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

Regulatory Insights

Date Released
December 23 2016

Government Agency
CFDA

Health Food Registration Application Service Guideline (2016)

保健食品注册申请服务指南（2016 版）

Regulation's Main Points

Health Food Registration Application Service Guideline (2016)

For Imported Product

1. Applicable Scope

This guideline applicable to the following registration applications:

- Health food that use raw materials other than those included in the health food raw materials list;
- First-time imported health food (exclude those health foods belong to vitamin supplements, minerals and other nutrients).

2. Requirements for Application Material Format

2.1 Registration applicant shall enter the health food registration application system through CFDA's website (www.cfda.gov.cn) or CFDA health food review center's website (www.bjsp.gov.cn), file and print the following forms: Domestic Health Food Registration Application Form (Appendix 1), Imported Health Food Registration Application Form (Appendix 2), Domestic Health Food Registration Alternation Application Form (Appendix 3), Imported Health Food Registration Alternation Application Form (Appendix 4), Domestic Health Food Registration Renewal Application Form (Appendix 5), Imported Health Food Registration Renewal Application Form (Appendix 6), Domestic Health Food Technical Transfer Registration Application Form (Appendix 7), Imported Health Food Technical Transfer Registration Application Form (Appendix 8), Domestic Health Food Registration Re-issue Application Form (Appendix 9), Imported Health Food Registration Re-issue Application Form (Appendix 10).

Please read through the instruction before file the form. The content shall be completed and no changes allowed, also in accordance with the submitted proof documents and application materials.

2.2 The first page of the application dossier shall be the table of content. Add an interval page between each material. The interval page shall indicate the name of the product, the name of the applicant, the name of the material. Each material shall be separated by visible signs. The serial number of each material shall be indicated in the table of content. The application dossier shall be staple.

2.3 Application materials shall be printed by A4 paper. Chinese characters shall be in Song typeface and no less than small 4 fonts, English characters shall be no less than 12 fonts. The content shall be completed, clear and no changes allowed.

Except registration application form, test report issued by the testing agency, notary documents, official certified documents and third party certified documents, the other application materials shall be stamped by the applicant's seal page by page. The seal shall conform to the related national rules and with legal efficacy. For imported health food registration applicant who do not own seal, shall be replace by legal person's signature or signature seal.

2.4 The same content (such as product name, registration applicant name, address etc.) in the application dossier shall be consistent with each other. For registration alternation application and registration renewal application, the name and address of the applicant's business license shall be consistent with the name and address of the registrant in health food registration certificate.

2.5 The foreign proof documents, foreign label and instruction book, abstract and keywords and other contents in the foreign references which can show product safety, health function, quality controllability shall be translated into Chinese. Put foreign materials attached behind the Chinese version.

2.6 Registration application form, product formula, label and instruction book, product technical requirements shall be filed out online and printed with seal on. The other application materials shall be scanned as PDF document and uploaded to the health food registration application system to print.

The registration applicant shall submit the original copy of application materials and the copy page (attach with barcode) after finish up online submission. The copy page shall be completed and clear enough. The content of the copy page shall be consistent with the original copy.

2.7 The new product registration application materials shall include one original copy and nine copies of the original copy. The application materials and supplementary materials of technical transfer registration, registration renewal and registration alternation shall include one original copy and three copies of the original copy. The registration re-issue application material shall include one original copy.

2.8 If need supplement materials, the registration applicant shall submit supplementary materials and finish online submission in order after receive the electronic review comment notice by acceptance number and login password. The supplementary materials shall be integrated and stamped with the same seal as the original applicant. Start from the fifth day after granted the <Review Comments Notice>, the applicant shall submit all supplementary materials at a time within 3 months.

The applicant shall verify the content of the registration certificate within the prescribed time limit according to the procedure. If the applicant has objections for the certificate, shall submit feedbacks with all errors and explanations to CFDA through the registration system.

