USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

Date: 6/22/2005

GAIN Report Number: CH5050

China, Peoples Republic of

FAIRS Product Specific

Interim Administrative Measures for Health Food Registration

2005

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Report Highlights:
This is an unofficial translation of Decree 19 the Interim Administrative Measures for Health Food Registration published by the State Food and Drug Administration on April 30, 2005. These measures go into effect on July 1, 2005. Exporters should carefully study the regulation and consult the importers to ensure their interpretation is accurate.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

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Executive Summary
On April 30, 2005, the State Food and Drug Administration (SFDA) published the Interim Administrative Measures for Health Food Registration. These measures stipulate that SFDA and its subsidiaries are responsible for assessment and review of food safety, effectiveness, quality control, and content of labeling before a health food is registered. Health food registration also covers alteration and technology transfer. SFDA authorized testing agencies are responsible for conducting sample testing on toxicology, functionality (including human and animal trial), stability, and so on. Health food labeling should indicate materials (ingredients), dosage, quality standards, shelf life, and applicable groups.

An imported health food must be registered at SFDA or their provincial offices by its Chinese representative office or Chinese agent. Refer to the Appendixes for detailed documentation requirements for imported health food registration, re-registration, and technology transfer.

A full text of this regulation in Chinese is posted on SFDA web site (www.sfda.gov.cn).

BEGIN TRANSLATION

Decree No. 19 of the State Food and Drug Administration

Reviewed and approved by the State Food and Drug Administration (SFDA), the Interim Administrative Measures for Health Food Registration was hereby promulgated and shall go into effect as of July 1, 2005.

Director Zheng Xiaoyu

April 30, 2005

Interim Administrative Measures for Health Food Registration

Chapter I General Principles

Article 1 These Measures are formulated in accordance with the Food Hygiene Law of the People's Republic of China and the Administrative Licensing Law of People's Republic of China to standardize the registration of health food, ensure the quality of health food, and guarantee the human food safety.

Article 2 Health food in the Measures refers to food claiming that it has certain health improving functions or is able to supply vitamins and mineral. It is good for a particular group of people and able to adjust body functions. But, it is not used to cure certain diseases. It will not have any form of harm whether it is acute or sub-acute or chronic.

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

Article 4 Health food registration refers to that further to the application filed by the applicant, the State Food and Drug Administration, in accordance with the legal procedure, conditions and requirements, conducts a systematic review of the safety, effectiveness, quality control of health food and the content of the instruction. The State Food and Drug Administration decides whether to permit it to enter the process of examination and approval of its registration. It includes examinations and approvals of applications for product registration, alteration, and technology transfer product registration.

Article 5 The State Food and Drug Administration is responsible for the regulation of national health food registration and examination and approval of health food.

Drug (Food) administrative departments in provinces, autonomous regions and municipalities entrusted by the State Food and Drug Administration, are responsible for examining domestic health food registration application package, checking the experiments of health food that applies for registration and sample experimental production, and arranging for the examination of samples.

The examination agencies designated by the State Food and Drug Administration are responsible for the health food safety toxicology test, functionality test (including animal test or human trial test), effective or marker ingredient test, hygiene test, and stability test. They will carry out the sample product test and reexamination test.

Article 6 The management of health food registration should follow the principles of being scientific, open, equal, fair, effective and convenient.

Chapter II Application, Examination and Approval

Section One General Provisions

Article 7 A health food registration applicant refers to those who files health food registration application, bears relevant legal responsibilities, and is granted health food approval certificate after the application is approved.

A domestic applicant is legally registered citizen, legal person or other organization in China.

An overseas applicant refers to legitimate foreign health food manufacturers. When an overseas applicant intends to handle the imported health food registration, it should be done by its the Chinese representative offices or the Chinese agents.

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

Article 9 The State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions, and municipalities should publish health food registration application materials submitted and relevant registration application forms, where the application is processed.

Article 10 Health food registration applicants should submit complete documents the registration requires in accordance with the Measures that supply authentic information, and be responsible for the authenticity of the documents and other materials submitted.

Article 11 Applicants are allowed to correct the mistakes in submitted application materials if they can be corrected immediately.

Article 12 When materials applicants submit are not complete and disagree with legal forms, drug (food) administrative departments in provinces, autonomous regions and municipalities and the State Food and Drug Administration should, immediately or within five days, inform applicants of all the materials required at one time. If the notification is overdue, the day when the application materials are received is taken as the day when it is

accepted. If the application is denied being processed, the applicant should be notified in writing of the reasons.

Article 13 In the course of examination, if any further materials are required, the State Food and Drug Administration should inform the applicant at one time. An applicant, after receiving the notification, should supply the materials required within five months. If the applicant fails to do so, the examination will be terminated. Under special circumstances where the applicants are unable to supply the required materials in the due time, an applicant should file written application to the State Food and Drug Administration and make explanations. The State Food and Drug Administration should respond with a decision within 20 days.

Article 14 If any materials for registration application are supplemented, the original examination period is extended by 30 days. The alteration application is extended by 10 days.

Article 15 If the product is granted registration after examination by law, the State Food and Drug Administration should issue health food approval certificate to the applicant application within the period as stipulated, and send it to the applicant within 10 days. If the application is denied, the State Food and Drug Administration should inform the applicant of the denial and explain the reason of rejection within the period as stipulated, and inform applicants of the rights to apply for reexamination in accordance with laws and administrative reconsideration, or file administrative litigation.

Article 16 The State Food and Drug Administration and drug (food) administrative authorities in provinces, autonomous regions and municipalities should notify of the interested parties, if any party with strong interests with the registration application is found in course of examination of health food registration application. Applicants and stakeholders can submit paper-based materials to articulate and appeal or request a hearing in accordance with laws.

