

Enforcement Rule of the Health Functional Food Act

Enacted by the Ordinance of the Ministry of Health and Welfare No. 270, Jan. 31, 2004

Amended by the Ordinance of the Ministry of Health and Welfare No. 300, Dec. 10, 2004

Amended by the Ordinance of the Ministry of Health and Welfare No. 363, Jul. 3, 2006

Amended by the Ordinance of the Ministry of Health and Welfare No. 373, Nov. 20, 2006

Article 1 (Purpose) The purpose of this Enforcement Rule is to provide matters delegated by the 「Health Functional Food Act」 and the Enforcement Decree of the Health Functional Food Act and matters necessary for the enforcement thereof.
<Amended on November 20, 2006>

Article 2 (Facilities criteria by business type) The facilities criteria by business type under Article 4 of the 「Health Functional Food Act」 (hereinafter referred to as the “Act”) shall be specified in annexed the Table 1.<Amended on November 20, 2006>

Article 3 (Application for business permission) (1) Any person, who intends to obtain a health functional food manufacture business permission under the provisions of Article 5(1) of the Act, shall submit a business permission application (including the application by electronic documents), annexed the Form 1, along with the documents (including electronic documents) according to the following subparagraphs to the

Commissioner of the Food and Drug Administration <Amended on November 20, 2006>:

1. Health functional food manufacture-specializing business

- (a) The type of product to manufacture and the manufacturing method document;
- (b) The arrangement plan of manufacturing facilities and the list of main machinery and apparatus;
- (c) The land use plan confirmation and the certified copy of building administrative register;
- (d) The quality manager appointment report under Article 16;
- (e) The education completion certificate under Article 13(2) of the Act (limited to the case where the education has been received in advance); and
- (f) The written result of water analysis by a drinking water re-examination laboratory under Article 35 of the 「Management of Drinking Water Act」 (limited to the case where the groundwater, etc. which is not tap water, is used for drinking water, or manufacturing process or washing, etc. of health functional food).

2. Health functional food manufacture venture business

- (a) A copy of venture business confirmation under Article 25 of the 「Act on Special Measures for the Promotion of Venture Businesses」 ;
- (b) Technical data on the functional ingredients and components of health functional food;
- (c) The type of product to manufacture and the manufacturing method document;
- (d) The quality manager appointment report under Article 16;

- (e) The document of manufacturing entrustment contract with a health functional food manufacture-specializing business; and
 - (f) The education completion certificate under Article 13(2) of the Act (limited to the case where the education has been received in advance).
- (2) If the pertinence of the applicant to Article 9(1)3 of the Act is not able to be internally verified, the Commissioner of the Food and Drug Administration may require the applicant (including electronic documents) to submit references necessary for verifying his identification in addition to the documents described in paragraph (1) <Amended on November 20, 2006>.
- (3) Upon granting a business permission for the health functional food manufacture business pursuant to paragraph (1), the Commissioner of the Food and Drug Administration shall issue a business permission certificate, annexed the Form 2. The Commissioner of the Food and Drug Administration shall make and maintain the Business Permission Administrative Register, annexed the Form 3, for the permitted matters.
- (4) If a business person has lost the business permission certificate or had it worn out, the business person, who intends to have a certificate reissued, shall submit a business permission certificate reissue application, annexed the Form 4, with the worn-out certificate (limited to the case where the certificate is worn-out) to the Commissioner of the Food and Drug Administration.

Article 4 (Modification of permitted matter) (1) When a person, who has obtained a permission for the health functional food manufacture business, intends to modify such

permitted matter under the latter part of Article 5(1) of the Act and Article 3 of the 「Enforcement Decree of the Health Functional Food Act」 (hereinafter referred to as the “Decree”), the person shall submit a modification permission application (including the application by electronic documents), annexed the Form 5, along with the business permission certificate and the documents (including electronic documents) described in the following subparagraphs to the Commissioner of the Food and Drug Administration <Amended on November 20, 2006>:

1. The arrangement plan of manufacturing facilities and the list of main machinery and apparatus;
2. The land use plan confirmation and the certified copy of building administrative register; and
3. The written result of water analysis by a drinking water examination laboratory under Article 35 of the 「Management of Drinking Water Act」 (limited to the case where the groundwater, etc. which is not tap water, is used for drinking water, or manufacturing process or washing, etc. of health functional food).

(2) When a person, who has obtained a permission for the health functional food manufacture business, intends to modify a matter which falls under any of the following subparagraphs under Article 5(2) of the Act, the person shall submit a modification permission application (including electronic documents), annexed the Form 5, along with the business permission certificate and the related documents (including electronic documents) which verify the modification facts to the Commissioner of the Food and Drug Administration, except for the modification by the

business status succession under Article 11 of the Act <Amended on November 20, 2006>:

1. The name of the representative (limited to a juridical person);
2. The title or trade name of the business establishment;
3. The workplace, the health functional food handling facilities or the water supply facilities from among the manufacturing facilities (limited to the health functional food manufacture-specializing business); and
4. The title or trade name of the manufacturing establishment which is entrusted with manufacturing the health functional food (limited to the health functional food manufacture venture business).

Article 5 (Business report, etc.) (1) Any person, who intends to report the health functional food import business or the health functional food sales business under the provisions of Articles 6(1) and (2) of the Act, shall submit a business report application (including the application(report) by electronic documents), annexed the Form 6, along with the documents (including electronic documents) described in the following subparagraphs, after equipping with the facilities necessary for the business, to the Commissioner of the Regional Food and Drug Administration or the head of local government (limited to the head of autonomous *Gu*; hereinafter the same shall apply) <Amended on November 20, 2006>:

1. The arrangement plan of business facilities;
2. The education completion certificate under Article 13(2) of the Act (limited to the case where the education has been received in advance);

3. The storage facility lease contract document (limited to the case where a storage facility is leased); and

4. The document of manufacturing entrustment contract with a health functional food manufacture-specializing business (limited to the health functional food distribution-specializing sales business).

(2) If the pertinence of the applicant to Article 9(2)3 of the Act is not able to be internally verified, the Commissioner of the Regional Food and Drug Administration or the head of local government may require the applicant to submit references necessary for verifying his identification in addition to the documents described in paragraph (1).

(3) Upon accepting a report pursuant to paragraph (1), the Commissioner of the Regional Food and Drug Administration or the head of local government shall, without delay, issue a business report certificate, annexed the Form 7, in case of the health functional food import business or a business report certificate, annexed the Form 8, in case of the health functional food sales business respectively.

(4) After the issuance of the business report certificate under paragraph (3), the Commissioner of the Regional Food and Drug Administration or the head of local government shall make and maintain the Business Report Administrative Register, annexed the Form 9, in case of the health functional food import business or the Business Report Administrative Register, annexed the Form 10, in case of the health functional food sales business respectively. In this case, the Commissioner of the Regional Food and Drug Administration or the head of local government shall semiannually report the business report administration status according to the format

of annexed the Form 11 to the Commissioner of the Food and Drug Administration within twenty days after the completion of half-year period.

(5) If a business person has lost the business report certificate or had it worn out, the business person, who intends to have a certificate reissued, shall submit a business report certificate reissue application, annexed the Form 12, with the worn-out certificate (limited to the case where the certificate is worn-out) to the Commissioner of the Regional Food and Drug Administration or the head of local government.

Article 6 (Modification of reported matter) (1) The modification matters that shall be reported by the person, who has filed the report of the health functional food import business or the health functional food sales business under the provisions of Articles 6(3) of the Act, shall be as follows, except for the modification by the business status succession under Article 11 of the Act:

1. The name of the representative (limited to a juridical person);
2. The title or trade name of the business establishment;
3. The place of the business establishment;
4. The place of the storage facility (limited to the case where a storage facility is leased); and
5. The title or trade name of the manufacturing establishment which is entrusted with manufacturing the health functional food (limited to the health functional food distribution specializing sales business).

(2) A person who intends to file a modification report shall submit a reported matter modification report (including the report by electronic documents), annexed the Form

13, along with the business report certificate to the Commissioner of the Regional Food and Drug Administration or the head of local government. <Amended on November 20, 2006>

Article 7 (Business discontinuance report) A person, who intends to file a business discontinuance report under the provisions of Article 5(2) or 6(3) of the Act, shall submit a business discontinuance report (including the report by electronic documents), annexed the Form 14, along with the business permission certificate or the business report certificate to the permission authorities or the report authorities within one month after the discontinuance. <Amended on November 20, 2006>

Article 8 (Item manufacture report, etc.) (1) A health functional food manufacture business person, who intends to file an item manufacture report under Article 7(1) of the Act, shall submit an item manufacture report (including the report by electronic documents), annexed the Form 15, along with the following documents (including electronic documents) to the Commissioner of the Food and Drug Administration <Amended on November 20, 2006>:

1. The manufacturing method document (including the document stating the reason for setting the shelf life);
2. Name and content of the ingredients or the components; and
3. The written result of examination of the standards and specifications (limited to the health functional food product complied with the standards and specifications).

(2) Upon receiving an item manufacture report under paragraph (1), the Commissioner of the Food and Drug Administration shall issue an item manufacture report certificate, annexed the Form 16, and record and maintain the subject matters in the Item Manufacture Report Administrative Register, annexed the Form 17.

(3) If a business person has lost the item manufacture report or had it worn out, the business person, who intends to have a certificate reissued, shall submit an item manufacture report certificate reissue application (including the application by electronic documents), annexed the Form 17(2), with the worn-out certificate (limited to the case where the certificate is worn-out) to the Commissioner of the Food and Drug Administration. <Newly inserted on November 20, 2006>

Article 9 (Modification report of item manufacture reported matter) (1) When a person, who has filed the item manufacture report, intends to modify a matter which falls under any of the following subparagraphs under the latter part of Article 7(1) of the Act, the person shall submit an item manufacture reported matter modification report (including the report by electronic documents), annexed the Form 18, along with the item manufacture report certificate to the Commissioner of the Food and Drug Administration, except for the health functional food for exports <Amended on November 20, 2006>:

1. The product name;
2. Content of the ingredients or the components; and
3. Extension of the shelf life.

(2) Notwithstanding the main sentence of paragraph (1), an item manufacture report shall be filed again if the functionality of the product in question is changed due to the modification of content of the main ingredients or the major components that have the functionality.

Article 10 (Import report of health functional food) (1) Any person who intends to file an import report under the provisions of Article 8(1) of the Act (hereinafter referred to as “import reporter”) shall submit a health functional food import report (including the report by electronic documents), annexed the Form 19, along with the documents (including electronic documents) described in the following subparagraphs to the Commissioner of the Regional Food and Drug Administration, who has the jurisdiction over the place of clearance of the health functional food imported, or the head of the National Quarantine Service entrusted the authority under Article 20(3) of the Decree (excluding heads of Incheon International Airport, Busan, Incheon and Gimhae National Quarantine Stations; hereinafter the same shall apply). In this case, an import report can be filed starting from five days ahead of the date when the health functional food is expected to arrive. If any of major reported matters, such as arrival port, expected arrival date, etc., is changed, such matter shall be reported in writing immediately (including electronic documents) <Amended on November 20, 2006>:

1. The written result of examination or the certificate of examination (limited to a case where the exemption from the whole or part of the examination is intended under the provisions of Article 8(3)2 of the Act);

2. A packaging paper that has a Korean label (If it is difficult to submit a packaging paper due to the transportation packaging etc., the document stating the Korean label contents may be submitted.); and
3. The identity preserved handling certificate under Article 11(1)7 of the 「Enforcement Rule of the Food Sanitation Act」 or the certificate recognized by the producing government to have an equivalent effect with the identity preserved handling certificate (limited to a case where the food, subject to genetically modified labeling, does not bear any genetically modified food label.).

(2) “Any reason as prescribed by the Ordinance of the Ministry of Health and Welfare” in Article 8(2) of the Act shall refer to one of the followings:

1. Where it is necessary to examine whether a health functional food complies with the standards and specifications of health functional food under Article 14 of the Act, the ingredients or the components under Article 15 of the Act, the standards of label under Article 17 of the Act, and the prohibition of false or exaggerated labeling and advertising under Article 18 of the Act;
2. Where any hazard to health is deemed to occur due to a health functional food; and
3. Where the Commissioner of the Food and Drug Administration recognizes that it is necessary to examine in order to promote the public health or protect the customers as a result of reviewing materials, etc. on a health functional food or the safety relating to ingredients or components.

(3) Upon receiving an import report of health functional food under paragraph (1), the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall carry out an examination for the health functional

food in question according to the health functional food import report and the method for examination of health functional food, described in annexed the Table 2, and issue a health functional food import report certificate, annexed the Form 20, if it is compliant as a result and the import reporter applies for such a certificate. <Amended on November 20, 2006>

(4) For the health functional food that is noncompliant as a result of examination under paragraph (3), the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall, without delay, notify the import reporter concerned and the competent head of the customs office of the noncompliance according to the format of annexed the Form 21. The import reporter concerned, who is notified of the fact, shall take one of the following measures:

1. To return it to the exporting country or send it to another country;
2. To convert to other use other than human consumption. In this case, the Commissioner of the Food and Drug Administration shall determine the consultation among the administrative authorities and the procedure matters necessary for the conversion to other use; and
3. To dispose.

(5) The Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall record the reports under paragraph (1) in the Health Functional Food Reports Acceptance Register, annexed the Form 22, and annually report the health functional food import report status to the Commissioner of the Food and Drug Administration within one month after the completion of year according to the format of annexed the Form 23. Provided, that if electronically

processed, the Reports Acceptance Register and the import report status report may be substituted with the electronic printouts.

(6) If the health functional food arrives later than the expected date previously reported under the latter part of paragraph (1), the delay shall not be included in the civil petitions treatment period under the provisions of Article 3 of the 「Enforcement Decree of the Civil Petitions Treatment Act」 . <Amended on November 20, 2006>

(7) The Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service may carry out the following matters with electronic documents under the conditions as determined by the Commissioner of the Food and Drug Administration:

1. To receive necessary documents necessary for the health functional food import report under paragraph (1);
2. To issue the health functional food import report certificate under paragraph (3);
and
3. To notify of the noncompliance as a result of the health functional food examination under paragraph (4).

(8) From the import reported health functional food under paragraph (1) that is deemed possible to be converted to other use, the Commissioner of the Food and Drug Administration may designate the health functional food subject to distribution control. In this case, detailed matters for designation procedures and method of the health functional food subject to distribution control, etc. shall be determined by the Commissioner of the Food and Drug Administration.

(9) Upon receiving the import report of the health functional food subject to distribution control under paragraph (8), the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall notify the Commissioner of the Regional Food and Drug Administration or the head of local government, who has jurisdiction over the place of the import reporter's business establishment, of the subject matters of the report.

Article 11 (Imported health functional food pre-confirmed registration, etc.) (1) Any person, who intends to apply for an imported health functional food pre-confirmed registration under Article 8(3)1 of the Act, shall submit an imported health functional food pre-confirmed registration application (including the application by electronic documents), annexed the Form 24, along with the following documents (including electronic documents) to the Commissioner of the Food and Drug Administration.
<Amended on November 20, 2006>:

1. Documents relating to the name of raw materials used and the component combination ratio used, the manufacturing method, and the name of food additives used and its amount, etc.;
2. The type and name of health functional food and the manufacturing method document;
3. A packaging paper that has a Korean label or contents of label;
4. The original copy of the written result of examination or the certificate of examination by a domestic or foreign officially recognized examination laboratory,

which confirms that the health functional food in question complies with the standards and specifications, etc. under Articles 14 and 15 of the Act; and

5. Documents relating to the location of manufacturing factory, the arrangement plan of building (including the arrangements of machinery and facilities), the floor plan of workplace etc., that manufactures the health functional food in question.

(2) Upon receiving an application for an imported health functional food pre-confirmed registration under paragraph (1), the Commissioner of the Food and Drug Administration shall confirm it according to the standards and procedures for imported health functional food pre-confirmed registration described in annexed the Table 3, and, if it is confirmed that the subject matters of the application comply with the standards, record the subject matters in the Imported Health Functional Food Pre-Confirmed Registration Register, annexed the Form 25, and notify the applicant of such subject matters of the registration. <Amended on November 20, 2006>

(3) If there is any modification of matters described in paragraphs (1)2 and 3, and the location of manufacturing factory in paragraph (1)5 from among the imported health functional food pre-confirmed registration matters under paragraph (2), an imported health functional food pre-confirmed registration modification application(including the application by electronic documents), annexed the Form 26, along with the original copy of the written examination result of the modified health functional food in question or the certificate of examination thereof by a domestic or foreign officially recognized examination laboratory(including electronic documents) to the Commissioner of the Food and Drug Administration. <Amended on November 20, 2006>

Article 12 (Compliance matters of business person) Matters to be complied by business person under Article 2 of the Decree pursuant to Article 10(1)5 of the Act shall be specified in annexed the Table 4.

Article 13 (Report on production records) A health functional food manufacture business person shall annually submit a report on production records, etc., according to the format of annexed the Form 27, within three months after the completion of year under Article 10(2) of the Act.

Article 14 (Business person status succession report) (1) Any person, who intends to file a business person status succession report under Article 11(3) of the Act, shall submit a business person status succession report (including the report by electronic documents), annexed the Form 28, along with the permission certificate or the report certificate, and the following evidential documents(including electronic documents) that prove the transfer of a right to the permission authorities or the report authorities. Provided, That if a certificate of personal seal impression of the transferor is unable to be submitted because the transferor is missing (including a case of moving-out without notification required by the 「Resident Registration Act」) but the permission authorities or the report authorities can endorse the transfer and acquisition through verification of fact, etc. or if the transferor and the transferee visit the permission authorities or the report authorities together and file a business person status succession report, a certificate of personal seal impression may not have to be submitted. <Amended on December 10, 2004, July 3, 2006 and November 20, 2006>

1. A copy of documents that prove the transfer and acquisition and a certificate of personal seal impression of the transferor in the case of transfer;
2. The documents that prove the status as the heir in the case of inheritance; or
3. In other cases, documents that prove the succession of business person status appropriately for each case.

