# REGULATIONS FOR APPLICATION OF HEALTH FOOD PERMIT

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Article 1 These Regulations are set forth pursuant to Paragraph 5 of Article 7 of the Health Food Control Act (hereinafter referred to as "the Act").

Article 2 Applications for permit and registration of manufacture and import for health food specified in Subparagraph 1 of Paragraph 1 of Article 3 of the Act by the applicants of health food (hereinafter referred to as applicants) pursuant to Paragraph 1 of Article 7 of the Act shall submit the application form along with product samples, the following documents and information to the central competent authority and pay the preliminary review fees:

1. Specifications and quantity of ingredients along with their sources of supplies issued by the product manufacturer.
2. Safety assessment report or academic literature reports as defined in the health food safety assessment methods announced by the central competent authority.
3. Health care effect assessment report.
4. Stability testing plan and results of the product and the ingredients with health care effects.
5. Product nutrient analysis report.
6. Product sanitation test report.
7. Identification report and the testing method of ingredients with health care effect in the product.
8. Product manufacturing process charts issued by the product manufacturer.
9. Documentary evidence to demonstrate compliance with Standards for Good Manufacturing Practices of Health Food issued by the product manufacturer.
10. In cases of entrusted manufacturing for products, the certificate of

entrusted manufacturing issued by the entrusted manufacturer.

11. In cases of authorized sales for products, the certificate of authorization.
12. The physical objects, color printouts, or color drafts of the Chinese label, container or outer packaging, and user instructions; the above items shall be attached separately for different packaging specifications, forms and materials; if the contents of user instructions are the same, any one version of one with any specifications, forms and materials may be adequate.
13. Documents of company, limited partnership, or business registration of the applicants.
14. Official certification documents verifying that the original product manufacturer is legally established or registered:
    (1) In cases of domestic manufacturers: the factory registration certificate but not for the manufacturers without registration by laws.
    (2) In case of foreign manufacturers: The original official certificate issued by a competent government agency responsible for product hygiene and safety or factory licensing in the country of origin shall be provided. The certificate shall specify full name of the government agency issuing the certificate with official stamp or authorized signature. If the certificate verifying the legitimacy of the original manufacturer is a copy of the original, the document shall be a certified true copy of the original by a notary public in the country of origin.
15. Other relevant research reports and literature in support of the product safety and health care effect.

The foregoing documents or information in languages other than English and Chinese must be accompanied with English or Chinese translations issued by a registered translation agency.

Article 3 Applicants in application for permit of health food manufactured and imported registration in Paragraph 1 of Article 7 of the Act with the products specified in Subparagraph 2 of Paragraph 1 of Article 3 of the Act shall submit an application form, with the product sample, the following

documents and information, and payment of the preliminary review fees to the central competent authority; the required documents and information shall be provided according to the provisions of the preceding Article, except for those mentioned in Subparagraph 2, 3 and 15 of Paragraph 1 of the preceding Article.

Article 4 Separate applications in the preceding two Articles shall be filed based on the one health care effect or specification standards of the products.

Article 5 The central competent authority, upon receiving applications in Article 2, shall conduct a preliminary review of the documents and information submitted by the applicants and may conduct on-site inspections if necessary.

If the documents and information in the preceding paragraph are incomplete, the applicants shall, within one month after receiving of the notice of the central competent authority, submit the supplementary documents and information, and may apply for a one-month extension if necessary. The application for extension is limited to one time only. Without submitting the supplementary documents and information within the time limit results in the rejection of the application.

Applicants unwilling to accept the rejection of the preliminary review can appeal for relief in either of the following manners:

1. Appeal to the central competent authority with reasons claimed within six months from the date following receiving of the notice of the preliminary review results. If rejected, an administrative appeal can be made pursuant to the Administrative Appeal Act.
2. Administrative appeal filed directly pursuant to the Administrative Appeal Act within 30 days from the date following receiving of the notice of the preliminary review results.

