

Provisions for Health Food Registration (interim)

Chapter I General Provisions

Article 1 With a view to standardizing the registration of health food, guaranteeing the quality of health food, ensuring food safety for people's consumption, the Provisions are formulated in accordance with Food Hygiene Law of the People's Republic of China and Administrative Reconsideration Law of the People's Republic of China.

Article 2 The health food mentioned in the Provisions refers to those foods which claim to have certain health functions or aim at supplementing vitamins and minerals, namely, those foods which are used for certain groups of people with the aim to adjust organic function instead of curing diseases and will not cause any acute, sub-acute or chronic damages to human body.

Article 3 The Provisions apply to the registration of both domestic and imported health food in the territory of the People's Republic of China.

Article 4 the registration of health food refers to the application and approval procedures of the State Food and Drug Administration to systematically assess and review the safety, effectiveness and quality control of the health food applying for registration, as well as their labels, package insert and other contents, and then determine whether to approve of the registration according to legal procedures, qualifications and requirements, depending on the application of the applicant. The procedures include the review and approval of registration application, application for alteration and registration application of technical transfer product.

Article 5 The State Food and Drug Administration is in charge of the registration administration work of the health food nationwide and responsible for the review and approval of health food.

The (food) and drug Administration departments of the provincial, autonomous and municipal regions directly under the Central Government are entrusted by the State Food and Drug Administration and are responsible for the acceptance and format review of registration application dossiers for domestic health food, checking the site for the testing and sample trial production of the health food in the registration application, and organize the inspection of the samples.

The inspection institution designated by the State Food and Drug Administration is responsible for the safety toxicology test, function test (including both animal testing and/or pre-eat test on human body, active ingredients or badge element test, hygiene test, stability test; and conducts the specific inspection and recheck of the samples.

Article 6 The registration and administration of health food should adhere to the principles of being scientific, open, just, efficient and convenient.

Chapter II Application and Approval

Section I General Requirements

Article 7 The applicant for health food registration refers to the person who applies for health food registration, is able to assume the relevant legal liabilities and holds the approval certificate for the health food after the application is authorized.

The applicant in Chinese territory should be the citizen, legal person or other organizations legally registered in the territory of China.

The foreign applicant should be a legal health food manufacturer in foreign countries. The imported health food registration of foreign applicants should be conducted by its representative office in China or the agency in China who is entrusted by the foreign manufacturer.

Article 8 The registration of health food includes the product registration application, the application of alteration and registration and the application of technical transfer product.

Article 9 The State Food and Drug Administration and the (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government, should publicize the dossiers needed for health food registration application and the relevant registration application model text at the department location where health food registration application is accepted.

Article 10 The health food registration applicant should submit complete and standard dossiers and provide actual conditions according to the provisions and should be responsible for the authenticity of the application dossiers.

Article 11 The applicant should be permitted to alter mistakes outright in the application dossiers submitted if any mistakes in the application dossiers is found outright.

Article 12 If the application Articles of the applicant are incomplete and do not conform to the legal formats, the State Food and Drug Administration and the (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government should inform the applicant of the dossiers needed outright or in 5 days; if they do not inform the applicant within the time limit, the application is namely accepted the day when the application dossiers are submitted. A written statement should be given to the applicant if the application is not accepted.

Article 13 In the review process, the State Food and Drug Administration should inform the applicant at one time of any other supplement dossiers needed. The applicant should submit the supplement dossiers within 5 months after they receive the notice. The application should be rejected if the supplement dossiers can not be submitted at due time. The applicant must submit a written application and state the reason for the delay if the supplement dossiers are overdue in special cases. The State Food and Drug Administration should respond within 20 days.

Article 14 In the event of supplement dossiers needed in the registration application, the review period should be prolonged by 30 days on the basis of the original review period and the period for the alteration of the application should be prolonged by 10 days.

Article 15 If the registration is approved after a legal review process, the State Food and Drug Administration should issue a health food approval certificate to the registration applicant in a stipulated time and deliver it in 10 days; if the registration is rejected, it should inform the applicant in a written form in a stipulated time, state the reason and inform the applicant of his right to apply for re-examination, administrative reconsideration or lodge administrative litigation.

Article 16 The State Food and Drug Administration and the (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government should inform the interested person if they find that there are application dossiers directly related to major benefits of other people in the review process of health food registration application. The applicant and the interested person can submit their statement and defense in written form or apply for a hearing according to the law.

Article 17 The State Food and Drug Administration should publicize the acceptance, review process of the health food registration application information and relevant information of approved health foods at their government website.

Article 18 The State Food and Drug Administration should duly adjust the function ranges of health foods, assessment and inspection methods of health foods, as well as the technical standard in the review accord to the development and need of science and technology and publish the information.

Section II the Product Registration Application and Approval

Article 19 The product registration application includes the domestic health food registration application and imported health food registration application.

The domestic health food registration application refers to the application of the applicant who registers to produce and sell health food in China.

The imported health food registration application refers to the registration application of health food which has been produced and sold in foreign territory and will be sold in Chinese market.

Article 20 The applicant should conduct relevant research work before he applies for the health food registration.

After the research work is completed, the applicant should submit the samples and relevant testing materials to an inspection institution designated by the State Food and Drug Administration for the relevant test and inspection.

If the applied health function is included the range published by the State Food and Drug Administration, the applicant should provide the product research report by an designated inspection institution; if the applied health function is not included in the range published, the applicant should conduct the animal test and pre-eating test on human body independently and provide the function research and development report to the inspection institution.

A product research and development report should include the research and development ideas, function screening process and expected effects. A function research and development report should include the name

of functions, application reasons, function testing, assessment method and testing results. If the animal test and pre-eating test on human body can not be done, the reason should be stated in the function research and development report and the relevant data should be submitted.

