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

Regulatory Insights

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Government Agency
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Health Food Recording Rules (Exposure Draft)

保健食品备案工作细则（征求意见稿）

Regulation's Main Points

Health Food Recording Rules (2017) (Exposure draft)

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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 Form and Requirements

2.1 Obtain Recording Login Account Number

Domestic health food recording applicant shall submit recording application to its provincial, autonomous, direct-controlled municipal FDA. its provincial, autonomous, direct-controlled municipal FDA shall assign recording management information system login account number to the applicant. The domestic health food recording applicant shall be the health food manufacturer or the original health food registrant.

Imported health food recording applicant shall bring related proof documents to CFDA administrative acceptance service department to submit the recording application. The acceptance service department shall assign recording management information system login account number to the applicant. Imported health food recording applicant (include the original registrant) shall be the marketed health food oversea manufacturer and trader.

The original registrant can be the recording applicant, which means the product owner who hold effective health food registration certificate or in-processing apply for health food registration, its registered product or the product processing in applying for registration compliance with the technical requirements of health food raw materials list and recording management rules.

2.2 File out the Recording Information Online

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 . Read the <Health Food Recording Management Information System Usage and Legal Responsibility Declaration> and the <Recording Applicant Take Legal Responsibility for the Authenticity of the Submitted Materials Commitment Letter >. Complete the recording applicant related information and the product recording information one by one according to the requirements of <Health Food Recording Management Information System Manual>. Carefully read through the instruction and following the requirements to file out the recording information. Online declared information shall be in accordance with the related information of the submitted proof documents and application materials.

The original registrant shall verify the automatically generated product related information in the system after get into the health food recording management information system, then make changes and improve the recording information.

After finish online filling and successfully upload the information, the system will automatically generate recording register form, product formulation form, label instruction book, product technical requirements. Download those documents. Put signature and recording applicant's stamp on those documents. Other recording paper materials (see 4.1 article) – except the test reports

issued by the testing agency, notary documents, official proof documents and the third party proof documents – shall be stamped with the recording applicant's official seal page-by-page. For the imported health food recording applicant who cannot provide seal, replace with the legal person's signature. All above described paper materials shall be scanned into electronic version (PDF format) and uploaded on health food recording management information system. Then print out an original copy with barcode, identification code, page number. Except the original copy which is printed from the system, the imported health food recording shall also submit the original materials under 5.2 article.

The first page of the original copy is the system automatically generated 'Table of Content'. Separator page shall be added for each material. Separator page shall indicate product name, recording applicant's name, material name. Use obvious separate mark between each material, also indicate the serial number of the material in the table of content. Recording materials shall be printed by A4 paper. Chinese character shall not smaller than Song Typeface Small 4 font. English character shall not smaller than Small 12 font. The content shall be completed, clear and no changes. All materials shall be stapled together to be a binder.

2.3 Submit Recording Paper Materials

After the recording applicant finish the online filing and submit information successfully on the health food recording management information system, FDA shall inform the applicant to come to submit the original paper materials within 5 business days. 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. FDA shall finish document all recording information for future reference and make recording voucher according to required format.

If the recording applicant did not finish submission after receive the notice of submit paper materials from FDA within 30 days, the recording management information system would automatically return the declared product recording information to the applicant. If the applicant wants to apply for the recording, shall resubmit the recording information through the system.

2.4 Recording Login Account Information Alternation

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.

3 Requirements for Recording Materials

The recording applicant shall provide complete health food recording application materials. 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.

3.1 The content (such as product name, name and address of the recording applicant etc.) of those recording materials shall be consistent. The name and address on the business license of the recording applicant shall be consistent with the name and address of the recording applicant on the health food recording voucher. The proof documents of imported health food shall be consistent with the content of the recording voucher.

Proof documents uploaded to the recording management information system by the recording applicant shall be consistent with the original documents and paper materials.

3.2 Foreign language proof document, foreign language label instruction book and abstracts & keywords etc. in foreign language references which indicate the product safety, health function and quality controllability shall be translated into formal Chinese. All foreign materials attached in the back.

3.3 Test reports which are provided by the recording applicant shall be issued by legal qualified food testing agency. And the agency shall achieve the CMA certificate.

3.4 The source of testing samples shall be clear and traceable. Samples shall be produced by pilot or up scale production process. The manufacturer shall have food production permit contains health food category. The imported recording product shall be the marketed product in the country (region) of origin.

