U.S. – China HPA Health Products Association

16192 Coastal Highway
Lewes, Delaware 19958-9776
info@uschinahpa.org
www.uschinahpa.org

SFDA REGULATORY UPDATES: End of Year 2011

December 15

Supervising guidance released to the supply companies of raw materials and packaging materials for health products and cosmetics manufacturers. The supervision on them includes access approval, process assessment, assessment management, and on-site assessment.

(1) Access approval: Regulate on the supplier access system, create supplier archive. Make assessments on suppliers' operational status, production capacity, quality guarantee system, product quality and delivery period, to ensure that national laws and regulations are honored during the purchase of safe raw materials and packaging materials.

(2) Process assessment: Create process assessment procedure and track system for raw materials and packaging materials, to ensure product quality safety during the supply process. Make assessments on the inspection and quarantine of goods, production and utilization, and sub-quality products.

(3) Assessment management: create an assessment system to make comprehensive appraisal of suppliers on a regular basis. Make performance appraisal on factors of product quality, delivery capacity, technology level and price costs. Abandon or improve those suppliers with unsatisfactory testing results.

(4) On-site assessment: conduct on-site assessment of key raw materials and packaging material suppliers on a regular basis, with evaluation standards including production capacity, processing level, and product quality control.

Production companies should follow the assessment contents and the character of raw materials and packaging materials, to identify key points of assessment

(1) Documents for assessment

1. supplier qualification, including corporate operation license, legal certificates for production and operation

2. quality management documents of supplier

3. documents and diagrams of production process and

4. documents of raw materials and packaging materials' function, standard and safety assessment, self-inspection reports of companies or valid testing reports issued by quality inspection institutions

(2) Inspection and testing of products

Production companies should exercise inspection and testing of the products under strict technique standards. Suppliers are required to provide valid testing reports and other qualification certificates.

(3) On-site inspection of key raw materials and packaging materials by suppliers

Production companies shall identify key points and principle for on-site inspections. The inspection will mainly cover the production environment, production technique, process control, storage condition, quality management and other factors that might impact the quality safety of products.

December 7

The English translation for some raw materials in health products is fixed.

车前子壳	PLANTAGINIS TESTA
葛花	PUERARIAE LOBATAE FLOS
枸杞子油	LYCII FRUCTUS OLEUM
瓜拉那	GUARANA
海龙	SYNGNATHUS
海马	HIPPOCAMPUS
黑加仑油	RIBIS FRUCTUS OLEUM

红花子	CARTHAMI FRUCTUS
鹿角	CERVI CORNUS
鹿角胶	CERVI CORNUS COLLA
鹿尾	CERVI CAUDA
鹿血	CERVI SANGUIS
蜜环菌菌丝体	AEMILLARIA MELLEA MYCELIUM
木蝴蝶	OROXMLI SEMEN
人参花	GINSENG FLOS
肉苁蓉	CISTANCHES HERBA
三七花	NOTOGINSENG FLOS
沙棘子油	HIPPOPHAE FRUCTUS OLEUM
山苦荬	IXERIS HERBA
山楂叶	CRATAEGI FOLIUM
柿叶	KAKI FOLIUM
水飞蓟	SILYBI FRUCTUS
乌药	LINDERAE RADIX
西红花	CROCI STIGMA
显齿蛇葡萄（茎叶）	AMPELOPSIS GROSSEDENTATAE CAULIS ET FOLUM
雄蚕蛾	BOMBYX♂
续断	DIPSACI RADIX
月见草油	OENOTHERAE SEMEN OLEUM
云芝	CORIOLUS
猪苓	POLYPORUS
紫苏梗	PERILLAE CAULIS
紫苏子油	PERILLAE FRUCTUS OLEUM
车前子壳	PLANTAGINIS TESTA

December 5

Cancellation procedures of health food approved license number released. The applicant can apply to food and drug administration departments at provincial level, with the original of approved license number, product approval certificate, and its annexes, as well as a commitment that the product has no investigation and punishment record, to cancel the approved license number.

November 4

Detailed detective measures released to detect 7 kinds of prohibited substances in cosmetics by liquid chromatography-tandem mass spectrometry; and 32 kinds of prohibited substances in hair dye by high performance liquid chromatography.

The 7 prohibited substances in cosmetics are Minoxidil, Hydrocortisone, Spironolactone, Estrone, Canrenone, Triamcinolone acetonide acetate, and Progesterone.