Article 21 After receiving the samples and relevant data submitted by the applicant, the inspection institution should conduct the safety toxicology test, function test, active ingredient test or badge substance test, hygiene test and stability test according to the health food inspection and assessment technology standard published by the State Food and Drug Administration, as well as the inspection methods published by other relevant departments and provided by the relevant industry. If the function is not included in the range published by the State Food and Drug Administration, the applicant should validate the function test and the methods of assessment and the test results, and submit the testing report.

Article 22 The applicant can apply for the health food registration only after the test report is issued by the inspection institution.

Article 23 When applying for the domestic health food registration, the applicant should fill in Application Form for Registration of Domestic Health Food according to the provisions and submit the application dossiers and samples to the (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government, where the sample trial production is located.

Article 24 The (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government should review the application dossiers on their standard and integrality forms and samples and send an acceptance or rejection notice to the applicant within 5 days after receiving the application dossiers

Article 25 Concerning those qualified registration applications, within 15 days after the acceptance of the application, the (food) and drug administration departments on the provincial , autonomous, municipal level under the Central Government should inspect the site of test and sample trial production, select samples for inspection, provide a review conclusion and submit the conclusion and application dossiers to the State Food and Drug Administration and at the same time send an inspection notice to the designated inspection institution and provide samples for inspection.

Article 26 The samples needed for health food registration application should be produced in the workshop which meets the Good Manufacturing Practice for Health Food and the processing must conform to the provisions in the Good Manufacturing Practice for Health Food.

Article 27 After receiving the inspection notice and samples, the inspection institution should inspect and recheck the samples and submit the inspection report to the State Food and Drug Administration and at the same time send the copies of the inspection report back to the (food) and drug administration department on the provincial, autonomous, municipal level under the Central Government and the applicant. In special cases, when the inspection institution cannot complete the inspection task within the stipulated time, it should inform the State Food and Drug Administration and the (food) and drug administration departments on the provincial, autonomous, municipal level under the Central Government in written form to state the reason in time.

Article 28 After receiving the review conclusion, application dossiers and samples submitted by the (food) and drug administration department the provincial, autonomous, municipal level under the Central Government, the State Food and Drug Administration should organize the technicians in the field of food, nutrition, pharmacy and medicine to conduct technical assessment and administrative review on the application dossiers and then give review decision within 80 days. It should issue Domestic Health Food License to the applicants whose application is approved.

Article 29 When applying for imported health food registration, the applicant should fill in Application Form for Registration of Imported Health Food according to the provisions and submit the application dossiers and samples to the State Food and Drug Administration.

Article 30 The State Food and Drug Administration should conduct the standard and integrality review of the format on the application dossiers and send a written notice to accept or reject the application within 5 days after receiving the application dossiers and samples. If the registration application meets the qualifications, the State Food and Drug Administration should send a inspection notice and the samples for inspection to the inspection institution within 5 days after accepting the application. Depending on the need, the State Food and Drug Administration can conduct inspection on the production site and testing site of the product.

Article 31 The inspection institution should conduct the sample inspection and recheck to the samples, send the inspection report to the State Food and Drug Administration and at the same time send copies of the inspection report to the applicant within 50 days after receiving the inspection notice and samples. In special cases when the inspection institution can not complete the inspection within the stipulated time, it should submit in a written form to state the reason to the State Food and Drug Administration in time.

Article 32 Within 80 days after accepting the application, the State Food and Drug Administration should organize technicians in the field of food, nutrition, pharmacy and medicine to conduct technical assessment and administrative review on the application dossiers and give review decision. It should issue Imported Health Food License to the applicant whose registration is approved.

Article 33 Health Food License is valid for 5 years. The approval document number of domestic health food is in the following form guoshijianzi (a good quality certification code)G + four-figured year code + four-figured serial number; The approval document number of imported health food is in the following form guoshijianzi :J + four-figured year code + four-figured serial number.

Section III Alteration of Registration and Approval

Article 34 Alteration of registration refers to the application in which the applicant asks to alter the content of the health food license and its appendixes.

Article 35 The applicant of registration alteration should be the holder of the health food license.

Article 36 The content, function name of health food, raw (additive) materials, techniques, dosage, expansion of the range of suitable users, reduction of the range of unsuitable users, which are specified in the health food license and are possibly to affect the safety and function should not be altered.

Article 37 The health food while applying for reducing the range of suitable users, expanding the range of unsuitable users, precautions and function Articles, and alter dosage, product specifications, storage life and quality standard should be the products which are being produced and sold. The additional function Articles must be within the range published by the State Food and Drug Administration.

Article 38 If applying for the alteration of the content specified in the Domestic Health Food License and its appendixes, the applicant should fill in the Alteration Application Form for Domestic Health Food Registration and submit the relevant data and explanation to the (food) and drug administration departments on the provincial autonomous and municipal level directly under the Central Government where the applicant is located.

Article 39 The (food) and drug administration departments of the province, autonomous region, and municipality directly under the Central Government should conduct standard and integrity review of the format of the application dossiers and send acceptance or reject notice within 5 days after receiving the application dossiers.

Article 40 Concerning the application for alteration of product name, storage life, dosage, reduction of the range of suitable users, expansion of the range of unsuitable users, precautions and function Articles, The (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should give a review conclusion and submit the application dossiers to the State Food and Drug Administration within 10 days after accepting the application. The State Food and Drug Administration should organize technicians in the field of food, nutrition, medicine and pharmacy to conduct technical assessment and administrative review on the application dossiers and give review decision within 40 days after receiving the review conclusion. If the alteration of application is approved, it should issue Alteration Approval of Domestic Health Food to the applicant and at the same time send copies of Alteration Approval of Domestic Health to the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government.