3.5 The same company cannot use the same formula to record health food in different name. The same company cannot use the same name to record health food in different formula. The same formula refers to the classification and usage level of raw materials and excipients are consistent. The same name refers to product's trade name, general name and attribute name are consistent.

4 Domestic Health Food Recording Materials and its Requirements

4.1 Recording Materials Catalog
(1) Health Food Recording Register Form, and Letter of commitment that recording applicant take legal responsibility for the authenticity of the submitted materials
(2) Registration proof document of the recording applicant body
(3) Product formulation material
(4) Production process material
(5) Safety and health function evaluation material
(6) Classification, name and related standard of direct-contact health food package material
(7) Samples of product label and instruction book
(8) Product technical requirements material
(9) All-items inspection report (meet product technical requirements) issued by legal qualified testing agency
(10) Product name material
(11) Other materials to declare product safety and health function
4.2 Requirements of the Recording Application Materials

4.2.1 Health Food Recording Register Form, and Letter of commitment that recording applicant take legal responsibility for the authenticity of the submitted materials.
The recording applicant shall read the <Declaration of Health Food Recording Management Information System Usage and Legal Responsibility> and < Letter of commitment that recording applicant take legal responsibility for the authenticity of the submitted materials > and file out the information through health food recording management information system.

4.2.2 Registration proof document of the recording applicant body
The recording applicant shall provide copy of <License of the Business Corporation>, uniform social credit code/organization code and other legal proof document. And the production permission proof documents consistent with the recording product.

The original registrant who have achieved health food approval certificate or declared health food registration shall provide produce approval certificate or the original voucher of change registration application to recording. If the recording applicant is the legal person or other organization, shall provide the material described in the first paragraph.

4.2.3 Product Formulation Material
Provide the product formulation form which is automatically generated by the health food recording management information system. The amount of raw material and excipient need to be enough for produce 1000 smallest dosage form unit.

Raw materials of nutrients supplement product (vitamin supplement, mineral supplement etc. health food) shall be ranked according the nutrients' order in <Health Food Raw Material List>. If the same nutrient use multiple compounds, rank those compounds by the amount level. Other product raw material shall be ranked according to <Health Food Raw Material List>.

Rank excipients by the amount level.

The selection of raw material and excipient shall conform to the below requirements:
(1) If the recording product's applicable population is 1-3 years old population, only the compound applicable for all population can be selected as raw material.

(2) The excipient selection only satisfies production process or improve the color, flavor and taste of the product, and also compliance with the usage instruction of the excipients list for health food recording product. The classification, quality standard and amount range shall conform to the excipients list.

(3) If the raw material has been pre-processed such as premix, encapsulation, microencapsulation, list the raw materials and excipients used in premix, encapsulation, microencapsulation.

4.2.4 Production Process Material

4.2.4.1 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 and product technical requirements shall be consistent.

4.2.4.2 If any raw materials and excipients have been pretreated by premix, encapsulation, microencapsulation, mark those in the following format: premix (xx, xx, xx), encapsulation (xx, xx, xx), microencapsulation (xx, xx, xx).

4.2.4.3 Not allow to change the chemical structure, composition etc. of the ingredient listed on <Nutrients Supplement Raw Materials List> by extraction, synthesis other reprocessing.

4.2.4.4 The dosage form selection shall be reasonable. The total daily recommended intake amount shall be less, the main dosage form shall be tablet, capsule (include hard capsule and soft capsule), granules, oral liquid. The product dosage form shall be adjusted according to the review and approval of registration product.

Sustained release dosage form, controlled release dosage form, pellet capsule, particle dosage form (nanometer), spray dosage form, sublingual absorb preparation, enteric-coated preparation, oral disintegrating tablets, membrane tablet, gastro-floating preparation and other dosage forms can not be selected for recording product. The recording applicant shall select reasonable dosage form for applicable population to avoid safety risks caused by unreasonable dosage form selection.

4.2.5 Safety and Health Function Evaluation Material

4.2.5.1 Provide functional component, hygiene, stability etc. self-inspection reports of three batches products which are produces through pilot or up scale production process.

4.2.5.2 Provide the instruction of raw material and excipient reasonable usage, instruction of product label instruction book and technical requirements compliance with related regulations. Besides nutrients supplements, other recording products shall provide proof documents for edible safety and function claims, provide strain identification report and strain toxicity test report if necessary.

4.2.5.3 Safety toxicity and function test materials are not required if conform to nutrients supplements recording rules and related national rules, also the production process is reasonable.

