ORGANIZACIÓN MUNDIAL DEL COMERCIO

G/TBT/N/CHN/160
26 de octubre de 2005

(05-4953)

Comité de Obstáculos Técnicos al Comercio Original: inglés

NOTIFICACIÓN

Se da traslado de la notificación siguiente de conformidad con el artículo 10.6.

1.	**Miembro que notifica:** REPÚBLICA POPULAR CHINA **Si procede, nombre del gobierno local de que se trate (artículos 3.2 y 7.2):**
2.	**Organismo responsable:** Administración Estatal de Productos Alimenticios y Farmacéuticos **Nombre y dirección (incluidos los números de teléfono y de telefax, así como las direcciones de correo electrónico y sitios Web, en su caso) del organismo o autoridad encargado de la tramitación de observaciones sobre la notificación, en caso de que se trate de un organismo o autoridad diferente:**
3.	**Notificación hecha en virtud del artículo 2.9.2 [** X **], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], o en virtud de:**
4.	**Productos abarcados (partida del SA o de la NCCA cuando corresponda; en otro caso partida del arancel nacional. Podrá indicarse además, cuando proceda, el número de partida de la ICS):** Productos alimenticios saludables
5.	**Título, número de páginas e idioma(s) del documento notificado:** *Provision on Registration of Health Food (interim)* (Disposición sobre el registro de los productos alimenticios saludables - provisional) – 34 páginas, disponible en chino
6.	**Descripción del contenido:** El reglamento técnico notificado abarca los siguientes puntos: objetivos, campo de aplicación, definición de producto alimenticio saludable, aplicación y aprobación del registro de productos alimenticios saludables, materiales básicos y excipientes, etiquetado y hojas informativas, pruebas y ensayos, reinscripción en el registro, reexaminación, responsabilidades legales.
7.	**Objetivo y razón de ser, incluida, cuando proceda, la índole de los problemas urgentes:** Protección de la salud de las personas
8.	**Documentos pertinentes:** -
9.	**Fecha propuesta de adopción:** 30 de abril de 2005 **Fecha propuesta de entrada en vigor:** 1º de julio de 2005
10.	**Fecha límite para la presentación de observaciones:** No se aplica
11.	**Textos disponibles en: Servicio nacional de información [X], o dirección, números de teléfono y de telefax, correo electrónico y dirección del sitio Web, en su caso, de otra institución:** WTO/TBT National Notification and Enquiry Center of the People's Republic of China (Centro nacional de notificación e información OMC-OTC de la República Popular China) Teléfono: (+86) 10 822 60618; telefax: (+86) 10 822 62448 Correo electrónico: tbt@aqsiq.gov.cn

Measures on the Administration of Health Food Registration

Chapter I
General Principles

Article 1 To standardise the registration of health food, guarantee the quality of health food, and ensure the safety of human food, these measures were formulated according to the Food Hygiene Law of the People's Republic of China and the Administrative Licensing Law of the People's Republic of China.

Article 2 What is called health food in these measures refers to food that proves certain health protective functions or to food that can supply vitamins or minerals. It is suitable to be consumed by a certain group of people and has the ability to regulate the organism, but its objectives are not to cure diseases; furthermore, this food will not cause any acute, sub acute or chronic harm.

Article 3 These measures apply for the registration of Chinese-produced as well as imported health food within the territory of the People's Republic of China.

Article 4 Health food registration refers to the application made by the applicant in accordance with the State Food and Drug Supervising Administration Bureau. According to the legal procedure and conditions and requirements, first a systematic evaluation and examination of the health food products safety, effectiveness, quality control and content of the label instruction is conducted and then it is decided whether to permit it to enter the examination and approval process, including examination and approval of applications for product registration, applications for modifications and technology transfer product registration.

Article 5 The State Food and Drug Supervising Administration Bureau is in charge for the nationwide health food products registration administration and is also responsible for examination and approval of health food products.

Drug (food) supervising administrative departments of provinces, autonomous regions and municipalities directly under the Central Government are entrusted by the State Food and

Drug Supervising Administration Bureau to be responsible for the examination of the acceptance and form of the domestic health products registration application materials, they conduct the examination of the health food test and prototype samples of the registration application and arrange examination of the samples.

The examination and testing agencies that are designated by the State Food and Drug Supervising Administration Bureau are in charge for the safety toxicology test, functionality test of the health food that applies for registration (including test on animals and/or human trial food test), effect or marker ingredient test measure, hygiene test, stability test etc. They will undertake the specific tasks of sample testing and re-examination testing.

Article 6 The administration of the health food registration should follow the principles of being scientific, open, fair, highly effective and for the convenience of people.

Chapter II
Application, Examination and Approval
Section One
General Provisions

Article 7 Health food registration applicant refers to somebody who hands in the health food registration application, assumes the corresponding legal responsibility, and who, after obtaining the application approval, holds the health food approval certificate.

A domestic applicant should be a legally registered citizen, legal entity or other organisation within Chinese borders.

A foreign applicant should be a legitimate foreign health food producing company. If a foreign applicant hands in the imported health food registration, it should do so through its representative office or authorised agency within Chinese borders.

Article 8 A health food registration application includes applications for product registration, modifications and technology transfer product registration.

Article 9 The State Food and Drug Supervising Administration Bureau and the drug (food) supervising administrative departments of provinces, autonomous regions and municipalities directly under the Central Government should at the place destined for submitting the health food registration application announce the required contents of the materials for the health food registration declaration and also a sample of relevant registration application form.

Article 10 Applicants applying for the health food registration should, as required, submit standard and complete materials that reflect the truth, at the same time they are responsible for the substantiality of the submitted documents and materials.

Article 11 Applicants submitting application materials can immediately correct the mistakes, they should be allowed to be corrected then and there.

Article 12 If the materials submitted by the applicant are incomplete or nonconforming with legal forms, the drug (food) supervising administrative departments of provinces, autonomous regions and municipalities directly under the Central Government and the State Food and Drug Supervising Administration Bureau should, only once and immediately or within 5 days, notify the applicant about the whole content of the materials that need to be supplemented. If the notification is overdue, the day on which the application materials were received is taken as the acceptance day. In case of no acceptance, the reason should be explained in writing.