Article 17 The State Food and Drug Administration should provide information on health food registration application accepted to be processed, examination process and health food successfully registered on its official website.

Article 18 The State Food and Drug Administration should make adjustment of functions, evaluation of health food, testing methods and evaluation technical standards in accordance with the development of science and technology, and make it public.

Section Two Product Registration Application, Examination and Approval

Article 19 Product registration applications include domestic health food registration application and imported health food registration application.

Domestic health food registration application refers to the registration application of health food that the applicants intend to manufacture and sell in China.

Imported health food registration application refers to the registration application of health food which has been manufactured and sold overseas for above a year and intends to be sold within the territory of China.

Article 20 An applicant, before applying for health food registration, should make relevant research.

As research is finished, an applicant should supply the sample and relevant materials to testing agencies designated by the State Food and Drug Administration for testing and examination.

If the functions of health food submitted are within those published by the State Food and Drug Administration, applicants should supply product research and development report to the testing agency designated. If the functions of the health food submitted are out of that published, applicants should carry out animal test and human trial test and supply product research and development report for the testing agency.

The product research and development report should include information on basic concept of the research and development, function screening process and expected effects. Function research and development report should include information on the name of the function, the reason for application, function testing, evaluation methods and test results. Unable to carry out animal tests and human trial tests, applicants should articulate reasons why they are unable to do so in the function research and development report and supply relevant materials.

Article 21 Receiving the sample and relevant materials supplied by an applicant, testing agencies should, in accordance with health food examination and evaluation technical norms published by the State Food and Drug Administration and the testing methods published by other relevant departments or offered by the enterprise, carry out safety toxicology tests, function tests, effective, or marked, ingredients tests, hygiene tests and stability tests. If the functions of the health food submitted are out of those published the State Food and Drug Administration, the testing agencies should check its function tests, testing methods and test results, and provide test reports.

Article 22 After testing agencies provide test reports, an applicant may apply for health food registration.

Article 23 To apply for domestic health food registration, an applicant should, in accordance with Measures, fill in the Application Form for Domestic Health Food Registration, and send the application materials and sample products to drug (food) administrative departments in provinces, autonomous regions and municipalities.

Article 24 Receiving the application materials and sample products, drug (food) administrative departments in provinces, autonomous regions and municipalities should review whether the form of application materials are standard and complete, and send out application accepted to be processed /rejection notification within five days.

Article 25 Over the approved registration application, drug (food) administrative departments in provinces, autonomous regions and municipalities should check testing and sample production sites, choose samples used for tests and provide suggestions that are sent to the State Food and Drug Administration along with application materials within 15 days after the application is received. Meanwhile, drug (food) administrative departments in provinces, autonomous regions and municipalities should send testing notifications to the approved testing agencies and supply samples for tests.

Article 26 Health food samples used for registration application should comply with Good Manufacture Practice for Health Food. So should its manufacturing process.

Article 27 Within 50 days after receiving the test notification and sample products, testing agencies should carry out examination over the sample and reexamination, send the test report to the State Food and Drug Administration, and send the report to drug (food) administrative departments in provinces, autonomous regions and municipalities and applicants. In exceptional cases where the test agencies are unable to finish the work in due time, the test agencies should report to the State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions and municipalities, and attach written explanations.

Article 28 Receiving the examination reports from drug (food) administrative departments in provinces, autonomous regions and municipalities, application dossiers and sample products, the State Food and Drug Administration should arrange food, nutrient, medical, pharmaceutical and other technical personnel to review the application dossiers of those that meet the requirements in terms of technology and administration within 80 days, and make a decision after the examination. If granted registration, applicants should be issued Domestic Health Food Registration Certificate.

Article 29 Applying for imported health food registration, an applicant should, in accordance with Measures, fill in the Application Form for Imported Health Food Registration, and send application materials and sample products to the State Food and Drug Administration.

Article 30 Within five days after receiving the application materials and sample products, the State Food and Drug Administration should examine whether the form of application materials are standard and complete, and send accepted to be processed/rejection notifications. Over the application that meeting the requirements, the State Food and Drug Administration should send test notification and sample products used for tests to the designated testing agencies within five days after the application is accepted. If needed, the State Food and Drug Administration may examine the manufacturing site and experiment site.

Article 31 Within 50 days after receiving the test notification and sample products, the testing agencies should carry out examination over the sample and reexamination, send the test report to the State Food and Drug Administration, and send the report to applicants. In exceptional cases where the test agencies are unable to finish the work in due time, the test agencies should report to the State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions and municipalities, and attach written explanations.

Article 32 Within 80 days after the application is accepted to be processed, the State Food and Drug Administration should arrange food, nutrient, medical, pharmaceutical and other technical personnel to carry out technical examination of application materials and administrative examination, and make a decision over the examination. If granted registration, applicants should be issued Imported Health Food Approval Certificate.

Article 33 Health Food Approval Certificate will be effective within 5 years after issued. The format for the batch number of domestic health food approval is state food hygiene mark G+4 digit year number+4 digit batch number. The format for the batch number of imported health food approval is state food hygiene mark J+4 digit year number+4 digit batch

number.

Section Three Alteration Application and Approval

Article 34 Alteration application refers to that an applicant applies to change health food approval certificate and its attached contents.

Article 35 An applicant applying for alteration should be the holder of health materials food approval certificate.

Article 36 The name, raw materials and supplementary, manufacturing techniques, eating instruction, applicable population and other items, which is crucial to the security of the drug, of the health food in health food approval certificate cannot be altered.

Article 37 The health food that enlarges applicable population, or narrows down inapplicable population, and alters notices, functions, intakes, product standards, best before date and quality standards should be the product that has been manufactured and sold. The newly added functions must be those within what the State Food and Drug Administration published.