The 32 prohibited substances in hair dye are 1,5-Naphthalenediol, 1-Naphthol, 2,4-Diaminophenoxyethanol HCl, 2,6-diaminopyridine, 2,7-Naphthalenediol, 2-amino-3-hydroxypyridine, 2-Chloro-*p*-phenylenediamine sulfate, 2-Methylresorcinol, 2-Nitro-*p*-phenylenediamine, 4-Amino-2-hydroxytoluene, 4-Amino-3-nitrophenol, 4-Amino-*m*-cresol, 4-Chlororesorcinol, 4-Nitro-*o*-phenylenediamine, 6-Amino-*m*-cresol, 6-Hydroxyindole, Hydroquinone, *m*-Aminophenol, *m*-Phenylenediamine, N,N-Bis(2-hydroxyethyl)-*p*-phenylenediamine sulfate, N,n-Diethyl-*p*-phenylenediamine sulfate, N,n-Diethyltoluene-2,5-diamine HCl, N-Phenyl-*p*-phenylenediamine, *o*-Aminophenol, *p*-Aminophenol, Phenyl methyl pyrazolone, *p*-Methylaminophenol sulfate, *p*-Phenylenediamine, Resorcinol, Toluene-2,5-diamine sulfate, Toluene-3,4-diamine, and *o*-Phenylenediamine

November 2

Further regulation on the administrative licensing of cosmetics and the new raw materials of cosmetics.

Applicants are not allowed to use the same product formula to apply for 2 or above administrative licenses of cosmetics. In the case of applying for the extension of copyright of the administrative licensing (record evidence), product labeling (including product information sheet) unrecorded in the documents (record evidence) shall be consistent with the original product application. In the case of change, the application of change shall be proposed based on related regulations and procedures.

1. Application for administrative licensing of raw materials of cosmetics. Before the toxicological testing, the testing institution shall exercise double sample

testing by using the qualitative and quantitative testing methods. The toxicological testing will formally start only after the substance, purity and density of the sample are confirmed as claimed by the applicant.

Applicants shall enclose into the cosmetics administrative licensing application material the qualitative and quantitative double testing reports on the submitted sample issued by related toxicological testing institutions. If the toxicological testing has been finished before Dec.1, 2011, and the applicant is unable to provide required double testing reports, then a letter of commitment consistent with submitted sample and the results of testing reports shall be presented.

2. The copy of the toxicological testing report in the administrative licensing of the raw materials of cosmetics is allowed. The copy shall feature signature and official seals by both the testing institution and producer.

3. Applicants shall provide materials such as quantitative and qualitative testing methods and impurity testing methods for the application of administrative licensing of raw materials of cosmetics. If testing methods stated in the “Sanitary Regulation of Cosmetics”, national standard, industry standard and other regulatory documents issued by SFDA, please list out the names of testing methods, otherwise you should provide a complete set of testing methods and submit testing reports issued by no less than 3 cosmetics administrative licensing institutions.

September 30

Revised China's Good Manufacturing Practices on Health Food released. The GMP certificate will be accessed by company structure and staff, plant and factory, facilities, raw materials and finish products, manufacturing management, quality management, and file management. Here are some more details from the regulation.

Companies shall create independent quality management departments. People in charge of production management and quality management shall be full-time employees and could not share title or responsibilities. They should hold degrees higher than junior college and medium-level technical certificate, having at least three years’ experiences in health food production and quality management, and receiving knowledge trainings related to food production.

Workers in direct contact with health products shall pass health examinations and receive health certificates before starting to work. A health test should be conducted for workers on an annual basis.

Waste water, gas and other materials produced from the production process shall be dealt with according to national regulations, so that they would not cause pollutions to the products.

The exposure process area for packaging materials and health food, including tablet, capsule, soft capsule, sterilizing oral liquid, pills, granular formulation, powder, tea, ointment should adopt the setting of the clean area no lower than 300,000.

The exposure process area for non-sterilizing oral liquid and probiotic products should adopt the setting of the clear area no lowers than 100,000.

The temperature and humidity of clean room (area) should be consistent with production process requirements. If there is no special requirement, the temperature should be controlled at 18-26℃, while the relative humidity should be controlled at 45-65%.

The formulation shaping, filling and split packaging should use automation equipment. If automation equipment could not fit due to special process, the product quality should be ensured through process testing.