Article 13 If any additional materials need to be supplemented in the course of examination, the State Food and Drug Supervising Administration Bureau should notify the applicant only once. The applicant should within 5 months after receiving the notification requesting the additional materials submit these materials. Not complying with the time limit for submitting the requested materials will result in cancelling the examination. Under special circumstances, if there is no possibility to submit the requested materials in due course, a written application explaining the reasons for this must be submitted to the State Food and Drug Supervising Administration Bureau. The State Food and Drug Supervising Administration Bureau should provide its decision on this matter within 20 days.

Article 14 In case any additional materials are required for the registration of the application, the examination period is extended by 30 days; if the application is modified, it is extended by 10 days.

Article 15 If, after going through the legal examination, the application qualifies for registration the State Food and Drug Supervising Administration Bureau should, within the allotted time, issue a health food approval certificate for the applicant which will be received within 10 days. If the application is not granted registration, the State Food and Drug Supervising Administration Bureau should, within the allotted time, inform the applicant in writing and explain the reason for its rejection. Furthermore, it should inform the applicant of the rights to apply for legal re-examination, administrative review or the possibility of taking a legal administrative action.

Article 16 If the State Food and Drug Supervising Administration Bureau and the drug (food) supervising administrative departments of provinces, autonomous regions and municipalities directly under the Central Government find out during the process of examination of the health food registration application that the application directly concerns major interests of other parties, they should inform the interested parties. Applicants and interested parties may submit their opinions in writing in order to explain and argue their cases or request for a legal hearing.

Article 17 The State Food and Drug Supervising Administration Bureau should announce relevant information concerning the acceptance of the health food registration application, process of the examination and health food approved for registration on its official website.

Article 18 The State Food and Drug Supervising Administration Bureau should make timely adjustments of: the health food function scope according to the development and requirements of science and technology, the evaluation and testing methods for the health food as well as technical standards of evaluation, etc., and should make corresponding announcements.

Section Two
Application for the Product Registration, Examination and Approval

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

Application for the domestic health food registration refers to the health food registration application that the applicant plans to produce and sell within Chinese borders.

Application for the imported health food registration refers to the registration application for health food that has been produced and sold outside the Chinese borders for more than one year and which the applicant plans to sell on market within the territory of China.

Article 20 Before applying for the health food registration, the applicant should make relevant research efforts.

After completing these research efforts, the applicant should provide samples and relevant test materials to the testing agencies that were designated by the State Food and Drug Supervising Administration Bureau for corresponding testing and examination.

If the health food functions in the intended application are within the limits proclaimed by the State Food and Drug Supervising Administration Bureau, the applicant should submit a product research and development report to the designated testing agencies. If the health food functions are not within the proclaimed limits, the applicant should conduct tests on animals and human trial food tests by oneself and submit a product research and development report to the designated agencies.

Product research and development report should contain research and development train of thought, the function screening process as well as expected effect. Function research and development report should contain the name of the function, reason for the application, function tests, evaluation methods and test results. If the applicant is not able to conduct tests on animals and human trial food tests, the reasons for this should be included in writing in the function research and development report, while submitting relevant materials at the same time.

Article 21 After the testing agencies have received the sample and relevant materials from the applicant, they should, in accordance with the health food testing and evaluation technical norms promulgated by the State Food and Drug Supervising Administration Bureau

as well as in accordance with testing methods issued by other related departments and provided by the enterprises, conduct safety toxicology tests, functionality tests, effective ingredient or marker ingredient tests, hygiene tests, stability tests, etc. of the sample. If the functions are not within the scope of those promulgated by the State Food and Drug Supervising Administration Bureau, the testing agencies should also validate its function tests, evaluation methods and test results, and then issue a test report.

Article 22 Only after the testing agencies have issued a test report, the applicant may apply for the health food registration.

Article 23 While applying for the domestic health food registration, the applicant should, as required, complete the Application Form for Domestic Health Food and present the application materials and samples to the sample producing agencies of the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government.

Article 24 The drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, after receiving the application materials and samples, examine if the application is standard and complete and within 5 days issue an acceptance or denial notification.

Article 25 To meet the requirements of the application registration, the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, within 15 days after accepting the application, examine testing and sample production sites, collect samples that should be used for testing, as well as give opinions on the examination and report them to the State Food and Drug Supervising Administration Bureau. At the same time, they should send a testing notification to the designed testing agencies and supply them with testing samples.

Article 26 Samples required for health food registration application should be produced in workshops that are in accordance with the Health Food Favourable Production Practice, and the course of processing also has to be in compliance with the Health Food Favourable Production Practice.

Article 27 After receiving the test notification and samples, the testing agencies should, within 50 days, conduct sample survey and review examinations of the collected samples, send a test report to the State Food and Drug Supervising Administration Bureau and make a copy for the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government and the applicant at the same time. Under special circumstances, if the testing agencies cannot conduct examinations in due time, they should report the reasons for this in writing to the State Food and Drug Supervising Administration Bureau and the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government in time.

Article 28 After receiving the examination opinions, application materials and samples from the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government, the State Food and Drug Supervising Administration Bureau should, within 80 days, set up food, nutrition, medical, pharmaceutical and other technical personnel that will conduct technical evaluation and administrative examination of the application materials and issue an examination decision. If registration is granted, a Domestic Health Food Approval Certificate will be issued to the applicant.

Article 29 If an applicant applies for the imported health food registration, he should complete the Application Form for Imported Health Food Registration as required and then send all application materials and samples to the State Food and Drug Supervising Administration Bureau.

Article 30 After receiving the application materials and samples, the State Food and Drug Supervising Administration Bureau should, within 5 days, examine if the application is standard and complete and issue an acceptance or denial notification. To meet the requirements of the application registration, the State Food and Drug Supervising Administration Bureau should, within 5 days after accepting the application, issue a test notification and provide the designed testing agencies with samples for testing. If necessary, the State Food and Drug Supervising Administration Bureau may inspect the production and testing sites of the product.

Article 31 The testing agencies should, within 50 days after receiving the test notification and samples, conduct a sample survey and review examinations of the collected

samples and send a test report to the State Food and Drug Supervising Administration Bureau and make a copy for the applicant at the same time. Under special circumstances, if the testing agencies cannot conduct examinations in due time, they should, in time, report the reasons for this in writing to the State Food and Drug Supervising Administration Bureau.

Article 32 After the acceptance of the application, the State Food and Drug Supervising Administration Bureau should, within 80 days, set up food, nutrition, medical, pharmaceutical and other technical personnel that will conduct technical evaluation and administrative examination of the application materials and issue an examination decision. If registration is granted, an Imported Health Food Approval Certificate will be issued to the applicant.

