Guidelines on Registration of Imported Food in Tablet or Capsule Form

(Date:2014-03-27)

I. New application for importation of food in tablet or capsule form

1. An application for registration of imported food in tablet or capsule form shall be accompanied by the following documents and materials:

(1) An application form

(2) The original copy and a Xerox copy of the ingredient list.

Explanation:

a. The ingredient list shall be the original issued by the original manufacturer and dated within one year.

b. The ingredient list shall include the detailed names and contents of all raw materials and food additives, and further indicate the detailed names and contents of raw materials and food additives of the empty capsule in the case of capsular food, and the names and contents of the raw materials of all excipients in the event of tablet food.

c. The ingredient list shall specify the Recommended Daily Dosage of the product.

d. The ingredient list shall specify the detailed chemical names of additives such as vitamins in the product, if any, for example Vitamin A, B_1, B_2, B_3, B_5, B_6, B_{12}, D, or E. The content shall specify the exact amount added in the form of weight in mg or mcg if indicated in I.U., or the number of I.U.s if indicated in mg or mcg.

e. The ingredient list shall specify the animal name if any raw material of the product is made from any livestock tissue or organ (including gland). In the event of cattle and sheep, the original of the relevant official health certificate shall also be produced indicating that such raw materials as their tissues or organs being used are neither directly nor indirectly sourced

from a pest area. The ingredient list shall further specify the name of the solvent used in processing, for verification purposes, if the raw materials being used are extracted and processed.

f. The ingredient list shall be accompanied by relevant information such as the scientific name of the type, part being used as raw material, and method of processing (including name of solvent used in processing, if any), for verification purposes, if the following are used as raw materials in the product: herbs, raw materials made from herbal sources, algae, mushrooms, microorganisms, or raw materials made from sources of microorganisms.

g. The combinations shall be broken down into individual components with their chemical name and percentage composition by weight if use any food additive combinations.

(3) The original official certificate evidencing the legitimacy of the original manufacturer.

Explanation:

a. The official certificate evidencing the legitimacy of the manufacturer shall be an original copy issued by a competent government agency responsible for product hygiene and safety or factory licensing in the country of origin and dated within the past two years. The certificate shall specify the name and address of the manufacturer, its business activities, categories of products, hygienic status of the factory, and full name of the government agency issuing the certificate with official stamp or authorized signature.

b. In case a Xerox copy of the factory license is submitted as the official certificate, the date of issue shall be within the past two years if the certificate does not show an expiry date. Such copy shall also be certified by a certification institution as a true copy of the original.

c. The original OEM certificate shall also be submitted in the event of OEM products.

d. The manufacturer shall be the actual completion of the tablet

or capsule.

(4) A Xerox copy of applicant's company registration or business registration (prepared locally).

Explanation:

The company registration or business registration shall indicate business items relating to importation of food stuff.

(5) An intact sample of the product to be imported.

Explanation:

In case the product is packed in thousand or above pieces or loose packs, or repacking locally is required after import, a sample of loose packed product about 20 tablets/capsules shall be submitted.

(6) Food details in three copies (prepared locally).

Explanation:

a. The English name of the product shall be consistent with that on the ingredient list and undertaking.

b. In the event of OEM products, the column of "name and address of manufacturer" shall specify the name and address of both the principal and the manufacturer.

(7) An undertaking.

(8) Two registration data sheets.

2. A license/permit will be issued for an application which meets the requirements of the Food Sanitation Control Act and related regulations with validity for five years. An application for extending the validity if necessary shall be filed with the Department of Health three months prior to the expiry, accompanied by an application form, the license/permit, relevant documentary evidence and an examination fee, provided each extension granted shall not exceed five years. A license/permit will be automatically nullified upon expiry if no application for extension is made within the prescribed time limit or an application for extension is disallowed. A license fee is further payable for a replacement license/permit.

3. In case laboratory testing is required for an application, applicant shall pay a test fee and submit sufficient samples of the product to the National Laboratories of Foods and Drugs, Department of Health subject to a notice sent by the department, within two months of the receipt of the notice. A one-month extension may be applied for where necessary, and will be deemed waived if not filed within the prescribed time limit, in which event the Department of Health will close the case directly. The test result will serve as reference when the Department of Health issues a license/permit.