(2) Upon receiving a report due to the inheritance under paragraph (1), the public official in charge shall confirm the certified copy of family registration by sharing administrative information under Article 21(1) of the 「Act on Promotion of the Digitalization of Administrative Affairs, etc. for Creation of Electronic Government」 . Provided, that if the reporter does not agree with, such copy shall be submitted.

<Newly inserted on July 3, 2006>

(3) If the pertinence of the applicant to Article 9(1)3 or 9(2)3 of the Act is unable to be internally verified, the permission authorities or the report authorities may require the applicant to submit references necessary for verifying the facts in addition to the documents described in paragraph (1). <Amended on July 3, 2006>

(4) When a person, who files a business person status succession report under paragraph (1), intends to modify the title or trade name of the business establishment under Articles 4(2)2 and 6(1)2, such modification is able to be included in the report.

<Amended on July 3, 2006>

Article 15 (Number of quality manager) Any person who intends to carry on business with the health functional food manufacture business permission under Article 12(1) of the Act shall employ one or more quality managers at each permitted business

establishment. Provide, That if the agricultural person, etc. under the provisions of Article 2 of the 「Act on the Special Measures for Development of Agricultural and Fishing Villages」 or the producer association under the provisions of Article 2 of the 「Fosterage of Agricultural and Fishery Products Processing Industry Act」, who has obtained the health functional food manufacture-specializing business permission, manufactures health functional food with domestic agricultural products as main ingredients, the quality manager can be employed jointly with other business establishment located in the same or adjacent local government. <Amended on November 20, 2006>

Article 16 (Report of appointment or dismissal of quality manager) When intending to appoint or dismiss a quality manager, a report(including the report by electronic documents), annexed the Form 29, shall be submitted along with the documents(including electronic documents) that verifies the qualification of the quality manager (limited to the case of appointment) to the Commissioner of the Food and Drug Administration under Article 12(4) of the Act. <Amended on November 20, 2006>

Article 17 (Recipients) (1) “Any reason as prescribed by the Ordinance of the Ministry of Health and Welfare” under Article 13(2) of the Act refers to one of the followings:

1. In case where a person is unable to receive such education due to *force majeure*, illness or accident of the person in question, overseas business trip, etc.; and

2. In case where an education is impossible to be received because the education institution has not been designated, etc.

(2) “Any reason as prescribed by the Ordinance of the Ministry of Health and Welfare” under Article 13(4) of the Act refers to case which conforms to paragraph

(1)1.

Article 18 (Education institutions, etc.) (1) The education institutions under Article 13(5)

of the Act shall be those institutions or organizations dedicated to education, designated and publicly announced by the Minister of Health and Welfare.

(2) The contents of education shall include the acts and subordinate statues and the system related to the health functional food, the safety and the quality control of the health functional food, the Good Manufacturing Practice, the personal sanitation, etc., and the details related to the education contents shall be determined by the Minister of Health and Welfare.

(3) The education institution may collect the expenses required for the education, such as publishing expenses for teaching materials, field training expenses, instructor allowances, etc. from the recipients.

(4) With respect to the education under Article 13(2) of the Act for registered sales person to the door-to-door sales business person, the telephone solicit sales business person, or the multi-level sales business person under Article 2 of the 「Door-to-Door Sales」, etc. Act, who intends to carry on the health functional food sales business, the corresponding door-to-door sales business person, the telephone

solicit sales business person, or the multi-level sales business person may conduct a self-education. <Amended on November 20, 2006>

(5) After conducting the self-education under paragraph (4), the door-to-door sales business person, the telephone solicit sales business person, or the multi-level sales business person shall issue an education completion certificate to the recipient, make a document of the details, such as the date and time of the education, the list of recipients, the education contents, etc., and submit the document to the report authorities within fifteen days after the date of the education along with the related verifying documents.

Article 19 (Education hours) (1) A person who intends to carry on a business shall receive education in advance under Article 13(2) of the Act for the following hours:

1. Health functional food manufacture business : Eight hours
2. Health functional food import business : Eight hours
3. Health functional food sales business : Four hours

(2) If a person, who has received the initial education under paragraph (1), falls under any of the following subparagraphs within one year after the date of the initial education, it shall be deemed that the person has completed the initial education for the corresponding business:

1. Where a person intends to carry on a business whose type is the same as the one for which he has received the education;

2. Where a person, who has received the education for the health functional food manufacture business, intends to carry on the health functional food import business or the health functional food sales business; and
3. Where a person, who has received the education for the health functional food import business, intends to carry on the health functional food sales business.

(3) The hours that a quality manager shall regularly receive education under Article 13(3) of the Act shall be six hours once a year. Provided, that the newly appointed quality manager shall receive an education within three months after the date of the appointment unless there is any justifiable reason.

(4) If a person has received the education as quality manager of the Good Manufacturing Practices application business establishment under Article 27(3), it shall be deemed that the person has completed the education under paragraph (3).

Article 20 (Education plan, etc.) (1) An education institution designated under Article 18(1) shall annually make an education plan, including the recipients and the education contents, and submit it to the Minister of Health and Welfare twenty days prior to the commencement of next year.

(2) An education institution shall issue a certificate of completion to the recipients upon their completion of education, and maintain the records related to the education, such as the certificate of completion issuance register, etc. for two years or more.

(3) An education institution shall notify the corresponding permission authorities or the corresponding report authorities of the recipient of the result of education within

one month after the completion date of education, and report the annual education record to the Minister of Health and Welfare by January 31 of the next year.

(4) Detailed matters necessary for the education under Articles 17 through 20 shall be determined by the Minister of Health and Welfare.

Article 21 (Scope of false or exaggerated labeling and advertising) The scope of false or exaggerated labeling and advertising under Article 18(2) of the Act shall be specified in annexed the Table 5.

Article 22 (Entry, Inspection, etc.) (1) The entry, the inspection, etc, under Article 20 of the Act shall be carried out at any time if deemed necessary for securing safety and maintaining quality control and distribution order of the health functional food.

(2) Notwithstanding paragraph (1), for the business establishment which has been filed a report under Article 6 of the Act or the business establishment which has been ordered a business suspension or heavier administrative measures under Article 32 of the Act, the entry, the inspection, etc. should be carried out more than once within six months after the date of the report or the administrative measure imposition, respectively.

(3) A relevant public official, who carried out the entry, the inspection, etc. under paragraph (1) or (2), shall record the results on the Records of Entry, Inspection, etc., annexed the Form 30, to be kept in the business establishment in question.

Article 23 (Amount of collection without compensation, procedures of examination

request, etc.) (1) The amount of collection of the health functional food, etc. without compensation under Article

20(1) of the Act shall be specified in annexed the Table 6.

(2) If a relevant public official collects the health functional food, etc. under Article 20(1) of the Act, he shall issue a collection certificate, annexed the Form 31.

(3) The relevant public official who collects the health functional food, etc. under Article 20(1) of the Act shall seal off and affix his seal and the seal of whose health functional food is collected, etc. to the health functional food, etc. in question at the site of collection.

(4) The Commissioner of the Food and Drug Administration, the Commissioner of the Regional Food and Drug Administration or the Mayor/*Do* governor shall immediately requests an examination laboratory under the provisions of Article 8(3)2 of the Act (hereinafter referred to as “examination laboratory”) to examine the health functional food which was collected under paragraph (3).

(5) When carrying out collecting and examining of the health functional food, etc. under Article 20(1) of the Act, the Commissioner of the Food and Drug Administration, the Commissioner of the Regional Food and Drug Administration or the Mayor/*Do* governor shall record the subject matters in the Collection Examination Records, annexed the Form 32, and keep the Records.

(6) The identification of a relevant public officials, who carries out the entry, collection, inspection, perusal, seizure, disposal or measure of business establishment closure, etc. under Article 20, 30, or 35(5), shall be described in annexed the Form 33.

Article 24 (Examination methods, etc.) (1) Requested for the examination under Article 23(4), the examination laboratory shall carry out the examination according to the standards and specifications of the health functional food, the ingredients, etc. Provided, That if the requesting authorities selects items for examination, the examination laboratory may examine the selected items only.

(2) Upon the completion of examination, the examination laboratory shall notify the requesting authorities of the examination results by the written results of test without delay, and notify the Commissioner of the Food and Drug Administration, the Commissioner of the Regional Food and Drug Administration, the Mayor/*Do* governor, and the head of local government without delay, if the product in question is deemed to be a product subject to disposal measure under Article 30 of the Act. In such case, the permission authorities or the report authorities shall take necessary measures in order to collect and dispose of the product in question without delay.

(3) If an examination laboratory requested for the examination is unable to carry out the examination due to deficiencies in technology or facilities, etc., the examination laboratory shall, without delay, send the samples required to examine (hereinafter referred to as “samples”) to another examination laboratory which is able to carry out the examination, and notify the requesting authorities of the fact.

(4) When an examination laboratory finds that it does not comply with the standards and specifications from the examination results under paragraph (1), the examination laboratory shall keep a part of the samples for sixty days after the completion of the examination. Provided, that if the health functional food or the ingredients are difficulty to store or easily rotten, this shall not apply.

(5) An examination laboratory which carries out examination shall make and keep the examination records. In such case, the examination records shall be kept for three years after the date when the final record was entered.

Article 25 (Self quality examination) (1) A person who has obtained the health functional food manufacture business permission shall carry out a self quality examination under Articles 21(1) and (2) of the Act according to the self quality examination standards described in annexed the Table 7.

(2) A health functional food manufacture business person shall keep the records on the self quality examination under paragraph (1) for two years.

Article 26 (Application for designation as Good Manufacturing Practices application business establishment, etc.) (1) Any person, who intends to be designated as a Good Manufacturing Practices

application business establishment under Article 22(3) of the Act, shall apply to the Commissioner of the Food and Drug Administration with an application (including the application by electronic documents) for designation as Good Manufacturing Practices application business establishment, annexed the Form 34, and the following documents (including electronic documents) <Amended on November 20, 2006>:

1. A copy of manufacturing process flowchart by item;
2. The arrangement plan of building and the floor plan of workplace (including the arrangements of machinery and facilities);
3. The list of machinery and facilities in quality control room;

4. The production records of previous year. Provided, that if the person does not have the records for the whole year, it may substitute the monthly production records of the last three months or more;
5. A copy of the certificate of completion of the initial education under Article 27(3);
and
6. The self assess results and related documents of the application and operation for three months or more according to the Good Manufacturing Practices under Article 22(1) of the Act.

(2) When designating a Good Manufacturing Practices application business establishment under paragraph (1), the Commissioner of the Food and Drug Administration shall issue a Good Manufacturing Practices application business establishment designation certificate, annexed the Form 35.

(3) When a business establishment, which has been designated as a Good Manufacturing Practices application business establishment under paragraph (2), intends to modify the location of designated business establishment, and the workplace, the health functional food handling facilities or the quality control laboratory from among the manufacturing facilities, an application (including the application by electronic documents) for modification, annexed the Form 36, and the following documents shall be submitted to the Commissioner of the Food and Drug Administration <Amended on November 20, 2006>:

1. The Good Manufacturing Practices application business establishment designation certificate

2. A copy of business permission certificate (limited to the case of the designation business establishment location modification); and
 3. The administration standards book of the Good Manufacturing Practices and the administration standards book of the general sanitation, and related forms (it means the standards book amended according to the location and the facilities, and related forms).
- (4) Detailed matters necessary for the designation and administration of the Good Manufacturing Practices application business establishment under paragraphs (1) through (3) shall be determined and publicly announced by the Commissioner of the Food and Drug Administration.

Article 27 (Education and training for business person, etc. of Good Manufacturing Practices application business establishment, etc.)

(1) The contents of education and training for the business person and the employees of Good Manufacturing Practices application business establishment under Article 22(3) of the Act shall be as follows<Amended on November 20, 2006>:

1. Matters relating to the 「Health Functional Food Act」 ;
2. Matters relating to the Good Manufacturing Practices;
3. Matters relating to the follow-up management of Good Manufacturing Practices, etc.; and
4. Other matters that the Commissioner of the Food and Drug Administration deems to be necessary.

(2) The recipient of education and training from among the employees under paragraph (1) shall be the quality manager in charge of Good Manufacturing Practices application, and such quality manager shall conduct a relevant education and training for other employees who engage in the business for one hour or more once a month.

(3) The education and training under Article 22(3) of the Act shall be carried out by an institution or organization dedicated to education, designated by the Commissioner of the Food and Drug Administration according to the types of the education and training that carried out prior to a designation of Good Manufacturing Practices application business establishment or due to the replacement of business person or quality manager (hereinafter referred to as “initial education and training”) and that carried out annually after the designation of Good Manufacturing Practices application business establishment (hereinafter referred to as “supplement education and training”), and the education hours and the education frequency shall be as follows:

1. Initial education and training : A business person shall receive eight hours at the same education and training, and a quality manager shall receive sixteen hours at the same education and training; and
2. Supplement education and training : A quality manager who corresponds to paragraph (2) shall receive eight hours of education and training annually.

(4) Other detailed matters necessary for the education and training under paragraphs (1) through (3) shall be determined and publicly announced by the Commissioner of the Food and Drug Administration.

Article 28 (Revocation of Good Manufacturing Practices application business establishment, etc.) The standards of revocation of Good Manufacturing Practices application business establishment,

etc. under Article 22(4) of the Act shall be specified in annexed the Table 8.

Article 29 (Entry and inspection of Good Manufacturing Practices application business establishment) “A certain period of time as prescribed by the Ordinance of the Ministry of Health and

Welfare” in Article 22(6) of the Act shall be three years.

Article 29-2 (Issuance of English certificate for export business person) (1) When a person who exports health functional food (hereinafter referred to as "an export business person" in this Article) requests for the issuance of any of the following certificates in English, the Commissioner of the Food and Drug Administration shall verify the facts and issue the corresponding certificate in English. In such a case, the export business person who intends to have such a certificate issued shall submit an application of English certificate for Export Health Functional Food, annexed the Form 39, (including the application by electronic documents) to the Commissioner of the Food and Drug Administration or the Commissioner of the Regional Food and Drug Administration.

1. Health certificate : A document certifying that the corresponding health function food is legally manufactured and distributed and is a sanitary product.

2. Certificate of free sales : A document certifying that the corresponding health functional food is a product which is sold freely without limitation in the Republic of Korea

3. Certificate of Good Manufacturing Practice applied establishment : A document certifying that the corresponding business establishment is an establishment suitable for the Good Manufacturing Practices under Article 22 of the Act.

(2) The health certificate, certificate of free sales and certificate of Good Manufacturing Practice applied establishment under paragraph (1) shall be described in annexed the Forms 40 through 42, respectively.

[Newly inserted on November 20, 2006]

Article 30 (Application documents for authorization of association establishment) Any person who intends to obtain an authorization of the establishment of association under Article 28(3) of the Act and Article 16(2) of the Decree shall submit to the Minister of Health and Welfare an application (including the application by electronic documents) for the establishment of the association along with the documents (including electronic documents) falling under the following subparagraphs <Amended on November 20, 2006>:

1. Minutes of the inaugural general meetings;
2. The articles of association;
3. The operational plan and the budget of Fees and expenditures;
4. An inventory of property;
5. A list of the officers;

6. The installation acceptance sheet of each officer;
7. The resume of officers; and
8. A copy of the resident registration certificate for each officer, and other copies of official documents that may be used for the purpose of identification.

Article 31 (Standards of administrative sanctions, etc.) (1) The standards of administrative sanctions under Articles 29 through 33 of the Act shall be specified in the annexed Table 9.

(2) When seizing a health functional food under Article 30 of the Act, the relevant public official shall issue a seizure certificate, annexed the Form 31.

Article 32 (Administrative sanctions register, etc.) (1) When imposing an administrative sanction under Articles 29 through 33 or 35 of the Act and holding a hearing under Article 36 of the Act, the permission authorities or the report authorities shall record the subject matters in the Administrative Sanctions and Hearing Register, annexed the Form 37, and keep the register.

(2) When the Commissioner of the Regional Food and Drug Administration or the head of local government revokes the business permission or orders a business establishment closure under Article 32 of the Act, the Commissioner of the Regional Food and Drug Administration shall, without delay, notify the other Commissioners of the Regional Food and Drug Administration and the head of local government shall, without delay, notify the other heads of local government respectively of the name of business establishment in question, the location of business establishment in question,

the name of business person in question, the resident registration number of the business person in question, the justification of revocation or closure, the date of revocation or closure, etc.

(3) When imposing an administrative sanction under Articles 32, 33, 35 and 38(2) of the Act, the Commissioner of the Regional Food and Drug Administration or the head of local government shall, without delay, report the name of the business establishment in question, business permission(report) number in question, the content of violation, the nature, period and item name of the administrative sanction, etc. according to the format of annexed the Form 38 to the Commissioner of the Food and Drug Administration.

Article 33 (Penalty surcharge collection procedure, etc.) (1) The exempted from penalty surcharge under the proviso of Article 37(1) of the Act shall be those in annexed the Table 10.

(2) The 「Enforcement Rule of the Management of the National Funds Act」 shall apply *mutatis mutandis* to the procedure for collecting penalty surcharge under Article 19(4) of the Decree. In such case, the payment notice shall include the method and period of raising an objection, etc. <Amended on November 20, 2006>

Article 34 (Standards of reward money payment) (1) The reward money under Article 40 of the Act shall be paid according to the following standards:

1. In case where a person who violates Article 5(1) or 23 of the Act is reported : Five hundred thousand (500,000) won or less; and

2. In case where a person who violates Articles 6(1) and (2), or 24 through 26 is reported : Two hundred thousand (200,000) won or less.

(2) The amount of reward money payment by detailed violation type, the payment method and procedure, etc. shall be determined and publicly announced by the Commissioner of the Food and Drug Administration.

Article 35 (Fees) (1) The fees under Article 42 of the Act shall be specified in annexed the Table 11.