The appeal in accordance with Subparagraph 1 shall not be accepted if an administrative appeal has been filed in Subparagraph 2 of the preceding paragraph prior to the appeal, or if both an administrative appeal and an appeal are filed.

Article 6 Applications filed in Article 2 and having passed the preliminary review are eligible for a secondary review.

Applications for the secondary review in the preceding paragraph shall be

filed, within 15 days from the day following the date of the notice of the preliminary review result, to the central competent authority with the payment of fee for the secondary review and with supplementary documents and information based on comments in the preliminary review. Failure to paying the secondary review fee or to submit supplementary documents and information, within the specified length of time, shall results in the rejection of the application.

Article 7 For the secondary review as stated in the preceding Article, the central competent authority may organize a review committee and call meetings to review the safety, health care effect, packaging, labeling and user instruction, and may conduct on-site inspections if necessary.

Article 8 The central competent authority shall notify the applicants in writing of the results of the secondary review in the preceding Article.

Article 9 If the documents and information in the secondary review are incomplete considered by the central competent authority in the preceding Article, the applicants shall, within one month after receiving the notice of the central competent authority, submit the supplementary documents and information, and may apply for a one-month extension if necessary. The application for extension is limited to one time only. Without submitting the supplementary documents and information within the time limit results in the rejection of the application.

Article 10 The review process of the central competent authority, the documents and information provided by the applicants, and corrections, extension, as well as remedies of the applications filed in Article 3 shall apply the provisions of Article 5 mutatis mutandis.

If the review results in the preceding paragraph are considered the concerns of safety or health efficacy, the central competent authority shall notify the applicants to apply for secondary reviews. The procedures of application and secondary reviews, on-site inspections, corrections, and extensions shall apply the provisions from Paragraph 2 of Article 6 up to the preceding Article mutatis mutandis.

Article 11 If the product analysis is considered necessary, the central competent authority shall notify the applicants to pay the testing fee and provide sample product in intact packaging of sufficient amount to the inspection

body designated by central competent authority for testing within one month from the date following receiving of the notification. Failure to pay the testing fee or provide the samples by the deadline shall result in the rejection of the application.

Article 12 Applicants unwilling to accept the rejection of the secondary review can appeal for relief. The relief shall apply the provisions from Paragraph 3 and 4 of Article 5 mutatis mutandis.

Article 13 If applications are reviewed and approved, the central competent authority shall notify the review results to the applicants in writing and the demand of payment of the permit fee, and a health food permit shall be issued after payment of the permit fee by the applicants.

The registered contents of the permit in the preceding paragraph shall include the following:

1. Product name in Chinese and English.
2. Name and address of the applicants and the responsible person.
3. Name and address of the product manufacturer.
4. Ingredients and appearance of the product.
5. The ingredients and quantities of the health care effects or serving as the quality control indicators of the product.
6. The item and descriptions of the health care effects.
7. Packaging specifications and materials of the product.
8. Expiration date, storage methods and conditions of the product.
9. The contents of the Chinese label, container or outer packaging, and user instructions.
10. Date and number of the permit issuance.
11. Other registration items designated by the central competent authority.

Article 14 The specifications and quantity of ingredients in Subparagraph 1 of Paragraph 1 of Article 2 shall be reviewed by case based on the following documents and information provided by the applicants:

1. The reports of quality control or sanitation test for the ingredient.
2. The manufacturing process and test report for the ingredients of the health care effects.

3. The manufacturing process of extraction or concentration for the ingredients not covered in the preceding subparagraph.
4. Authentication reports of medicinal plant assessment if the ingredients can be used in edible Chinese herbal medicines.
5. The origin certification of the strains and identification reports of the species if the ingredients are microorganism; identification reports of the strains if the ingredients are lactobacillus.

Article 15 The target of reports for assessment, test, analysis and identification in Subparagraph 2 to 7 of Paragraph 1 of Article 2 shall be the products manufactured from production lines in the factory.