Article 33 The health food approval certificate will be valid for a period of 5 years. The number form for the domestic health food product approval document is: Guoshijianzi (Chinese health food characters) G + 4 digit year number + 4 digit serial number. The number form for the imported health food product approval document is: Guoshijianzi (Chinese health food characters) J + 4 digit year number + 4 digit serial number.

Section Three
Application for Modifications, Examination and Approval

Article 34 An application for modifications refers to an application in which the applicant proposes modifications of the content of items stated in the health food approval certificate and its attachments.

Article 35 Application for modifications applicant should be the health food approval certificate holder.

Article 36 The content of items stated in the health food approval certificate that might have an impact on safety and function of the health food, such as function name, raw (supplementary) material, technology, eating methods, population expansion suitability scope and population reduction unsuitability scope, etc. may not be modified.

Article 37 Health food products in the application for the population reduction suitability scope, population expansion unsuitability scope, precautions, function items, dosage change, product specifications, best before guarantee date and quality standards, should be products that have already been produced and sold. The added function items must be within the scope promulgated by the State Food and Drug Supervising Administration Bureau.

Article 38 If the applicant is applying for modifications of the contents of the Domestic Health Food Approval Certificate and its attachments, he should complete the Application Form for Domestic Health Food Modification, and submit relevant materials and explanations to the local drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government.

Article 39 The drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, within 5 days after receiving the application materials, examine if the application is standard and complete and issue an acceptance or denial notification.

Article 40 The drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, within 10 days after receiving the application, give examination opinions on the change of product name, best before guarantee date, dosage, population reduction suitability scope, population expansion unsuitability scope, precautions and function items and together with the application materials report to the State Food and Drug Supervising Administration Bureau.

The State Food and Drug Supervising Administration Bureau should, within 40 days after receiving the examination opinions and application materials, set up food, nutrition, medical, pharmaceutical and other technical personnel that will conduct technical evaluation and administrative examination of the application materials and issue an examination decision. If modification is granted, an Official Domestic Health Food Modification Approval will be issued to the applicant and a copy will be made for the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government at the same time.

Article 41 The drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, within 10 days after receiving the application, give examination opinions on the modifications of the product specifications and quality standards and together with the application materials report to the State Food and Drug Supervising Administration Bureau. They should also issue a test notification and provide samples used for testing to the designated testing agencies.

After receiving the test notification and samples, the testing agencies should, within 30 days, conduct sample survey and review examinations of the collected samples, send a test report to the State Food and Drug Supervising Administration Bureau and make notification copy for the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government and the applicant at the same time.

The State Food and Drug Supervising Administration Bureau should, within 50 days after receiving the examination opinions, application materials and samples, set up food, nutrition, medical, pharmaceutical and other technical personnel that will conduct technical evaluation and administrative examination of the application materials and issue an examination decision. If modification is granted, an Official Domestic Health Food Modification Approval will be issued to the applicant and a copy will be made for the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government at the same time.

Article 42 If the applicant is applying for modifications of the contents of the Imported Health Food Approval Certificate and its attachments, he should complete the Application Form for Imported Health food Modification, and submit relevant materials and explanations to the State Food and Drug Supervising Administration Bureau.

Article 43 The State Food and Drug Supervising Administration Bureau should, within 5 days after receiving the application materials, examine if the application is standard and complete and issue an acceptance or denial notification.

Article 44 The State Food and Drug Supervising Administration Bureau should, within 40 days after receiving the modification application for change of product name, best before guarantee date, dosage, population reduction suitability scope, population expansion unsuitability scope, precautions and function items, arrange food, nutrition, medical, pharmaceutical and other technical personnel to perform technical evaluation and

administrative examination and make a decision after the examination. If modification is granted, an Official Imported Health Food Modification Approval will be issued to the applicant.

Article 45 The State Food and Drug Supervising Administration Bureau should, within 5 days after accepting the modification application for change of product specification, quality standards as well imported health food company's overseas production site, issue a test notification and provide examination samples to the designated testing agencies. If necessary, the State Food and Drug Supervising Administration Bureau may inspect the production and testing sites of the product.

The testing agencies should, within 30 days after receiving the test notification and samples, conduct a sample survey and send a test report to the State Food and Drug Supervising Administration Bureau, and make a copy for the applicant at the same time.

The State Food and Drug Supervising Administration Bureau should, within 50 days after accepting the application, arrange food, nutrition, medical, pharmaceutical and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination. If modification is granted, an Official Imported Health Food Modification Approval will be issued to the applicant.

Article 46 If the applicant is applying for the change of his own name, address and authorised agency within Chinese borders, he should, within 20 days after the subject item has been altered, complete the Domestic Health Food Modification Record Form or the Imported Health Food Record Form, and should, together with relevant materials, report to the State Food and Drug Supervising Administration Bureau for the record.

Article 47 The validity of the Official Imported Health Food Modification Approval is identical to that of the original health food approval certificate. If the term of validity expires, an application for re-registration should be submitted for both of them.

Article 48 If requesting for reissuing of the health food approval certificate, the applicant should submit a written application to the State Food and Drug Supervising Administration Bureau and explain the reasons for this. If applying for the reissuing is the result of loss, the applicant should submit the original part of the lost-property notice published in the national public newspaper. If applying for reissuing is the result of damage,

the applicant should return the original health food approval certificate. If the application is, after examining, in accord with the requirements, a health food approval certificate will be reissued with the original document's number of approval, the term of validity will not change. Reissued health food approval certificate should have the original date of approval and give clear indication of the word "Reissued".

Section Four
Application for Technology Transfer Product Registration, Examination and Approval

Article 49 An application for technology transfer product registration refers to an application in which the holder of the health food approval certificate transfers the right to produce and sell its products and the production technology to another health food production enterprise and jointly applies for approval and issuance of a new health food approval certificate for that enterprise.

Article 50 A domestic health food producing enterprise that accepts the transfer must be an enterprise that has legitimately obtained the health food sanitary certificate and is in compliance with the Health Food Favourable Production Practice.

A foreign health food producing enterprise that accepts the transfer must be in compliance with the corresponding local production standards of quality control.

Article 51 The transferor should sign a contract with the transferee, transfer all the technical data to the transferee, and instruct the transferee to produce three batches of products in a row that will be in accord with the quality standards for the product.

Article 52 If more than one applicant jointly holds the health food approval certificate, at the time of technology transfer they should agree on co-signing the transfer contract.