Article 38 Applying for altering the contents of Domestic Health Food Approval Certificate and its attachments, an applicant should fill in the Application Form of Domestic Health Food Alteration, and send relevant materials and instruction to food (drug) administrative departments in provinces, autonomous regions and municipalities where the applicant is located.

Article 39 Drug (food) administrative departments in provinces, autonomous regions and municipalities should examine whether the form of materials are standard and complete, within five days after receiving the application materials, and send accepted to be processed or rejection notifications.

Article 40 Over application for alteration of name, best before date, intake, narrowing down the group of people applicable, and enlargement of the group of people, inapplicable, drug (food) administrative departments in provinces, autonomous regions and municipalities should provide the results of examination within 10 days after receiving the materials, and deliver that, along with application materials, to the State Food and Drug Administration.

The State Food and Drug Administration should, within 40 days after receiving the results of examinations and application materials, arrange food, nutrient, medical, pharmaceutical and other technical personnel to examine the application materials, and make a decision over it. If granted alteration, applicants should be issues Domestic Health Food Alteration File, and copied to drug (food) administrative departments in provinces, autonomous regions and municipalities.

Article 41 Over the application for alteration of product quality and standards, drug (food) administrative departments in provinces, autonomous regions and municipalities should provide the results of examination and conclusions within 10 days after the application is processed, send that, along with application materials, to the State Food and Drug Administration, and meanwhile send test notifications to the approved testing agencies and offer samples for test.

Testing agencies that receive test notifications and samples, should carry out examinations within 30 days, send test reports to the State Food and Drug Administration and copy it to the drug (food) administrative body that sends the test notifications and applicants.

The State Food and Drug Administration should arrange food, nutrition, medical, nutrient, pharmaceutical and other technical personnel to carry out technical examination of the application materials and administrative examination within 50 days after receiving the examination reports, and make a conclusion over the examination. If granted alteration, applicants should be issues Domestic Health Food Alteration File that is copied to drug (food) administrative departments in provinces, autonomous regions and municipalities.

Article 42 Applying for altering the contents of Imported Health Food Approval Certificate and its attachment, an applicant should fill in the Application Form for Imported Health Food Alteration, and send relevant materials and instruction to the State Food and Drug Administration.

Article 43 The State Food and Drug Administration should check whether the form of application materials are standard and complete within five days after receiving the application materials, and send out accepted to be processed or rejection notifications.

Article 44 Over application for altering the product name, best before date, intake, narrowing down the group of people applicable, and enlargement of the group of people inapplicable, notice and functions, the State Food and Drug Administration should arrange food, nutrient, medical, pharmaceutical and other technical personnel to carry out technical examination of its application materials and administrative examination within 40 days after the application is processed, and provide results of examination. If granted alteration, applicants should be issued Imported Health Alteration File.

Article 45 Over the application for altering the product standards, quality standard and the overseas location where foreign health food producers manufacture the products imported to China, the State Food and Drug Administration should send to designated testing agencies test notifications and samples to be tested within five days after the application is processed. If needed, the State Food and Drug Administration may carry out on-site examination of that health food production site.

Testing agencies that receive test notifications and samples, should carry out examinations of the sample within 30 days, send test reports to the State Food and Drug Administration and applicants.

The State Food and Drug Administration, within 50 days after the application is received, arrange food, nutrient, medical, pharmaceutical and other technical personnel to carry out technical examination of application materials and administrative examination and make a conclusion. If granted alteration, applicants should be issued Imported Health Food Alteration File.

Article 46 Over application for altering the name, address and China's representative agent of the applicant, the applicant should, in accordance with Measures, fill in the Memo Form for Domestic Health Food Alteration or the Memo Form for Imported Health Food Alteration within 20 days after that item is altered, and send that, along with relevant materials, to the State Food and Drug Administration for memo.

Article 47 The valid period of Health Food Alteration File is identical to that in the certificate before alteration. When the valid period of the File expires, they should be re-registered all together.

Article 48 Requests for re-issuance of health food certificate, an applicant should send written application and instruction to the State Food and Drug Administration. Applying for reissuing due to loss, an applicant should send the original copy of the national newspaper where the loss declaration is published. Applying for reissuing due to damage, an applicant should send back original health food approval certificate. If qualified after examination, health food approval certificate will be reissued, and use the previous serial number, and the expiration date does not change. Reissued health food approval certificate should bear the previous approval date and print words of “reissued”.

Section Four Technology Transfer Product Registration Application and Approval

Article 49 Technology transfer product registration application refers to that holders of the health food approval certificates transfer the rights to sell and manufacturing technologies to another health food manufacturer, and, along with that health food manufacturer, apply for a new health food approval certificate for the transferees.

Article 50 The domestic transferee of the rights to sell and technology must be enterprises that legally obtain the health food hygiene approval certificates and comply with Good Manufacture Practice for Health Food.

Foreign transferees must be enterprises that meet the local production quality management requirements.

Article 51 Transferor should sign contract with transferees, transferring all the technology to transferees and guiding transferees till the transferees produce three batches of products meeting the quality requirements in a row.

Article 52 In cases where more than one holder own the health food approval certificate, when transferring the technology, they should co-sign the transfer contract.

Article 53 When health food with the Domestic Health Food Approval Certificate or Imported Health Food Certificate is transferred within China, health food certificate holders and transferees should co-sign the Application Form for Domestic Health Food Technology Transfer Registration or the Application Form for Imported Health Food Technology Transfer Registration, and send relevant materials and samples to drug (food) administrative body where the transferee is located, along with the transfer contract.