The testing record of each batch of products should include the quality testing record of intermediate products and finished products, so that people could have track of all the quality testing conditions of such batch of products.

Samples should be kept for each batch of products. The packaging of samples should be consistent with the products sold in the market. The amount of sample should satisfy the needs of three whole testing according to quality standards, or at least 4 products with independent packaging should be kept. Samples should be stored in special areas or warehouses, classified by variety or batch number. The samples should be kept until one year after the shelf life is overdue, and total time should be no less than 2 years.

September 30

Revised draft on the Method for the Assessment of Assisting the Protection Against Chemical Injury of Liver Function of Health Product released. Animal testing required.

September 28

Procedures of Accepting and Examining the Administrative License for Health Products released. Registration application form can be downloaded from www.bjsp.gov.cn, the website of Assessment Center.

Besides the Registration and Application Form of Health Products, testing reports, certified documents, official documents and third-party documents provided by testing institutions, the application materials should feature applicant seals or seals on the perforation on each page. Registration or re-registration for new products requires applicants to submit one original copy and eight copies of application materials. Registration for change or technical transfer products requires applicants to submit one original copy and six copies of application materials.

Key Inspection Points of the Administrative Licensing for Domestic Health Products

1. Product registration form;

2. Copies of applicant's identity card, operation license and other legal registration documents of related institutions

3. Materials for common name and no repetition of names with registered drugs of health food

4. No rights violation guarantee made by applicants

5. Certified documents for label registration (not required for products with no labels)

6. Product R&D report (including product research idea, function selection process and expected result)

7. Product formula (source material and accessories) and formula evidence

8. Effect/symbolic ingredient, testing methods of contents and effect/symbolic ingredient

9. Production process diagram and related materials

(1) Production process diagram

It should include the production process line, stages and related technical standards.

(2) Information about production process

a. detailed description of production process, including all production steps and technical standards

b. equipment and model required for each step

c. if the extract serves as material, provide production process of the extract.

(3) related research materials

(4) self-testing reports of three batches of samples

10. product quality standard and information (including quality standards for raw material, accessories)

11. variety, name, quality standard and evidence for the packaging materials of direct contact product

12. testing reports and related materials provided by testing institutions

(1) testing reports should be provided by institutions authorized by SFDA. The valid period of the testing report shall be 5 years after issuing date by the testing institution. Overdue testing report will not be accepted.

(2) testing report and materials.

Testing reports shall be presented in the following order

a. virology security testing report;

b. functional testing report (including animal functional testing report and /or human body diet testing report);

c. Doping and illegal drug testing reports (apply for registration of easing weariness, reducing fat and improving growth functions);

d. effect content and symbolic content testing report

e. stability testing report

f. sanitary testing report

g. other testing reports (such as raw material variety appraisal report, toxicity testing report etc.)

All testing reports should be attached with the testing application form and a testing acceptance notice having been signed by the testing institution.

13. product label, instruction book draft

14. other materials that may assist the product application

(1) legal registration documents of raw material producers

(2) testing reports of raw materials and accessories

(3) invoice of purchasing raw materials. If raw materials are donated, provide related documents offered by raw material producers. If the applicant purchases from raw material suppliers, he or she should also provide copy of supply agreement between supplies and raw material producers.

(4) If extracts are used as materials, the applicant should also provide evidence for production proves and quality standards with stamped seals by suppliers.

(5) Provide the sub-contracted processing agreements between applicant and sample making units

(6) Provide effective operation license, sanitary permit, and formulation of applied products

(7) If the formula uses substances that need special reporting and approval, such as fungus, probiotics, nucleic acid, endangered species of wild fauna and flora, coenzyme Q10 and soybean isoflavone, the applicant should provide related materials according to Management Measures of Healthy Product Registration, and other approval regulations.

(8) If the products use chemical synthetics as materials, the applicant should provide edible evidence, amount of food and security evaluation materials.

(9) Reference materials

15. sealed sample with smallest package sales

16. if the product function is not included in the regulations by SFDA, the applicant shall provide materials as required.

Key Inspection Points of the Administrative Licensing for Imported Health Products

The application for the registration of imported health products requires the following materials:

1. Institutions of the producing country (region) shall provide certified documents of fitting local production quality management regulations. The certified documents should meet following requirements:

(1) applied products are produced by foreign producers trusted by the applicant. The producing company in the certified documents should be the trusted company, and a letter of attorney shall also be provided.