Article 53 If health food that already holds the Domestic Health Food Approval Certificate or Imported Health Food Approval Certificate is transferred within the Chinese borders, the holder of the health food certificate and the transferee should jointly complete the Application Form for Domestic Health Food Technology Transfer Product Registration, or the Application Form for Imported Health Food Technology Transfer Product Registration,

and submit relevant materials and samples, together with the transfer contract to the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government where the transferee is located.

Article 54 The drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, after receiving the application materials, examine if the application is standard and complete and within 5 days issue an acceptance or denial notification.

To meet the requirements of the application for technology transfer, the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, within 10 days after accepting the application, give examination opinions and together with the submitted materials report to the State Food and Drug Supervising Administration Bureau. At the same time, they should send a testing notification to the designed testing agencies and supply them with testing samples.

Article 55 After receiving the test notification and samples, the testing agencies should, within 30 days, conduct sample survey and send a test report to the State Food and Drug Supervising Administration Bureau and make a copy for the drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government and the applicant at the same time.

Article 56 The State Food and Drug Supervising Administration Bureau should, within 20 days after receiving the examination opinions, application materials and test reports of the sample products, make a decision on the examination. If the registration is granted, a new Domestic Health Food Approval Certificate and a new number of the approval will be issued to the transferee. The term of validity of the certificate should not change, while the original Domestic Health Food Approval Certificate or Imported Health Food Approval Certificate that were obtained by the transferor should be taken over and cancelled.

Article 57 If health food that already holds the Imported Health Food Approval Certificate is transferred outside Chinese borders, the holder of the health food certificate and the transferee should jointly complete the Application Form for Imported Health Food Technology Transfer Product Registration, and submit relevant materials and samples,

together with the transfer contract to the State Food and Drug Supervising Administration Bureau.

The State Food and Drug Supervising Administration Bureau should, after receiving the application materials, examine if the application is standard and complete and within 5 days issue an acceptance or denial notification. To meet the requirements of the application for technology transfer, the State Food and Drug Supervising Administration Bureau should, within 5 days after accepting the application, issue a test notification and provide examination samples to the designated testing agencies. If necessary, the State Food and Drug Supervising Administration Bureau may inspect the production sites of the transferee.

Article 58 The testing agencies should, within 30 days after receiving the test notification and samples, conduct sample examinations and send a test report to the State Food and Drug Supervising Administration Bureau and make a copy for the applicant at the same time. The State Food and Drug Supervising Administration Bureau should, within 20 days after receiving the test report of the samples, make a decision on the examination. If the registration is granted, a new Imported Health Food Approval Certificate and a new number of the approval will be issued to the transferee. The term of validity of the certificate should not change, while the original Imported Health Food Approval Certificate that was obtained by the transferor should be taken over and cancelled.

Chapter III

Raw Materials and Supplementary Materials

Article 59 Health food raw materials refer to the primary materials that have a connection with the functions of the health food. Health food supplementary materials refer to the excipient and other additional materials that are used while producing health food.

Article 60 Raw materials and supplementary materials that are used in the production of health food should be in accordance with national standards and hygiene requirements. If there are no national standards, industry standards or independently formulated quality standards should be provided together with the information on raw and supplementary materials.

Article 61 Raw materials and supplementary materials that are used in the production of health food should be safe and harmless for human health. In case of materials that require a limit on usage, this usage may not exceed the limit stipulated by relevant state regulations.

Article 62 Raw materials and supplementary materials that are not allowed to be used in the production of health food by the State Food and Drug Supervising Administration Bureau and other related government departments are prohibited to be used as health food raw or supplementary materials.

Article 63 Raw materials and supplementary materials that are allowed to be used in health food production, as announced by the State Food and Drug Supervising Administration Bureau, raw materials and supplementary materials that are edible, as announced by the Ministry of Health, or allowed to be used in the production of ordinary food, can be used as the health food raw and supplementary materials.

Article 64 If the raw materials and supplementary materials in the registration application that are used in the production of health food are not in the scope of the Article 63 of these Measures, the applicant should, in accordance with related stipulations, provide relevant safety toxicology tests evaluation and food safety information.

Article 65 The State Food and Drug Supervising Administration Bureau should, in time and in accordance with the development and requirements of science and technology, announce a name list of raw materials that are allowed or prohibited to be used in health food.

Article 66 Raw materials and supplementary materials that are used in the production of imported health food should comply with all related Chinese stipulations on the use of raw and supplementary materials in health food.

Chapter IV

Labels and Instructions

Article 67 While applying for the health food product registration, the applicant should submit the instructions and labels manuscript sample.

Article 68 The instructions manuscript sample and health food labels in the application registration should include the name of the product, main raw (supplementary) materials, effective/marker ingredient and their content, health functions, applicable population, inapplicable population, dosage and usage, specifications, best before guarantee date, storing methods, precautions etc.

The labels of the health food already approved for production and marketing should be in accordance with the relevant national regulations.

Article 69 Naming of the health food should be in accordance with the following principles:

1. Be in compliance with relevant national law, regulations, standards and standard stipulations;
2. Reflect the product's true attributes, be clear, easy to understand an in compliance with the conventions of Chinese language;
3. As general name should not be used a drug name that has already been approved and registered.

Article 70 The name of the health food should consist of three parts: brand name, general name and attribute name. All three should be in accordance with following requirements:

1. The registered trademark or other names of the product can be used as the brand name;
2. The general name should be accurate and scientific and words that clearly or with suggestion exaggerate its healing effects and functions are not allowed to be used.
3. The attribute name should indicate the objective pattern of the product; its representations should be standard and accurate.

Article 71 The State Food and Drug Supervising Administration Bureau should, according to relevant national standards, regulations, product application materials and sample test situation, examine the instructions manuscript sample and health food labels.

Chapter V
Testing and Examination

Article 72 Safety toxicology tests refers to animal tests of the sample products submitted by the applicant and conducted by testing agencies, in accordance with the

procedures of toxicological evaluation of health food safety and testing methods promulgated by the State Food and Drug Supervising Administration Bureau, in order to examine health food safety. If necessary, human trial tests may be carried out.

Function tests refer to animal tests and/or human trial tests of the sample products submitted by the applicant and conducted by testing agencies, in accordance with the procedures of health food function evaluation and testing methods promulgated by the State Food and Drug Supervising Administration Bureau or provided by the enterprises, in order to verify the health food's health care functions.

