, the name and address of the manufacturer, product name and the issuing date.

6.2 The Documentary Evidence Showing the Product Has Been on the Market for More Than One Year

Documentary evidence issued by government departments or legal services from the country of origin indicating the product has been on the market for more than one year. Or the safety report of sales and population consumption condition.

The documentary evidence of one year sales should clarify the product has been on the market as health food in the country of origin. The document should specify the organization that issues the evidence, the name and address of the recorder, the name and address of the manufacturer, product name and the issuing date. Should specify regulations, laws and standards which the product is in conformity with. Should specify the product is allow to enter the market. Should specify

the function and consumption population and other relevant materials which are in conformity with the recording application materials.

6.3 Original text of regulations and standards in the country of origin. The guarantee issued by manufacturer that imported health food is in conformity with China laws, regulations and standards. The self-examination report showing that the quality management system is running effectively. For materials regarding quality management system, credentials issued by government authority or institutions appointed by government authority should be submitted indicating its conformity with GMP. The credentials should specify the organization that issues the evidence, the name and address of the manufacturer, product name and the issuing date.

6.4 Recorder should insure the source and traceability of samples for tests. The imported recording product should be the same as those on the market of country of origin.

6.5 The Package and Label Instruction Book in the Country of Origin.
Should provide the picture and real object of label instruction book, and the notarized Chinese translation.

6.6 For recording applied by representative office in China, recorder should also provide registration licence of foreign enterprise China representative.

For recording applied by domestic agent, notarized letter of authorization and business license of the agent are required. The letter of authorization should list recorder, name of committed agent, product name, commitments and issuing date.

6.7 The recording materials should be in Chinese, the English version should be attached to the end. The translations of documentary evidence, label instruction book should be notarized and in accordance with original text.

6.8 Documentary evidence and letter of authorization should be original in official language with recorder's stamp or legal representative's signature. The documents should get confirmed by notary organization in country of origin and China consulate. All documents should be in validity.

6.9 There could be several products listed in documents of sales status, quality management system, GMP etc. If these products are recorded at one time, the original documents should be submitted for one products, and copies should be submitted for others. A written indication should be submitted with the copies pointing which product is the original documents attached to. If these products are not recorded at one time, the original documents should be submitted for one products, and notarized copies should be submitted for others, A written indication should be submitted with the copies pointing which product is the original documents attached to.

7 Recording Modification

For recorded health food which needs to be modified, the application should be submitted through application procedure to the same acceptance department as its application. The modification shall

be approved if all materials are qualified. CFDA should add the modification information in the system and keep all materials for future inspection.

The stamped application is required if contact person, contact details are modified. Acceptance department should get the information updated in time.

For recorded health food asked for rectification by supervision department result from a non-conformity of the name(trademark), the modification procedure should be taken.

8 Supplementary Provisions

This guide is a trial and will be revised regarding to any adjustments of <Health Food Ingredients List> or recording procedure.

Original Chinese Document listed Below

国家食品药品监督管理总局关于印发保健食品备案工作指南（试行）的通知

（食药监特食管〔2017〕37号）

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/>bjba.zybh.gov.cn <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/>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。