(2) The fees under paragraph (1) shall be paid by state Fee stamps where the relevant authorities of permission, report, application, examination, etc. is the state, and by Fee stamps issued by the corresponding local government where the relevant authorities of permission, report, application, examination, etc. is a local government. Provided, That if it falls under any of the following subparagraphs, it can be paid in cash (including payment in electronic cash and according to the method of electronic settlement by information and communication network) at a financial institution designated by the corresponding authorities or a government office dedicated to postal and telegraphic service. <Amended on November 20, 2006>:

1. Report fees where a health functional food import report under Article 8(1) of the Act is carried out with electronic documents under Article 10(7);
2. Fees for any kind of examinations; and
3. Domestic and foreign travel expenses for on-site inspection for an imported health functional food pre-confirmed registration application under Article 11.

Article 36 (Standards of fine for negligence to be imposed) The standards of fine for negligence to be imposed against a person who violates matters which shall be complied with by the business person under the proviso of Article 21(3) of the Decree, shall be specified in annexed the Table 12.

ADDENDA <No. 270, January 31, 2004>

Article 1 (Enforcement date) This Rule shall enter into force on the date of its promulgation. Provided, That the provisions of subparagraph 1(i)(2) of the annexed Table 1 shall enter into force two years after the enforcement date of this Rule.

Article 2 (Transitional measures concerning change of the permission authorities for health functional food manufacture-specializing business) Any person, who has filed a report of the food

manufacture business or food processing business, which falls under a health functional food in accordance with the standards and specifications under Article 14(1) of the Health Functional Food Act, to the head of local government under Article 22(5) of the Food Sanitation Act at the time this Rule enters into force, shall apply for a health functional food manufacture-specializing business permission to the Commissioner of the Food and Drug Administration after having the facilities in accordance with the facilities criteria by business type described in Article 2 within

six months after this Rule enters into force. In such case, the fees for business permission shall be exempted.

Article 3 (Transitional measures concerning change of the report authorities for health functional food item manufacture report) Any person, who has notified of the item manufacturing

notification of food, which falls under a health functional food in accordance with the standards and specifications under Article 14(1) of the Health Functional Food Act, to the head of local government under Article 22(6) of the Food Sanitation Act at the time this Rule enters into force, shall file an item manufacture report to the Commissioner of the Food and Drug Administration with documents described in Article 8(1) within six months after this Rule enters into force. In such case, the fees for item manufacture report shall be exempted.

Article 4 (Transitional measures concerning health functional food import business report) Any person, who has filed the report on imported food, which falls under a health functional food in accordance with the standards and specifications under Article 14(1) of the Health Functional Food Act, to the Commissioner of the Regional Food and Drug Administration under Article 22(5) of the Food Sanitation Act at the time this Rule enters into force, shall file a business report to the Commissioner of the Food and Drug Administration after having the facilities in accordance with the facilities criteria described in Article 2 within six months after this Rule enters into force. In such case, the fees for business report shall be exempted.

Article 5 (Amendment to other Enforcement Rules) The Enforcement Rule of the Food

Sanitation Act shall be amended as follows:

“Special nutritional food, canned and bottled food” shall replace “health supplement food, special nutritional food, canned and bottled food” in the proviso of Article 21(1).

In annexed the Table 3, “special nutritional food” shall replace “health supplement food, special nutritional food and ginseng products” in the food subject to application of subparagraph (1), “image, internet, and product explanation relating to product sale” shall replace “image, and product explanation relating to product sale” in items of subparagraph 2, subparagraph 2(a)(1) shall be deleted, and subparagraph 2(a)(3) shall be provided as follows:

(3) Expression of food and nutritional functions and effects of nutrition components of product (e.g. function and effects of vitamin, calcium, iron, amino acid, fatty acid, etc.)

Subparagraph 1(e)(3) of the annexed Table 8 shall be deleted.

“Special nutritional food (limited to the weight control food from among meal substitute foods)” shall replace “health supplement food and special nutritional food (limited to the weight control food from among nutrient supplement foods and meal substitute foods)” in subparagraph 11 of the annexed Table 12 and subparagraph 2(o).

ADDENDA <No. 300, December 10, 2004>

Article 1 (Enforcement date) This Rule shall enter into force on the date of its promulgation.

Article 2 (Application Examples concerning import health functional food subject to close examination) The amended provisions of subparagraph 2(a)(2) of the annexed Table 2 shall apply to

the health functional food imported after this Rule enters into force.

Article 3 (Transitional measures concerning attaching documents for business person status succession report) Notwithstanding the amendment of Article 14(1), if a report has been filed for the business person status succession report at the time this Rule enters into force, the previous provisions shall apply.

ADDENDUM (Ordinance for partial amendment of the Enforcement Rule of the Health Functional Food Act, etc. for administrative information sharing and document reduction)

<No. 363, July 3, 2006>

This Rule shall enter into force on the date of its promulgation.

ADDENDA <No. 373, November 20, 2006>

Article 1 (Enforcement date) This Rule shall enter into force on the date of its promulgation.

Article 2 (Application examples concerning the criteria of administrative sanctions, etc.)

(1) The amended provisions, annexed the Table 9, shall apply to the violations after the Rule enter into force.

(2) The amended provisions of subparagraph (5), annexed the Table 10, shall be applied to the penalty surcharges after this Rule enters into force.

(3) The amended provisions, annexed the Table 11, shall apply to the modification reports, item manufacture report reissue applications, business status succession reports and English certificate applications after this Rule enters into force.

Article 3 (Transitional measures concerning the criteria of administrative sanctions) In applying the criteria of administrative sanctions on the acts committed before this Rule enters into force, the previous provisions shall apply.

[Annexed the Table 1] <Amended on December 10, 2004, November 20, 2006>

Facilities criteria by business type (relating to Article 2)

1. Health functional food specializing manufacturing business

a. The location etc. of building equipped with manufacturing facilities of health functional food, storage facilities of ingredients and products, etc. (hereinafter referred to as the “building”).

(1) The building shall be at a sufficient distance not to take bad effect from the location that generate the excreta or the livestock wastewater under Article 20(1) of the Act on the Disposal of Sewage, Excreta and Livestock Wastewater, or the chemicals or other contaminated matters under Article 2 of the Toxic Chemicals Control Act.

(2) The structure of the building shall be suitable for maintaining adequate temperature and humidity and for being well ventilated in accordance with the characteristics of health functional food to be manufactured.

(3) The construction materials of the building shall not contaminate or negatively influence the health functional food.

b. Workplace

(1) The workplace shall be an independent building or separated from the facilities used for purposes other than health functional food manufacturing (referred to case where it is separated by wall, floor etc.; hereinafter the same shall apply).

(2) The workplace refers to ingredient processing room, manufacturing room, packaging room and other necessary work room used for the purposes of manufacturing, and each facility shall be separated or partitioned (referred to the case where it is separated by partitions, curtains etc.; hereinafter the

same shall apply). Provided, That if it is deemed that automation of the manufacturing process or the specific characteristics of the facility or product makes it unnecessary to be separated or partitioned and each facility is able to be divided (referred to case where it is differentiated by lines or ropes etc.; hereinafter the same shall apply), this shall not apply.

(3) The floor, interior wall and ceiling of the workplace shall be constructed in accordance with the following structures:

(a) The floor shall be made of concrete and other materials that are water-proof, and water drainage shall be guaranteed.

(b) The interior wall shall be furnished with light-colored water-proof materials or painted with antiseptic paint up to 1.5 meters above the floor.

(c) The ceiling shall be easy to clean and foreign materials or dust shall not be piled up or solidification water shall not drop.

(4) The workplace shall be fully equipped with ventilation facilities in order to ventilate odor, poisonous gas, smoke, steam, etc. that is generated from the workplace.

(5) The brightness of workplace shall be 220 lux or more. Provided, that if it is not directly processed the health functional food or ingredients because of the automation facilities etc., this shall not apply.

(6) The workplace shall have the facilities that keep off the mouse and vermin, etc.

c. Health functional food handing facilities

- (1) The health functional food handling facilities such as machinery and apparatus etc. necessary for manufacturing health functional food shall be comply with, in accordance with the characteristics, the manufacturing standards stipulated under the standards and specifications of the health functional food.
- (2) In accordance with the characteristics of items to be manufactured, the machinery and apparatus etc. necessary for selection, washing, weighing, combination, culture, extraction, concentration, refining, disinfection, extrusion, correction of deformities, electrification, packaging etc. of ingredients shall be equipped.
- (3) Among the handling facilities, the part that makes direct contact with the health functional food shall be made of sanitary water-proof materials (referred to stainless, aluminum, FRP, teflon etc, that do not absorb water; hereinafter the same shall apply), be easy to wash and be possible to be disinfected or sterilized with boiling water, steam, germicide etc.
- (4) Thermometers or other instruments measuring temperature shall be installed in the freezing or refrigeration facilities and heat treatment facilities and adequate temperature shall be maintained.

d. Water supply facilities

- (1) Water supply facilities shall be equipped in order to supply tap water or underground water, etc. that complies with the Management of Drinking Water Act.

(2) In case of using underground water etc., the source of such water shall be 20 meter or more apart from the toilets, waste disposal facilities, animal breeding farms and any other place that may pollute the underground water.

e. Toilet

(1) A flush toilet with a water-purifier tank shall be located in a place that does not influence the workplace. Provided, that if there is a toilet nearby that is easy to access, additional toilets may not be required.

(2) The toilet shall be water-proof using concrete or other materials, and the floor and the interior wall (1.5 meters from the floor) shall be tiled or be painted with water-proof paint.

f. Changing room and washing facilities

(1) The changing room and flushing facility shall be separated from the workplace, and there shall be sufficient facilities for workers to use under sanitary surroundings.

(2) The changing room shall have the ventilation facilities that leads to outside, and it shall be kept clean.

g. Storage facilities such as warehouse, etc.

The storage facilities such as warehouse, etc. with sufficient room shall be in place so that raw materials, half-finished products, end products and return products etc. are separated or partitioned and sanitarily stored and managed.

h. Quality control room

The quality control room for self quality examination, ingredient examination and quality control of step-by-step manufacturing process shall be in place and the machinery, apparatus and reagents etc. necessary for such test examination shall be equipped, and when the business person operates two or more manufacturing establishment(including the manufacturing establishments under Article 21(1)1 of the Food Sanitation Act and Article 26(1) of the Pharmaceutical Affairs Act and they may be used jointly. Provided, that if, under Article 21(2) of the Act, the Commissioner of the Food and Drug Administration decides that an examination laboratory may be entrusted the examination because it is improper that a business person carries out the examination by himself, this shall not apply.

i. Special cases concerning on facilities criteria application

(1) If a health functional food specializing manufacturing business person lacks production capability to manufacture or a part of manufacturing facilities is insufficient, the person may entrust a person who has obtained health functional food specializing manufacturing business permission to manufacture the health functional food.

(2) The health functional food specializing manufacturing business establishment, that can be entrusted or requested to manufacture from the health functional food manufacturing business person or the health functional food distribution-specializing sales business person, shall be designated as the Good

Manufacturing Practices application business establishment under Article 22(2) of the Act.

- (3) The manufacturing facilities of health functional food may be used for manufacturing food or food additives. Provided, that if the Commissioner of the Food and Drug Administration recognizes and publicly announces that there is possibility of inter-contamination between the products, this shall not apply.
- (4) When the person, who carries on medicine manufacturing with permission from the Commissioner of the Food and Drug Administration under Article 26 of the Pharmaceutical Affairs Act, intends to operate the health functional food manufacturing business, such medicine manufacturing facilities may be used as health functional food manufacturing facilities in case where the Commissioner of the Food and Drug Administration recognizes and publicly announces that the medicine to be manufactured may be contaminated by the health functional food.

2. Health functional food venture manufacturing business

- a. The health functional food venture manufacturing business shall be a venture business that satisfies the requirements for venture business under Article 2-2 of Act on Special Measures for the Promotion of Venture Businesses and obtains a venture business confirmation under Article 25 of the same Act.

- b. The health functional food venture manufacturing business person shall use the manufacturing facilities of the health functional food specializing manufacturing business under Article 2.1a of the Decree.
- c. The health functional food venture manufacturing business person shall obtain the venture business confirmation under Article 25 of Act on Special Measures for the Promotion of Venture Businesses before the expiration date of the validity of the venture business confirmation under Article 18-2 of the Enforcement Decree of Act on Special Measures for the Promotion of Venture Businesses.
- d. The health functional food venture manufacturing business person shall develop and keep the technology on functionality ingredients or components of health functional food.

3. Health functional food import business

- a. Business establishment

An independent business establishment shall be in place for business operations.

Provided, that if there exist no obstruction in the business operations, other establishment may be jointly used.

- b. Storage facilities such as warehouse, etc.

- (1) The storage facilities such as warehouse, etc. with sufficient room shall be in place so that the health functional food is sanitarily stored. In this case, storage facility may be in place or leased outside the district where the business report is submitted.
- (2) The storage facility shall have the facilities that keep off the mouse and vermin, etc.

4. Health functional foods general sales business

a. Business establishment

An independent business establishment shall be in place for business operations, and if there exist no obstruction in the business operations, other establishment may be jointly used or a business office may only be in place.

b. Display stand and sale stand

The health functional foods general sales business establishment shall install display stand or sale stand (in case of cold or frozen products, freezer or refrigerator) for storing and selling sanitarily the health functional food. Provided, that if there is no sale place, it is not necessary to install.

c. Storage facilities such as warehouse, etc.

- (1) The storage facilities such as warehouse, etc. with sufficient room shall be in place so that the health functional food is sanitarily stored. In this case,

storage facility may be in place or leased outside the district where the business report is submitted. Provided, that if the sales-only facility that has sufficient room for storage and management of products is installed or it is not necessary to have storage facility such as a separate warehouse, etc., this shall not apply.

(2) The storage facility shall have the facilities that keep off the mouse and vermin, etc.

5. Health functional food distribution–specializing sales business

a. Business establishment

An independent business establishment shall be in place for business operations. Provided, that if there exist no obstruction in the business operations, other establishment may be jointly used.

b. Entrust manufacturing facilities

The health functional food distribution–specializing sales business person shall use the manufacturing facilities of the health functional food specializing manufacturing business under Article 2.1a of the Decree.

c. Storage facilities such as warehouse, etc.

(1) The storage facilities such as warehouse, etc. with sufficient room shall be in place so that the health functional food is sanitarily stored. In this case,

storage facility may be in place or leased outside the district where the business report is submitted.

- (2) The storage facility shall have the facilities that keep off the mouse and vermin, etc.

[Annexed the Table 2] <Amended on December 10, 2004, November 20, 2006>

Import report and examination method of health functional food
(relating to Article 10)

1. Types and scopes of examination

a. Document examination and the scopes

The document examination means the examination that determines the propriety by reviewing the report document, etc. and the following health functional food is subject to the document examination. However, in case of the examination for determining the propriety of (1) through (3), the examination of the standards and specification, ingredients or components, standards of label under Article 14, 15 or 17 of the Act may be exempted.

- (1) The health functional food imported for obtaining of foreign currencies under Article 34(1)1 and 34(1)2 of the Enforcement Decree of Foreign Trade Act.
- (2) The health functional food for study and research (including certain amount of import products for study and research in order to be recognized as health functional food or ingredients or components under Article 14(2) and 15(2) of the Act).
- (3) The health functional food imported for the exposition and exhibition, etc. to obtain foreign currencies.
- (4) The health functional food imported after the imported health functional food pre-confirmed registration under Article 8(3)1 of the Act.
- (5) The re-imported health functional food, re-imported within three years, among those that have completed the close examination stipulated item c and the manufacturing country, manufacturing establishment, product name, manufacturing method, ingredients and combination ratio are identical.
- (6) Among the health functional foods that have not been decided as noncompliant as a result of the previous close examination, the health functional food recognized by the Commissioner of the Food and Drug Administration that the safety is ensured.

b. Sensory examination and the scopes

The sensory test means the comprehensive examination that determines the propriety based on the appearance, taste, scent, color, labeling, package, close examination records of product in addition to the document examination, and

among the health functional food subject to the document examination under item a the following health functional food is subject to the sensory examination.

- (1) Where the Commissioner of the Regional Food and Drug Administration or head of the National Quarantine Service recognizes that it is necessary to verify the facts.
- (2) Where the Commissioner of the Regional Food and Drug Administration or head of the National Quarantine Service recognizes that there is a major hazardous facts.

c. Close examination and the scopes

The close examination means the examination conducted using the physical, chemical or microbiological methods in addition to the document examination and the sensory examination, and the following health functional food is subject to the close examination.

- (1) The health functional food being imported for the first time.
- (2) The health functional food that has recognized to be sanitarly harmful as a result of the document examination and the sensory examination.
- (3) The health functional food recognized at home and abroad to contain harmful substances that give reasons for concern.
- (4) The health functional food imported within three years by the import reporter who has not performed the measures for the noncompliant health functional food under Article 10(4).

- (5) The health functional food re-imported within five times by the import reporter who has been decided as noncompliant as a result of the close examination followed by the import report, the random sample examination, or the collection-based examination under Article 20 of the Act (limited to the health functional food that has been decided as noncompliant and the health functional food that the manufacturing country, manufacturing establishment, product name, manufacturing method, ingredients and combination ratio are identical.
- (6) The health functional food imported by the business person who has passed the previous examination through fraudulent means such as attaching false documents etc. within 3 years.
- (7) Among the health functional foods that has been carried out the close examination under (1), the health functional food whose standards and specifications or ingredients or components, publicly announced or recognized under Articles 14 and 15 of the Act, are newly established or reinforced.
- (8) Among the health functional foods that has been carried out the close examination under 2a(2) and the manufacturing country, manufacturing establishment, product name, manufacturing method, ingredients and combination ratio are identical, the health functional food re-imported more than the minimum import amount within three years.

d. Random sample examination and the scopes

The random sample examination means the close examination conducted pursuant to the decision by the Commissioner of the Food and Drug Administration from among the health functional foods that are subject to the examinations under 1a and 1b.