4.2.6 Classification, name and related standard of direct-contact health food package material.
List the classification, name, standard number, standard content and usage basis of direct-contact health food package material according to the production process and stability test etc.
4.2.7 Samples of product label and instruction book.

Product label shall compliance with the related law, regulation and other related rules. If involve in 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 be complete and standardized, which include the below content:

[Product Name] Automatically generated once the applicant filed out the recording information in the system, include brand name, general name and attribute name.

[Raw Materials] List all raw materials according to article 4.2.3.1

[Excipients] List all excipients according to article 4.2.3.1

[Functional Component and its content] Select the featured ingredient with stable character, accurate quantity, specific correlation with product function as functional component. The index value of functional component shall be determined by formulation, raw materials quality requirements, production, testing results and other factors. Except nutrients supplements, shall use the minimum index value in the technical requirement as the index value of functional component to show in the label instruction book listed value.
Nutrients supplement shall list all nutrient as functional component. The listed value shall be the certain theoretical value of any nutrient contain in the smallest unit, which calculated by the product formulation, for example, tablet shall mark as 'each tablet contains xx'. 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>. The rank of functional components shall be the same as nutrients' order in <Health Food Raw Materials List>.

[Applicable Population] In accordance with <Health Food Raw Materials List>; specific population that safe to consume the product and with applicable function requirements.
The applicable population of nutrients supplements shall be marked as "xx need supplement xx + age + population", "Adults, pregnant woman, breastfeeding woman need supplement xx". 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 and 11-13 years old, marked as 7-13 years old. If the product contains three or more vitamins and minerals, marked as 'xx population need supplement multiple vitamins and minerals'. 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'. The population range shall in accordance with the format in raw materials list.

[Non-applicable population] The current scientific basis is not enough to support the product applicable for infant, pregnant woman, breastfeeding woman etc. The current rules stipulate that shall mark those specific populations. If select two or more continual age groups as non-applicable population, shall combine those age groups to show and the format shall be in accordance with <Health Food Raw Materials List>. Non-applicable population shall include:

(1) under 1 years old;
(2) Specific population which not be included in the applicable population; not in accordance with health food raw materials list rules and may exist edible safety risks.
(3) Specific population which need to be indicated by current rules;
(4) If the product selects one of the following dosage form: oral tablet, lozenge, chewable tablet, capsule, shall exclude the population who met exist edible safety risks caused by edible method;
(5) Determine the non-applicable population by the applicable range of raw materials and excipients.

[Health Function] Mark health function according to the rules.
Nutrients supplement shall list all supplement vitamins or minerals, described as 'supplement xx, xx'; For the product contains three or more vitamins or minerals, described as 'supplement multiple vitamins or minerals', but cannot described 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] The description shall be standardized and detailed. Description sequence is intake amount, edible method. Shall mark daily intake times and intake amount for each time. If different applicable population need follow different intake amount, shall mark separately for each applicable population.

Tablet (except lozenge, chewable tablet, effervescent tablet), capsule and oral liquid shall be taken orally, for age 1-3 years old population, shall break the soft capsule to eat; Lozenge shall be put in mouth; chewable tablet shall be chewed; effervescent tablet shall be resolved by water and then drink; granules shall be resolved by water and drink.

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 shall for the smallest dosage form unit (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), in accordance with the edible method. For examples, tablet: X g/tablet; capsule: X g/capsule; oral liquid: X ml/bottle; granules: X g/bag. Each recording product shall only declare one product specification.

[Storage method] The recording applicant shall identify the storage method by health food stability test according to CFDA's procedure and method.

[Shelf life] The recording applicant shall identify the shelf life by health food stability test according to CFDA's procedure and method. For example, if the accelerated test shows that the product's shelf life is 2 years, mark the shelf life as 'xx months'. Mark as 'xx days' if not enough one month.
[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 or swallowed.

4.2.8 Product Technical Requirement Material

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

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.

[Product Name] Automatically generated once the applicant filed out the recording information in the system, include brand name, general name and attribute name.

[Raw Materials] List all raw materials according to article 4.2.3.1

[Excipients] List all excipients according to article 4.2.3.1

[Production Process] Shall be automatically generated after select from the <Product Technical Requirement – production process recommended database>. Select master operation, key control parameters one by one according to the real production operation procedure; Master operation with the same description can be selected repeat.

If any raw materials have been pretreated by premix, encapsulation, microencapsulation, mark those in the following format: premix (xx, xx, xx), encapsulation (xx, xx, xx), microencapsulation (xx, xx, xx).