Article 54 Drug (food) administrative departments in provinces, autonomous regions and municipalities should review whether the form of application materials are standard and complete within five days after receiving the application materials, and send accepted to be processed or rejection notifications.

Over technology transfer product registration application that meets the requirements, drug (food) administrative departments in provinces, autonomous regions and municipalities should offer the results of examination within 10 days after the application is processed, send the application materials to the State Food and Drug Administration, and send to testing agencies test notifications and samples for tests.

Article 55 Testing agencies that receive the test notification and sample should carry out examination of samples within 30 days, send the test report to the State Food and Drug Administration, and copy it to the drug administrative body that notifies the agency to conduct examination and applicants.

Article 56 The State Food and Drug Administration should provide the results of examination within 20 days after receiving the examination results, application materials and examination reports of the sample. If granted registration, the transferees are issued new domestic health food approval certificate and a new serial number. But, the valid period of the certificate does not change. Meanwhile, the Domestic Health Food Approval Certificate or the Imported Health Food Approval Certificate obtained by transferor should be cancelled.

Article 57 When the health food with Imported Health Food Approval Certificate is transferred outside China, health food certificate holders and transferees should co-sign the Application Form for Imported Health Food Technology Transfer Product Registration, and send relevant materials and samples to the State Food and Drug Administration, along with transfer contract.

The State Food and Drug Administration should check whether the form of application materials are standard and complete and send accepted to be processed or rejection notifications within 5 days after the application materials are received. Over those meeting the requirements, the Administration should send to testing agencies test notifications and samples for tests within 5 days after the application is processed. If needed, the State Food and Drug Administration may carry out on-site examination of the transferee's production.

Article 58 Testing agencies that receive the test notifications and samples should carry out examination of the samples within 30 days, send the test report to the State Food and Drug Administration, and copy that to applicant. The State Food and Drug Administration should provide results of examination within 20 days after receiving the sample test report. If granted registration, transferees are issued a new Imported Health Food Approval Certificate and a new serial number. But, the valid period of the certificate does not change. The Imported Health Food Approval Certificate the transferor obtained will be cancelled.

Chapter III Raw Materials and Supplementary Materials

Article 59 Raw materials of health food refer to the primary materials that related to the functions of health food. Supplementary materials of health food refer to excipients or other added materials that are used to produce health food.

Article 60 Raw materials and supplementary materials used in the production of health food should comply with the national standards and hygiene requirements. In absence of national standards, the industry standards or self-stipulated standards can be used. Relevant materials on raw materials and supplementary materials should be supplied.

Article 61 Raw materials and supplementary materials used to produce health food should be safe and not harmful to human health. Materials that can be used in producing food with a limit can exceed that limit as stipulated by the government.

Article 62 Raw materials and supplementary materials that the State Food and Drug Administration and other government departments prohibit from being used in producing

health food should be used to produce health food.

Article 63 Raw materials and supplementary materials that the State Food and Drug Administration stipulates can be used in producing health food and that the Ministry of Health approves can be consumed and used to produce normal food can be used as the raw materials and supplementary materials to produce health food.

Article 64 If raw materials and supplementary materials that are used in producing health food the applicants applies for registration are uncovered by Article 63. The applicant should, in accordance with Measures, supply the toxicology evaluation test report of that raw material and supplementary material and relevant food safety materials.

Article 65 The State Food and Drug Administration should, in accordance with development of science and technology, make it public the material list of what can be used and what is prohibited.

Article 66 Raw materials and supplementary materials used is producing imported health food should comply with China's regulations on raw materials and supplementary materials used to produce health food.

Chapter IV Labels and Specifications

Article 67 When applying for health food registration, an applicant should submit a draft script of product specification and labels.

Article 68 The script of labels and specifications of health food to be registered should include product name, major raw materials and supplementary materials, effective and marker ingredients and content, functions, people applicable, people inapplicable, intake and the method of intake, standards, best before date, storage methods and other important notes.

The label of the health food allowed to go to market should comply with relevant national regulations.

Article 69 Naming of health food should comply with following principles:
1) In compliance with relevant national laws, regulations, standards;
2) Reflecting the true nature of the product, clear, easy to understand and in compliance with Chinese language.
3) Using the name of medicine that has been registered is not allowed.

Article 70 Name of health food should consist of three parts—brand name, general name and attribute name. They must comply with principles below:
1) Brand name can use the registered product trademark or other names;
2) General name should be accurate and scientific, and is not allowed to make an explicit or implicit statement of therapeutical effects or exaggerate the function;
3) Attribute name should state the product's authentic configuration, the statement should be standard accurate.

Article 71 The State Food and Drug Administration should, in accordance with relevant national standards, stipulations, application materials and sample test results, examinate the draft script of the label and specification.

Chapter V Testing

Article 72 Safety toxicology test refers to that designated testing agencies, in accordance with the health food safety toxicology examination procedures and examination methodology published by the State Food and Drug Administration, carry out animal tests to check whether the sample food from the applicants is safe to eat. If necessary, human trial test should be carried out.

Function test refers to that the designated testing agencies, in accordance with the health food function examination procedures and examination methodology published by the State Food and Drug Administration or provided by the enterprise, carry out animal tests, or human trial tests, to check whether the sample food from the applicants have the health improvement functions.

Effective or marker ingredients test refers to that designated testing agencies, in accordance with the health food effective or marker ingredient examination procedures published by the State Food and Drug Administration and other relevant departments or provided by the enterprises, examinate the content of the sample's effective marker ingredients and the change of that content within the valid period.

Hygiene test refers to that designated testing agencies, in accordance with the examination procedures published by relevant government sectors or provided by the enterprises, examinate the submitted sample's hygiene indicators and other indicators related to the product quality (except the effective or marker ingredients).