2. Imported health functional food examination methods, etc.

a. General matter

(1) When there exists concern that the health functional food subject to examination may be released before the result of examination is verified, The Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service may seal the imported health functional food in question or take other necessary measures.

(2) When the reported amount of the health functional food imported for the first time is less than the minimum import amount determined by the Commissioner of the Food and Drug Administration, the health functional food in question shall be taken the close examination by the examination laboratory.

(3) Deleted <on Nov. 20, 2006>

b. Close examination method of samples and notification of the result

(1) When conducting close examination, the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall examine whether the sample complies with the standards and specifications

or the ingredients or the components of the health functional food, publicly announced or recognized by the Commissioner of the Food and Drug Administration under Article 14 or 15 of the Act. In this case, priority examination items and hazardousness-informed items may be examined in priority and newly established items or reinforced items may be examined in priority for the health functional food subject to the close examination under 1a(7).

(2) The examination on the standards and specifications or the ingredients or the components, etc. of the imported health functional food may focus on items that has frequently been decided noncompliant, items that are highly hazardous to the human body, or items on pesticide residue, pathogenic microorganism, or etc., depending on the results of previous close examination.

c. Recognition of certificate of examination or written result of examination issued by domestic or foreign officially recognized examination laboratory When the import reporter submits the certificate of examination or the written result of examination issued by domestic or foreign officially recognized examination laboratory recognized by the Commissioner of the Food and Drug Administration, the whole or part of the close examination on the health functional food in question may be exempted.

3. The detailed standards of report and examination

The Commissioner of the Food and Drug Administration shall determine and publicly announce the detailed process on the report and examination of the imported health functional food.

[Annexed the Table 3]

Imported health functional food pre-confirmed registration standard and procedures, etc. (relating to Article 11)

1. Health functional food subject to pre-confirmed registration application

The health functional food intended to apply for pre-confirmed registration under Article 8(3)1 of the Act, from among the health functional food to be exported to Korea.

2. Pre-confirmed registration applicant and contents of pre-confirmed matters

a. Applicant: The person who manufactures the health functional food to be exported to Korea (hereinafter referred to as “manufacturer” in this table)

b. Contents of pre-confirmed matters

The Commissioner of the Food and Drug Administration shall confirm the following matters by submitted documents and on-site inspection:

- (1) Whether it complies with the facilities criteria under Article 4 of the Act;
- (2) Whether it complies with the standards and specifications, etc. under Articles 14, 15 and 17 of the Act;
- (3) Whether it complies with the false labeling, etc. under Article 18 of the Act;
and
- (4) Whether it complies with the prohibition of sales, etc. under Articles 23 through 26 of the Act.

3. Revocation of pre-confirmed registration

a. The Commissioner of the Food and Drug Administration may revoke the registration if the health functional food of pre-confirmed registration falls under any of the following items:

- (1) When it is revealed that it does not comply with the contents of pre-confirmed matters described in 2b;
- (2) When the modification matters are not submitted after modifying any matters described in Article 11(3); or

(3) When the domestic or foreign officially recognized written result of examination (or certificate of examination) and the documents submitted has been identified as false ones.

b. The Commissioner of the Food and Drug Administration shall notify the manufacturer, through the exporting government, of the reasons of revocation, the date thereof, etc. when revoke the pre-confirmed registration.

4. Pre-confirmed registration health functional food import report process, etc.

a. Import report and issue of report certificate

(1) A person who intends to import the registered health functional food (hereinafter referred to as “importer” in this table) shall write the pre-confirmed registration number of the health functional food in question in the health functional food import report under Article 8 of the Act (hereinafter referred to as “report” in this table) and submit it to the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service.

(2) In case of the report with the registration number, the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall issue, without delay, the health functional food import report

certificate to the importer after the document examination under 1a of the Table 2.

b. Close examination of pre-confirmed registration health functional food

(1) The Commissioner of the Food and Drug Administration may conduct the close examination under 1c of the Table 2, when he recognizes that there exist concerns for safety on the registered health functional food.

(2) When conducting the close examination in accordance with (1), the Commissioner of the Food and Drug Administration shall notify the manufacturer through the exporting government of the fact.

[Annexed the Table 4] <Amended on November 20, 2006>

Compliance matters of business person (relating to Article 12)

1. Health functional food manufacturing business

a. The health functional food specializing manufacturing business person shall sanitarily manage the manufacturing facilities and apparatus in order to prevent hazards and maintain and manage them not to cause difficulty in work through regular inspection.

- b. The health functional food manufacturing business person shall keep the business permission certificate, the item manufacture report certificate, the self standards and specifications recognition documents, and the functionality labeling and advertising pre-deliberation certificate.

- c. The health functional food manufacturing business person shall make and keep for three years documents on production and work operation and related documents on delivery, shipment and use of ingredient receipts and disbursements. In this case, it may be substituted by keeping the product standards, the manufacture management standards and the manufacture management records of the manufacturing product.

- d. The health functional food manufacturing business person shall have the transaction details including name of sales business establishment, name of product, amount, date of providing, etc. and the returning details and keep them for two years.

- e. When using underground water, etc. that is not tap water, the health functional food specializing manufacturing business person shall use water recognized that it is suitable to drink as the result of the yearly (every six months for drinking-form health functional food) analysis in accordance with the drinking water standards under Article 5 of the Management of Drinking Water Act by a drinking water examination laboratory under Article 35 of the Management of Drinking Water Act.

- f. The health functional food specializing manufacturing business person shall not manufacture health functional food by entrustment or request from any person who does not obtain the business permission or file the business report under this Act.

- g. When manufacturing health functional food with the genetic modification technology, the health functional food manufacturing business person shall comply with the regulation on the genetic modification that is determined and publicly announced by the Commissioner of the Food and Drug Administration.

- h. When manufacturing or manufacturing and selling the health functional food subject to the genetic modification labeling but not making label that it is genetically modified food, the health functional food manufacturing business person shall keep the certificate that proves the reasons such as the identity preserved handling certificate, etc. for two years from the date of manufacture.

- i. If the delivered health functional food has any problem with safety or functionality or it is of inferior quality, the health functional food manufacturing business person shall recall voluntarily the product in question and keep the record for two years.

- j. When verifying the hazardous facts (including side-effect cases) that have a bad effect on the public health in relation to the health functional food, the health functional food manufacturing business person shall report, without delay, to the business permission authority or the report authority, and take necessary safe measures.

- k. When receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc., the health functional food manufacturing business person shall take the post measures in accordance with the administrative measures and report, without delay, to the disposition authority.

- l. When the health functional food is manufactured upon the entrustment, the truster or the trustee may conduct the self quality examination.

- m. The health functional food manufacturing business person shall not entrust any business establishment that is not designated as the Good Manufacturing Practices application business establishment, and any business establishment that is not designated as the Good Manufacturing Practices application business establishment shall not manufacture the product in question by the entrustment or the request.

2. Health functional food import business

- a. The health functional food import business person shall regularly inspect and sanitarily manage the storage facilities, etc. in order to prevent hazards for importing, storing and distributing the health functional food.
- b. The health functional food import business person shall keep the business report certificate, the standards and specifications recognition certificate and the functionality labeling and advertising pre-deliberation certificate.
- c. The health functional food import business person shall keep the import report certificate, the shipping document and content list (invoice) and the sale record for two years from the import date. Provided, that if the sell-by-date is two years and more, they shall be kept until the sell-by-date.
- d. The health functional food import business person shall have the transaction details including name of sales business establishment, name of product, amount, date of providing, etc. and the returning details and keep them for two years.
- e. When importing health functional food manufactured with the genetic modification technology, the health functional food import business person shall comply with the regulation on the genetic modification that is determined and publicly announced by the Commissioner of the Food and Drug Administration.

- f. When importing the health functional food subject to the genetic modification labeling but not making label that it is genetically modified food, the health functional food import business person shall keep the certificate that proves the reasons such as the identity preserved handling certificate, etc. for two years from the date of import.

- g. If the imported health functional food has any problem with safety or functionality or it is of inferior quality, the health functional food import business person shall recall voluntarily the product in question and keep the record for two years.

- h. When verifying the hazardous facts (including side-effect cases) that have a bad effect on the public health in relation to the health functional food, the health functional food import business person shall report, without delay, to the report authority of the business, and take necessary safe measures.

- i. When receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc., the health functional food import business person shall take the post measures in accordance with the administrative measures and report, without delay, to the disposition authority.

3. Health functional food sales business

- a. The health functional food sales business person shall regularly inspect and sanitarily manage the facilities for storage, display and sale, etc. in order to prevent hazards for storing, distributing and selling the health functional food.
- b. The health functional food sales business person shall keep the business report certificate and the functionality labeling and advertising pre-deliberation certificate (limited to the case of receiving the functionality labeling and advertising pre-deliberation certificate).
- c. The health functional food sales business person shall keep the details of the health functional food provided for two years.
- d. When receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc., the health functional food sales business person shall take the post measures in accordance with the administrative measures and report, without delay, to the disposition authority.
- e. The door-to-door sales business person, etc. shall manage that a door-to-door sales person, etc. does not make false or exaggerated labeling or advertising

which may cause to misled or confuse that it is efficient and effective in preventing and curing disease, or it is a medicine.

f. The health functional food distribution-specializing sales business person shall entrust a business establishment that is designated as the Good Manufacturing Practices application business establishment with manufacturing products.

g. The door-to-door sales business person, etc. shall keep the list of name, address, resident registration number, telephone number, registration date, registration number, etc. of door-to-door sales persons, etc. in the business establishment, and, when a door-to-door sales person, etc. is changed, notify quarterly (by the end of month that the next quarter starts) the head of local government, who has jurisdiction over the location of business establishment of the fact.

[Annexed the Table 5] <Amended on November 20, 2006>

Scope of false or exaggerated labeling and advertising

(relating to Article 21)

1. Case falls under labeling or advertising which may cause to mislead or confuse that it is efficient and effective in preventing and curing diseases, or it is a medicine

- a. Labeling or advertising which expresses that it prevents disease or group of diseases;
 - b. Labeling or advertising which expresses that it is effective against disease or group of diseases. Provided, that if it is the useful effectiveness, not for disease, but for the health use of the human body structure and function, this shall not apply;
 - c. Labeling or advertising which expresses that it is effective against a characteristic sign or symptom of disease;
 - d. Labeling or advertising which alludes to relation with disease by utilizing the product name, academic materials, photographs, etc. Provided, that if it is a labeling or advertising which expresses that it is helpful to reduce the occurrence risk of disease, this shall not apply;
 - e. Labeling or advertising which expresses that it is included among medicines;
 - f. Labeling or advertising which expresses that it substitutes medicine; or
 - g. Labeling or advertising which expresses that it increases the efficiency of medicine or the effectiveness of curing disease.
2. Case falls under labeling or advertising which is not truthful or exaggerated
- a. Labeling or advertising which is different in contents from what was permitted or reported under Articles 5 through 7 of the Act or what was filed for the import report under Article 8 of the Act;
 - b. Labeling or advertising which expresses the functionality that is not recognized by the Commissioner of the Food and Drug Administration;

- c. Labeling or advertising which expresses the fact that is untruthful in relation to award, recognition, selection, or license by the government or the related official authority; or
 - d. Labeling or advertising which dazes or may daze consumers by expressing “Best”, “Most”, or “Special”, etc. without ground of objective facts. In this case, this shall apply for the foreign transcription of “Best”, “Most”, or “Special”, etc. and the Korean transcription of foreign languages.
3. Case falls under labeling or advertising which may cause consumers to be deceived, misled, or confused;
- a. Advertising which utilizes various kinds of testimonial or story of personal experience, or express “rush of orders”, “group recommendation” or other similar expression;
 - b. Labeling or advertising which expresses that doctor, dentist, Korean oriental doctor, veterinary, college professor or other person guarantees the functionality of the product, or designates, officially approves, recommends, guide or use the product. Provided, that if it is labeling or advertising which expresses that they participate directly in the research and development, this shall not apply;
 - c. Labeling or advertising which may confuse as foreign product by using foreign language or confuse to secure the technical cooperation with foreign company;
 - d. Advertising which indirectly makes product of other business establishment to be understood dissimilarly by emphasizing the matters that has little connection with

the manufacturing method, quality, nutrients, raw materials, components or effectiveness of the product in question; or

e. In case of comparison labeling or advertising, labeling or advertising that the comparison matches or and the comparison standards are not clear or the comparison matters and the comparison methods are not appropriate.

4. Case of labeling or advertising with the name solely used for medicines (including prescription of Korean oriental medicine) Labeling or advertising about the ingredients solely used for medicines determined by the Commissioner of the Food and Drug Administration under Article 24(3) of the Act.

[Annexed the Table 6]

The collection amount of health functional food, etc.
(relating to Article 23)

| Type of health functional food | Collection amount | Reference |
|--|-------------------|--|
| Liquid product | 600g(ml) | <p>1. the collection amount stands for the total weights or volume of each sample, and the materials for examination (sample) shall be collected within the collection amount. Provided, That if it is concluded that the examination result may be effected by the pollution because of collecting the sample, the minimum package unit may be collected even though the minimum package unit of the sample exceeds the collection amount.</p> <p>2. The health functional food that has the bacteriological examination item shall be collected six, in this case it may collected more than the collection amount.</p> <p>3. When two or more are collected, the container or the package and the date of manufacture shall be identical.</p> |
| Tablet . Capsule . powder . Granule . pill | 200g(ml) | |
| Other health functional food | 400g(ml) | |
| Ingredients or components ◦ natural product ◦ components | 1 kg 500g | |

| | | |
|--|--|--|
| | | <p>4. In case of volume examination, the additional necessary amount for the volume examination determined on the standards and specification of the health functional food may be collected even though it exceeds the collection amount.</p> |
|--|--|--|

[Annexed the Table 7]

Self quality examination standard (relating to Article 25)

1. Examination of health functional food

- a. The self quality examination shall carry out according to the manufacture items for sale
- b. The application point of time of self quality examination cycle shall be calculated with the date of manufacture of the product.
- c. The application of examination items shall be limited to the examination items of the product in question. Provided, that if the specific food additives are not used during the manufacturing process of the health functional food, the relevant item may be omitted.

d. The self quality examination shall conduct according to the following section:

(1) Health functional food (excluding ingredients or components) : one or more per month, items on common and individual standards and specifications

(2) Functionality ingredients or components : one or more by manufacture unit (lot), items on standards and specifications

(3) Raw materials and container or package used (Provided, That if the manufacturing business establishment of the product in question has the written result of test that states the suitability as a result of the self quality examination or official examination laboratory examination, it may be omitted)

(a) Items on standards and specifications in accordance with the related regulations by products of raw materials in question : one or more per month

(b) Items on standards and specifications in accordance with the related regulations by products of container or package in question : one or more per two months

2. The Commissioner of the Food and Drug Administration shall determine and publicly announce other detailed matters relating to the self quality examination.

[Annexed the Table 8]

Standards of revoke the designation of Good Manufacturing Practices
standards application business establishment, etc.
(relating to Article 28)

| Violation | Related Act | Standards of sanction |
|---|--------------------------|-------------------------------|
| 1. Where it fails to comply with the Good Manufacturing Practices so that it does not conform the criteria. | Article 22(4) of the Act | correction |
| 2. Where the business suspension disposition is imposed three or more times or is imposed for two or more months under Article 32 of the Act, or where the penalty surcharge is imposed in lieu of the business suspension disposition. | Article 22(4) of the Act | revocation of the designation |
| 3. Where the business person and the employees fail to receive an education and training. | Article 22(4) of the Act | correction |
| 4. Where it is not performed two or more times in succession after the correction measures due to the violation of above 1 or 3. | Article 22(4) of the Act | revocation of the designation |

[Annexed the Table 9] <Amended on November 20, 2006>

Standards of administrative sanction (relating to Article 31)

I . General standard

1. Violation of two or more times

- a. If the violation requires business suspension only, or if the violation requires item or items manufacturing suspension only for a certain item or items (All items being manufactured and processed under the same standards and specifications from among the standards and specifications of health functional food; hereinafter the same shall apply), the overall suspension period shall be the total of the longest suspension period and half of the each suspension period of other penalties.
- b. If the violation requires one or more business suspension and one or more item or items manufacturing suspension, each suspension period for business suspension, item or items manufacturing suspension shall be calculated as stipulated in the above a and suspensions shall be given; if the business suspension period exceeds or equals the item or items manufacturing suspension period, only the business suspension period shall be imposed; if the business suspension period falls short of the item or items manufacturing suspension period, the business suspension period and an additional suspension period that equals the difference between the item or items

manufacturing suspension period and the business suspension period shall be concurrently imposed; and if the violation requires one or more items suspension and one or more item suspension, the suspension shall be imposed under this applicable *mutatis mutandis*.

2. The administrative sanctions being given in accordance with the number of violations shall be applied if the same violation (in case of items, it refers to the same violation regards the same item; hereinafter the same apply) is committed in the last one year (three years in case of violation of Article 23 of the Act). The application standard date shall be the date of administrative sanction and the date when it is uncovered again after the sanction (in case of collection-based examination, the date when the permission or reporting authority received the examination result).
3. If the identical item manufactured on the same date are uncovered the violation, the act of violation shall be deemed as the same violation. However, in case of false or exaggerated advertising, if the identical item advertises in the same medium the act of violation shall be deemed as the same violation.
4. Where the violation has been uncovered forth time, if the sanction standard of the third violation was item or items manufacturing suspension, six months of the item or items manufacturing suspension shall be imposed; and if it was business

suspension, business permission revocation or business establishment closure shall be imposed.

5. When imposing administrative sanction again after the administrative sanction under the provisions of subparagraph 1, it shall be deemed that each violation caused to the previous sanction has been imposed a corresponding administrative sanction when applying to the administrative sanction standard according to the number of violation.