[Classification, name and related standard of direct-contact health food package material] Shall be described by words.

[Sensor Requirements] Describe the appearance (color, form etc.) and content (color, taste, odour, 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 the testing method is created by the applicant, provide the whole content; 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.

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

[Functional Component] Indicate the name, 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 each tablet, each pill), 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>.
Except nutrients supplements, other products' functional component index value shall be the content of each 100 gram or 100 ml.
If the testing method is created by the applicant, provide the whole content; 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.

[Weight Deviation Index (net weight and allowable negative tolerance index)] Described by words.

[Quality Requirements of Raw Materials and Excipients] List the standard number.

4.2.9 All-items inspection report (meet product technical requirements) issued by legal qualified testing agency.
The recording applicant shall authorize the legal qualified testing agency to conduct all-item inspection of the product technical requirements. The testing agency shall conduct test according to the applicant proposed items and method in the product technical requirements, and then issue functional component, hygiene, stability tests all-items inspection report of three batches. Stability test refers to the testing agency use the delivered samples to test changes of product stability key indicator within the shelf life according to CFDA's test procedure, method and the test method in the application materials.
Test report shall include the conclusion of if the test result meet for the current regulation, guideline, mandatory national standard and technical requirements.
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.

4.2.10 Product Name
Product name consist of brand name, general name and attribute name, in accordance with <Measures for Health Food Registration and Recording> and other rules. Product name shall conform to related law and regulations. 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.

If the product excipients contain one flavor, can place bracket after the product name to describe flavor, such as sweet orange; Place bracket after the product name to describe the applicable population according to population range, such as pregnant.

The attribute name will be automatically generated in the system after the dosage form been identified.

Product name will be automatically generated in the system after the applicant input brand name, raw materials name and dosage form. Nutrients supplements' general name can be selected from the below:
(1) Rank all nutrients' name according the nutrient's order in <Health Food Raw Materials List>. If the nutrients supplement contains three or more nutrients, muse use all nutrients' name as general name.
(2) If nutrients supplement contains three or more vitamins or minerals, use 'multiple vitamins or minerals' as general name, but cannot use 'one raw material name + multiple vitamins or minerals' as general name.
(3) If the nutrients supplement contains three or more vitamin B (vitamin B1, B2, B6, B12, niacin, pantothenic acid, folic acid etc.), use 'niacin vitamin' as general name.

4.2.11 Other materials can show product safety and health function
Provide the table of content of the following documents, use symbol to separate each documents:
(1) Food permission certificate contains health food category;
(2) If the sample is manufactured by OEM, provide original OEM agreement.
(3) Scientific references with source, author, year, volume, issue, page number etc.

5 Requirement of Imported Health Food Recording Materials

5.1 General Requirement
(1) The Chinese translation of foreign proof documents and foreign label instruction book shall be notarized by Chinese notary authorities and in accordance with the original content.

(2) Any proof documents, authorization letter (agreement) etc. issued by oversea institute shall be the original copy with the official language of the country of origin and company's seal or legal representative's (or authorized person) signature. The original copy shall be notarized by the notary authorities and confirmed by the Chinese embassy in the country of origin. Proof documents, authorization letter (agreement) etc. shall be used within specify expiration date.

(3) The authorization letter shall specify recording applicant, the name of the authorized agency, product name, commitment and issue date.

5.2 Requirements of Imported Product Recording Materials
Submit the domestic product required materials and the below:

5.2.1 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.

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 on 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.

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.

5.2.3 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 need to provide 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.

5.2.4 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.

5.2.5 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.

5.2.6 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.

5.2.7 The authorization letter shall identify recording applicant, authorized agency name, product name, authorized matters and issue date of authorization letter.

6 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.

7 Health Food Recording Cancellation

FDA shall cancel health food recording if one of below situation happen during the recording period through daily supervision and report.

(1) Recording materials false;
(2) Safety issues existed in production process, formulation of the recording product;
(3) The production permit has been withdrawn;
(4) The recording applicant apply for cancellation;
(5) Other situation according to the law;

8 Information Disclosure

The recording applicant shall file out the recording information in the system truthfully. After receive the recording voucher, FDA shall disclose the information, alternation and cancellation status of the recording form on their website. CFDA health food review center shall submit the related product recording electronic information to CFDA information center. CFDA shall disclose the product recording information and its attachment, cancelled original registration certificate, cancelled or altered recording product related information according to the requirements immediately.