Stability test refers to that testing agencies, in accordance with the examination methodologies published by relevant government sectors or provided by the enterprises, examinate the change of the submitted sample's hygiene indicators and other indicators during the valid period (in addition to effective or marker ingredients).

Sample test refers to that testing agencies, in accordance with the quality standards the applicants submit, carry out a comprehensive examination of the sample sent by food and drug administrative departments.

Reexamination refers to that testing agencies conduct reexamination of the effective or marker ingredient examination methodologies the applicants submit.

Article 73 The State Food and Drug Administration is responsible for designating the test agencies for health food tests, sample tests and reexamination. The specific procedures of that will be drafted later.

Article 74 Designated testing agencies should, in accordance with health food test and examination technology standards and examination methods published by other relevant departments, present test report in due time. Health food examination technology standards should be drafted and published by the State Food and Drug Administration.

Article 75 Designated testing agencies should, in accordance with the service standard, price standard and legal conditions stipulated by the government, offer applicants with secure, convenient, stable and reasonably priced service, and fulfill the obligations of service.

Article 76 Designated testing agencies should act legally, ensure the tests are scientific, standard, open, fair, equal and honest.

Article 77 Applicants should provide food and drug administrative departments with required materials and cooperate in selecting samples for tests and offer standard materials for tests.

Article 78 Testing agencies that are responsible for the sample tests and reexamination tests of health food submitted should not be allowed to carry out the product test of that product.

Chapter VI Re-registration

Article 79 Health food re-registration refers to that the State Food and Drug Administration, according to an applicant's application and statutory procedures, conditions and requirements, examine whether to extend the valid period of the health food approval certificate when it expires.

The applicant for re-registration should be the holder of the health food approval certificate.

Article 80 An applicant who has to extend the valid period of the health food approval certificate should apply for re-registration three months prior to the expiration of the valid period.

Article 81 To apply for domestic health food re-registration, an applicant should, in accordance with regulations, fill in the Application Form for Domestic Health Food Re-registration, and send the application materials to the drug (food) administrative body where the applicant is located.

Article 82 Drug (food) administrative departments in provinces, autonomous regions and municipalities should check whether the form of application materials are standard and complete within five days after the application materials are received, and send out acceptation or rejection notifications.

Article 83 Over the re-registration applications that meet the requirements, drug (food) administrative departments in provinces, autonomous regions and municipalities are commissioned by the State Food and Drug Administration to provide results of examination within 20 days after the application is processed and copy that to the State Food and Drug Administration for check.

Article 84 The State Food and Drug Administration should provide examination results within 20 days after the examination opinions are received. If within 20 days no notification of denial of re-registration is issued, drug (food) administrative departments in provinces, autonomous regions and municipalities issue applicants certificates of re-registration. If the applicant is denied re-registration, the State Food and Drug Administration should notify drug (food) administrative departments in provinces, autonomous regions and municipalities of informing applicants of denial of re-registration and offering explanations.

Article 85 To apply for re-registration of imported health food, an applicant should, in accordance with regulations, fill in Application Form for Imported Health Food Re-registration, and send application materials to the State Food and Drug Administration.

Article 86 The State Food and Drug Administration should check whether form the application materials are standard and complete within five days after the application materials are received, and send out accepted to be processed or rejection notifications.

Article 87 Over the re-registration application that meets the requirements, the State Food

and Drug Administration should make a verdict within 20 days after the application is processed. If granted re-registration, applicants are issued re-registration certificates. If unable to meet the requirements, applicants should be issued notifications of denial of re-registration and informed of reasons.

Article 88 In cases below, health food are refused re-registration:
1) Unable to apply for re-registration in due time;
2) Cancel health food approval certificate in accordance with relevant laws and regulations;
3) Raw materials and supplementary materials and products with problems in food safety;
4) Materials or manufacturing techniques used in production of health food is incompatible with the existing regulations;
5) Other cases in which there is conflict with relevant national regulations.

Article 89, The State Food and Drug Administration should make announcements about refused re-registration; cancel its health food approval serial number.

Chapter VII Re-examination

Article 90 If an applicant disagrees with the refusal made by the State Food and Drug Administration, the applicant may write to the State Food and Drug Administration to ask for re-examination and attach reasons for re-examination within ten days after receiving the notification of denial of re-registration.

Article 91 Receiving the request for re-examination, the State Food and Drug Administration should, in accordance with previous application period and, make re-examination. If the denial of re-registration is cancelled, the applicant should be issued health food approval certificates. If the verdict is unchanged, a second request for re-examination will not be accepted. However, an applicant may, in accordance with relevant laws, ask the State Food and Drug Administration for administrative reconsideration or turn to the People's court for administrative litigation.

Article 92 The scope of re-examination is confined to previous application items and application materials.

Chapter VIII Legal Liabilities

Article 93 In cases below, the State Food and Drug Administration may, in accordance with the requests of the stakeholder or its responsibilities, follow the Article 69 of Administrative Licensing Law to take actions after checking:
1) A staff of administrative departments abuses his or her powers to grant registration;
2) Exceeding one's statutory authority to grant registration;
3) Violate legal regulations to grant registration;
4) Granting registration to a unqualified applicant or applicant unable to meet the legal requirements;
5) In cases where in accordance with laws, administrative departments may cancel health food approval certificates.

Article 94 In cases below, the State Food and Drug Administration should cancel the according health food approval serial number:
1) A health food approval certificate holder applies for cancellation;
2) Confirming that the product has potential safety concerns;
3) In cases where there is violation of laws and regulations, the health food approval certificate should be cancelled;
4) Other cases where the certificate should be cancelled by laws.