6. In case of administrative sanction against violation based on the examination result, the sanction shall be imposed the person responsible for the violation after decision which process causes the violation among the manufacture, transport, display, storage or sales of the product in question. Provided, That if it is imported product, the importer may be imposed the sanction even though the process of manufacture or import causes the violation, and if a manufacturer or a distribution-specializing sales business person manufactures the product by entrustment, the sanction may be imposed the “the business person who manufactures the product in question” (the trustee) and “the manufacturer and distribution-specializing sales business person in question who request the entrust manufacture” (the truster) all together even though the person responsible for the violation is the business person who manufactured the product in question.

7. In case of administrative sanction against distribution-specializing sales business person under the proviso of subparagraph 6, if the weighing of violation of the sanction falls under the item or items manufacturing suspension, such sanctions shall be deemed as the item or items manufacturing suspension imposed on the products manufactured by the manufacture business establishment responsible for the violation.

8. In case of administrative sanction against health functional food import business establishment, if the weighing of violation of the sanction falls under the item manufacturing suspension, one third of the item manufacturing suspension period shall be imposed as business suspension; if the weighing of violation of the sanction falls under the items manufacturing suspension, half of the items manufacturing suspension period shall be imposed as business suspension

9. The sanction period may be reduced within the half of suspension period in case of business suspension or item or items manufacturing suspension and within the three months or more of business suspension in case of business permission revocation or business establishment closure, where it falls under any of the followings:

a. Where it is deemed that it is a mere violation among the violations of the standards and specifications of health functional food so that it may injure the health of the human body in regard of the public health;

- b. Where it is deemed that the violation, among the violations of the standards of label, is not committed intentionally or by negligence but simply mechanical error, such as the omission of manufacturing date for the part of products;
- c. Where a person only manufactures or import, but not distribute the health functional food;
- d. Where the voluntary recall of the health functional food is carried out sincerely in accordance with Article 31-2 of the Food Sanitation Act;
- e. Where it is a mere violation or is committed by trivial carelessness without intention, among the violations regarding to the health functional food sales business;
- f. Where the prosecutor suspends the indictment or the court suspends the decision on the violation in question; or
- g. Where it is deemed that it is necessary for the policy of supply and demand of health functional food.

II. Individual standard

| Type of violation | Act | Standard of administrative sanction | | |
|---|-----------------------|---------------------------------------|-------------------------------|--------------------------------|
| | | First violation | Second violation | Third violation |
| 1. When it is not suitable for the facilities criteria prescribed in Article 4(1) of the Act | Article 31 of the Act | order to improve or repair facilities | | |
| 2. When the health functional food manufacturing business permission is not obtained under the provisions of Article 5(1)(former part) of the Act | Article 35 of the Act | closing measures | | |
| 3. When the modification permission is not obtained under the provisions of Article 5(1)(latter part) of the Act | Article 32 of the Act | business suspension: 15 days | business suspension:: 1 month | business suspension:: 2 months |
| 4. When the business is operated without the business report under the provisions of Articles 6(1) and 6(2) of the Act | Article 35 of the Act | closing measures | | |
| 5. When the item manufacture report is not filed under the provisions of Article 7(1) (former part) of the Act | Article 32 of the Act | business suspension: 7 days | business suspension:: 15 days | business suspension:: 1 month |
| 6. When the health functional food import report is not filed under the provisions of Article 8(1) of the | Article 32 of the Act | business suspension: 1 month | business suspension: 2 months | business suspension: 3 months |

| | | | | |
|---|-----------------------|---------------------------------|----------------------------------|----------------------------------|
| Act | | | | |
| 7. Violation of Article 10(1)2, 10(1)3 or 10(1)4 | Article 32 of the Act | | | |
| a. When sell any product whose sell-by-date has been passed, display or store such product for sale, or use such product for manufacturing health functional food | | business suspension: 15 days | business suspension: 1 month | business suspension: 2 months |
| b. When fail to exchange any product that is rotten, deteriorated, or disposed, or whose sell-by-date has been passed, without any justifiable reason | | business suspension: 7 days | business suspension: 15 days | business suspension: 1 months |
| c. When sell any product by stirring up speculative spirit, such as providing sales promotion gift or free gift, etc | | order of correction | business suspension: 1 months | business suspension: 2 months |
| 8. When the person who succeeds to the status of the business person fails to report within one month under the provisions of Article 11(3) of the Act | Article 32 of the Act | business suspension: 7 days | business suspension: 15 days | business suspension: 1 month |
| 9. When fail to employ the quality manager under the provisions of | Article 32 of | business suspension: | business suspension: | business suspension: |

| | | | | |
|--|------------------------|-------------|-------------|-------------|
| Article 12(1) of the Act | the Act | 7 days | 15 days | 1 month |
| | Articles | | | |
| | 32 | | | |
| 10. Violation Article 18(1) of the Act | and 33 | | | |
| | of the | | | |
| | Act | | | |
| | <manufacturing | | | |
| | business> | | | |
| a. When make labeling or advertising | items manufacturing | business | business | business |
| which may cause to mislead or | suspension: | suspension: | suspension: | suspension: |
| confuse that it is efficient and | 2 months | 2 months | 3 months | 3 months |
| effective in preventing and curing | <import business sales | | | |
| disease, or it is a medicine | business> | | | |
| | business | business | business | business |
| | suspension: | suspension: | suspension: | suspension: |
| | 1 month | 2 months | 3 months | 3 months |
| b. When make labeling or | <manufacturing | | | |
| advertising which is not truthful | business> | | | |
| or exaggerated | item manufacturing | business | business | business |
| | suspension: | suspension: | suspension: | suspension: |
| | 2 months | 2 months | 3 months | 3 months |
| | <import business sales | | | |
| | business> | | | |
| | business | business | business | business |
| | suspension: | suspension: | suspension: | suspension: |
| | 1 month | 2 months | 3 months | 3 months |
| c. When make labeling or | <manufacturing | | | |

| | | | |
|-----------------------------------|-----------------------------------|-------------|-----------------------|
| advertising which may cause | business> | | |
| consumers to be deceived, | item manufacturing | business | business |
| misled, or confused | suspension: | suspension: | suspension: |
| | 2 months | 2 months | 3 months |
| | <import business, sales business> | | |
| | business | business | business |
| | suspension: | suspension: | suspension: |
| | 1 month | 2 months | 3 months |
| d. When make labeling or | <manufacturing | | |
| advertising with the name solely | business> | | |
| used for medicines (including | item manufacturing | business | business |
| prescriptions of Korean oriental | suspension: | suspension: | suspension: |
| medicine) | 2 months | 2 months | 3 months |
| | <import business, sales business> | | |
| | business | business | business |
| | suspension: | suspension: | suspension: |
| | 1 month | 2 months | 3 months |
| e. When make labeling or | business | business | business |
| advertising whose contents have | suspension: | suspension: | suspension: |
| not been deliberated or which is | 2 months | 3 months | 3 months |
| different in contents from what | | | business permission |
| was deliberated under Article | | | revocation or |
| 16(1) of the Act. However, the | | | business |
| case where the sanction is | | | establishment closure |
| imposed due to the same violation | | | |
| under item a through d shall be | | | |
| excluded. | | | |

| | | | | |
|--|------------------------------|---|------------------------------|-------------------------------|
| 11. Violation of Article 21(1) of the Act | Article 32 and | | | |
| a. When fail to conduct the self quality examination | 33 of the Act | business suspension: 15 days | business suspension: 1 month | business suspension: 2 months |
| b. When fail to keep the records of the self quality examination | | item manufacturing suspension: 15 days | business suspension: 15 days | business suspension: 1 month |
| 12. When a person, not designated as a Good Manufacturing Practices application business establishment, makes labeling or advertising with the title of the Good Manufacturing Practices application business establishment or similar contents under Article 22(5) of the Act | Article 32 of the Act | business suspension: 15 days | business suspension: 1 month | business suspension: 2 months |
| 13. When sell the following health functional food or manufacture, import, use, store, transport or display the following health functional food for sale under Article 23 of the Act | Article 32 and 33 of the Act | | | |
| a. It is rotten or spoiled so that it may injure the health of the human body. | | <manufacturing business> business suspension: 1 month | business suspension: 2 | business suspension: 3 |

| | | | |
|---------------------------------------|----------------------------|---------------------|---------------|
| | and disposal of | months and | months and |
| | product in question | disposal of | disposal of |
| | < | product in | product in |
| | | question | question |
| | import business | | |
| | business suspension: | business | business |
| | 15 days | suspension: 1 | suspension: 2 |
| | and disposal of | month and | months and |
| | product in question | disposal | disposal of |
| | | of product in | product in |
| | | question | question |
| b. It contains or is adhered | business | | |
| with any poisonous or | permission | | |
| detrimental substance, or there | revocation | or | |
| is any possibility thereof, and it is | business | | |
| or may be contaminated with any | establishment | | |
| pathogenic microorganism so that | closure | and | |
| it may injure the health of the | disposal of product | | |
| human body. | in question | | |
| c. It may injure the health of the | <manufacturing | | |
| human body because it is filthy, | business> | | |
| any foreign substance is mixed or | items | business | business |
| added, or there is any other | manufacturing | suspension: 1 month | suspension: 2 |
| reason. | suspension: 1 | and disposal of | months and |
| | month and disposal | product in | disposal of |
| | of product in | question | product in |
| | question | | question |

| | | | | |
|---------------------------------------|-----------------------------------|----------------------|-----------------|-----|
| | <import business, sales business> | | | |
| | business suspension: 7 days | business suspension: | business | |
| | and disposal of | 15 days and | suspension: 1 | |
| | product in question | disposal of | month | |
| | | product in | and disposal of | |
| | | question | product in | |
| | | | question | |
| d. It is manufactured by a person | <manufacturing | | | |
| without business permission under | business> | business | business | |
| Article 5 (1) of the Act. | business | suspension: | 2 suspension: 3 | |
| | suspension: | 1 months | and months | and |
| | month and disposal | disposal | of disposal | of |
| | of product | in product | in product | in |
| | question | question | question | |
| | <import business, sales business> | | | |
| | business | suspension: business | business | |
| | 15 days and disposal | suspension: | 1 suspension: 2 | |
| | of product | in month | and months | and |
| | question | disposal | of disposal | of |
| | | product | in product | in |
| | | question | question | |
| e. It is prohibited from importing or | <manufacturing | | | |
| is imported without the report | business> | | | |
| under Article 8 of the Act. | business | business | business | |
| | suspension: 1 | suspension: 2 | suspension: 3 | |
| | month | months and | months | |
| | and disposal of | disposal of | and disposal of | |

| | | | |
|---|---|--|---|
| | product in question | product in question | product in question |
| | <input type="text" value="business sales business"> | | |
| | business suspension: 15 days and disposal of product in question | business suspension: 1 month and disposal of product in question | business suspension: 2 months and disposal of product in question |
| 14. Violation of Articles 24(1) and (2) of the Act | Article 32 of the Act | | |
| a. When fail to manufacture, use or store the health functional food, whose standards and specifications are determined, in accordance with the standards | item manufacturing business suspension: 1 month and disposal of product in question | business suspension: 1 month and disposal of product in question | business suspension: 2 months and disposal of product in question |
| b. When sell or manufacture, import, use, store, transport or display for sale the health functional food which does not comply with the standards and specifications | business suspension: 15 days and disposal of product in question | business suspension: 1 month and disposal of product in question | business suspension: 2 months and disposal of product in question |
| c. When use the ingredients solely used for medicine | item manufacturing business suspension: 1 month and disposal of product | business suspension: 1 month and disposal of product | business suspension: 2 months and disposal of product |

| | | | |
|--|----------------------------------|---------------|---------------|
| | in question | disposal | disposal of |
| | | of product in | product in |
| | | question | question |
| d. When manufacture the health | | business | business |
| functional food whose | itemmanufacturing | suspension: 1 | suspension: 2 |
| combination, mixture ratio or | suspension: 1 monthand | month and | months and |
| content is identical with or similar | disposal of product | disposal of | disposal of |
| to medicine | in question | product in | product in |
| | | question | question |
| e. When import, sell, or display the | | business | business |
| health functional food whose | business suspension: | suspension: 1 | suspension: 2 |
| combination, mixture ratio or | 15 days and disposal | month and | months and |
| content is identical with or similar | of product in | disposal of | disposal of |
| to medicine | question | product in | product in |
| | | question | questio |
| 15. Violation of Article 25 of the Act | Article | | |
| | 32 of | | |
| | the Act | | |
| a. When manufacture, import or sell | <manufacturing and | | |
| the health functional food that | import business> | | |
| violates the standards of label | business suspension:business | business | |
| under Article 17(1)1 through 5 | 15 days and disposal suspension: | 1 suspension: | 2 |
| of the Act | of product in month | and months | and |
| | question | disposal | of disposal |
| | | product | in product |
| | | question | question |
| | <sales business> | | |

| | | | | |
|--|---------------------|---------------------|---------------------|-----|
| | business | business | business | |
| | suspension: 7 days | suspension: 15 days | suspension: 1 | |
| | and disposal of | and disposal of | month | and |
| | product in question | product | in disposal | of |
| | | question | product | in |
| | | | question | |
| b. When manufacture, import or sell | <manufacturing | and | | |
| the health functional food that | import business> | | | |
| violates the standards of label | order of correction | business | business | |
| under Article 17(1)6 of the Act | | suspension: 15 days | suspension: | |
| | | and disposal of | 1 month | and |
| | | product | in disposal | of |
| | | question | product | in |
| | | | question | |
| | <sales business> | | | |
| | order of correction | business | business | |
| | | suspension: 7 | suspension: 15 days | |
| | | days | and disposal of | |
| | | and disposal | product | in |
| | | of product | in question | |
| | | question | | |
| 16. Violation of Article 26 of the Act | Article | | | |
| | 32 of | | | |
| | the Act | | | |
| a. When make labels upon its | business | business | business | |
| container or package, or | suspension: 1 | suspension: 2 | suspension: 3 | |
| advertising which may mislead | month | months and | months and | |

| | | | | |
|--|--------------------------------------|--|--|---|
| <p>public into thinking that it has sitological or physiological functions and effects, etc. for the human body structure and function, even though it is not a health functional food</p> | | <p>and disposal of product in question</p> | <p>disposal of product in question</p> | <p>disposal of product in question</p> |
| <p>b. When sell, store or display for sale anything that is labelled or advertised as one analogous to health functional food</p> | | <p>business 15 days and disposal product in question</p> | <p>suspension: suspension: of month and disposal of product question</p> | <p>business 1 suspension: months and disposal of product question</p> |
| <p>17. Violation of the order of correction under Article 29 of the Act</p> | <p>Article 32 of the Act</p> | <p>business suspension: 7 days</p> | <p>business suspension: 15 days</p> | <p>business suspension: 1 month</p> |
| <p>18. Violation of Article 30(1) and (3) of the Act</p> | <p>Article 32 of the Act</p> | | | |
| <p>a. When violate the order to take measures necessary for eliminating any hazard to food sanitation to the business person</p> | | <p>business suspension: 7 days</p> | <p>business suspension: 15 days</p> | <p>business suspension: 1 month</p> |
| <p>b. When violate the order to recall or dispose the health functional food in question or violate the order to change the ingredients, manufacturing method,</p> | | <p>business suspension: 1 month</p> | <p>business suspension: 2 months</p> | <p>business suspension: 3 months</p> |

components or mixture ratio of
the health functional food in
question to the business person
upon recognizing that any hazard
to sanitation has occurred or is
deemed to occur

| | | | | |
|---|--------------------------|------------------------------------|------------------------------------|-------------------------------------|
| 19. Violation of order to improve or repair facilities | Article 32 of the Act | business suspension: 15 days | business suspension: 1 month | business suspension: 2 months |
|---|--------------------------|------------------------------------|------------------------------------|-------------------------------------|

| | | | | |
|---|--------------------------|--|--|--|
| 20. When continue to carry on the business in violation of the business suspension order under Article 32(1)8 of the Act | Article 32 of the Act | business permission revocation or business establishment closure | | |
|---|--------------------------|--|--|--|

| | | | | |
|--|--------------------------|---|--|--|
| 21. When a business person continues to suspend his business for six months or more without any justifiable reason under Article 32(1)9 of the Act | Article 32 of the Act | business permission revocation or business establishment closure | | |
|--|--------------------------|---|--|--|

| | | | | |
|--|--------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| 22. When violate the order of suspension of item manufacturing under Article 33 of the Act | Article 32 of the Act | business suspension: 1 month | business suspension: 2 months | business suspension: 3 months |
|--|--------------------------|------------------------------------|-------------------------------------|-------------------------------------|

| | | | | |
|---|---------------|---------------------|--|--|
| 23. Other violations other than subparagraphs 1 through 22 | Article 29 of | order of correction | | |
|---|---------------|---------------------|--|--|

[Annexed the Table 10] <Amended on November 20, 2006>

The penalty surcharge exemption (relating to Article 33)

If it falls under any of the following subparagraph, among the individual standard of the Table 9 relating to Article 31, the penalty surcharge shall not be imposed in lieu of business suspension, item or items manufacturing suspension.

1. Where it falls under subparagraph 7c;
2. Where it falls under subparagraphs 10a through e;
3. Where it falls under subparagraphs 13d and e;
4. Where it falls under subparagraphs 14c, d and e; or
5. Where it falls under the second violation among the cases that the first violation is subject to the one month or more business suspension.