Article 16 The safety assessment report and the health care effect assessment report in Subparagraph 2 and 3 of Paragraph 1 of Article 2, respectively, shall be taken pursuant to the assessment provisions in Paragraph 2 of Article 3 of the Act by third parties other than the researching and developing units of the ingredients in the product.

Article 17 The stability testing plan and results, product nutrient analysis report, product sanitation test report, and identification report of ingredients with health care effect in the product in Subparagraph 4 to 7 of Paragraph 1 of Article 2, respectively, should be taken by testing, and the testing shall be conducted according to the following provisions:

1. The target of reports shall be the products at least 3 batches manufactured from production lines in the factory.
2. The reports using the target of the products at least 2 batches among the 3 batches in the preceding subparagraph should have been completed within the past 3 years.
3. The products in the Subparagraph 1 should be within their expiration date.

Article 18 The test objects of the stability testing for the ingredients with health care effects in Subparagraph 4 of Paragraph 1 of Article 2 should be the specific ingredients with health care effects in the product. If the specific ingredients with health care effects cannot be determined by contemporary techniques, other one with health care effects claimed by the applicants can be used as the test objects of the stability testing.

The test objects of the stability testing for the ingredients with health care

effects pursuant to Article 2 for the health foods in Article 3 shall be the ingredients designated by the central competent authority in the Specification Standards for Health Foods.

Article 19 The items of analysis in product nutrient analysis report in Subparagraph 5 of Paragraph 1 of Article 2 shall include the values of calories and nutrients defined by Regulations on Nutrition Labeling for Prepackaged Food Products.

Article 20 The items and content of product sanitation test report in Subparagraph 6 of Paragraph 1 of Article 2 shall provide sufficient evidence for the product meeting the provisions of the Sanitation Standards for Health Foods. Relevant regulations of the Act Governing Food Safety and Sanitation shall apply if those are not covered in the aforementioned Sanitation Standards. Identification report and the testing method of ingredients with health care effect in the product.

Article 21 The items and content of the identification report of ingredients with health care effect in the product in Subparagraph 7 of Paragraph 1 of Article 2 shall include qualitative and quantitative results of the ingredients with health care effect in the product.

The items and content of the identification report of ingredients with health care effect in the product pursuant to Article 2 for the health foods in Article 3 shall meet the standards designated by the central competent authority in the Specification Standards for Health Foods.

The testing method for the identification of ingredients with health care effect in the product in the preceding two paragraphs shall be the announced or recommended methods by the central competent authority preferentially; otherwise, scientific evidence and comparative reports indicating non-inferiority or superiority to the announced or recommended methods shall be required for using other testing method.

The documents and information of the standard operating procedures and validation for the testing methods shall also be provided with the identification report submitted by applicants pursuant to Paragraph 1 and 2.

If situation in the latter part of Subparagraph 1 of Paragraph 1 of Article 3 of the Act, the identification report of each ingredient with health care

effect in the product shall be issued by applicants.

Article 22 The product manufacturing process charts in Subparagraph 8 of Paragraph 1 of Article 2 shall include the preparation of the raw materials, processing procedures and conditions of processing.

If the processing procedures involving extraction in the preceding paragraph, the method of extraction and the solvent shall be provided; the degree of concentration shall be also indicated for concentration processes.

Article 23 The documentary evidence in Subparagraph 9 of Paragraph 1 of Article 2 shall include the documents of the control for the manufacturing process and quality control, engineering diagrams of quality control and other documents and information verifying compliance with good manufacturing practices.

The documents and information in the preceding paragraph may be substituted with officially certificate documents verifying compliance with the respective good manufacturing practices from the country of origin for imported products; the certificate documents within effective period to be verified compliance with the Pharmaceutical Good Manufacturing Practice Regulations by the central competent authority shall be provided for domestic products manufactured by the pharmaceutical companies.

Article 24 The documents and information in the preceding Article shall be issued separately by the respective factories for the products manufactured in different stages from different factories.