Effective or marker ingredient tests refer to tests of the sample products submitted by the applicant and conducted by the testing agencies, in accordance with the testing methods for effective or marker ingredients of health food promulgated by the Stat Food and Drug Supervising Administration Bureau, relevant departments or provided by the enterprises, in order to examine the content changes during he validity period.

Hygiene tests refers to tests of the sample products submitted by the applicant and conducted by the testing agencies, in accordance with the testing methods promulgated by relevant government departments or provided by the enterprises, in order to test the hygiene and product quality indicators (besides the effective or marker ingredients).

Stability tests refer to tests of the sample products submitted by the applicant and conducted by the testing agencies, in accordance with the testing methods promulgated by relevant government departments or provided by the enterprises, in order to test the change of hygiene and product quality related indicators (besides the effective or marker ingredients) during the validity period.

Sample tests refer to tests of the sample products provided by the food and drug supervising administrative departments and conducted by the testing agencies, in accordance with the quality standards submitted by the applicant, in order to make full examination of the samples.

Re-examination tests refer to recheck tests of quality standards of the effective or marker ingredients testing methods submitted by the applicant and conducted by the testing agencies.

Article 73 The State Food and Drug Supervising Administration Bureau is responsible for designating the testing agencies for health food tests, sample tests and re-examination tests. The concrete measures will be formulated separately.

Article 74 The designated testing agencies should, in accordance with the health food testing and evaluation technology standards and other testing and evaluation methods promulgated by other relevant government departments, conduct tests and examinations and within the stipulated or agreed time submit test and examination reports. The health food testing and evaluation technology standards should be formulated and promulgated by the State Food and Drug Supervising Administration Bureau.

Article 75 The designated testing agencies should, in accordance with the national service standards, charging standards and legally stipulated conditions, provide secure, convenient, stable and reasonably priced services for the applicant, and fulfil the duties of universal service.

Article 76 The designated testing agencies should, in accordance with law, guarantee that the tests and examinations are scientific, standard, open, fair and just and they must not submit false reports.

Article 77 The applicant should provide relevant materials required for sampling, cooperate in selecting the testing samples in order provide standard testing substance for the food and drug supervising administrative departments.

Article 78 Registration application sample tests and recheck tests of the health food must not be conducted by those testing agencies that are responsible for the tests of the product.

Chapter VI
Re-registration

Article 79 Health food re-registrations refers to the examination and approval process of application for extending the term of validity of the health food approval certificate upon its expiration date, carried out by the State Food and Drug Supervising Administration Bureau according to applicant's application, legal procedure, conditions and requirements.

Article 80 If an extension of the term of validity of the health food approval certificate is required upon its expiration; the applicant should apply for re-registration three months in advance to the term of validity expiration date.

Article 81 While applying for domestic health food re-registration, the applicant should as required complete the Application Form for Domestic Health Food Re-registration and submit the application materials to the local drug (food) administrative departments in provinces, autonomous regions and municipalities directly under the Central Government in place of his location.

Article 82 The drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should, after receiving the application materials, examine if the application is standard and complete and within 5 days issue an acceptance or denial notification.

Article 83 To meet the requirements of the application re-registration, the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government that were authorised by the State Food and Drug Supervising Administration Bureau should, within 20 days after accepting the application, give examination opinions and report them to the State Food and Drug Supervising Administration Bureau for examination.

Article 85 The State Food and Drug Supervising Administration Bureau should make a decision after examination within 20 days after receiving the examination opinions. If there is no re-registration denial notification issued within 20 days, the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government should issue a re-registration certificate for the applicant. If the re-registration is denied, the State Food and Drug Supervising Administration Bureau should

notify the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government to issue a notification of denial of re-registration and explain reasons for it to the applicant. .

Article 85 While applying for imported health food re-registration, the applicant should as required complete the Application Form for Imported Health Food Re-registration and submit the application materials to the State Food and Drug Supervising Administration Bureau.

Article 86 The State Food and Drug Supervising Administration Bureau should examine if the application is standard and complete and within 5 days after receiving the application materials issue an acceptance or denial notification.

Article 87 To meet the requirements of the application re-registration, the State Food and Drug Supervising Administration Bureau should, within 20 days after accepting the application, make a decision after examination. If conforming to the requirements, re-registration will be granted and a re-registration certificate will be issued to the applicant. If not conforming to the requirements, a notification of denial of re-registration together with an explanation for this will be issued to the applicant

Article 88 In case of one of the following circumstances concerning health food, re-registration will be denied:

1. Re-registration application was not submitted within the stipulated time;
2. Health food approval certificate was cancelled in accordance with relevant laws and regulations;
3. Existing food safety problems with raw and supplementary materials of the products;
4. Raw materials used in production or production techniques are not in accordance with existing regulations;
5. Other circumstances that do not fulfil relevant state regulations.

Article 89 If re-registration is denied, the State Food and Drug Supervising Administration Bureau should issue an announcement and cancel its health food approval number.

Chapter VII
Re-examination

Article 90 If the applicant has objections concerning the State Food and Drug Supervising Administration Bureau registration denial decision, he may, within 10 days after receiving the denial notification, submit a written application for re-examination to the State Food and Drug Supervising Administration Bureau and provide reasons for re-examination.

Article 91 After receiving the re-examination application, the State Food and Drug Supervising Administration Bureau should, in accordance with the original application items examination time limit and requirements, conduct re-examination and make a re-examination decision after that. If the denial of the registration is cancelled, a corresponding health food approval certificate should be issued to the applicant. If the original decision is maintained, no more re-examination application will be accepted, but the applicant may, in accordance with relevant laws, apply for administrative reconsideration at the State Food and Drug Supervising Administration Bureau or file an administrative litigation at the People's Court.

Article 92 The scope of re-examination is restricted to the original application items and application materials.

Chapter VIII
Legal Liabilities

Article 93 Under one of the following circumstances, the State Food and Drug Supervising Administration Bureau may, on the basis of the request made by the advantaged and disadvantaged parties or its authority, take actions after verification, in accordance with the stipulations of Article 69 of Administrative Licensing Law:

1. The personnel of an administrative department abuses its powers in order to grant registration permission;
2. Exceeding legal authority to grant registration permission;
3. Violating legal procedures to grant registration permission;
4. Granting registration to an applicant who is not qualified or does not conform to the legal requirements;

5. Other circumstances under which the health food certificate could be cancelled in accordance with law.

Article 94 Under one of the following circumstances, the State Food and Drug Supervising Administration Bureau should cancel the health food approval corresponding registration number:

1. Holder of the health food approval certificate applies for cancellation;
2. It was confirmed that the product has existing safety problems;
3. If the laws and regulations have been violated, the health food approval certificate should be cancelled;
4. Other circumstances under which the health food certificate could be cancelled in accordance with law.