[Annexed the Table 11] <Amended on November 20, 2006>

Fees (Relating Article 35)

| Section | Fees |
|--|--|
| 1. business permission, modification permission or modification report | |
| a. business permission(initial) | 50,000won |
| b. modification permission or modification report | 30,000won |
| c. business report certificate reissue application | 5,300won |
| 2. business report or modification report | |
| a. business report(initial) | 28,000won |
| b. modification report | 9,300won(where the location modification is included: 26,500won) |
| c. business report certificate reissue application | 5,300won |
| 3. item manufacture report or modification report | |
| a. item manufacture report | 20,000won |
| b. modification report | 10,000won |
| c. item manufacture report reissue application | 5,300won |

4. import report, import examination, pre-confirmed registration application of import health functional food

20,000won

a. import report

Based on the Examination Fees Table

b. import examination

determined by the regulation of the Food and Drug Administration and the Korea Center for Disease Control and Prevention Examination Request

c. pre-confirmed registration application

(1) initial registration

28,000won (However, the domestic and foreign travel expenses for on-site inspection shall be determined by the Commissioner of the Food and Drug Administration)

(2) modification registration

17,000won

5. application for recognition of the standards and specifications

100,000won (However, additional fees for examination shall be determined based on the Examination Fees Table determined by the regulation of the Food and Drug Administration and the Korea Center for Disease Control and Prevention Examination Request)

| | |
|---|--|
| <p>6. application for recognition of the functionality ingredients or components</p> | <p>100,000won</p> |
| <p>7. application for the functionality labeling or the deliberation of advertising</p> | <p>100,000won</p> |
| <p>8. entrusted examination of self quality examination</p> | <p>Based on the fees regulation of food sanitation examination laboratories designated under Article 18 of Food Sanitation Act</p> |
| <p>9. Good Manufacturing Practices standards application business establishment designation</p> | |
| <p>a. initial application</p> | <p>200,000won</p> |
| <p>b. modification application</p> | <p>100,000won</p> |
| <p>10. business person status succession report</p> | <p>9,300won</p> |
| <p>11. English certificate application</p> | <p>2,000won each</p> |

[Annexed the Table 12]

Standard of fine for negligence imposition (relating to Article 36)

1. Health functional food manufacture business

| No. | Type of violation | Amount |
|-----|---|--------------|
| 1 | Business person who fails to make or keep for three years documents on production and work operation and related documents on delivery, shipment and use of ingredient receipts and disbursements | 1,000,000won |
| 2 | Business person who fails to use water recognized that it is suitable to drink as the result of the yearly (every six months for drinking-form health functional food) analysis in accordance with the drinking water standards under Article 5 of the Management of Drinking Water Act by a drinking water examination laboratory under Article 35 of the Management of Drinking Water Act, when using underground water, etc. that is not tap water | 1,000,000won |
| 3 | Business person who manufacture health functional food by entrustment or request from any person who does not obtain the business permission or file the business report under this Act | 1,000,000won |
| 4 | Business person who fails to comply with the regulation on the genetic modification that is determined and publicly announced by the Commissioner of the Food and Drug Administration when manufacturing health functional food with the genetic modification technology | 1,000,000won |
| 5 | Business person who fails to recall voluntarily the product in question or keep the record for two years when the delivered health functional food has any problem with safety or functionality or it is | 1,000,000won |

| | | |
|----|--|------------|
| | of inferior quality | |
| 6 | Business person who fails to have the transaction details including name of sales business establishment, name of product, amount, date of providing, etc. and the returning details or keep them for two years | 500,000won |
| 7 | Business person who fails to keep the certificate that proves the reasons such as the identity preserved handling certificate, etc. for two years from the date of manufacture when manufacturing or manufacturing and selling the health functional food subject to the genetic modification labeling but not making label that it is genetically modified food | 500,000won |
| 8 | Business person who fails to report, without delay, to the business permission authority or the report authority, and take necessary safe measures, when verifying the hazardous facts (including side-effect cases) that have a bad effect on the public health in relation to the health functional food | 500,000won |
| 9 | Business person who has taken the post measures in accordance with the administrative measures after receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc. but fails to report, without delay, to the disposition authority | 500,000won |
| 10 | Business person who fails to keep the business permission certificate, the item manufacture report certificate, the self standards and specifications recognition documents, and the functionality labeling and advertising pre-deliberation certificate. | 300,000won |

2. Health functional food import business

| NO. | Type of violation | Amount |
|-----|---|--------------|
| 1 | Business person who fails to keep the import report certificate, the shipping document and content list (invoice) and the sale record for two years from the import date or until the sell-by-date if the sell-by-date is two years and more | 1,000,000won |
| 2 | Business person who fails to comply with the regulation on the genetic modification that is determined and publicly announced by the Commissioner of the Food and Drug Administration when importing health functional food manufactured with the genetic modification technology | 1,000,000won |
| 3 | Business person who fails to recall voluntarily the product in question or keep the record for two years, when the imported health functional food has any problem with safety or functionality or it is of inferior quality, | 1,000,000won |
| 4 | Business person who fails to have the transaction details including name of sales business establishment, name of product, amount, date of providing, etc. and the returning details and keep them for two years | 500,000won |
| 5 | Business person who fails to keep the certificate that proves the reasons such as the identity preserved handling certificate, etc. for two years from the date of import, when importing the health functional food subject to the genetic modification labeling but not making label that it is genetically modified food | 500,000won |
| 6 | Business person who fails to report, without delay, to the report authority of the business, and take necessary safe measures, when verifying the hazardous facts (including side-effect cases) | 500,000won |

| | | |
|---|---|------------|
| | that have a bad effect on the public health in relation to the health functional food | |
| 7 | Business person who fails to keep the business report certificate, the standards and specifications recognition certificate and the functionality labeling and advertising pre-deliberation certificate | 300,000won |
| 8 | Business person who has taken the post measures in accordance with the administrative measures after receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc. but fails to report, without delay, to the disposition authority | 300,000won |

3. Health functional food sales business

| NO. | Type of violation | Amount |
|-----|---|------------|
| 1 | Business person who fails to keep the business report certificate and the functionality labeling and advertising pre-deliberation certificate | 300,000won |
| 2 | Business person who fails to keep the details of the health functional food provided for two years | 300,000won |
| 3 | Business person who has taken the post measures in accordance with the administrative measures after receiving the administrative measures necessary to take post measures, such as order of correction, sanction of disposal, order to improve or repair facilities, etc. but fails to report, without delay, to the disposition authority | 300,000won |

| | | | | | | |
|---|----------------------|--|-----------|------|--|------------|
| <h2 style="margin: 0;">Business Permission Application</h2> <p style="margin: 5px 0;"> <input type="checkbox"/> Health functional food specializing manufacture business <input type="checkbox"/> Health functional food venture manufacturing business </p> <p style="margin: 0;">※ Refer to application guideline</p> | | Treatment period 14 days | | | | |
| Applicant | ① Name | ② Resident registration No. | | | | |
| | ③ Address | (Tel.: _____) | | | | |
| | ④ Trade name (title) | | | | | |
| | ⑤ Place | (Tel.: _____) | | | | |
| <p style="text-align: center;">I apply business permission under Article 5(1) of the 「Health Functional Food Act」 and Article 3 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD): _____</p> <p style="text-align: center;">Applicant _____ (signature or seal)</p> | | | | | | |
| To the Commissioner of the Food and Drug Administration | | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">Fee stamp</td> <td style="text-align: center;">Fees</td> </tr> <tr> <td style="height: 20px;"></td> <td style="text-align: center;">50,000 won</td> </tr> </table> | Fee stamp | Fees | | 50,000 won |
| Fee stamp | Fees | | | | | |
| | 50,000 won | | | | | |
| <p>※ Documents required</p> <ol style="list-style-type: none"> 1. Health functional food specializing manufacturing business <ol style="list-style-type: none"> a. The type of product to manufacture and the manufacturing method document b. Arrangement plan of manufacturing facilities and list of main machinery and apparatus c. Land use plan confirmation and certified copy of building administrative register d. Quality management appointment report under Article 16 e. Education certificate under Article 13(2) (limited to the case where the education has been received in advance) f. The written result of water analysis by a drinking water examination laboratory under Article 35 of the Management of Drinking Water Act (limited to the case where the underground water, etc. which is not tap water, is used for drinking water, or manufacturing process or washing, etc. of Health Functional Food) 2. Health functional food venture manufacturing business | | | | | | |

- a. Copy of venture business confirmation under Article 25 of Act on Special Measures for the Promotion of Venture Business
- b. Technical data on the functional ingredients and components of health functional food
- c. The type of product to manufacture and the manufacturing method document
- d. Quality management appointment report under Article 16
- e. The document of manufacturing entrustment contract with a health functional food manufacture- specializing business
- f. Education certificate under Article 13(2) (limited to the case where the education has been received in advance)

210 mm×297 mm(general paper 60g/m²(recycled product))

※

Application

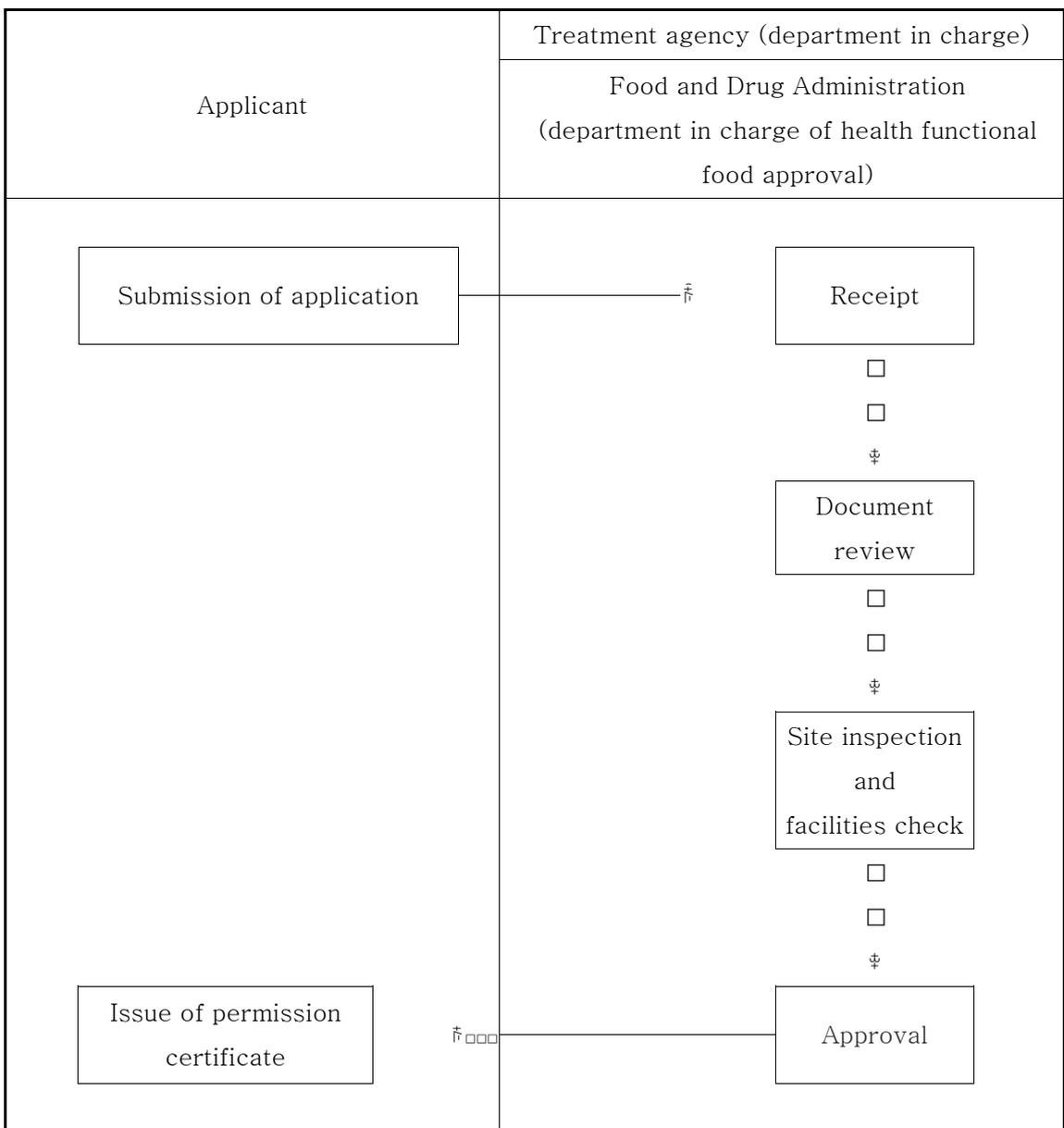
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guidance

| | |
|------------------|--|
| Agency submitted | Food and Drug Administration |
| Notice | <ol style="list-style-type: none"> 1. In case falling Restrictions on business permission, etc. under Article 9 of the Act , no business permission shall be granted. <ul style="list-style-type: none"> - To confirm the case of Restrictions on business permission, etc. and identify business person, give information on birth place, the householder of business person etc. to permission agency. 2. The matters shall not be in the violation of Act of building, Act of city planning, and other related Act. 3. When Business permission is applied, it shall be submitted with the application of item manufacture report. 4. Where a person, who intends to discontinue the business, shall report it. |

| | |
|--|--|
| | <p>5. Where a person, who carries on business without permission, shall be punished by imprisonment for not more than seven years or a fine not exceeding one hundred million won. In this case, imprisonment and a fine may be imposed concurrently.(Article 43 of Health Functional Food Act).</p> |
|--|--|

This application is processed as below:



No.

Business Permission Certificate

Name of business establishment :

Place of business establishment :

Representative :

Resident registration number :

Address :

Type of business :

Permission conditions :

I permit the health functional food () manufacturing business under and Article 5(1) of the 「Health Functional Food Act」 and Article 3 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

the Commissioner of the Food and Drug Administration (seal)

Health Functional Food (Specializing.Venture) Manufacturing

Business Permission Administrative Register

1. Business permission matter [GMP designation: Yes or No]

| | | | | |
|---------------------------------------|---|-------------------|---------------------|------------|
| ① Name of business establishment | | Joint seal | | |
| ② Business report No. | No. | ③ Permission date | (YY/MM/DD): | |
| ④ Place of the business establishment | Head office | (Tel.:) | | |
| | Factory | (Tel.:) | | |
| ⑤ Representative | Name | | | |
| | Resident registration No. | - | | |
| | Address | | | |
| ⑥ Business report condition | | | | |
| ⑦ Major product items | | | | |
| ⑧ Entrusted with manufacturing | Name of business establishment on consignment | Permission No. | Date of consignment | |
| | | | Beginning | Completion |
| | | | | |
| | | | | |
| | | | | |

2. Business permission matter, modification permission and report

| | | | | | |
|--------------------|----------|---------------------------|--------------------|----------|---------------------------|
| Date (YY/MM/DD) | Contents | Recorder position.name | Date (YY/MM/DD) | Contents | Recorder position.name |
|--------------------|----------|---------------------------|--------------------|----------|---------------------------|

5. Remarks

| |
|--|
| |
|--|

(page 3)

6. Other matters of administrative measures

| Date (YY/MM/DD) | Classification | Content of measures | Recorder position.name |
|-----------------|----------------|---------------------|------------------------|
| | | | |

7. Administrative sanction matters

| Sanction date (YY/MM/DD) | Documents No. | Violation matters | Sanction contents and period | Recorder position.name |
|-----------------------------|------------------|----------------------|---------------------------------|---------------------------|
|-----------------------------|------------------|----------------------|---------------------------------|---------------------------|

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

[Annexed the Form 4]

| | |
|--|------------------|
| Business Permission Certificate Reissue | Treatment period |
| | Immediately |

| Application | | | | |
|--|----------------------|--|------|-----------|
| <input type="checkbox"/> Health functional food specializing manufacture business <input type="checkbox"/> Health functional food venture manufacturing business | | | | |
| Applicant | ① Name | ② Resident registration No. | | |
| | ③ Address | (Tel: _____) | | |
| | ④ Trade name (title) | | | |
| | ⑤ Place | (Tel: _____) | | |
| Reissue reason | | | | |
| <p style="text-align: center;">I apply business permission certificate reissue under Article 3(4) of the Enforcement Rule of the 「Health Functional Food Act」 .</p> <p style="text-align: center;">Date (YY/MM/DD): _____</p> <p style="text-align: center;">Applicant _____ (signature or seal)</p> <p style="text-align: center;">To the Commissioner of the Food and Drug Administration</p> | | | | |
| ※ Documents required Permission certificate if the permission certificate is worn-out. | | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">Fees</td> </tr> <tr> <td style="text-align: center;">5,300 won</td> </tr> </table> | Fees | 5,300 won |
| Fees | | | | |
| 5,300 won | | | | |

210 mm×297 mm(general paper 60g/m²(recycled product))

This application is processed as below:

| | |
|-----------|---|
| Applicant | Treatment agency (department in charge) |
|-----------|---|

| | |
|---|--|
| | Food and Drug Administration (department in charge of health functional food approval) |
| <div style="border: 1px solid black; padding: 5px; margin-bottom: 20px; width: 80%; margin-left: 20px;"> Submission of application </div> | <div style="border: 1px solid black; padding: 5px; margin-bottom: 20px; width: 80%; margin-left: 20px;"> Receipt </div> <div style="text-align: center; margin: 10px 0;"> <input type="checkbox"/> ₩ </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 20px; width: 80%; margin-left: 20px;"> Review </div> <div style="text-align: center; margin: 10px 0;"> <input type="checkbox"/> ₩ </div> |
| <div style="border: 1px solid black; padding: 5px; width: 80%; margin-left: 20px;"> Issue </div> | <div style="border: 1px solid black; padding: 5px; margin-bottom: 20px; width: 80%; margin-left: 20px;"> Approval </div> |

210 mm×297 mm(general paper 60g/m²(recycled product))

[Annexed the Form 5] <Amended on Nov. 20, 2006>

(front)

| | |
|---|------------------|
| Modified Matters on Health Functional Food | Treatment period |
|---|------------------|

| | | | |
|---|--|--|--|
| (Specializing .Venture) Manufacturing Business | | | |
| Permission application | | <input type="checkbox"/> Permission <input type="checkbox"/> Report | |
| ① Name | | ② Resident registration No. | - |
| ③ Name of business establishment | | ④ Permission No. | |
| ⑤ Modification matters | | | |
| Classification | | before modification | after modification |
| Place of the business establishment | | | |
| Name of juridical person representative | | | |
| Title or trade name of business establishment | | | |
| Workplace, health functional food handling facilities or water supply facilities among the manufacturing facilities | | (attached modification contents or floor plan) | (attached modification contents or floor plan) |
| Title or trade name of the manufacturing establishment which is entrusted with manufacturing health functional food | | | |
| ⑥ Modification reason | | | |
| <p>I apply (report) a modification of health functional food manufacture business under Article 5 of the 「Health Functional Food Act」 and Article 4 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Applicant (Reporter) (signature or seal)</p> | | | |
| To the Commissioner of the Food and Drug Administration | | Fee stamp | Fees |
| | | | 30,000 won |
| <p>※ Documents required</p> <p>1. Modification permission of permission matters (limited to place of the business establishment)</p> | | | |

modification)