Article 95 In the process of health food registration, if personnel of the State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions and municipalities violate the regulations, in cases below, the administrative departments can, in accordance with Article 72, 73, 74 and 75 of Law of Administrative Permission, take actions:

1) Refusal to process health food registration application which meets the legal requirements;
2) Refusal to make public materials for health food registration application;
3) Unable to inform applicants according to laws when the health food registration application processed;
4) In cases where the application materials are incomplete and not standard, unable to inform applicants of what are further required at one time;
5) Unable to explain reasons why the application is refused to be processed or rejected;
6) Granting registration to health food that does not comply with the Measures, or exceed one's statutory authority to grant registration;
7) Refusal to grant registration to health food that comply with the Measures or unable to grant registration in due time;
8) Charging an applicant individually or charging an applicant not in compliance with legal stipulations;
9) Asking for or taking bribery, or for other interests.

Article 96 During the process of health food registration, the State Food and Drug Administration should provide compensation according to the national compensation law if the Administration violates the regulation and harms the legal rights and benefits of applicants.

Article 97 An applicant hides relevant information or provides fake material or sample products to apply for registration. Over this, the State Food and Drug Administration should refuse to process that application or grant registration, and issue warnings to the applicant. The applicant is not allowed file that particular health food application within a year.

Article 98 In cases where an applicant gets the health food approval certificate by cheating and bribery, the State Food and Drug Administration should cancel his or her health food approval certificate, and health food approval serial number. The applicant is not allowed to file registration application for that particular health food within three years.

Article 99 In cases where designated testing agencies violate the article 75 of the Measures, the State Food and Drug Administration should ask it to make corrections in due time. As for wrongly charged fees, the State Food and Drug Administration or other relevant government departments should ask the agency to return that to the applicant. In serious cases, the health food testing certificate will be cancelled.

Article 100 In cases where designated testing agencies violate the Measures to conduct examination or make errors during the test and examination, the State Food and Drug Administration should issue warnings and ask it to make corrections. In serious cases, its health food examination certificate will be cancelled.

Article 101 In cases where the designated testing agencies issue fake test reports or examination reports, its health food examination certificate will be cancelled. Illegal earnings will be confiscated. In cases of crimes, agencies must bear the criminal responsibilities.

In cases where designated testing agencies issue test reports or examination reports that are unauthentic and brings about loss, the agencies should bear the legal liabilities.

Chapter IX Supplementary Provisions

Article 102 Working periods mentioned in the Measures are working days, excluding statutory holidays.

Article 103 Packaging materials and containers that have direct contact with health food must comply with national eating or medical requirements ensure the safety of human health and safety standards.

Article 104 The rights to explain the regulation rests with the State Food and Drug Administration.

Article 105 The Measures shall go into effect as of July 1, 2005.

Prior to the Measures, other measures on health food registration that are incompatible with the Measures will be terminated.

Appendix I Application Items for Product Registration

1. Application Items for Domestic Health Food Registration

1) Application Form for a Health Food Registration.

2) Photocopies of an applicant's identity card, operation certificate or other legal registration certificates issued by other sectors.

3) An applicant is required to supply proof that the intended name must be different from drugs that have been registered (which can be generated from the online database of the State Food and Drug Administration).

4) Certificate to show the applicant do not infringe others' patent right.

5) Certificate of trademark registration (except unregistered trademark).

6) A report on the research and development of the product (including basic concept of the research and development, function screening process and expected effects).

7) The formula producing health food (raw materials and supplementary materials) and its justification; sources of raw materials and supplementary materials and their usage justification.

8) Functional ingredients/marker ingredients and the contents, and testing methods for functional ingredients/marker ingredients.

9) Sketch of the producing technique, its detailed explanation and relevant research materials.

10) Product quality standards and its formulation explanation (including quality standards for raw material and supplementary materials).

11) Category, name, quality standards and selection basis of materials that have direct contact with the package.

12) Test reports and other relevant materials issued by testing agencies, as follows:

A. Test Application Form;

B. Notification of testing request accepted by testing agencies;

C. Security toxicology test report;

D. Function test report;

E. Test reports on dopes, illegal drugs, etc. (Registration application for functions including alleviation of physical fatigue, losing weight, and improving growing functions);

F. Effective ingredient test report;

G. Stability test report;

H. Hygiene test report;

I. Other test reports (including examination reports on raw material, test reports on virulence of bacterial categories).

13) Samples of labels and instructions.
14) Other materials helpful to product assessment and review.
15) Two sealed samples in the sale package of minimal degree.

Note:

a. In terms of registration application of products made from epiphyte, beneficial bacterium, nucleic acid, enzyme preparation, amino acid chelate, applicants are required to supply above materials, but also to provide applications in accordance with relevant regulations

b. In terms of registration application of products made from nationally protected wildlife, applicants are required not only to supply above materials, but also to present the certificate issued by relevant government departments to show that an applicant is allowed to use that particular raw materials, and the trade contact signed by the raw materials provider and applicant.

c. In terms of registration application of the health food for adding to vitamins or minerals, an applicant is not required to provide test report on animal test reports or human trial test reports and function research and development reports and function research and development report.

d. In terms of registration application of health food whose functions are outside the list published by the State Food and Drug Administration, applicants are required not only to supply materials above on raw materials, but also to provide materials below on newly added functions: (1) Function research and development reports including information on function's name, application reasons and justification, the process of function testing and testing methods, research process and relevant data, function assessment procedures and justification of testing methods, and scientific literatures. (2) An applicant's self-test report on product function evaluation in accordance with the function evaluated process and test methods. (3) The test report issued by designated testing agencies on product function assessment in accordance with the function evaluation process and the test methods, and test report on testing assessment.

e. In terms of one single applicant applying for different forms of the same health food, if one form of that health food has undergone all the tests required and been issued testing reports, other forms of that health food can be waived of function and safety toxicology tests. But, the applicant is required to supply photocopies of those test reports. Essential change in the manufacturing techniques and changes affecting the security and functions are not covered.