Article 41 In the event of the application for alteration of product specifications and quality standard, the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should give review conclusion and send the conclusion and application dossiers to the State Food and Drug Administration with in 10 days after accepting the application and at same time send an inspection notice and samples for inspection to the designated inspection institution. The inspection institution should inspect the samples and submit an inspection report to the State Food and Drug Administration and at the same time send copies of the inspection report to The (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government and the applicant within 30 days after receiving the inspection notice and samples. The State Food and Drug Administration should organize technicians in the field of food, nutrition, medication and pharmacy to conduct technical assessment and administrative review and give a review decision within 50 days after receiving the review conclusion, application dossiers and samples. If the alteration is approved, it should issue Alteration Approval of Domestic Health Food and send the copies of Alteration Approval of Domestic Health Food to the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government.

Article 42 If applying for alteration of the content of Imported Health Food License and its appendixes, the applicant should fill in Application Form of Imported Health Food Alteration and submit the relevant data and explanation to the State Food and Drug Administration.

Article 43 The State Food and Drug Administration should conduct format review on the standard and integrality of the application dossiers and send a acceptance or reject notice within 5 days after receiving the application Articles.

Article 44 In the event of the application for altering product name, storage life, dosage, reducing the range of suitable users and expansion of unsuitable users, precaution and function Articles, the State Food and Drug Administration should organize technicians in the field of food, nutrition, medicine and pharmacy to conduct technical assessment and administrative review on the application Articles and give a review decision within 40 days after accepting the application. If the application is approved, it should issue Alteration Approval of Imported Health Food.

Article 45 In the event of the application for altering product specifications, quality standard and production site by the health food manufacturer in foreign territory, the State Food and Drug Administration should send an inspection notice and samples for inspection to the designated inspection institution within 5 days after accepting the application. Depending on the need, the State Food and Drug Administration should conduct production site inspection of the product.

The inspection institution should conduct sample inspection and submit an inspection report to the State Food and Drug Administration and at the same time send the copies of the inspection report to the applicant within 30 days after receiving the inspection notice and samples.

The State Food and Drug Administration should organize technicians from the field of food, nutrition, medicine and pharmacy to conduct technical assessment and administrative review on the application dossiers and give a review decision with 50 days after accepting the application. If the alteration is approved, it should issue Alteration Approval of Imported Health Food to the applicant.

Article 46 In the event of the application for altering the name and address of the applicant and the agency in Chinese territory, the applicant should fill in Filing Form of Domestic Health Food Alteration or Filing Form of Imported Health Food Alteration according to provisions and submit the Form with relevant data to the State Food and Drug Administration for filing within 20 days after the dossier is altered.

Article 47 The valid period of Alteration Approval of Health Food is the same with that of the original health food license and the re-registration application should be needed after the valid period expires.

Article 48 If applying for the reissue of health food license, the applicant should submit a written application to the State Food and Drug Administration and state the reason. The applicant should submit the original of the lost license declaration in nationwide openly-circulated newspapers and magazines if applying for the license because of the loss; The applicant should return the original of the health food license if the license needs to be reissued because of damage. If the application is approved after review, the health food license should be reissued and the original approval document date should remain and the valid period should not change. The original approval date should be specified on the reissued health food license and the phrase “reissue” should be marked on it.

Section IV Technical Transfer Product Registration Application and Approval

Article 49 The technical transfer product registration application refers to the action of health food license holder who completely transfers the production and sales rights of the product and production technology to the health food manufacturer and the two parties apply together for new health food license for the recipient party of the transfer.

Article 50 The health food manufacturer receiving the transfer in Chinese territory must be the enterprise which legally possesses the health food hygiene license and meets Good Manufacturing Practice for Health Food.

The health food manufacturer receiving the transfer in foreign territory must meet the relevant local practices on production quality administration.

Article 51 The transfer party should sign an agreement with the recipient party and transfer all the technical data to the recipient party and guide the recipient party to produce consecutively three lot numbers of samples in accordance with quality standard of the product.

Article 52 If multi-applicants hold the health food license they should sign synchronously the transfer agreement together at the time of technology transfer.

Article 53 In the event of the transfer in Chinese territory of health food which has obtained Domestic Health Food License or Imported Health Food License, the health food license holder and recipient party should together fill in Application Form for Technical Transfer Production Registration of Domestic Health Food or Application Form for Technical Transfer Production Registration of Imported Health Food and submit the relevant dossiers and samples, with transfer agreement enclosed, to the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government where the recipient party is located.

Article 54 The (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should conduct format review on the standard and integrality of the application dossiers and send a acceptance or reject notice within 5 days after receiving the application dossiers.

If the registration application on technical transfer product conforms to the requirements, the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should give review conclusion and submit the conclusion and application dossiers to the State Food and Drug Administration and at the same time send an inspection notice and samples for inspection to the designated inspection institution within 10 days after accepting the application.

Article 55 The inspection institution should conduct sample inspection and submit the inspection report to the State Food and Drug Administration and at the same time send copies of the inspection report to the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government where the inspection is located and the applicant within 30 days after receiving the inspection notice and samples.

Article 56 The State Food and Drug Administration should give a review decision within 20 days after receiving review conclusion, application dossiers and inspection report of the samples. If the application is approved, it should issue to the recipient party a new Domestic Health Food License and new approval document number and the valid period of the license remains the same. At the same time, it should reclaim and cancel the original *Domestic Health Food License or Imported Health Food License* held by the transfer party.

Article 57 If applying for the transfer in foreign territory of health food which has obtained Imported Health Food License, the holder of the health food license and the recipient party should together fill in Application Form for Technical transfer Product Registration of Imported Health Food and submit relevant dossiers and samples to the State Food and Drug Administration, with the transfer agreement enclosed.

The State Food and Drug Administration should conduct format review on the standard and integrality of the application dossiers and send a acceptance or reject notice within 5 days after receiving the application dossiers. If the application conforms to the requirements, it should send a inspection notice and samples for inspection to the designated inspection institution within 5 days after accepting the application. Depending on the need, the State Food and Drug Administration should conduct production site inspection of the recipient party.