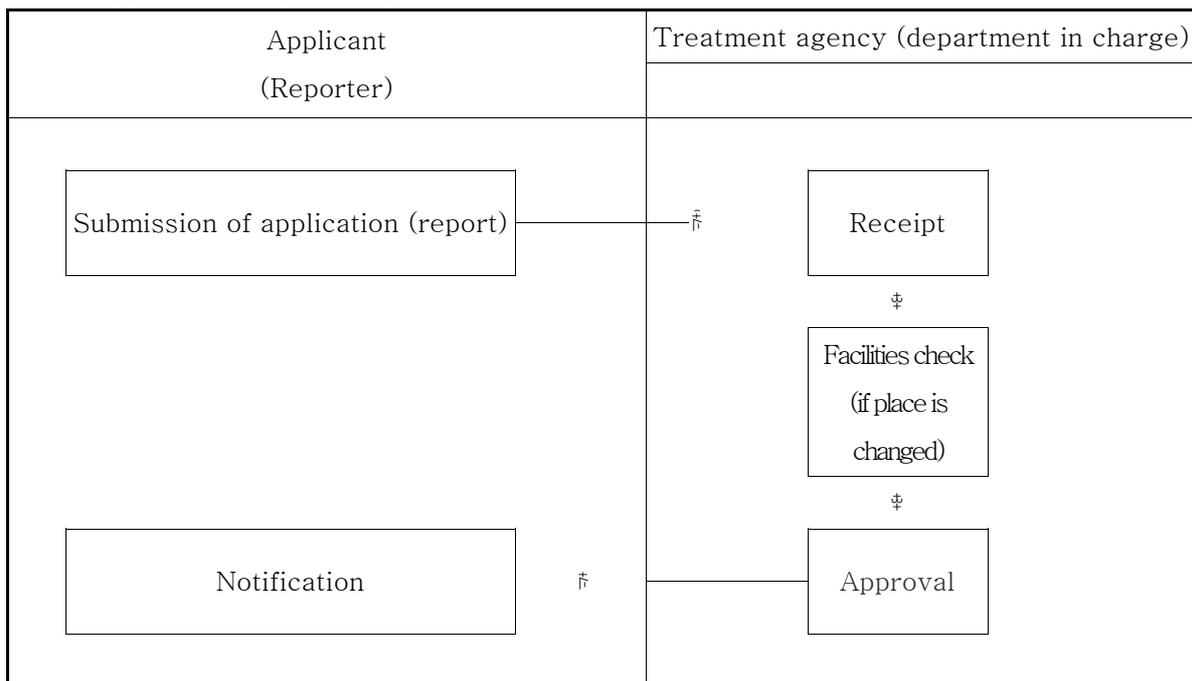
- a. Business permission certificate
 - b. Arrangement plan of manufacturing facilities and list of main machinery and apparatus
 - c. Land use plan confirmation and certified copy of building administrative register
 - d. The written result of water analysis by a drinking water examination laboratory under Article 35 of the Management of Drinking Water Act (limited to the case where the underground water, etc. which is not tap water, is used for drinking water, or manufacturing process or washing, etc. of health functional food).
2. Modification report of permission matters
- a. A copy of business permission certificate
 - b. Workplace from among manufacturing facilities, modification contents on handling facilities or water supply facilities of the health functional food (including floor plan)
 - c. Document of manufacturing entrustment (limited to the case of health functional food manufacturing venture business)

210 mm×297 mm(general paper 60g/m²(recycled product))

(back)

| | | | |
|---|------------------------------|------------------|--|
| Agency submitted | Food and Drug Administration | Treatment period | 1. modification permission 14 days 2. modification report: 7 days |
| <p>※ Notice</p> <p>1. Among permission matters, when the place of business establishment is changed, modification permission shall be granted.</p> <p>2. Among permission matters, when the following matters are changed, the modification matters shall be reported:</p> <p>a. the name of the representative (limited to a juridical person);</p> <p>b. title or trade name of the business establishment;</p> <p>c. workplace, health functional food handing facilities or water supply facilities among the manufacturing facilities (limited to the health functional food specializing manufacturing business); or</p> <p>d. title or trade name of the manufacturing establishment which is entrusted with manufacturing health functional food (limited to the health functional food venture manufacturing business)</p> <p>3. The modification report for the succession status of business status under Article 11 of the Act is excluded.</p> | | | |

This application (report) is processed as below:



| | | | |
|---|----------------------|---------------------------------------|------------------------------|
| Business Report | | | Treatment period |
| <input type="checkbox"/> health functional food import business <input type="checkbox"/> health functional food sales business | | | Immediately |
| ※ Refer to report guidance | | | |
| Applicant | ①Name | | ② Resident registration No. |
| | ③Address | (Tel.:) | |
| | ④ Trade name (title) | | ⑤ Detailed types of business |
| | ⑥Place | (Tel.:) | |
| <p>I report a business under and Article 6 of the 「Health Functional Food Act」 and Article 5 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Applicant (signature or seal)</p> | | | |
| To the Commissioner of the Regional Food and Drug Administration or To the Head of local government | | Fee stamp or import certificate stamp | Fees |
| | | | 28,000won |
| ※ Documents required <ol style="list-style-type: none"> 1. Arrangement plan of business facilities 2. Education certificate under Article 13(2) of the Act (limited to the case when the education has been received in advance) 3. Storage facility lease contract document (limited to the case where a storage facility is leased) 4. Document of manufacturing entrustment contract with health functional food | | | |

manufacture- specializing business (limited to health functional food distribution specializing sales business)

210 mm×297 mm(general paper60g/m²(recycled product))

※ Report guidance

(back)

<Business that shall be reported to the Commissioner of the Regional Food and Drug Administration>

- health functional food import business

<Business that shall be reported to the Head of local government>

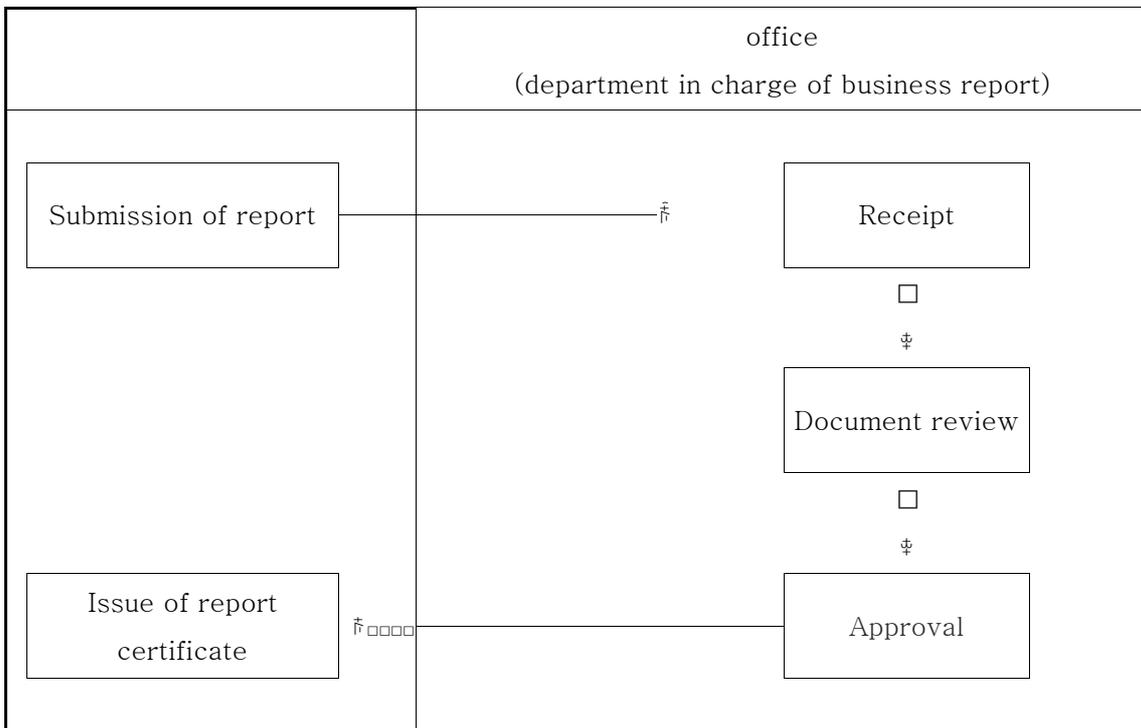
- health functional food sales business

※ Notice

1. In case falling restrictions on business permission, etc., under Article 9 of the Act, no business permission shall be granted.
 - To confirm the case of restrictions on business permission, etc. and identify business person, give information on birth place, the householder of business person etc. to report agency.
2. When a person who intends to discontinue the reported business, it shall be reported.
3. Any person who carries on business without report shall be punished by imprisonment for not more than five years or a fine not exceeding fifty million won. In this case, imprisonment and a fine may be imposed concurrently.(Article 44 of the Health Functional Food Act).
4. Any person who intends to report the business report shall examine whether the matters be violated or conflicted with the following Acts and subordinate statutes related to business report, in addition to the Acts and subordinate statutes under the provisions of Article 4 of the Rule:
 - National Land Utilization Act, Act on the Disposal of Sewage, Excreta and Livestock Wastewater, Farmland Act, School Health Act, Outdoor Advertisement, etc. Control Act, River Act, Act on the Improvement of Water Quality Support for Residents of the Riverhead of the Han River System, Water Quality Conservation Act, Noise and Vibration Control Act, Tourism Promotion Act, Act on the Establishment and Operation of Private Teaching Institutes, Juvenile Protection Act, Labor Standards Act, Industrial Placement and Factory Construction Act, Parking Lot Act, Local Tax Act, etc. and any other related Acts.

This application is processed as below:

| | |
|----------|---|
| Reporter | Treatment agency(department in charge) |
| | Regional Food and Drug Administration, <i>Si/Gun/Gu</i> |



[Annexed the Form 7] <Amended on November 20, 2006>

(front)

No.

Business Report Certificate

Name of business establishment:

Place of business establishment:

Representative:

Resident registration number:

Address:

Type of business: Health functional food import business

Report conditions:

I accept the business report under Article 6 of the 「Health Functional Food Act」 and Article 5 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

the Commissioner of the Regional Food and Drug Administration (seal)

210 mm×297 mm(preservative paper(1 class)120g/m²)

(back)

No.

Business Report Certificate

Name of business establishment:

Place of business establishment:

Representative:

Resident registration number:

Address:

Type of business: Health functional food sales business

(detailed types:)

Report conditions:

I accept the business report under Article 6 of the 「Health Functional Food Act」 and Article 5 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

the Head of local government (seal)

210 mm×297 mm(preservative paper(1 class)120g/m²)

(back)

Health Functional Food

Import Business Report Administrative Register

1. Business report matters

| | | | | |
|---------------------------------------|---------------------------|------------------------|-------------------|-----------------|
| ①Name of business establishment | | | Joint seal | |
| ②Business report No. | No. | ③Report acceptance day | (YY/MM/DD): | |
| ④ Place of the business establishment | Head office | (Tel.:) | | |
| | Business place | (Tel.:) | | |
| ⑤ Representative | Name | | | |
| | Resident registration No. | - | | |
| | Address | | | |
| ⑥ Business report condition | | | | |
| ⑦ Import registration item | Name of product | Registration No. | Registration date | Recognition No. |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

2. Modification report contents of business report matters

| Date (YY/MM/DD) | Modification contents | Recorder position.name | Date (YY/MM/DD) | Modification contents | Recorder position.name |
|--------------------|-----------------------|------------------------|--------------------|-----------------------|------------------------|
| | | | | | |

210 mm×297 mm(preservative paper(1 class)120g/m²)

3. Scale of business establishment

| Scale of business place | | Number of employees | | |
|--|---|---------------------|--------|---------|
| ① Ground area | m ² | ④ Whole personnel | | persons |
| ② Building area | m ² | ⑤ Head office | | persons |
| ③ Business place area | subtotal m ² | ⑥ Business place | Office | persons |
| -business establishment | m ² | | Sales | persons |
| -warehouse | m ² | | Others | persons |
| ⑦ Classification of building ownership | own. lease (security money won, monthly rent won) | | | |

4. Remarks

5. Other matters of administrative measures

| Date (YY/MM/DD) | Classification | Content of measures | Recorder |
|-----------------|----------------|---------------------|----------|
| | | | |

6. Administrative sanction matters

| Sanction date (YY/MM/DD) | Documents No. | Violation matters | Sanction contents and period | Recorder position.name |
|-----------------------------|------------------|----------------------|---------------------------------|---------------------------|
| | | | | |

Health Functional Food (General Distribution Specializing)

Sales Business Report Administrative Register

1. Business report matters

| | | | |
|---|---|------------------------------|-------------|
| ① Name of business establishment | | Joint seal | |
| ② Business report No. | | ③ Report acceptance day | (YY/MM/DD): |
| ④ Place of the business establishment | Head office | (Tel.:) | |
| | Business place | (Tel.:) | |
| ⑤ Representative | Name | | |
| | Resident registration No. | - | |
| | Address | | |
| ⑥ Business report condition | | ⑦ Detailed types of business | |
| ⑧ Classification of business type for health functional food general sales business | Business place sales, Door-to-door sales, Telephone solicit sales, Electronic commerce, Mail order sales, Multi-level sales, Others () | | |

2. Modification report contents of business report matters

| Date (YY/MM/DD) | Modification contents | Recorder position.name | Date (YY/MM/DD) | Modification contents | Recorder position.name |
|--------------------|-----------------------|------------------------|--------------------|-----------------------|------------------------|
| | | | | | |

3. Scale of business establishment

| Scale of business place | | Number of employees | | |
|--|---|---------------------|---------|---------|
| ① Ground area | m ² | ④ Whole personnel | persons | |
| ② Building area | m ² | ⑤ Head office | persons | |
| ③ Business place area -business establishment -warehouse | subtotal m ² | ⑥ Business place | Office | persons |
| | m ² | | Sales | persons |
| | m ² | | Others | persons |
| ⑦ Classification of building ownership | own.lease(security money won, monthly rent won) | | | |

4. Remarks

5. Other matters of administrative measures

| Date (YY/MM/DD) | Classification | Content of measures | Recorder position.name |
|-----------------|----------------|---------------------|------------------------|
| | | | |

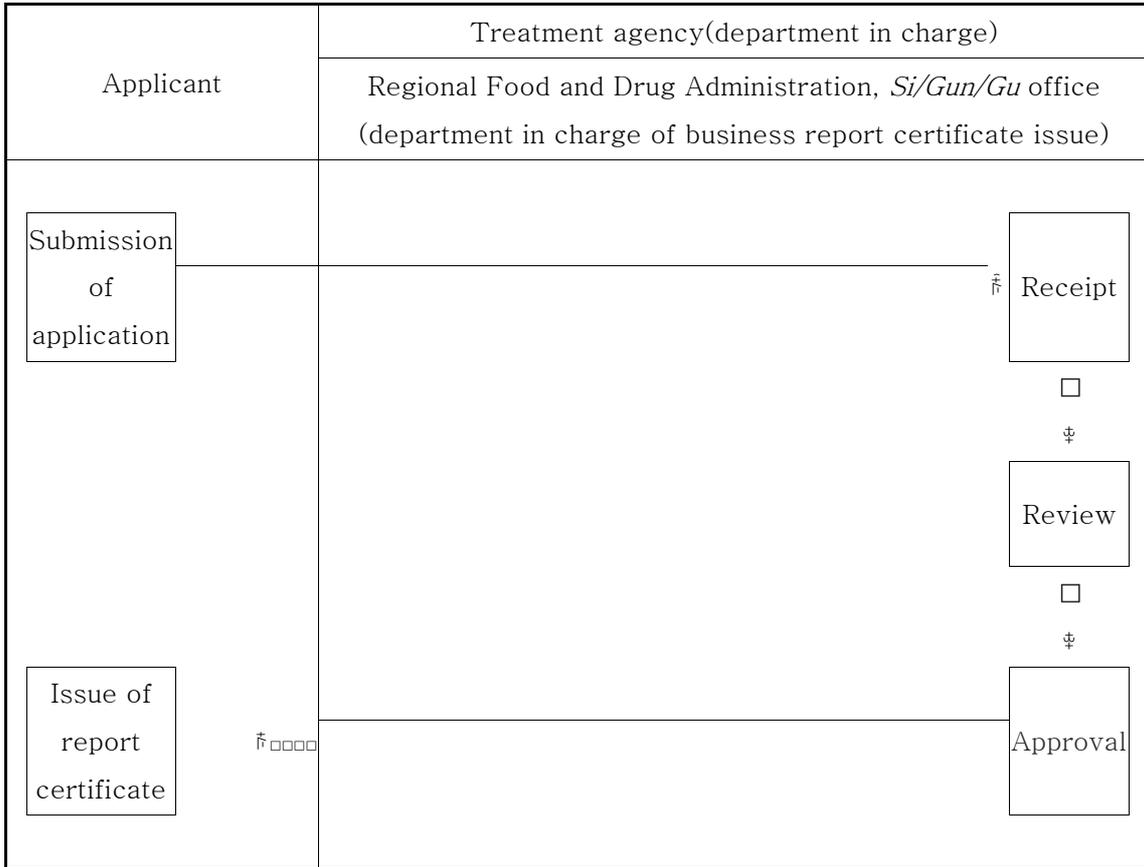
6. Administrative sanction matters

| Sanction date (YY/MM/DD) | Documents No. | Violation matters | Sanction contents and period | Recorder position.name |
|-----------------------------|------------------|----------------------|---------------------------------|---------------------------|
| | | | | |