2. Application Items for Imported Health Food Registration

In terms of imported health food registration application, applicants are required not only to supply application materials on raw materials and functions declared as did with domestic health food, but also to supply materials below:

1) The certificate to prove that the producer of the health food meets quality management standards where the manufacturer is based, and the certificate should be issued by a relevant department where the manufacturer is based.
2) If foreign enterprises' representative offices in China handle registration, they are required to present photocopies of Registration Certificate of Foreign Enterprises' Representative Offices in China.

If agents in China are entrusted by foreign enterprises to handle registration, they are required to present a copy of notarized entrust letter and the photocopy of the operation license of entrusted agents.

3) Certificate to show that the product has been produced and sold where the manufacturer is based for more than one year. That certificate must be attested by the notary agency where the health food is produced and confirmed by the Chinese embassy or consulate in the residing country.
4) Relevant product standards of the country or region where the manufacturer is based

or stipulated by certain international organizations.

5) Samples of packages, labels and instruction to be used where that product goes to market.

6) Samples of three continuous batch numbers, three times of what is needed for being tested.

Application materials above must be in Chinese and attached with the original language. Materials in languages other than Chinese can be taken as reference. The Chinese translation must be notarized by Chinese notary agencies to ensure the translated parts are coherent with original meanings. Quality standards to be registered (in Chinese) must be in compliance with quality standards of Chinese health food in format.

Appendix II Application Items for Alteration

1. Application Items for Domestic Health Food Alteration

1) Application Form of Domestic Health Food Alteration or Memo Form for Domestic Health Food Alteration.

2) Names of altered items, reasons and proof.

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

4) Photocopies of health food approval documents and its appendix.

5) Newly proposed label of health food, draft specifications, attached by detailed alteration note.

Notes:

a. In terms of application for narrowing down applicable population, enlarging inapplicable population and alteration of important and notes, an applicant is required not only to supply information on the above items, but also to supply the product manufacturing and selling certificate issued by provincial health food administrative departments where the applicant are based.

b. In terms of application for altering intake, an applicant is required not only to supply materials on above item, but also to supply:

1) The product manufacturing and selling certificate issued by provincial health food administrative departments where the applicants are based;

2) Regarding application for decreasing intake, it is required to submit the test report that designated testing agencies produce after conducting function tests over the intended dose;

3) Regarding application for increasing intake, it is required to submit the test report that designated testing agencies produce after conducting toxicological safety tests over the intended dose and function tests to compare the original intake with the intended intake.

c. In terms of application for altering Product specification, best before date and quality standards, an applicant is required to not only supply materials on above items, but also supply:

1) The product manufacturing and selling certificate issued by provincial health food administrative departments where the applicants are based;

2) Reports able to prove alteration will not change product safety and function, relevant research materials, scientific literature or test reports. In terms of application for altering quality standard, an applicant is required to supply relevant testing materials and literature review on quality standard research;

3) Revised quality standard;

4) Effective and marker ingredients, hygiene and stability self-test reports of samples with three continuous batch numbers;

5) Samples with three continuous batch numbers, which should be three times of what is needed for the test (except application for altering best before date).

d. In terms of application for adding functions of health food, an applicant is required not

only to supply materials above, but also to supply:

1) The product manufacturing and selling certificate issued by provincial health food administrative departments where the applicants are based;

2) Revised quality standard;

3) Function test report of newly added functions of health food.

e. In terms of application for altering the name of health food, an applicant is required not only to supply materials above, but also to supply proof that the intended new name must be different from drugs that has been registered (which can be generated from the online database of the State Food and Drug Administration).

f. In terms of application for altering applicants' own names or addresses, applicants are required not only to supply materials above, but also to present applicant's name alteration or address alteration documents issued by local industry and commerce administrative departments.

2. Application Items for Imported Health Food Alteration

1) Application Form of Imported Health Food Alteration or Memo Form for Imported Health Food Alteration.

2) Names of altered items, reasons and proof.

3) If foreign enterprises' representative offices in China handle alteration, they are required to present photocopies of Registration Certificate of Foreign Enterprises' Representative Offices in China.

If an agent in China is entrusted by foreign enterprises to handle alteration, they are required to present original copy of notarized entrust letter and the photocopy of the operation license of entrusted agents.

4) Photocopies of health food approval documents and its appendix.

5) Health food alteration certificates issued by relevant agencies where that particular health food is produced and relevant materials. That certificate must be attested by the notary agencies where the health food is produced and confirmed by the Chinese embassy or consulate in the residing country.

Notes:

a. In terms of application for narrowing down applicable population, enlarging inapplicable population and altering warnings, an applicant is required not only to supply information above, but also to supply samples of changed label and SP after alteration.

b. In terms of application for altering intake (product specification unchanged), an applicant is required not only to supply materials above, but also to supply:

1) As for application for decreasing intake, it is required to submit the test report that designated testing agencies produce after conducting function tests over the intended intake;

2) It is required to submit the test report that designated testing agencies produce after conducting toxicological safety tests over the intended and function tests to compare the original intake with the intended dose;

3) Samples of labels and specifications after alteration.

c. In terms of application for altering Product specification, best before date and quality standards, an applicant is required to not only supply materials on above items, but also to supply:

1) Reports able to prove that alteration will not change product safety and function, relevant research materials, scientific literature and or test reports. In terms of application for altering product specification, the applicant is required to supply relevant research materials and scientific literature on quality standard research;

2) Effective and marker ingredients, hygiene and stability self-test reports of samples with three continuous batch numbers;

