Guidelines on Registration for Extension, Alteration, Transference and Reissuance of Health Food Permits

(Date:2013-07-23)

I. Registration for Extension of Health Food Permit

1. Terms of extension for the application: within three months prior to the expiry date of the permit.

2. The following document and material shall be submitted:

(1) Application form for extension.

(2) Original copy of the permit.

(3) Original copy of certificate stating that the manufacturer continues to manufacture and to sell the product, or the original copy of the product ingredient fact sheet.

(4) Commercial product sample.

Explanation:

a. The commercial product shall be labeled properly in accordance to the requirements of the health food control regulations.

b. For the commercial product with a different quantity, the sample shall be submitted.

(5) Commercial product’s label, outer package and instructions.

Explanation: For the product with a different quantity, the material required by this section shall be submitted. It is exempted if all of the product instructions are the same.

(6) Review fee.

3. If the product is in accordance to the health food control regulations, the extension application will be approved and granted an extension of a maximum of five years. The original permit expires automatically if it is overdue and application for an extension is not made or the extension application has been denied.

II. Registration for Alteration of Health Food Permit

Any alterations to the permit’s registration including the product name in Chinese or in foreign language, name, address and company representative of the applicant, name and address of the manufacturer, ingredient quantity, package (inner and outer package or package quantity),

name and address of the toll manufacturer and so on shall be applied by submitting the following document and material for the application of registration alteration:

1. Basic document and material:

(1) Application form for alteration.

(2) Original copy of the permit.

(3) Two copies of the registration alteration form.

Explanation: The document and material stated herein is required only when the label, outer package and instructions need to be modified or redesigned as a result of the registration alteration.

(4) Review fee.

2. Other documents and materials:

The following document and materials shall be submitted by the item of registration alteration:

(1) Alteration of product name in Chinese or in foreign language:

a. Original copy issued by the manufacture stated the

alteration of product name.

b. Original copy of recognition.

Explanation: The applicant shall state by a form of recognition that the changed name has nothing to do with plagiarism or insinuation of another's registered trademark, or it shall assume legal liability for all losses and the Department of Health will forthwith announce the cancellation of the permit.

(2) Alteration of name, address and company representative of the applicant:

Duplicate copy of the corporation registration certificate with the completed the alteration.

(3) Alteration of the manufacturer's original registered name:

Refers to the alteration of the manufacturer's original registered name.

a. For domestic products, the duplicate copy of the factory license with the completed the alteration shall be submitted.

b. For imported products, the official certificate stating

the alteration of the manufacturer’s name shall be submitted.

(4) Alteration of the manufacturer’s address:

a. Due to address code reorganization:

- For domestic products, the duplicate copy of the factory license with the completed the alteration shall be submitted.
- For imported product, the official certificate stating the alteration of the manufacturer’s name shall be submitted.

b. Due to factory relocation:

Certificate of the manufacturer’s conformation to the regulation of goods manufacturing practice.

Explanation:

- For domestic products, the material regarding the manufacturing process control in accordance to the regulation of goods manufacturing practice enacted by the Department of Health shall be submitted. If necessary, the Department of Health is entitled to

execute an on-site inspection of the manufacturer premises.

- For domestic products, the complete text of goods manufacturing practice regulations by the country of origin, quality control plan and the original copy of the official certificate stating the compliance of goods manufacturing practice regulations by the country of origin shall be submitted.

(5) Alteration of ingredient fact sheet:

a. Original copy of the certificate issued by the manufacturer stating the alteration of the ingredient quantity.

Explanation: The alteration of ingredient quantity is limited to the flavor, taste and color etc. and must not affect the health effects and stability. The alteration application for health effects shall be filed as a new case.

b. Original copy of the authentication report of health effects ingredient.

c. Original copy of the general nutrients analysis report.

(6) Alteration of package (inner and outer package, package quantity, trademark name):

a. Certificate issued by the manufacturer stating the alteration of the package.

b. For the alteration of inner packages, the stability test report of health effects shall be submitted.

c. Sample for each product.

Explanation: For package with alteration, each sample of the products shall be submitted.

(7) Alteration of name and address of the toll manufacturer:

Original copy of certificate stated the alteration of toll manufacturer’s name and address.

(8) Alteration of manufacturer:

It stating that the product has been made by another manufacturer or additional ones.

a. For those who acquire the permit according to Art.3.1(1) of the Act, the following documents and

materials shall be submitted:

i. Toll manufacturing contract. (Exempted if the product is not made on a toll manufacturing basis.)
ii. Product ingredient specification fact sheet issued by the manufacturer.
iii. Authentication report of health effects ingredient (three batches) and its test method.
iv. Stability test report of health effects (three batches).
v. Manufacturing process summary issued by the manufacturer.
vi. Certificate of good manufacturing practice.
vii. Product sanitary test specification and its test report (three batches).
viii. General nutrients analysis report (three batches).

b. For those who acquire the permit according to Art.3.1(2) of the Act, the following documents and materials shall be submitted:

i. Toll manufacturing contract. (Eempted if the

product is not made on a toll manufacturing basis.)

ii. Product ingredient specification fact sheet issued by the manufacturer.

iii. Ingredient specification test report (three batches).

iv. Stability test report of health effects (three batches).

v. Manufacturing process summary issued by the manufacturer.

vi. Certificate of good manufacturing practice.

vii. Product sanitary test specification and its test report (three batches).

viii. General nutrients analysis report (three batches).

(9) Alteration of health effects:

Refers to those who acquire the permit according to Art.3.1(1) of the Act, and who intend to apply for the alteration of health effects stated on the permit. The process, fees and review shall be followed by the rule of a new application and the original copy of the permit shall be submitted.

III. Registration for Transference of Health Food Permit

If the permit is required to transfer from company A to company B, the following documents and materials shall be submitted by company B for the application of transference registration:

1. The original copy of the certificate, which has been, notarized, stating that company A agrees to transfer the permit to company B.
2. The original copy of the certificate issued by the manufacturer allows company B to sell the product.
3. The original copy of the previously issued permit.
4. Review fee and permit fee.

IV. Registration for Reissuance of Health Food Permit Due to Loss

The following documents and materials shall be submitted:

1. Recognition of the applicant.

2. Review fee and permit fee.

V. Registration for Replacement of Health Food Permit Due to Staining or Breakage

The following documents and materials shall be submitted:

1. Application form.
2. The original copy of the previously issued permit.
3. Review fee and permit fee.

VI. Notices

1. The document or material, not in English, shall be translated into Chinese or English by a certified translation agency.
2. All application forms for registration alteration and extension of health food permits can be downloaded from our official website (www.doh.gov.tw special download section).
3. Please send the application with the cheque review fee (payee: Food and Drug Administration, Ministry of

Health and Welfare) by registered mail, or go in person to the Food and Drug Administration (Address: No.161-2, Kunyang St, Nangang District, Taipei City 115-61, Taiwan.), pay the review fee at the information counter and deliver the application to the receipt counter.