II. Application for extension of license/permit for importation of food in tablet or capsule form

1. Period of application: within three months prior to the expiry of the original license/permit.
2. Documents and materials required for the application:
   (1) An application form.
   (2) The original license/permit.
   (3) The original agreement of the original manufacturer to continue to sell the product or the original formula of the raw materials of the product.
   Explanation:
   Such document shall be the original issued by the original manufacturer and dated within one year.
   (4) A product as marketed.
3. A license/permit will be issued for an application for extension which meets the requirements of the Food Sanitation Control Act and related regulations with validity for five years. Application for further extension may be filed three months prior to the expiry. The license/permit will be automatically cancelled upon expiry if no application is made within the prescribed time limit.

III. Application for amendment of particulars on license/permit for importation of food in tablet or capsule form

An application for amendment of the particulars on a license/permit shall be made accompanied by the following documents and

materials in the event of any changes to such particulars, including the Chinese or English name of the product; name, address and responsible person of the applicant; name and address of the original manufacturer (overseas distributor):

1. Basic documents and materials:

(1) An application form.

(2) The original license/permit.

(3) Two amendment data sheets.

2. Other documents and materials:

Other documents and materials shall be submitted depending on the particular to be amended:

(1) English product name:

a. Original certificate of change of product name issued by the original manufacturer.

b. An undertaking.

(2) Chinese product name:

An undertaking.

(3) Name of applicant:

a. Document numbers and list of all approval documents regarding the amendment of applicant’s name.

b. A Xerox copy of the amended company registration or business registration.

c. The original agreement of the original manufacturer to continue to sell the product.

(4) Address or responsible person of applicant:

a. Document numbers and list of all approval documents regarding the amendment of applicant’s address or responsible person.

b. A Xerox copy of the amended company registration or business registration.

(5) Name of original manufacturer:

a. Official certificate evidencing the change of the name of the original manufacturer.

b. Document numbers and list of all approval documents regarding the amendment of the original manufacturer's name.

NB Product registration shall be filed according to the procedure for new applications if the product is to be manufactured by another manufacturer.

(6) Address of original manufacturer:

Document numbers and list of all approval documents regarding the amendment of the original manufacturer's address, as well as the following documents:

a. Change of address due to rearrangement of street numbers:

Official certificate evidencing the change of the address of the original manufacturer.

b. Change of address due to relocation of factory:

An official certificate evidencing the legitimacy of the original manufacturer.

Explanation:

i. The official certificate evidencing the legitimacy of the original manufacturer shall be an original copy issued by a competent government agency responsible for product hygiene and safety or factory licensing in the country of origin and dated within the past two years. The certificate shall specify the name and address of the manufacturer, its business activities, categories of products, hygienic status of the factory, and full name of the government agency issuing the certificate with official stamp or authorized signature.

ii. In case a Xerox copy of the factory license is submitted as the official certificate, the date of issue shall be within the past two years if the certificate does not show an expiry date. Such copy shall also be certified by a certification institution as a true copy of the original.

(7) Change of overseas distributor:

The original document issued by the original manufacturer evidencing the commissioning of sale.

IV. Application for transfer of license/permit for imported food in tablet or capsule form

1. Where a license/permit is to be transferred from Company A to Company B, Company B shall submit an application for transfer registration accompanied by the documents and materials required for a new application, as well as the following documents:

   (1) The original document evidencing Company A's agreement to transfer the license/permit to Company B.

   (2) The original document issued by the original manufacturer evidencing its agreement to distribute the products by Company B.

   (3) The original license/permit.

2. The following included in Company A's original application may be submitted in Xerox copies in an application for transfer:

   (1) The ingredient list of the raw materials.

   (2) The official certificate evidencing the legitimacy of the original manufacturer.

V. Application for replacement license/permit for importation of food in tablet or capsule form

The application shall be made to the Department of Health accompanied by the following documents and materials:

1. An application form.
2. A set of Xerox copies of all documents and materials submitted in the original application.

VI. Notes

1. Any document or material in other foreign language than English must be accompanied by a Chinese or English translation by a registered translation company.
2. All forms and documents required for an application for registration of imported food in tablet or capsule form are available for purchase at the general window of the Food and

Drug Administration, Ministry of Health and Welfare at No.161-2, Kunyang St, Nangang District, Taipei.

3. Please send along with your application a money order or remittance slip for the examination fee for the application (with the Food and Drug Administration, Ministry of Health and Welfare as payee) by registered mail.