2.9 If any changes happen to the contact person, contact number etc. of the registered product, the applicant shall submit the alternation application stamped with the applicant's seal to the acceptance institute immediately. The acceptance institute shall update the related information immediately.
2.10 For registration renewal, the applicant shall make appropriate arrangement of the submission time. The health food registration renewal shall ben submitted and approved 6 months prior to the expiration of the validity.

2.11 If the product which will pursue the technical transfer application is in-process of other registration issues, the technical transfer application will not be accepted before finish those issues.

The applicant can submit the registration alternation application or the registration renewal application when dealing with the technical transfer application. But if the registration renewal application or registration alternation application has been accepted, the technical transfer application shall be terminated.

The applicant can apply for the registration alternation for multiple matters, the related registration renewal can be accepted at the same time. If those applications cannot be processed at the same time due to objective reasons, the review center shall inform the applicant in written and explain reasons. And if the applicant has no objections, the alternation application matters are terminated automatically.

If the name and address of the applicant have been changed during the registration process, the applicant shall provide supplementary alternation application.

If the applicant submitted multiple alternation matters at different times, the review time limit of the latest accepted alternation matters would be the review time limit of all matters.

2.12 If the product which pursue new product registration, technical transfer, registration alternation, registration renewal has been included into the health food raw materials list and in accordance with related technical requirements, the acceptance institute will not accept it.

2.13 For the product registration which has not been approved, the applicant can submit written application to recall the following materials within 1 month since receive the disapproval decision letter: authorization letter which show the oversea applicant authorize the domestic agency to handle the registration, proof documents issued by oversea institute. The other materials and sample will not be returned.

3. Requirement of the content of the application materials
Health food registration application materials shall be integrated and in accordance with <Measures for health food registration and recording>, <Measures for health food registration test and re-test>, <Technical guidelines of health food test and evaluation>, <Health food registration review rules> etc. regulations.

3.1 The product which apply for registration shall has sufficient scientific basis of safety, health function and quality controllability. The applicant shall provide the source of scientific basis, table of content and the content, as well as the comparison research with the product formula, production process etc. technical requirements. Also, the applicant shall submit the demonstration and summary of the product safety, health function, quality controllability by order.

3.2 The source of tests and research samples shall be clear and traceability. The sample shall be produced by pilot or above scale up production. The manufacturer facility shall be established appropriate manufacturing quality management system, which can be effective operated. The sample of first time imported product registration shall be the on sale product in the country (region) of origin.

3.3 The submitted demonstration report or research report etc. shall include the starting and ending time of the research, location, research purpose, method, basis, process, result, conclusion, department, researcher's seal etc. The authorization agreement and other related materials shall be provided if authorize a third party to conduct the research.

If the functional component, hygiene, stability tests are conducted by the applicant itself, the applicant shall implement quality control test, report establishment, sample and archives management according to <Measures for health food registration test and re-test>, also the self-test report shall in accordance with the requirements in the regulation.

If the functional component, hygiene, stability tests are authorized to be done by the testing agency, the authorized agency shall be any legally qualified food testing agency.

3.4 Experimental records, equipment usage records, pilot manufacturing records and other original materials shall be long-term archived for future references by the applicant. No need to submit those materials for the registration application. But the review center can conduct inspection for those materials if necessary.

3.5 The same company cannot use the same formula to register for health food in different names. Cannot use the same name to register health food in different formulas.

The same formula means the classification and usage of raw ingredients and excipients are all the same. The same name means the brand name, general name and attribute name of the product are all the same.

3.6 When the applicant resubmits the registration application after receive the disapproval decision, shall use the product name of the first-time application and provide a copy of the disapproval decision letter (stamped with the applicant's seal), resubmission reasons, detailed description and explanation about the original disapproval comments, comparison with the original application materials, other related materials. Al above materials shall be at front of the application dossier.

If the changed key contents affect the product safety, health function, quality controllability in the resubmitted application, the applicant shall re-conduct the product research & development, supplementary research & development or evaluation demonstration.