Article 95 If in the process of health food registration, the State Food and Drug Supervising Administration Bureau, the drug (food) supervising administrative departments in provinces, autonomous regions and municipalities directly under the Central Government and their personnel violate the provisions of these Measures in any of the following situations, this will be handled in accordance with Article 72, 73, 74 and 75 of the Administrative Licensing Law.

1. Not accepting health food registration application that conforms to legal requirements;

2. Refusal to announce the items of application materials for health food registration at the place where the application is accepted;

3. Not fulfilling the legal duty of advising the applicant in course of the health food registration application accepting and examination process;

4. Failure to advise the applicant once only of the content of materials that should be added and corrected, if the health food application materials submitted by the applicant are incomplete or not in accordance with the statutory format;

5. Failure to explain, in accordance with the law, the reasons for not accepting the health food registration or its denial;

6. Granting registration to health food registration application that in not in accordance with the conditions stipulated in these Measures or granting registration while overstepping the legal authority;

7. Refusal to grant registration to application that is in accordance with conditions stipulated in these Measures or failure to grant registration within the time limit stipulated in these Measures;

8. Arbitrary charging or charging that is not in accordance with standards for statutory items;

9. Asking for or receiving bribes or seeking other benefits.

Article 96 If the State Food and Drug Supervising Administration Bureau causes damage to the legitimate rights and interests of the parties concerned as a result of violation of these Measures, in course of the health food registration process, it should provide compensation according to the state compensation law.

Article 97 If an applicant conceals the relevant information or provides false materials or sample products while applying for health food registration, the State Food and Drug Supervising Administration Bureau will refuse to accept the application or grant registration and will issue a warning to the applicant; such an applicant will not be allowed to submit registration application for the health food again within one year.

Article 98 If an applicant obtains the health food approval certificate by cheating, bribery or by any other improper means, the State Food and Drug Supervising Administration Bureau should cancel its health food approval certificate and health food registered number of approval; such an applicant will not be allowed to submit health food registration application again within three years.

Article 99 If the designated testing agencies violate the provisions of Article 75 of these Measures, the State Food and Drug Supervising Administration Bureau should order them to make corrections within a set time. In relation to the fees charged in violation of the law, the State Food and Drug Supervising Administration Bureau or other relevant government departments should order them to be refunded; in serious cases, the Health Food Testing Qualification Certificate will be revoked.

Article 100 If the designated testing agencies fail to conduct tests or examinations in accordance with these Measures or make mistakes in the process of testing and examination, the State Food and Drug Supervising Administration Bureau should give a warning and order

them to make corrections in set time; in serious cases, the Health Food Testing Qualification Certificate will be revoked.

Article 101 If a designated testing agency issues a false test or examination report, its Health Food Testing Qualification Certificate will be revoked; illegally gains will be confiscated; in case of constitution of crime, legal liability will be investigated in accordance with law.

If the test and examination results provided by the designated testing agencies are not truthful and cause losses, they should assume corresponding legal liabilities.

Chapter IX
Supplementary Articles

Article 102 Working periods stipulated in these Measures are calculated on the basis of working days, legal holidays are not included.

Article 103 Packing material and containers that have direct contact with the health food should be in accordance with the state edible or medicine requirements, and conform to the standards for safeguarding human health and safety.

Article 104 The State Food and Drug Supervising Administration Bureau should be responsible for the interpretation of these Measures.

Article 105 Corresponding health food regulations issued prior to these Measures that are not in accordance with them should cease to be executed from the date of implementation of these Measures.

Appendix I:

Product Registration Application Items

1. **Domestic Health Food Registration Application Items**:

1. Application Form for Health Food Registration

2. Photocopies of applicant's identity card, business license or certificates of legal registration issued by other agencies.

3. Reference material stating that the health food general name submitted in the registration application is not a duplicate of a drug name that has already been approved and registered (retrieved from the State Food and Drug Supervising Administration Bureau official website database).

4. A written guarantee that the applicant does not constitute an infringement to the patents already obtained by other parties.

5. Trademark registration certificate (if trademark is not registered yet, it does not have to be provided)

6. Product research and development report (including research and development train of thought, function screening process, expected effects etc.)

7. Product formulation (raw materials and supplementary materials) and formulation basis; sources of raw materials and supplementary materials and their usage basis.

8. Effect/marker ingredients, content and testing methods of effect/marker ingredients.

9. Production technology diagram and its detailed explanation together with relevant materials.

10. Product quality standards and its preparation explanation (including raw material and supplementary material quality standards).

11. Type, name, quality standards and selection basis of packing materials that have direct contact with the products.

12. Test reports issued by testing agencies together with relevant materials including:

- Test Application Form;
- Test acceptance notification issued by the testing agencies;
- Safety toxicology test report;
- Function test report;
- Test report on stimulants and prohibited drugs (alleviation of physical fatigue, weight loss and improving growth functions declared in the registration application);
- Effective ingredient test report;
- Stability test report;
- Hygiene test report;
- Other test reports (for example: examination report on raw material, test report on bacterial virulence etc.).

13. Draft sample of product labels and instructions.

14. Other materials that could be helpful by the product evaluation.

15. Two sealed samples in the smallest sales package.

Notes:

* As to registration application for products in which fungus, beneficial bacteria, nucleic acid, enzyme preparation and amino acid chelate etc. are used as raw materials, relevant materials must be provided in accordance with related requirements, in addition to the above mentioned materials.

* As to registration application for products in which wild animals and plants which usage is restricted by the state are used as raw materials, a certificate issued by related government department to the supplier of such raw materials for its exploitation and development and a purchase and sale contract between the raw materials supplier and the applicant must be provided, in addition to the above mentioned materials.

* As to registration application for health food whose aim is to supply vitamins and minerals, animal function evaluation test report and/or human trial test report, function research and development report are not required.