(2) the certified documents shall clarify the name of document issuing institution, name of product, name of producing company and the date of issuance.

(3) the issuing institution shall be the government departments of industry associations in the producing country.

2. If it is the standing representative office of foreign companies in China applies for registration, it should provide the copy of “Registration Certificate of Standing Representative Office of Foreign Companies in China”.

If the agent institution of foreign producing companies intends to apply for registration, it should provide original copy of the letter of attorney and the copy of operation license of the agent institution.

3. Certified documents for products sold in producing countries for more than one year. This document should be identified by the public authorization institution and China's embassies in producing countries, and also meets the following requirements:

(1) the certified document shall clarify the name of issuing institution, name of applicant, name of producing company, name of product and the date of issuance.

(2) certified document shall clarify legal and other related standards of producing countries. The products shall be allowed to produce and sell in the country (or region). If it is only allowed to produce, rather than sell in the country, such product registration proposal will not be accepted.

(3) the issuing institution of certified documents should be the government departments or industry associations,

4. Product standards made in producing countries (region) or international organizations

5. the packaging, label, instruction book of the products in producing country (region) should be listed under the label and instruction book item

6. the quantity of samples with three consecutive batch number triples that required by the testing

7. Other matters for attention

(1) in the product registration application form, applicant for the imported product is the owner of the product, while producing company is the real producer of the product (if the applied product is produced by the applicant, then the producing company is the applicant; if the applied product is produced by foreign companies trusted by the applicant, then the producing company is the trusted company).

(2) name of product, name of producing company, name of the agent institution (Chinese, English) should be consistent.

(3) certified documents and the letter of entrustment should be original copies, using official language of the producing country (or region); needing identification by notary agency of the country (region) and Chinese embassies or consulates in the country.

(4) if the valid period is marked in the certified documents, then these documents should before the valid period is due

(5) certified document and letter of entrustment should have seals and signatures by legal representatives (authorizer)

(6) these application materials should be presented with original copies and Chinese language; materials with foreign languages should be attached as reference. The Chinese translation should be notarized by the notary agency, and consistent with the contents of original copy. The quality standard for the applied product should be consistent with the national health food quality standard system.

Key Inspection Points of the Administrative Licensing for Domestic Health Food Products with Transferred Technology

1. registration application form for health food products with transferred technology

2. Copies of identity card, operation license and other legal certified documents

3. Original copy of technology transfer contract signed by assignor and recipient authorized by notary agencies. The technology transfer contract signed by the assignor and recipient should be clear, complete and with no signs of revising.

4. copy of health food sanitary license issued by the provincial health food production supervision and administration department

5. certified documents issued by provincial health food production supervision and administration department showing the recipient obeys the “Regulation on the Production of Health Food”.

6. original copy of health food approval documents (including health food approval certificate, the attachment and health food change approval document)

7. letter of commitment made by the assignor on non-violation of laws or regulations within 2 years.

8. Materials to support on-site inspection

(1) product formula

(2) production process diagram and instruction

(3) product quality standard

(4) if the multi-applicants for the health food certificate change into a single ownership, and the recipient has no production capacity, then it should provide the sub-contract processing agreement signed with the assignor.

9. other matters for attention of the technology transfer application:

(1) If the joint ownership by multi-applicants (double applicants) of the health food approval certificates changes into single ownership, the registration should follow the technology transfer application process.

a. if the technology owner is the assignor but has no production capacity, it could trust health food production company with capacity to produce and provide the copy of certified documents showing the recipient has production capacity.

b. if some applicants intend to cancel the registration, it should provide the cancellation certified documents issued by local industry and commerce administration departments.

(2) for health food with the identical raw materials and accessories, flavors but different colors, if during the new product registration no security toxicology testing or functional testing has been carried out, the applicant shall provide reports of the toxicology or functional testing.

Key Inspection Points of the Administrative Licensing for Imported Health Food Products with Transferred Technology

1. Administrative licensing for imported health product with inbound technology transfer

(1) besides the application materials according to the key inspection points for administrative licensing of domestic health products with transferred technology, other materials shall be provided:

(2) if it is the standing agent institution trusted by foreign producing companies responsible for the registration issue, it should provide the copy of “registration certificate of standing office of foreign companies in China”.

If it is the agent institution trusted by foreign producing companies responsible for the registration issue, it should provide the original copy of the letter of entrustment and the copy of operation license of the agent institution.