Article 58 The inspection institution should conduct sample inspection and submit the inspection report to the State Food and Drug Administration and at the same time send the copy of the inspection report to the applicant within 30 days after receiving the inspection notice and samples. The State Food and Drug Administration should give a review decision within 20 days after receiving the inspection report of the samples. If the registration is approved, it should issue to the recipient party a new Imported Health Food License and new approval document number and the valid period of the license remain the same. At the same time, it should reclaim and cancel the original Imported Health Food License held by the transfer party.

Chapter III Raw Materials and Additive Materials

Article 59 Raw materials of health food refers to the original materials related to the function of health food. Additive materials of health food refer to the excipients and other additives used in the production of health food.

Article 60 The raw materials and additive materials used in health food should conform to the national standard and hygiene requirements. If there is no national standard, the applicant should provide industry standard or his own quality standard and provide relevant dossiers related to the raw materials and additive materials.

Article 61 The raw materials and additive materials used in health food should not harm human health. If there is content limit for the ingredient, its content should not exceed the national standard.

Article 62 The raw materials and additive materials which are prohibited to be used in health food and articles which are prohibited to be used by the State Food and Drug Administration and relevant governmental departments must not be used as raw materials and additive materials in health food.

Article 63 The raw materials and additive materials which are published by the State Food and Drug Administration and can be used in health food, which are published or are approved as eatable by Ministry of Health and which can be used in the production of ordinary food, can be used as the raw materials and additive materials of health food.

Article 64 If the raw materials and additive materials used in the health food which applies for registration are not included in the range of Article 63, the applicant should provide the test report on the safety and toxicology assessment and relevant food safety data according to relevant provisions.

Article 65 The State Food and Drug Administration should duly publish the list of materials which can be and can not be used in health food according to the development and need of science and technology.

Article 66 The raw materials and additive materials used in imported health food should conform to all the provisions for the health food use of raw materials and additive materials in China.

Chapter IV Label and Package Insert

Article 67 If applying for health food product registration, the applicant should submit the sample copies of package insert and label of the product.

Article 68 The sample copies of label and package insert of the product applying for registration should include name of the product, major raw (additive) materials, active ingredients/badge substance and content, health function, suitable users, unsuitable users, dosage and administration, specifications, storage life, storage method and precautions.

The label of the health food which has been approved to be sold in the market should conform to the relevant national provisions.

Article 69 The naming of health food should conform to the following principles:

- (I) Conform to the provisions of relevant laws, rules, regulations, standards and practices in China;
- (II) Reflect the real qualities of the product; simple and understandable and accord with Chinese language habits;
- (III)The name of medicine whose registration has been approved must not be used as generic name.

Article 70 The name of health food should be composed of three parts: brand name, generic name and attribute name. Brand name, generic name and attribute name must conform to the following principles:

- (I) The registered trademark or other names of the product can be used as brand name;
- (II) Generic name should be accurate and scientific and must not use the phrases which will explicitly or implicitly indicate curing effects and exaggerate the functions.
- (III) Attribute name should specify the objective shape of the product and its description should be standard and accurate.

Article 71 The State Food and Drug Administration should inspect the content of the sample copies of label and package insert according to relevant standards, provisions, product application dossiers and sample inspection situations.

Chapter V Test and Inspection

Article 72 Safety toxicology test refers to the animal test and the pre-eating test on human body under necessary conditions conducted by the inspection institution on the samples submitted by the applicant in order to verify the food safety according to the safety toxicology assessment procedures and inspection methods published by the State Food and Drug Administration.

Function test refers to the animal test and/or the pre-eating test on human body conducted by the inspection institution on the samples submitted by the applicant in order to verify the health function according to the health food function assessment procedures and inspection methods published by the State Food and Drug Administration or provided by the industry.

Active ingredient or badge substance inspection refers to the inspection conducted by the inspection institution on the samples submitted by the applicant in order to find out the content of active ingredient or badge substance and its content changes during storage line according to the inspection methods of health food on active ingredient or badge substance published by the State Food and Drug Administration and relevant departments or provided by the industry.

Hygiene test refers to the hygiene and product quality-related index (active ingredient or badge substance excluded) inspection conducted by the inspection institution on the samples submitted by the applicant according to the inspection methods published by relevant governmental departments or provided by the enterprise.

Stability test refers to the hygiene inspection and the inspection to find out the content changes of product quality-related indexes (active ingredient or badge substance excluded) during storage life conducted by the inspection institution according to the inspection methods published by relevant governmental departments or provided by the enterprise.

Sample inspection refers to the complete inspection of all the Articles on the samples provided by food and drug administration departments according to the quality standard for which the applicant applies.

Recheck refers to the inspection to recheck the inspection methods for the active ingredient or badge substance in the quality standard for which the applicant applies.

Article 73 The State Food and Drug Administration is responsible for designating the inspection institution to conduct health food testing, sample inspection and rechecking. The specific provisions should be formulated separately.

Article 74 The designated inspection institution should conduct testing and inspection and give a test and inspection report in stipulated or agreed time according to health food inspection and assessment technology standards and inspection and assessment methods issued by other relevant departments. The inspection and assessment technology standards for health food should be formulated and issued by the State Food and Drug Administration.

Article 75 The designated inspection institution should offer safe, convenient and stable service with reasonable price to the applicant and fulfill its duty of general service according to the service standard, quotation standard set by the country and the qualifications set by the law.

Article 76 The designated inspection institution should adhere to the law, guarantee scientific, standard, open, just and fair testing and inspection, and must not give false report.

Article 77 The applicant should provide relevant data needed to the food and drug administration departments and cooperate to select inspection samples and provide standard material used in the inspection.

Article 78 Sample inspection and recheck of the health food applying for registration must not be conducted by the inspection institution which conducts the experiments and tests of the product.