The floor plan of the different factories in the pharmaceutical company shall also be required for the domestic products manufactured by the pharmaceutical companies in the latter part of Paragraph 2 of the preceding Article and manufactured by the different factories.

Article 25 The content and the labeling for the physical objects, color printouts, or color drafts in Subparagraph 12 of Paragraph 1 of Article 2 shall meet the provisions in Articles 13 and Articles 14 of the Act as well as the relevant regulation of the Act Governing Food Safety and Sanitation.

The size of the printouts and drafts shall be the same as the physical objects, and the displayed texts in printouts and drafts shall be clear and legible.

Article 26 The relevant research reports and literature in Subparagraph 15 of Paragraph 1 of Article 2 shall be reliable and accurate scientifically.

Article 27 Applications for extension of the permit for health food by applicants pursuant to Paragraph 1 of Article 8 of the Act shall submit an application form within 3 months prior to the expiry date of permit along with the following documents and information to the central competent authority and pay the related fees:

1. Original permit.
2. The certificate documents issued by the product manufacturer within the past one year consent to manufacture products based on the content of originally issued permit or table of ingredient content, except for the certificate documents provided by the product manufacturer same as the permit holder.
3. The documents and information set forth in Subparagraph 10 to 12 of Paragraph 1 of Article 2.
4. Other essential documents and information designated by the central competent authority.

After expiration of the health food permit, applicants with the needs of production and import for health food shall file an application for permit renewal, but the application filed within six months by the expiration of the permit may be waived of the requirement for secondary review and exempted from submission of the following documents and information:

1. For applications filed pursuant to Article 2: The documents and information set forth in Subparagraph 2, 3, 4, and 15 of Paragraph 1 of Article 2.
2. For applications filed pursuant to Article 3: The documents and information set forth in Subparagraph 4 of Paragraph 1 of Article 2.

After approval of the applications filed pursuant to the preceding Paragraph, the central competent authority shall issue a new permit with a new permit number.

Article 28 Applications for amendment of the permit for health food by applicants pursuant to Paragraph 3 of Article 7 of the Act shall submit an application form along with the original permit to the central competent authority and pay the related fees.

In addition to the foregoing requirements, the following documents and information shall be additionally submitted according to the application of

amendment:

1. Product name change in Chinese or English for imported products: The certificate documents of consent to change of the product names issued by the original product manufacturer.
2. Change of name, address or responsible person of applicants holding the permit:
   (1) The documents and information set forth in Subparagraph 13 of Paragraph 1 of Article 2.
   (2) A complete list of health food products with the numbers and expiry dates of permit and product name.
3. Addition or change of product manufacturer: The documents and information set forth in Subparagraph 1, 4 to 12 and 14 of Paragraph 1 of Article 2.
4. Relocation of the product manufacturer: The documents and information set forth in Subparagraph 4, 9 and 14 of Paragraph 1 of Article 2.
5. Change of the original product manufacturer’s name:
   (1) The documents and information set forth in Subparagraph 14 of Paragraph 1 of Article 2.
   (2) A complete list of health food products with the numbers and expiry dates of permit and product name from the original product manufacturer.
6. Building number adjustment of the original product manufacturer’s address:
   (1) In cases of domestic manufacturers: The documents issued by a competent government agency certifying the address building number adjustment.
   (2) In case of foreign manufacturers: The original certificate issued by a competent government agency of the country of origin with its full title certifying the building number adjustment, whereas photocopies of the certificate shall be notarized as a true copy of the original by a notary public in the country of origin.
   (3) A complete list of health food products with the numbers and expiry dates of permit and product name from the original

product manufacturer.