2. Administrative licensing of imported health food with outbound transferred technology

(1) registration application form of health food with transferred technology

(2) documents showing that the products are allowed to produce and sell in the producing country (region) where the recipient belongs. These documents need identification by notary agencies and Chinese embassies or consulates in the producing country (region).

(3) documents issued by institutions in the recipient’s country (region) showing that the producing company meets the production quality management regulations.

(4) transfer contract. This contract needs identification by notary agencies and China’s embassies or consulates in the recipients’ country (region). The documents should be translated in Chinese and notarized by notary agencies.

(5) if it is the standing agent institution trusted by foreign producing companies responsible for the registration issue, it should provide the copy of “registration certificate of standing office of foreign companies in China”.

If it is the agent institution trusted by foreign producing companies responsible for the registration issue, it should provide the original copy of the letter of entrustment and the copy of operation license of the agent institution.

(6) original copy of health food approval certificates (including health food approval documents and appendix, health food change approval documents.

(7) the reports about functional and symbolic formula, sanitary and stability testing of three consecutive batches of samples produced by assignee issued by testing institutions

(8) a letter of commitment for non violation of laws and regulations within 2 years

(9) the quantity of three consecutive batches of samples produced by the assignee triple the quantity of testing requirements

Key Inspection Points of the Administrative Licensing for the Change of Imported Health Food

1. application form for the change of imported health food or record form for the change of imported health food

2. title, reason and evidence for the change items. The reason and evidence should include the certified documents allowing change items issued by the administration departments of the producing country (region). These documents should be confirmed by notary agencies and China's embassies or consulates in the producing country (region).

3. if it is the standing agent institution trusted by foreign producing companies responsible for the issue, it should provide the copy of "registration certificate of standing office of foreign companies in China".

If it is the agent institution trusted by foreign producing companies responsible for the issue, it should provide the original copy of the letter of entrustment and the copy of operation license of the agent institution.

4. copy of health food approval certified documents and the appendix

5. certified documents or materials issued by related agencies in the producing country (region) showing the items have changed. These documents should be confirmed by notary agency or China's embassies or consulates in the producing country.

6. other matters for attention

(1) the applicant shall be the owner of the health food certified document

(2) narrow the scale of suitable crowd, expand the scale of unsuitable crowd; the application for the change of matters for attention also requires the label and instruction book sample after the change is made.

(3) the application for the change of edible amount (product standard unchanged) requires the following materials:

a. the change application for the reduction of edible amount requires the testing reports issued by the testing agency based on corresponding functional tests

b. the change application for the increase of edible amount requires the testing reports issued by the testing agency based on toxicology safety tests and the comparative functional test between changed edible amount and original edible amount.

c. Label and instruction book sample after change happens.

(4) It needs other materials to complete the application for the change of product standard, shelf life and quality standard:

a. research materials, science papers or testing reports showing that the change would deliver no impacts on the product safety and function. The application for the registration of the change of quality standards also requires testing materials related to the quality research work;

b. the self-testing report about the effect content, symbolic content, sanitary condition and stability of three consecutive batches of sample products.

c. three consecutive batches of sample products required by testing (changing shelf life excluded)

d. label, instruction book and quality standard sample after change.

(5) the application for the increase of health food functional items, other materials are needed:

a. the functional testing report issued by defined agency about the increase of functional items

b. label, instruction book and quality standard sample after change

(6) If the health food producing company intends to apply for the change of production location outside China, it should also provide the following materials:

a. certified documents issued by the administration department in the country (region) of the new production location, showing that the production condition fits the local production quality management regulation

b. certified documents showing that the product is allowed to sell in the country (region) where the new production site is located

c. self-testing reports of effect and symbolic contents, sanitary and stability of three consecutive batches of samples produced on the new production site.

d. samples of the three consecutive batches of products produced in the

new production site to be tested

e. label, instruction book samples after change

(7) the application for the change of product name requires the above materials and also the search materials (SFDA official website data base) showing that the changed product name is not identical with any names already registered, the label, instruction book samples after change, and a letter of commitment about no violation of laws and regulations within 2 years.

(8) the record items of the change of applicant name or place name require the certified documents issued by administration agencies in the producing country (region) showing the production site is unchanged, and the label and instruction book sample after change.

(9) record items of changing domestic agent institution requires the letter of entrustment and notarial documents showing that the foreign health food producer entrusts new agent in China and terminates the contracts with its original agent.