Chapter VI Re-registration

Article 79 health food re-registrations refers to the review procedures conducted by the State Food and Drug Administration according to the application of the applicant in accordance with legal procedures, qualifications and requirements in order to extend the valid period of the health food license when its valid period expires.

The applicant of health food re-registration should be the holder of health food license.

Article 80 If the valid period of health food license expires and needs to be extended, the applicant should apply for re-registration 3 months before the valid period expires.

Article 81 When applying for domestic health food re-registration, the applicant should fill in Application Form for Domestic Health Food Re-registration according to the provisions and submit the application Articles to the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government where the applicant is located.

Article 82 The (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should conduct format review on the standard and integrality of the application Articles and send an acceptance or reject notice within 5 days after receiving the application Articles.

Article 83 If the re-registration application conforms to the requirements, trusted by the State Food and Drug Administration, the (food) and drug administration departments on the provincial ,autonomous ,and municipal level directly under the Central Government should give and submit review conclusion to the State Food and Drug Administration within 20 days after accepting the application.

Article 84 The State Food and Drug Administration should give a review decision within 20 days after receiving the review conclusion. If the re-registration disapproval notice is not issued within 20 days, the (food) and drug administration departments on the provincial, autonomous, and municipal level directly under the Central Government should issue re-registration certificate to the applicant; if re-registration application is not approved, the State Food and Drug Administration should inform the (food) and drug

administration departments on the provincial ,autonomous ,and municipal level directly under the Central Government with re-registration disapproval notice and state the reason.

Article 85 If applying for imported health food re-registration, the applicant should fill in Application For Imported Health Food Re-registration according to the provisions and submit the application Articles to the State Food and Drug Administration.

Article 86 The State Food and Drug Administration should conduct format review on the standard and integrity of the application Articles and send an acceptance or reject notice within 5 days after receiving the application Articles.

Article 87 In the event of re-registration application which conforms to the requirements, the State Food and Drug Administration should give a review decision within 20 days after accepting the application. If the application conforms to the requirements, re-registration should be approved and a re-registration certificate should be issued to the applicant; if the application does not conform to the requirements, a disapproval notice should be sent to the applicant and the reason should be stated.

Article 88 Re-registration should not be approved if the health food is under the following conditions:

- (I) Fail to submit the re-registration application within the stipulated time limit;
- (II) Withdrawn health food license according to relevant laws and rules;
- (III) Food safety problems exist in the raw materials, additive materials and products;
- (IV) The raw materials and techniques to produce health food do not conform to the present regulations;
- (V) There are other conditions which do not conform to relevant provisions in China.

Article 89 If the re-registration is not approved, the State Food and Drug Administration should issue a proclamation and cancel its health food approval document number.

Chapter VII Re-examination

Article 90 If the applicant has opposition to the application disapproval decision made by the State Food and Drug Administration, the applicant can file a written re-examination application and state the reason to the State Food and Drug Administration within 10 days after receiving the application disapproval notice.

Article 91 After receiving the re-examination application, the State Food and Drug Administration should re-examine the application according to the examining period and the requirements of the original application Articles and give a re-examination decision. If the registration disapproval decision is withdrawn, it should issue the health food approval document to the applicant; if the original decision is affirmed and more re-examination applications should be not accepted, the applicant can file administrative reconsideration to the State Food and Drug Administration or administrative litigation to the peoples' court according to relevant laws and regulations.

Article 92 The content of re-examination is limited to the original application Articles and original application data

Chapter VIII Legal Liabilities

Article 93 According to the demand of the interested person or authority of office, the State Food and Drug Administration can handle the case after verifying in accordance with Article 69 in the Administrative Licensing Law of People's Republic of China if there is one of the following conditions:

- (I) The personnel in administrative organs a give registration decision in case of abusing their authority and dereliction of their duty;
- (II) Exceeding their legal authority to give registration decision;
- (III) Disobeying legal procedures to give registration decision;
- (IV) Approving the registration of the applicant who is not qualified or in accordance with legal requirements;
- (V) Other conditions which will lead to the withdrawal of health food approval documents according to the law.

Article 94 The State Food and Drug Administration should cancel the health food approval document number in the following conditions:

The holder of health food license applies for canceling the license;

- (I) Safety problems is confirmed in the products;
- (II) Breaking the laws and regulations and the health food license should be withdrawn;
- (III) Other conditions in which license should be legally cancelled.

Article 95 In the process of health food registration, the State Food and Drug Administration and the (food) and drug administration departments on the provincial ,autonomous ,municipal level directly under the Central Government and their actions should be handled according to Article 72, 73, 74 and 75 if they break the Provisions and lead to the following conditions:

- (I) Refusing to accept the health food registration application which conform to legal requirements;
- (II) Failing to publicize the health food registration application Articles in the working place where the application is accepted;
- (III) Failing to perform the duty of disclosure to the applicant in the process of health food application acceptance and review;

- (IV) Failing to inform the applicant at one time of the complete supplement Articles needed when the application Articles submitted by the applicant is not complete and in accordance with legal format;
- (V) Failing to state the reason according to law why the health food registration application is rejected or not approved;
- (VI) Giving approval decision to the health food registration application which does not conform to the Provisions or giving approval decision in case of exceeding their legal authority;
- (VII) Giving disapproval decision to the health food registration application which conforms to the Provisions or giving approval decision beyond the stipulated time limit of the Provisions.
- (VIII) Making charges without authorization or failing to charge according to legal standard quotations;
- (IX) Extorting or accepting bribes or soliciting other benefits.

Article 96 In the process of health food registration, the State Food and Drug Administration should compensate according to the provisions of State Compensation Law if it breaks the Provisions and damages the legal rights of the party concerned.