* As to registration application for functions that are out of the scope of function items promulgated by the State Food and Drug Supervising Administration Bureau, except the above mentioned materials according to the use of raw materials, following relevant materials concerning the new functions must be provided: (*) Function research and development report, including function name, reasons and basis for application, function evaluation process and testing methods, research process and relevant data, basis for the establishment of function evaluation process and testing methods, scientific documentation etc. (*) Self-examination report of product functions evaluation tests, conducted by the applicant in accordance with the function evaluation process and testing methods. (*) Product function evaluation test report, in accordance with the function evaluation process and testing methods and verification report on evaluation of testing methods, both issued by the designated testing agencies.

* As to registration application for different dosage forms of the same product by the same applicant, if one of those dosage forms has already undergone all tests as required, and the testing agencies have issued testing reports, the registration for different dosage forms could be exempt from function and safety toxicology tests, but photocopies of those function and toxicology tests reports must be provided. Changes in technology that have an impact on product safety and functions are exceptions.

2. Imported Health Food Application Registration Items:

As to registration application for imported health food, in addition to materials provided in accordance with the requirements of application materials for domestic health food according to the use of raw materials and functions, the following materials must be provided:

1. Certificate issued by relevant agency of the country (area) of production testifying that the producer complies with corresponding local standards of production quality control.

2. If the registration is handled by a representative office of the foreign producer in China, photocopies of the Registration Certificate of Foreign Enterprise Representative Office in China should be provided.
If the registration is handled by a representative agency in China which has the authorisation of a foreign producer, the notarised original letter of authorisation as well as photocopies of business license of the authorised representative agency should be provided.

3. Document that testifies that the product has been produced and marketed in the country (area) of production for more than one year, notarised by a notary organ of the country of production and confirmed by the Chinese Embassy or Consulate in that country.

4. Relevant standards of the country (area) of production or international organisations that are in connection with the product.

5. Samples of packages, labels and instructions of the product marketed in the country (area) of production.

6. Sample products from three consecutive batches, three times of the quantity required for testing centre.

The above-mentioned materials must be submitted in Chinese language with the original text attached, materials in foreign languages could be attached for reference. Chinese translation should be notarised by a domestic notary organ in order to ensure its consistency with the original content of the text. Registration application product quality standards (Chinese version) should conform to the format of the Chinese health food quality standards.

Appendix 2

Application Items for Modification Application

1. Application Items for Domestic Health Food Modification

1. Application Form for Domestic Health Food Modification or Domestic Health Food Modification Record Form.

2. Name, reason and basis of specific items of the health food that will be changed.

3. Photocopies of applicant's identity card, business license or certificates of legal registration issued by other agencies.

4. Photocopies of the health food approval certificate together with its appendixes.

5. Revised version of the health food labels, draft of the instruction booklet together with detailed revision explanation.

Notes:

* As to modification application for population reduction suitability scope, population expansion unsuitability scope and precautions, except for the above-mentioned materials, documents issued by the health food supervising administrative departments on the level of provinces in place where the product has been produced, testifying that the product has been produced and sold, must be provided.

* As to modification application for change of dosage (product specification does not change), except for the above mentioned materials, following materials must be provided: (*) Documents testifying that the product has been produced and sold issued by the health food supervising administrative departments on the level of provinces in place where the product has been produced; (*) If applying for dosage reduction modification, test report issued by the designated testing agencies, after they have conducted function evaluation tests for the planned change of dosage, should be provided.;(*) If applying for dosage increase

modification, test report issued by the designated testing agencies, after they have conducted toxicology and safety evaluation tests for the planned change of dosage, should be provided.

* As to modification application for change of product specification, best before date and quality standards, except for the above mentioned materials, following materials must be provided: (*) Documents testifying that the product has been produced and sold issued by the health food supervising administrative departments on the level of provinces in place where the product has been produced; (*) Evidence that the change will not effect the product's safety and functions, together with relevant research materials, scientific research documents and/or test reports. Among them, when applying for quality standards modification registration, research work materials on experiments of quality standards together with documentation materials should also be provided; (*) Quality standards after revision; (*) Self-check report on effect or marker ingredient, hygiene and stability tests of sample products from three consecutive batches; (*) Sample products from three consecutive batches, three times of the quantity required for tests (best before date change is an exception).

* As to modification application for increasing health food function items, except for the above mentioned materials, following materials must be provided: (***) Documents testifying that the product has been produced and sold, issued by the health food supervising administrative departments on the level of provinces in place where the product has been produced; (***) Quality standards after revision, (***) Function study test report on the function increasing items.

* . As to modification application for change of product name, except for the above-mentioned materials, reference material stating that the health food general name submitted in the registration application is not a duplicate of a drug name that has already been approved and registered (retrieved from the State Food and Drug Supervising Administration Bureau official website database) must be provided.

* As to modification record form for the change of applicant's own name and/or address, except for the above-mentioned materials, documents testifying the change of applicant's own name and/or address, issued by the local industry and commerce administration departments, must be provided.

2. Application Items for Imported Health Food Modification Application

1. Application Form for Imported Health food Modification or Domestic Health Food Modification Record Form.

2. Name, reason and basis of concrete items of the health food that will be changed.

3. Photocopies of applicant's identity card, business license or certificates of legal registration issued by other agencies.

4. If the modification issue is handled by a representative office of the foreign producer in China, photocopies of the Registration Certificate of Foreign Enterprise Representative Office in China should be provided.

If the modification issue is handled by a representative agency in China which has the authorisation of a foreign producer, the original notarised letter of authorisation together with photocopies of business license of the authorised representative agency should be provided.

4. Photocopies of the health food approval certificate together with its appendixes.

5. Certificate of modification, together with related materials, issued by relevant departments in the country (area) of production, notarised by a notary organ of the country (area) of production and confirmed by the Chinese Embassy or Consulate in that country.

Notes:

* As to modification application for population reduction suitability scope, population expansion unsuitability scope and precautions items, except for the above mentioned materials, actual form of label and instruction booklet after modification must be provided.

* As to modification application for change of dosage (product specification does not change), except for the above mentioned materials, following materials must be provided: (*) If applying for modification of dosage reduction, test report issued by the designated testing agencies, after they have conducted function evaluation tests for the planned change of dosage, should be provided; (*) If applying for modification of dosage increase, test report issued by

the designated testing agencies, after they have conducted toxicology and safety evaluation tests for the planned change of dosage, should be provided; (*)Actual form of label and instruction booklet after modification.