(10) the application materials should be provided in the Chinese version with original copy attached. Foreign language materials should be added to the appendix for reference. The Chinese translation needs notarization by domestic notary agencies to ensure the consistency with the original contents; the product quality standard (Chinese version) should be consistent with the format of China's health food quality standard.

Key Inspection Points of the Administrative Licensing for Re-registration of Imported Health Food

1. Re-registration form for imported health food

2. If the foreign company's standing representative office in China is responsible for the re-registration issue, it should provide the "Registration Document for Foreign Company's Standing Representative Office in China"

3. Copy of approval documents of health food (including health food approval document and appendix, and the documents of the change of health food).

4. The certified documents issued by related departments in the producing country (region) showing the production company respects local quality management regulation and that the product is allowed to produce and sell. The documents shall be notarized by notary agency and confirmed by China's embassies or consulates in the producing country.

5. A summary of the product's import and sales condition in the past 5 years.

6. A summary of China's consumers' feedback on the product in the past 5 years

7. Smallest sales package, label and instruction book sample of the health food

8. Formula, process, effect or symbolic contents, testing methods and quality standard of the health food

9. Letters of commitment

(1) if requirements on the product technology are unchanged, a letter of commitment shall be provided

(2) if the functional appraisal method requires change of product technology, other materials like the testing reports on the product's consistency with existing regulations shall be provided.

* Note: if the above materials are not fully available, the applicant shall state the reason in a written form during the re-registration application.

Key Inspection Points of the Administrative Licensing for Re-issuing the Approval Documents

1. The applicant shall submit a written form application to the SFDA and state the reason

2. The original copy of the lost property notice publicized in national papers or magazines.

September 21

Regulation on the Naming of Health Products released. Any word which would possibly cause confusion or misunderstanding, fake, exaggerating words, words stating or indicating treatment function, are all not allowed to be used in the product name.

September 21

Guidance on the Application and assessment of the New Function of Health Product released. To claim new function of health product, 15 kinds of materials are required to submit in the application; for imported health products, 7 more items of materials are required.

1. Application material items for new functional health food product registration

(1) registration application form for new functional health food product (domestic)

(2) copies of applicant identity card, operational license or other legal registration documents

(3) the searching materials showing that the title of the health food product applying for registration is not identical with any drug titles already registered (search from the database eof SFDA)

(4) the letter of commitment stating that the applicant would not violate the property rights owned by others

(5) label registration certified documents (not required if there is no label registration)

(6) product R&D report (including research ideas, function selection process, function research report, functional self-testing report, expected result).

(7) product formula (raw material and accessories) and formula evidence; the evidence for the origin and usage of raw materials and accessories.

(8) effect content/symbolic ingredient, content and testing methods

(9) production process diagram, detailed instruction and related research materials

(10) product quality standard and compilation notice (including the quality standards for raw material and accessories)

(11) variety, name, quality standard and selection evidence for the packaging materials of direct contact products

(12) testing reports and related materials issued by testing agencies, including:

a. testing application form;
b. testing acceptance notice
c. safety and toxicology testing reports
d. functional testing reports;
e. new functional testing and appraisal methods, testing reports of the testing results
f. testing reports about stimulant and illegal drugs (apply for registration of reducing fatigue, fat and enhancing body function)
g. functional content testing report
h. stability testing report
i. sanitary testing report
j. other testing reports (raw material appraisal report, toxicology report)

(13) product label, instruction book sample

(14) other materials to support the application

(15) two sealed samples with the simplest sales packages

***Note:**

1. if the applied registration product is made from substances including fungus, probiotics, nucleic acid, enzyme preparation and amino acid chalet, it should provide related materials according to the regulations.

2. if the applied registration product is made from wild flora and fauna protected by the national regulations, it should provide certified documents showing that the government departments allows the exploitation and usage of such materials and also the sales contracts between raw material suppliers and the applicant.

2. Material items for the registration application of new functional health food products

The application for the registration of imported functional health food products requires the following materials:

(1) application form for the new functional health food product (import)

(2) certified documents showing that the product producer respects local quality management regulations

(3) if it is the standing representative office of foreign companies in China is responsible for the registration issue, it should provide the copy of "registration documents of foreign company's standing representative office in China".

If it is the agent institution trusted by foreign production companies, it should present the original copy of the letter of entrustment and the copy of agent institution operational license.