Article 97 If the applicant holds back relevant situations, or provides false Articles or samples in health food registration application, the State Food and Drug Administration should not accept the application or give a disapproval decision and give warning to the applicant; the applicant must not file registration application of the same health food again in one year.

Article 98 If the applicant obtains the health food license through cheating, bribery and other unfair measures, the State Food and Drug Administration should withdraw its health food license and cancel its health food approval document number and the applicant must not file registration application again in three years.

Article 99 If the designated inspection institution breaks Article 75 of the Provisions, the State Food and Drug Administration should order it to rectify the situation within specified period; and the State Food and Drug Administration or relevant governmental departments should order it to refund illegal charges; Qualification Certificate for Health Food Testing should be withdrawn if the offence is serious.

Article 100 If the designated inspection institution fails to conduct test or inspection according to the Provisions or makes mistakes and causes accident in the testing and inspection process, the State Food and Drug Administration should give warning and order it to rectify the situation within specified period; Qualification Certificate for Health Food Testing should be withdrawn if the offence is serious.

Article 101 If the designated inspection institution gives a false test report or inspection report, its Qualification Certificate for Health Food Testing should be withdrawn; the illegal gains should be confiscated if there are any; it should be prosecuted for their criminal liabilities according to law. If the designated inspection institution gives a false test or inspection and they results and causes losses, the inspection institution should take relevant legal liabilities.

Chapter IX Supplementary Provisions

Article 102 The working period of the Provisions is computed on the basis of working days and does not include national holidays.

Article 103 The packaging materials and containers having direct contact with health food must conform to the national food or drug requirements and conform to human health and safety standards.

Article 104 The Provisions should be interpreted by the State Food and Drug Administration.

Article 105 The Provisions will come into effect as of July 1, 2005.

In the event of conflict between the provisions formulated before and this Provision, this Provision should prevail.

Appendix 1:

Application dossiers for Product Registration

I .Application dossiers for Domestic Health Food Product Registration:

- (I) Application Form for Health Food Registration.
- (II) The copies of ID card, business license of the applicant or legal registration certificates issued by other institutions.
- (III) Provide the generic name of the health food applying for registration and the search materials to testify that the name is different from the drug names whose registration has been approved (searching from the data base of the website of the State Food and Drug Administration).
- (IV) The guarantee of the applicant which ensures that he should not infringe on the patent obtained by other people.
- (V) Providing documents of registered trademark (do not need to provide if the trademark is not registered).
- (VI) Product research and development report (including research and development ideas, function screening process, expected effect).
- (VII) Product ingredients (raw materials and additive materials) and foundation for the ingredients; sources of raw materials and additive materials and foundation for the use of these materials.
- (VIII) Active ingredient/badge substance and their content and their inspection methods.
- (IX) Sketch of production technology and its detailed specifications and relevant research data.

(X) Product quality standard and its compilation specifications (including quality standard of raw materials and additive materials).

Categories, names, quality standard of packaging materials having direct contact with products and the foundation for selection.

(I) Inspection reports and relevant data from the inspection institution, including:

- 1.the application form for testing;
- 2.the inspection acceptance notice from the inspection institution;
- 3.the safety toxicology test report;
- 4.the function test report;
- 5.the test report of dopes and illegal drugs (including registration applying for the function of relieving physical fatigue, losing weight and improving growth);
- 6.the active ingredient inspection report;
- 7.the stability test report;
- 8.the hygiene test report;
- 9.the other inspection reports (the appraisal report of raw materials, the vaccine virulence test report) .

(II) Sample copies of product labels and package insert.

(III) Other materials which will help the assessment of the product.

(IV) Two samples of the smallest sealed packs for sale.

Notes:

1. The registration application of the products which are made of fungus, probiotics, nucleic acid, enzyme preparation, amino acid chelate must provide relevant application Articles according to relevant provisions besides the above-mentioned Articles.
2. The registration application of the products which are made of wild animals and plants whose utilization is restricted in China must provide approval document granted by relevant governmental departments to the raw material supplier to permit their development and utilization of the raw material, as well as purchase and sale contracts signed by the raw material supplier and the applicant.

3. The registration application of the products for the purpose of vitamin and mineral supplement does not need to provide the animal function test report and/or pre-eating test on human body report and function research and development report.

4. If the application function is not included in the function range published by the State Food and Drug Administration, besides providing the above-mentioned Articles as raw materials, the applicant must provide Articles related to the new function: (1) the function research and function report: including name of the function, reason and foundation for the application, function assessment procedures and inspection methods as well as research progress and relevant data, the foundation and scientific document and data for the establishment of function assessment procedures and inspection methods. (2) The self-test report of function assessment testing conducted by the applicant according to function assessment procedures and inspection methods. (3) The inspection report on the function assessment of the products from the designated inspection institution according to function assessment procedures and inspection methods, as well as the validation report on the inspection methods

5. If the same applicant applies for the registration of the different formulations of the same product, all the tests have been completed on one kind of formulation according to the provisions and the inspection institution has issued inspection report, the registration of other formulations can be exempted from the function and safety toxicology test. However, the copies of test reports of the function and safety toxicology tests which have been completed must be submitted. The substantial change of the techniques which will affect food safety and function should be excepted from this provision.

II. Registration Application Articles of Imported Health Food Product

The applicant of the registration application of imported health food must provide the following Articles besides providing the Articles needed for domestic health food application according to its raw materials used and function application: .

(I) The documents granted by relevant institutions in manufacturing country (region) to the product manufacturer to state that the product conforms to the relevant local production quality standard.

(II) Foreign manufacturers which are represented by permanent representative office in China for registration should provide the copy of Registration Certificate for Permanent Chinese Representative Agency of Foreign Companies.

Foreign manufacturers which entrust the agency in China with the registration application must provide original letter of trust which has been notarized and the copy of the business license of the agency entrusted.