* As to modification application for change of product specification, best before date and quality standards, except for the above mentioned materials, following materials must be provided: (*) Evidence that the change will not effect the product's safety and functions, together with relevant research materials, scientific research documents and/or test reports. Among them, when applying for quality standards modification registration, research work materials on experiments of quality standards together with documentation materials should also be provided; (*) Self-check report of effect or marker ingredient, hygiene and stability tests of sample products from three consecutive batches; (*) Sample products from three consecutive batches, three times of the quantity required for tests (best before date change is an exception). (*) Actual form of label, instruction booklet and quality standards after modification.

* As to modification application for increasing health food function items, besides the above mentioned materials, following materials must be provided: (*) Function study test report on the function increasing items; (*) Actual form or draft of label, instruction booklet and quality standards after modification.

* As to modification application for health food producing enterprise internal changes for the production site outside the Chinese borders, besides the above mentioned materials, following materials must be provided: (*) Documents issued by the country's (area's) administrative departments where the new production site is located testifying that the conditions under which has been the product produced are in accordance with the corresponding local production quality control standards. (*) Documents testifying that the product was granted free sale permission in the country (area) where the new production site is situated; (*) Self-check report on effect or marker ingredient, hygiene and stability tests of sample products from three consecutive batches that were produced in the new production site; (*) Sample products from three consecutive batches that were produced in the new production site, three times of the quantity required for tests; (*) Actual form of label and instruction booklet after modification.

* As to modification application for change of product name, except for the above mentioned materials, reference material stating that the health food general name submitted in the registration application is not a duplicate of a drug name that has already been approved and registered (retrieved from the State Food and Drug Supervising Administration Bureau official website database), together with actual form or draft of label and instruction booklet after modification must be provided.

* As to modification record form for the change of applicant's own name and/or address, except for the above mentioned materials, documents issued by the country's (area's) administrative departments testifying that the production site of the product has not changed as well as actual form of label and instruction booklet after modification must be provided.

* As to the modification record form for the change of representative agency in China, except for the above mentioned materials, a letter of authorisation by the foreign health food producing company for his new representative agency in China that will handle the registration matter, together with cancellation of the original letter of authorisation, both notarised documents, must be provided.

The above-mentioned materials must be submitted in Chinese language with the original text attached; materials in foreign languages could be attached for reference. Chinese translation should be notarised by a domestic notary organ in order to ensure its consistency with the original content of the text. Registration application product quality standards (Chinese version) should conform to the format of the Chinese health food quality standards.

Appendix 3

Technology Transfer Product Registration Application Items

1. Items for Domestic Health Food Technology Transfer Product Registration Application

1. Application Form for the Health Food Technology Transfer Registration.

2. Photocopies of applicant's identity card, business license or certificates of legal registration issued by other agencies.

3. Effective transfer contract notarised by a notary organ and signed by both the transferor and the transferee.

4. Photocopies of the transferee's health food hygiene license, issued by the health food supervising administrative departments on the level of provinces.

5. Documents testifying that the transferee is in accordance with the Health Food Favourable Production Practice, issued by the health food production supervising administrative departments on the level of provinces.

6. Originals of the health food approval documents (including the health food approval certificate and its appendixes).

7. Sample products produced by the transferee from three consecutive batches, three times of the quantity required for tests.

2. Items for Imported Health Food Technology Transfer Product Registration that is transferred within the Chinese borders

1. Except for material items for domestic health food technology transfer product registration application, the following materials must be provided:

If the registration issue is handled by a representative office of the foreign producer in China, photocopies of the Registration Certificate of Foreign Enterprise Representative Office in China should be provided.

3. Items for Imported Health Food Technology Transfer Product Registration that is transferred outside the Chinese borders

1. Application Form for the Health Food Technology Transfer Registration.

2. Documents testifying that the product was permitted to be produced and sold in the transferee's country (area) of production, notarised by a notary organ of the country (area) of production and confirmed by the Chinese Embassy or Consulate in that country.

3. Documents issued by relevant departments of the country (area) where the transferee is located, testifying that the producer complies with corresponding local standards of production quality control.

4. Transfer contract. This contract must be notarised by a notary organ of the country (area) where the transferee is located and confirmed by the Chinese Embassy or Consulate in that country.

5. If the registration is handled by a representative office of the foreign producer in China, photocopies of the Registration Certificate of Foreign Enterprise Representative Office in China should be provided.
If the registration is handled by a representative agency in China which has the authorisation of a foreign producer, the notarised original letter of authorisation as well as photocopies of business license of the authorised representative agency should be provided.

6. Originals of the health food approval documents (including health food approval certificate together with its appendixes and official health food modification approval).

7. Test reports on effect or marker ingredient, hygiene and stability tests of sample products from three consecutive batches that were produced by the transferee, issued by the designated testing agencies.

8. Sample products produced by the transferee from three consecutive batches, three times of the quantity required for tests.

Appendix 4

Re-registration Application Items

1. Items for Domestic Health Food Product Re-registration Application

1. Application Form for Domestic Health Food Re-registration.

2. Photocopies of applicant's identity card, business license or certificates of legal registration issued by other agencies.

3. Originals of the health food approval documents (including health food approval certificate together with its appendixes and an official health food modification approval).

4. Photocopies of documents testifying that the product was permitted to be produced and sold, issued by the health food production supervising administrative departments on the level of provinces in place where the product has been produced.

5. Summary of sales situation within 5 years.

6. Summary of the consumer's feedback to product within 5 years.

7. Smallest sales packages of the health food and actual form of label and instruction booklet.

Notes: If the above-mentioned materials cannot be completely provided, while submitting the re-registration application, the applicant must provide a written explanation of reasons for this.

2. Items for Imported Health Food Product Re-registration Application

1. Application Form for Imported Health Food Re-registration.

2. If the re-registration is handled by a representative office of the foreign producer in China, photocopies of the Registration Certificate of Foreign Enterprise Representative Office in China should be provided.

If the re-registration is handled by a representative agency in China which has the authorisation of a foreign producer, the notarised original letter of authorisation as well as photocopies of business license of the authorised representative agency should be provided.

3. Photocopies of the health food approval documents (including health food approval certificate together with its appendixes and an official health food modification approval).

4. Documents issued by the relevant departments of the country (area) where the product has been produced, testifying that the producing enterprise complies to the corresponding local production enterprise quality standards as well as that the product was permitted to be produced and sold. These documents must be notarised by a notary organ of the country (area) of production and confirmed by the Chinese Embassy or Consulate in that country.

5. Summary of sales and import to China within 5 years.

6. Summary of the Chinese consumer's feedback to product within 5 years.

7. Smallest sales packages of the health food and actual form of label and instruction booklet.