4. Terminology and Definition

4.1 Scientific basis refers to any scientific references, evaluation tests, risk evaluations, authorities and statistics etc. related with safety, health function and quality controllability of the product which apply for health food registration.

(1) Reference basis: research paper published on the domestic core journals or international core journals; descriptions in Chinese traditional herbal ancient books; reference analysis and evaluation report; officially released international standards, national standards, risk evaluations, statistics etc. by international recognized food hygiene authorities or Chinese authorities and related departments.

(2) Test basis: test reports issued by testing agency; research tests conducted by the applicant; food safety risk evaluation report issued by risk evaluation agency etc.

4.2 Reference analysis and evaluation report refers to the scientific reference evaluation reports (about product safety and health function) provided by professional technical workers through reference retrieval, selection and analysis. The reference data collection shall be accurate. Reference retrieval and selection shall be repeatable.

4.3 Safety Evaluation Test refers to the testing agency use submitted health food or its ingredients to conduct the test which aim to verify the edible safety according to CFDA rules and requirements.

4.4 Health Function Evaluation Test refers to the testing agency use submitted health food conduct the test which aim to verify the health function according to CFDA rules and requirements.

4.5 Functional Component Test refers to the applicant or testing agency use submitted samples to detect quantity of the functional components and its variables within the expiration date according to the testing method in the application materials.

4.6 Hygiene Test refers to the applicant or testing agency use submitted samples to conduct whole items inspection of product technical requirements according to the index test method in the application materials.

4.7 Stability Test refers to the applicant or testing agency use submitted samples to detect variables of the product stability key index within the expiration date according to CFDA's health food stability test procedure, method and test method in the application materials.

Product stability key index include appearance, microorganism, disintegration time limit, water content, PH, acid value, peroxide value, mycotoxin, properties listed in physical index and other index which will be easily to change along with storage condition and time.

Product instability key index include identification, ash content, pollutant (such as Pb, total As, total Hg etc.), pesticide residue, synthetic pigments and sweeteners (usage limit conform to national standard and current rules) and other index which will not be easily to change along with storage condition and time. Also include antioxidant index (usage limit conform to national standard and current rules).

5 – 11 for Domestic Products

12. Requirements of Imported Product Registration Application Materials

12.1 General Requirements
(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 registration applicant, the name of the company who was authorized, product name, commitment and issue date.

12.2 Requirements of Imported New Product Registration, Registration Renewal, Registration Alternation, Technical Transfer Application Materials.

(1) Qualification proof document issued by government authorities or legal service organization from the country of origin to show that the registration 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.

(2) 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, registration 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.

(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.

(4) Package, label, instruction book samples of the product which on the market of country of origin.

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

Where an overseas registration applicant authorizes an agency within China to handle registration matters, the original copay of notarized authorization letter and the photocopy of the business license of the authorized agency shall be submitted.

Except the above materials, the applicant shall provide the following materials base on different registration application categories.

12.2.1 Imported Product Registration Alternation Application

Shall provide alternated product package, label and Instruction book samples, proof documents issued by the government authorities or legal service organizations from the country of origin to show that the application matters have been alternated, and the following materials:
(1) For the alternation application of changing the name and address of imported product registrant, shall provide the proof document issued by the government authorities or legal service organizations from the country of origin to show that the production site has not been changed.

(2) For the alternation application of changing oversea production site of imported product registrant, shall provide the proof document issued by the government authorities or legal service organizations from the new production site country to show that the product has been available for sale in that country, package and label instruction book samples of the product marketed in the new production site country, functional component test and hygiene test and stability test reports on three batches' testing samples are manufactured in the new production site issued by testing agency with legal qualifications. If changed the oversea production site and the country of origin at the same time, shall provide related materials according to technical transfer requirements.

12.2.2 Imported Product Oversea Technical Transfer Registration Application

Shall provide the transfer agreement notarized by the notary organ in the country of transferee and confirmed by the local Chinese embassy.