(III) The documents of the products which have been produced and sold more than one year in the manufacturing country (region) should be notarized by the notary office of the manufacturing country (regions) and validated by Chinese embassy or consulate in the manufacturing country.

(IV) Relevant product standard of the manufacturing country (region) or international body.

(V) The original packaging, label and package insert of the product used in the market of the manufacturing country (region)

(VI) The samples of three consecutive lot numbers and the amount should be three times of the amount needed for inspection.

The application Articles must use Chinese language with the original language version enclosed, and the Articles in foreign language can be enclosed as reference. The Chinese version should be notarized by the notary office in Chinese territory to ensure that it is consistent with the content of original version; The product quality standard (Chinese version) for the registration application must conform to the product standard format for health food in China.

Appendix 2:

Application dossiers for Alteration

Application dossiers for Domestic Health Food Alteration

- (I) Application form for health food alteration or filing form for health food alteration.
- (II) The name of the special Article alteration and its reason and foundation.
- (III) The copies of ID card, business license of the applicant or other legal registration documents issued by other institutions.
- (IV)The copies of approval document of health food and its appendixes.
- (V) The samples of the label, package insert for revision with detailed revision statement enclosed.

Note:

1. In the event of the application for reducing the range of suitable users, expanding the range of unsuitable users and altering precautions, besides the above-mentioned Articles, the applicant must provide the document issued by the manufacturing location's provincial food and drug administration to testify that the product has been produced and sold in the market.
2. In the event of the application for dosage alteration (product specifications do not change), besides the above-mentioned Articles, the applicant must provide: (1) the document issued by the manufacturing location's provincial food and drug administration department to testify that the product has been manufactured and sold in the market; (2) the application for dosage reduction should provide the test report granted by the designated inspection institution which conducts function assessment test according to the planned dosage reduction; (3) the application for dosage increase should provide the test report granted by the designated inspection institution which conducts toxicology safety test according to the planned dosage increase, as well as the function assessment report according to the comparison between the planned dosage alteration and the original dosage.
3. In the event of the application for alteration of product specifications, storage life and quality standard, besides the above-mentioned Articles, the applicant must provide: (1) the document issued by the manufacturing location's provincial food and drug administration department to testify that the product has been manufactured and sold in the market; (2) the foundation to testify that the alteration will not affect the safety and function of the product and relevant research data, scientific documents and/or test reports, in

which, the registration application for quality standard alteration should provide the test dossiers and documents about the quality standard research; (3) quality standard after revision; (4) the self-test report on the active ingredient or badge substance, hygiene, stability of the products from three consecutive lot numbers; (5) three consecutive lot numbers of the samples and the amount is three times of the amount needed for inspection (storage life alteration excluded)

4. In the event of alteration application for increasing health food function dossiers, besides the above-mentioned dossiers, the applicant must provide: (1) the document issued by the manufacturing location's provincial food and drug administration department to testify that the product has been manufactured and sold in the market; (2) the quality standard after the alteration; (3) function test report for the increased function article.

5. In the event of application for altering product name, besides the above-mentioned Articles, the applicant must provide the product's generic name to be used after alteration and the search materials to testify that the name is different from the drug names whose registration have been approved (searching from the data base of the website of the State Food and Drug Administration).

6. In the event of filing Articles of the name and/or address alteration of the applicant, besides the above-mentioned Articles, the applicant must provide the documents granted by local industrial and trade administration departments to testify the name and/or address alteration of the applicant.

II. Application dossiers for Imported Health Food Alteration

(I) Application form for imported health food or filing form for imported health food.

(II)The name of alteration Article and its reason and foundation.

(III) In the event of the alteration application of foreign manufacturer conducted by its permanent representative office in China, the applicant must provide the copy of the Registration Certificate for Foreign Company's Permanent Representative Office in China.

In the event of the alteration for foreign manufacturer entrusting the agency in China, the applicant must provide the notarized original letter of trust and the copy of the business license of the trusted agency.

(I) The copies of approval document of health food and its appendixes.

(II) The document granted by the relevant agency of the manufacturing country (region) to testify that the Article has been altered and the relevant materials. The document must be validated by the notary office in the manufacturing country (region) and the Chinese embassy or consulate in the manufacturing country (region).

Note:

1. In the event of the application for reducing the range of suitable users, expanding the range of unsuitable users and altering precautions, besides the above-mentioned dossiers, the applicant must provide the sample of the label and package insert after the alteration.
2. In the event of the application for dosage alteration (product specifications do not change), besides the above-mentioned Articles, the applicant must provide: (1) the application for dosage reduction should provide the test report granted by the designated inspection institution which conducts the function assessment test according to the planned dosage reduction; (2) the application for dosage increase should provide the test report granted by the designated inspection institution which conducts the toxicology safety test according to the planned dosage increase, as well as the function assessment report according to the comparison between the planned dosage alteration and the original dosage. (3) The label and package insert after alteration.
3. In the event of the application for alteration of product specifications, storage life and quality standard, besides the above-mentioned Articles, the applicant must provide: (1) the foundation to testify that the alteration will not affect the safety and function of the product and relevant research data, scientific documents and/or test report, in which, the registration application for quality standard alteration should provide the test dossiers and documents about the quality research; (2) the self-test report on the active ingredient or badge substance, hygiene, stability of the products from three consecutive lot numbers; (3) three consecutive lot numbers of samples for inspection (storage life alteration excluded); (4) the samples of label, package insert and quality standard after alteration.
4. In the event of alteration application for increasing health food function Articles, besides the above-mentioned Articles, the applicant must provide: (1) the function test report for the increased function Article; (2) the label, package insert or quality standard after the alteration and their sample copies.
5. In the event of the application inside the health food manufacturing enterprise for altering production site outside of Chinese territory, besides the above-mentioned Articles, the applicant must provide: (1) the document granted by the administrative departments to testify that the production conditions conform to relevant local production quality administration standard; (2) the document to testify that free sale of the product is permitted in the country where new production site is located; (3) self-test report of active ingredient or badge substance, hygiene, stability of three consecutive lot numbers of products manufactured at the new production site; (4) samples for inspection of three consecutive lot numbers manufactured at the new production site. (5) the label and package insert after alteration.
6. In the event of the application for altering product name, besides the above-mentioned Articles, the applicant must provide the product's generic name to be used after alteration and the search materials to testify that the name is different from the drug names whose registration have been approved (searching from the data base of the website of the State Food and Drug Administration), as well as the label, package insert after the alteration.
7. In the event of filing Articles of the name and/or address alteration of the applicant, besides the above-mentioned Articles, the applicant must provide the documents granted by the manufacturing country (region)'s administration departments to testify that the production site has not been altered and provide the label and package insert after the alteration.