3) Samples with three continuous batch numbers, which should be three times of what is needed for the test (except application for altering best before date);

4) Samples of labels and instructions after alteration.

d. In terms of application for adding functions of health food, applicants are required not only to supply materials above, but also to supply:

1) Function test report of newly added functions of health food;

2) Samples of labels and instructions and quality standards.

e. In terms of application for altering the manufacturing site outside China, applicants are required not only to supply materials above, but also to supply:

1) The certificate to prove that new manufacturing site meets quality management standards where the new side is based, the certificate should be issued by relevant departments where the new site is based;

2) The certificate to prove that the health food is allowed to be sold where the new site is based;

3) Effective and marker ingredients, hygiene and stability self-test reports of samples with consecutively three continuous batch numbers which should be produced in the new site;

4) Samples with three different batch numbers that should be produced in the new site;

5) Samples of labels and specifications after alteration.

6) In terms of application for altering the name of health food, an applicant is required not only to supply materials above, but also to supply proof that the intended name must be different from the drug that has been registered (which can be generated from the online database of the State Food and Drug Administration). It is also required to supply samples of labels and instructions after alteration.

7) In terms of application for altering applicants' own names or addresses, an applicant is required not only to supply materials above, but also to the certificate issued by relevant departments in the country or region where the health food is produced to prove that manufacturing site is unchanged. It is also required to supply samples of labels and specifications after alteration.

8) In terms of application for altering agents in China, an applicant is required to supply materials above, but also to supply entrust letter and notarizations to prove that foreign health food manufacturers entrust new agents in China while canceling the entrust relations with previous agents.

Application materials above must be in Chinese and attached with original language. Materials in languages other than Chinese can be taken as reference. The Chinese translation must be notarized by Chinese notary agencies to ensure the translated parts are coherent with original meanings. Quality standards to be registered (in Chinese) must be in compliance with quality standards of Chinese health food in format.

Appendix III Application Items for Technical-Transfer Product Registration

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

1) The Application Form for Health Food Technology Transfer Registration.

2) Photocopies of applicant's identity card, operation license or other legal registration certificates issued by other sectors.

3) Effective transfer contract signed by both sides and notarized.

4) Photocopy of technology transferee's health food hygiene license issued by provincial level health food administrative departments.

5) Certificate that proves technology transferee complies with Good Manufacture Practice for Health Food, which is issued by provincial level health food administrative departments.

6) Original copy of health food certificate (including health food certificate and its annexes and health food alteration file).

7) Samples with three continuous batch numbers produced by technology transferees, which should be three times of what is needed for the test.

2. Application Items for Registration of Imported Health Food Technology Transfer to Chinese Enterprises

In addition to following Section One, applicants are required to supply:

If foreign enterprises' representative offices in China handle registration, they are required to present photocopies of Registration Certificate of Foreign Enterprises' Representative Offices in China.

If agents in China are entrusted by foreign enterprises to handle registration, they are required to present original copy of notarized entrust letter and the photocopy of the business license of entrusted agents.

3. Application Items for Imported Health Food Technology

1) The application form for health food technology transfer registration.

2) Certificate to prove that the country or region where technology transferee is based allows that particular health food to be produced and sold in that country or region. That certificate should be notarized by notary agencies of countries where the technology transferee is based and approved by Chinese embassies or consulates of that country.

3) Certificate issued by relevant agencies of where the technology transferee is based to prove that the health food is in compliance with the local quality management standards.

4) Transfer contract. That contract must be notarized by notary sectors of countries where the technology transferee is based and approved by Chinese embassies or consulates of that country.

5) If foreign enterprises' representative offices in China handle registration, they are required to present photocopies of Registration Certificate of Foreign Enterprises' Representative Offices in China.

If agents in China are entrusted by foreign enterprises to handle registration, they are required to present original copy of notarized entrust letter and the photocopy of the operation license of entrusted agents.

6) Original copy of health food approval certificate (including health food approval certificate and its attachments and health food alteration file).

7) Effective and marker ingredients, hygiene and stability self-test reports of samples with three continuous batch numbers which should be produced in the new site.

8) Samples with three continuous different batch numbers produced by technology transferees, which should be three times of what is needed for the test.

Appendix IV Application Items for Re-registration

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

1) Application form for domestic health food re-registration.
2) Photocopies of applicant's identity card, business license or other legal registration certificates issued by other agencies.
3) Copy of health food approval certificate (including health food approval certificate and its attachments and health food alteration file).
4) Copy of certificate to prove that health food administrative departments where that health food is produced allows that health food to be manufactured and sold.
5) Summary of sales over the past 5 years.
6) Summary of consumer feedbacks over the past 5 years.
7) Samples of the package of health food of minimal degree, labels and specifications.

Notes:

If unable to supply materials above, an applicant must supply a written explanation when applying for re-registration.

2. Application Items for Imported Health Food Re-registration

1) Application form for domestic health food re-registration.
2) If foreign enterprises' representative offices in China handle registration, they are

required to present photocopies of Registration Certificate of Foreign Enterprises' Representative Offices in China.

If agents in China are entrusted by foreign enterprises to handle registration, they are required to present copy of notarized entrust letter and the copy of the business license of entrusted agents.

3) Copy of health food approval certificate (including health food approval certificate and its attachments and health food alteration file).

4) Certificate to prove that the country or region where the health food is produced allows that particular health food to be produced and sold in that country or region. That certificate should be notarized by notary agencies of countries where the health food is produced and approved by Chinese embassies or consulates of that country.

5) Summary of imports and sales in China over the past 5 years.

6) Summary of Chinese consumer feedbacks over the past 5 years.

7) Samples of the package of health food of minimal degree, labels and specifications.

END TRANSLATION