7. Change of ingredients and content of pigments, flavors or sweeteners but not of other ingredients and the no affection of product safety: The documents and information set forth in Subparagraph 1, 5, and 7 of Paragraph 1 of Article 2.
8. Amendment to the inner or outer packaging specification, form, material and trademark:
   (1) The documents and information set forth in Subparagraph 12 of Paragraph 1 of Article 2.
   (2) In cases of the change to the inner packaging: The documents and information set forth in Subparagraph 4 of Paragraph 1 of Article 2.
   (3) In cases of the imported products: The certificate documents of consent to the changes issued by the original product manufacturer.
   (4) In cases of the change to the packaging materials: The documents and information in compliance with the Sanitation Standard for Food Utensils, Containers and Packages.
9. Change of Chinese labels, outer packaging, and user instructions:
   (1) The documents and information set forth in Subparagraph 12 of Paragraph 1 of Article 2.
   (2) In cases of the imported products: The certificate documents of consent to change of Chinese labels, outer packaging, and user instructions issued by the original product manufacturer.
   (3) In cases of the changes of the nutrition facts labeling but not of product ingredients and content:
      A. The documents and information set forth in Subparagraph 1 and 5 of Paragraph 1 of Article 2.
      B. The evaluation report on the rationale of amendment issued by the product original manufacturer within the past one year.
10. Change of expiration date, storage methods and conditions of the product: The documents and information set forth in Subparagraph 4

of Paragraph 1 of Article 2.

Article 29 Applications for the amendment of Chinese label, container or outer packaging, and user instructions of the health food products are exempted in one of the following situations:

1. Amendment of patterns or colors.
2. Proportionate reduction or enlargement of the approved images and texts.
3. Movement of the position of the approved images and texts.
4. Amendment of the fonts of the approved text.

The amendment in the preceding paragraph of the labels, container or outer packaging and user instructions which contain the content stipulated by relevant authorities other than those specified in the Act shall be subject to the provisions of respective regulations.

For items exempted from amendment applications as set forth in the first paragraph, the permit holder shall produce a written record for retention.

Article 30 Applications for transference of the permit for health food by applicants pursuant to Paragraph 3 of Article 7 of the Act shall submit an application form along with the original permit to the central competent authority and pay the related fees:

1. Original permit.
2. Transferor’s certificate document of consent to transfer of the permit holder.
3. The certificate documents of consent to the transferee selling the products issued by the original product manufacturer.
4. The documents and information set forth in Subparagraph 10 to 13 of Paragraph 1 of Article 2 issued by the transferee.

Article 31 Applications for reissuance or replacement of the permit for health food due to defacement or loss by applicants pursuant to Paragraph 2 of Article 8 of the Act shall submit an application form along with a statement that declares the original permit document null and void to the central competent authority and pay the related fees, while the originally issued permit should be returned for replacement application.

The new permit issued under the replacement or reissuance application as referred in the preceding paragraph shall bear the same expiration date as

the original permit.

Article 32 If the documents and information are incomplete considered by the central competent authority in the applications filed by applicants pursuant to Articles 27, 28, 30 or the preceding Article, the applicants shall, within one month after receiving of the notice of the central competent authority, submit the supplementary documents and information, and may apply for a one-month extension if necessary. The application for extension is limited to one time only. Without submitting the supplementary documents and information within the time limit results in the rejection of the application.

Article 33 The foregoing documents and information in languages other than English and Chinese in the applications filed by applicants pursuant to Articles 27, 28, 30 or 31 must be accompanied with English or Chinese translations issued by a registered translation agency.

If it is necessary to issue or reissue a new permit in the applications filed by applicants pursuant to Articles 27, 28, 30 or 31, a certificate processing fee shall be collected.

Article 34 Applications in accordance with the provisions of the Regulations may be filed by the applicants on the web platform of Taiwan Food and Drug Administration of the Ministry of Health and Welfare, and the documents and information in the applications shall be scanned and uploaded to the web platform.

After completion of applications by applicants for permit extension, amendment of registration contents, document transference or document replacement pursuant to provisions in the preceding paragraph, the original permit document shall be sent to the central competent authority for registration or cancellation.

Article 35 These Regulations shall come into effect on the date of promulgation.