8. In the event of the application for filing of the agency alteration in Chinese territory, besides the above-mentioned Articles, the applicant must provide the letter of trust and notarization to testify that foreign health food manufacturer entrusts Chinese agency with the registration application and at the same time withdraw the trust with the original agency.

The application Articles must use Chinese language with the original language attached, and the Articles in foreign language can be enclosed as reference. The Chinese version should be notarized by the notary office in Chinese territory to ensure that it is consistent with the content of original version; The product quality standard (Chinese version) for the registration application must conform to the product standard format for health food in China.

Appendix 3:

Application dossiers of Technical Transfer Product Registration

I. Application Articles of Domestic Health Food Technical Transfer Product Registration

- (I) Application form for health food technical transfer product registration.
- (II) The copies of ID card, business license and legal registration documents issued by other institutions.
- (III) Valid transfer contract signed by both the transfer party and the recipient party and notarized by the notary office.
- (IV) The copy of the recipient party's health food hygiene license issued by provincial health food production supervision and administration departments.
- (V) The documents issued by the provincial health food production administration department to testify that the recipient party conforms to Good Manufacturing Practice for Health Food.
- (VI) The original approval documents for health food (including health food approval document and its appendixes and alteration approval for the health food).
- (VII) Sample of three consecutive lot numbers produced by the recipient party and the amount is three times of the amount for testing.

II. Product Registration Application Dossiers of Imported Health Food Transferred to Chinese Territory

Besides the applications Articles submitted according to domestic health food technical transfer registration, the applicant must provide the following dossiers:

In the event of registration conducted by permanent representative office of the foreign manufacturer, the applicant should provide the copy of Registration Certificate for Permanent Chinese Representative Agency of Foreign Companies.

In the event of the registration conducted by Chinese agency entrusted by foreign manufacturer, the applicant must provide the original of notarized letter of trust and the copy of business license of the trusted agency.

III. Product Registration Applications Articles of Imported Health Food Transfer Outside of Chinese Territory

- (I) Application form for health food technical transfer Registration.
- (II) The documents to testify that the product is permitted to be produced and sold in the recipient party's manufacturing country (region) and the document should be notarized by the notary office in the manufacturing country (office) and validated by the Chinese embassy or consulate in that country.
- (III) The document issued by relevant departments in the recipient party's country (region) to testify that the manufacturer of the product conforms to the relevant local production quality administration standard.
- (IV) Transfer contract. The contract must be validated by the notary office in the recipient party's country (region) and the Chinese embassy or consulate in that country.
- (V) In the event of registration conducted by permanent representative office of the foreign manufacturer, the applicant should provide the copy of Registration Certificate for Permanent Chinese Representative Agency of Foreign Companies.
In the event of the registration conducted by Chinese agency entrusted by the foreign manufacturer, the applicant must provide the original of notarized letter of trust and the copy of business license of the trusted agency.
- (VI) The original of health food approval documents (including health food approval certificate and its appendixes and the copy of business license of the trusted agency).
- (VII)The test report issued by the designated inspection institution on active ingredient or badge substance, hygiene, stability of three consecutive lot numbers of samples produced by the recipient party.
- (VIII) Three consecutive lot numbers of samples produced by the recipient party and the amount is three times of the amount needed for inspection.

Appendix 4:

Application Dossiers for Re-registration

I. Application Articles for Domestic Health Food Re-registration

- (I) Application form for domestic health food re-registration.
- (II) The copies of ID card, business license of the applicant or legal registration document issued by other institutions.
- (III) The copy of health food approval documents (including health food approval certificate and its appendixes and approval certificate of health food alteration).

(IV) The copy of the documents issued by the production site's provincial health food production administration departments which permit the production and sales of the product.

(V) Summary of sales in the past five years.

(VI) Summary of consumer's feedback on the product in the past five years.

(VII) The smallest pack for sale, label and package insert of the health food.

Note: If the applicant can not submit the complete above-mentioned Articles, the applicant must submit in a written form to state the reason with the re-registration application.

II. Application Dossiers of Imported Health Food Re-registration

(I) Application form for imported health food re-registration.

(II) In the event of re-registration conducted by permanent representative office of the foreign manufacturer, the applicant should provide the copy of Registration Certificate for Permanent Chinese Representative Agency of Foreign Companies.

In the event of the re-registration conducted by Chinese agency entrusted by foreign manufacturer, the applicant must provide the original of notarized letter of trust and the copy of business license of the trusted agency.

(III) The copy of health food approval documents (including health food approval certificate and its appendixes and approval certificate of health food alteration).

(IV) The documents issued by relevant institutions of the manufacturing country (or region) to testify that the manufacturer conform to relevant local production quality administration standard and the products are permitted to be produced and sold and the documents must be notarized by the notary office in the manufacturing country (office) and validated by the Chinese embassy or consulate in that country.

(V) Summary of import and sales in China in the past 5 years.

(VI) Summary of consumer's feedback on the product in the past five years.

(VII) The smallest pack for sale, label and package insert of the health food.