(4) certified documents showing the product has been sold in the producing country (region) for more than 1 year. The documents should be notarized by the notary agencies in the producing country and confirmed by China's embassies or consulates.

(5) product standards in the producing country (region) or by international associations

(6) packaging, label and instruction book samples used by the product in the producing country (region)

(7) the quantity of samples products with three consecutive batches triple that required by the testing

These application materials shall be translated into Chinese with original copy as attachments. Foreign language materials could be added to the appendix for reference. The Chinese translation should be notarized by the notary agencies to ensure the consistency with original contents. The registration application product quality standard (Chinese) should be consistent with the format of Chinese health food quality standard.

September 20

Health Food Manufacturing Permission Management released, for the supervision of manufacture of health food inside China.

Application companies should lodge the application towards the provincial food and drug supervision and management departments and submit the following materials:

(1) health food production permit application form;

(2) copy of operation license and the notice of prior approval of company names issued by the industry and administration departments

(3) copy of identity certificates of the legal representative (corporate person in charge) of the applying companies

(4) certified documents of legal usage of production site

(5) the map of production site and surrounding environment, plan sketch of the production factory (including production workshop, testing place and warehouse)

(6) plan sketch of the production workshop (including locker room, wash room, human channel, logistics channel, gas valve, the direction of human and logistics flow, air cleanness degree, the inlet opening and exhaust outlet of the cleaning system, plan sketch of the air flow system, plan sketch of processing equipment); the graph paper shall mark real size;

(7) copy of production variety of the registration document of domestic health food product, quality standard or product technology requirement, label instruction sample;

(8) planned preparation form, and formula of variety (main ingredient); processing graph;

(9) list of major production equipments and testing machines'

(10) production and quality management system menu;

(11) quality testing reports on three consecutive batches of sample products

(12) testing reports issued by qualified testing agencies about air cleanness and water quality in the past year

(13) resume, degree and copy of certificates of people in charge of production and quality management, registration form for technical staff

(14) if it is the legal representative (corporate person in charge) is responsible for applying for the heal food production permit, it should provide original copy of the identity certificates; if it is the agent responsible for applying for the health food production permit, it should provide the letter of entrustment issued by the applying legal representative (corporate person in charge), copy of the identification certificates of both side, and other the original copy of the identification documents of the entrusted agent.

(15) other materials to support the permit approval

If the processing and extracting of the raw materials need to be finished by the entrusted companies, they should provide documental evidence of instructions of the process, the intermediate product quality standard, the requirements on storage and transportation and the legal production rights.

The provincial food and drug supervision and management departments should conduct formal examination of the regularity and completeness of application materials within five days after receiving the materials, and make decisions about whether to accept the application. The departments shall carry out technology examination of the materials and on-site inspection within 20 days after the day of acceptance. They should issue the health food production permit if the examinations show the application satisfies the basic condition and requirements by the health food production regulation; for these not consistent with the regulations, the departments shall decline the application and state the reason in

a written form, informing applying companies of their rights of request for re-examination, administrative re-examination and filing administrative proceedings.

The valid period of the health food production permit is 5 years. If the valid period of the health food production permit is about to expire, and the company intends to extend the permit, then the company should raise application toward the issuing departments. If the application is lodged after the valid period is due, then this should be deemed as a new application for health food production permit.

August 15

Revised draft on the method for the assessment of 4 kinds of functions of health product released, namely Method for the Assessment of Alleviating Lead Excretion Function, Method for the Assessment of Clear the Throat Function, Method for the Assessment of Improving Nutritional Anaemia Function, and Method for the Assessment of Protection of Gastric Mucosa Function. Animal testing and human testing all required.

August 2

Revised draft on the method for the assessment of 5 kinds of functions of health product released, namely Method for the Assessment of Assisting Blood Sugar Reduction Function, Method for the Assessment of Assisting Blood Lipids Reduction Function, Method for the Assessment of Antioxidative Function, Method for the Assessment of Weight Control Function, and the Method for the Assessment of Alleviating Eye Fatigue Function. Animal testing and human testing required for the first 4 functions assessment. Human testing required for the last 1 function assessment.

The U.S. – China Health Products Association is working towards the development of China's natural health product industry by advocating for a more open and transparent regulatory environment. The association is committed to increasing the trade and availability of its member's products, which will benefit the health and wellbeing of both industry and consumers alike.