[Annexed the Form 12] <Amended on November 20, 2006>

| | | | | |
|---|-------------------|----------------|---------------------------|------------------|
| <h2 style="margin: 0;">Business Report Certificate Reissue Application</h2> <p style="margin: 0;"> <input type="checkbox"/> health functional food import business <input type="checkbox"/> health functional food sales business </p> | | | | Treatment period |
| | | | | Immediately |
| Applicant | Name | | Resident registration No. | - |
| | Address | (Tel.: _____) | | |
| | Trade name(title) | | Type of business | |
| | Place | (Tel.: _____) | | |
| Reason | | | | |
| <p>I apply a business report certificate reissue under Article 5 of the 「Enforcement Rule of the Health Functional Food Act」 .</p> <p style="text-align: center;">Date (YY/MM/DD): _____</p> <p style="text-align: center;">Applicant _____ (signature or seal)</p> <p>To the Commissioner of the Regional Food and Drug Administration or To the Head of local government</p> | | | | |
| <p>※ Notice</p> <p>Health functional food import business shall be submitted to the Commissioner of the Regional Food and Drug Administration and health functional food sales business shall be submitted to the head of local government</p> <p>※ Documents required</p> <p>Permission certificate if the permission certificate is worn-out.</p> | | | | Fees |
| | | | | 5,300 won |

This application is processed as below:



210 mm×297 mm [general paper60g/m²(recycled product)]

<The business type that the modification shall be reported to the Commissioner of the Regional Food and Drug Administration>

- Health functional food import business

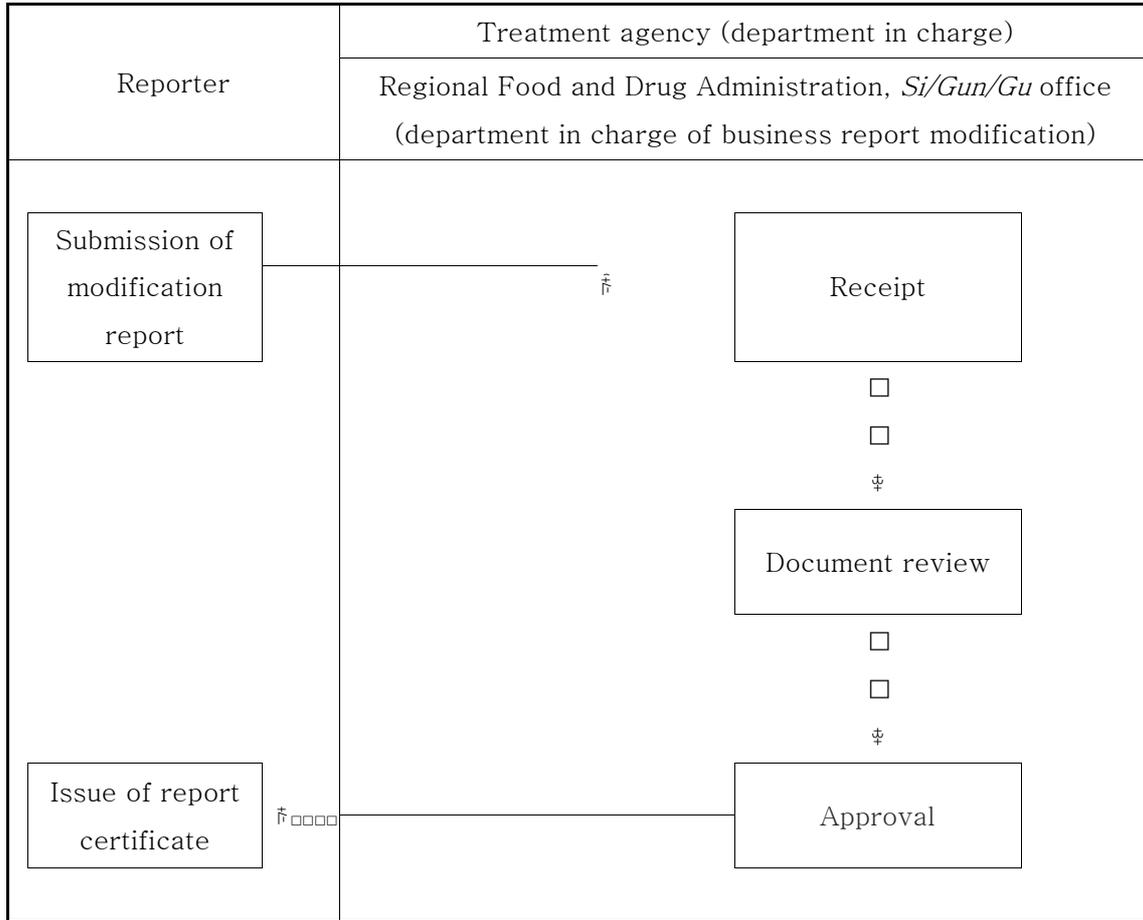
<The business type that the modification shall be reported to the head of *Si/Gun/Gu*>

- Health functional food sales business

※ Notice

1. If the following reported matters are modified, the matters shall be reported to the report authorities.
 - a. The name of the representative (limited to a juridical person)
 - b. The title or trade name of the business establishment
 - c. Place of the business establishment
 - d. Place of storage facility (limited to the case where a storage facility is leased.)
 - e. The title or trade name of the manufacturing establishment that is entrusted with manufacturing the health functional food (limited to health functional food distribution specializing sales business)
2. The modification of the business status succession under Article 11 of the Health Functional Food Act is excluded.
3. A person who does not report the modification shall be punished by administrative measurement and fine for negligence not exceeding three million won under Article 47(1) of the Health Functional Food Act.

This application is processed as below:



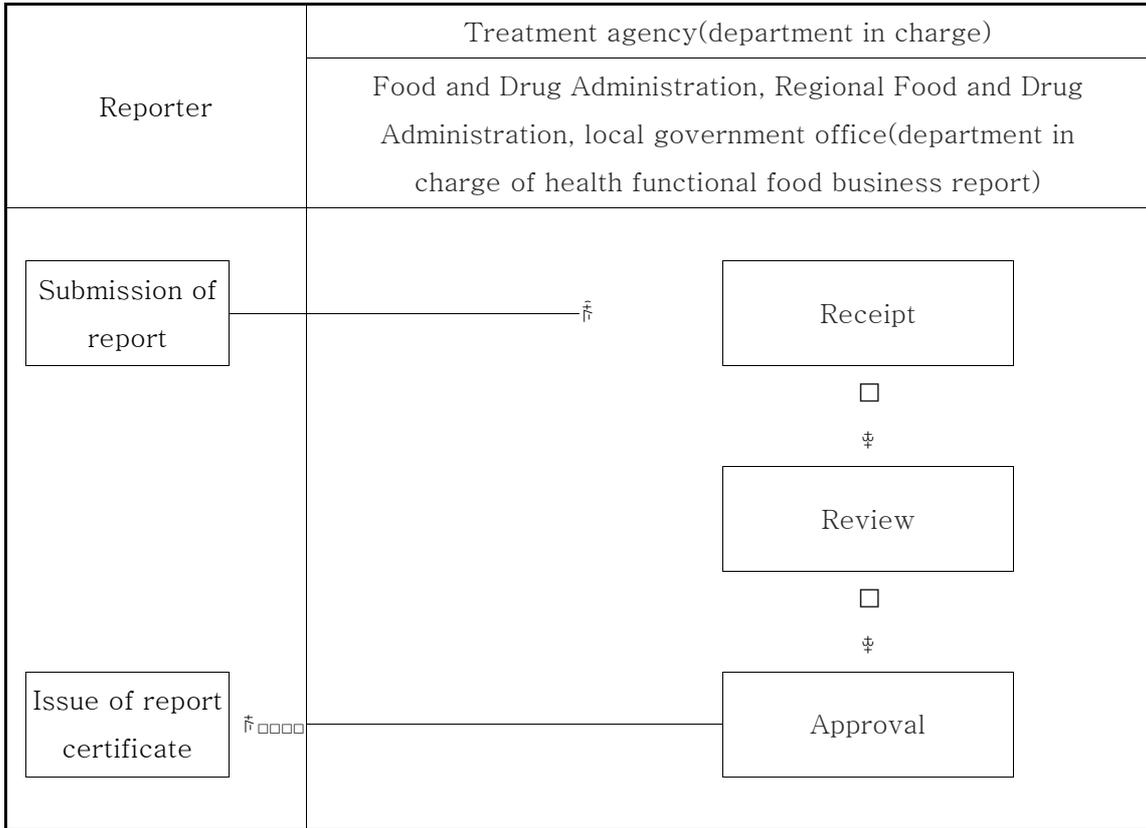
[Annexed the Form 14] <Amended on November 20, 2006>

| Business Discontinuance Report | | | Treatment period |
|--|-------------|----------------------------------|------------------|
| | | | Immediately |
| Applicant | ① Name | ② Resident registration No. | - |
| | ③ Address | (Tel.: _____) | |
| Business establishment | ④ Type | ⑤ Name of business establishment | |
| | ⑥ Place | (Tel.: _____) | |
| ⑦ Discontinuance date | (YY/MM/DD): | | |
| ⑧ Reason | | | |
| <p>I report a business discontinuance under Article 5(2) or Article 6(3) of the 「Health Functional Food Act」 and Article 7 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter _____ (signature or seal)</p> <p>To the Commissioner of the Food and Drug Administration or To the Commissioner of the Regional Food and Drug Administration or To head of local government</p> | | | |
| ※ Documents required | | | Fees |
| A business permission certificate or a business report certificate | | | free |

※ Report guidance

A person who intends to file a business discontinuance report shall report to the permission authorities or the report authorities within one month after the discontinuance.

This application is processed as below:



210 mm×297 mm(general paper60g/m²(recycled product))

| Health Functional Food Item Manufacture Report | | | |
|--|----------------------------------|---------------------------|------------------------------------|
| Reporter | ① Name | | ② Resident registration No. |
| | ③ Address | | |
| Business establishment | ④ Name of business establishment | | |
| | ⑤ Place | | |
| ⑥ Items of product or recognition No. | | ⑦ Business permission No. | No. |
| ⑧ Name of product | | ⑨ Sell-by date | Date (month/year) from manufacture |
| ⑩ Contents of ingredients or components | | | |
| ⑪ Consumption amount and consumption method | | | |
| ⑫ Warning notice for consumption | | | |
| ⑬ Packaging method and packing unit | | | |
| ⑭ Type of product | | | |
| ⑮ Main functionality | | | |
| <p>I report a item manufacture of health functional food under and Article 7 of the 「Health Functional Food Act」 and Article 8 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter (signature or seal)</p> | | | |
| To the Commissioner of the Food and Drug Administration | Fee stamp | | Fees |
| | | | 20,000won |
| <p>※ Documents required</p> <p>1. A manufacturing method document (including the document for the establishment of sell-by date)</p> | | | |

2.Name and contents of ingredients or components

3. The examination result of the standards and specifications (limited to the health functional food product complied with the standards and specifications)

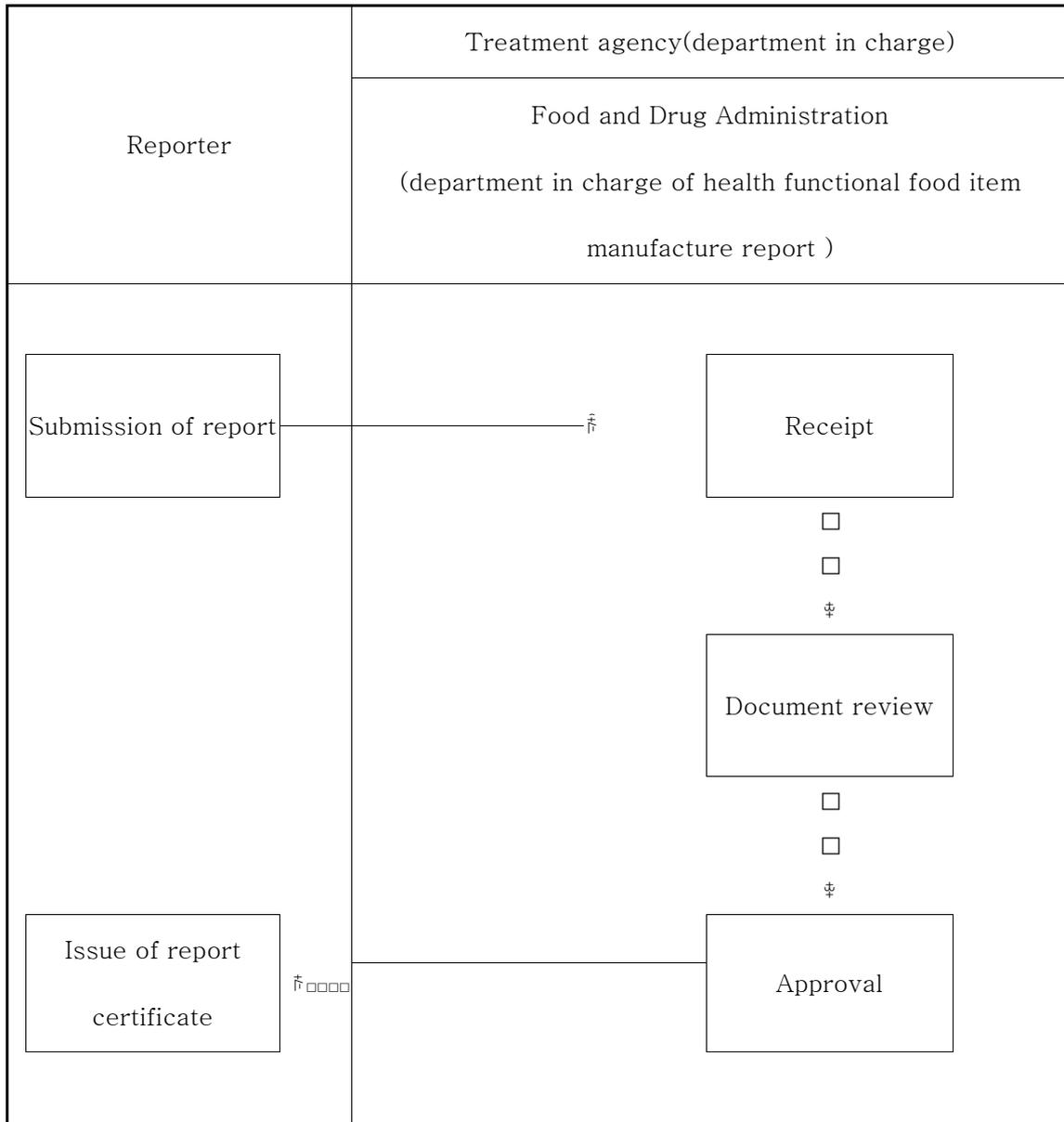
210 mm×297 mm(general paper60g/m²(recycled product))

※ Report guidance

(back)

| Agency submitted | Food and Drug Administration | Treatment period | 7 days |
|------------------|--|------------------|--------|
| Notice | <p>1. An item manufacture report shall be filed again if the functionality of the product in question is changed due to the modification of content of the main ingredients or the major components that have the functionality.</p> <p>2. A person who manufactures and sells a product without filling an item manufacturing report required shall be punished by imprisonment for not more than five years or a fine not exceeding fifty million won under Article 44 of the Health Functional Food Act. In this case, imprisonment and a fine may be imposed concurrently.</p> | | |

This application is processed as below:



No.

**Health Functional Food
Item Manufacture Report Certificate**

Business permission (No) : No.

Name of business establishment :

Place :

Type of business :

Name of product : (Type of
item :)

Manufacturing method.contents of ingredients or components.type
of product : (recorded in back)

I accept a report of health functional food item manufacture report
under Article 7 of the 「Health Functional Food Act」 and Article 8
of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

the Commissioner of the Food and Drug Administration (seal)

(back)

| | | |
|--|------------|--|
| ① Manufacturing method, contents of ingredient or component, type of product | | |
| Modification and sanction matters | | |
| ② Date (YY/MM/DD) | ③ Contents | ④ Recorder position.name (signature or seal) |
| | | |

Health Functional Food

Item Manufacture Report Administrative Register

(Name of business establishment : _____)

1. Item manufacture report matters Business permission number No.

| | | | | |
|--|-----|--------------------------|-------------|---------------------|
| ① Item report No. | No. | ② Name of product | | |
| ③ Items of product or recognition No. | | ④ Date of acceptance | (YY/MM/DD): | |
| ⑤ Contents of ingredients or components | | | | |
| ⑥ Main functionality | | | | |
| ⑦ Type of product | | ⑧ Packing unit | | |
| ⑨ Consumption amount and, consumption method, warning notice | | ⑩ Sell-by date | | |
| ⑪ Item manufacture condition | | ⑫ Recorder position.name | position | |
| | | | name | (signature or seal) |

2. Report matters modification report contents

| Name of product | | | Contents of ingredients or components | | |
|--------------------|--------------------------|---------------------------|---------------------------------------|--------------------------|---------------------------|
| Date (YY/MM/DD) | Modification contents | Recorder position.name | Date (YY/MM/DD) | Modification contents | Recorder position.name |

| | | | | | |
|--|--|--|--|--|--|
| | | | | | |
|--|--|--|--|--|--|

210 mm×297 mm(preservative (1class)120g/m²)

(back)

| Sell-by date | | | Remark | | |
|--------------------|-----------------------|-------------------------------|--------|--|--|
| Date (YY/MM/DD) | Modification contents | Recorder position .name | | | |
| | | | | | |

3. Administrative sanction matters

| Sanction date (YY/MM/DD) | Documents No. | Violation matters | Sanction contents and period | Recorder position.name |
|-----------------------------|------------------|-------------------|---------------------------------|---------------------------|
| | | | | |

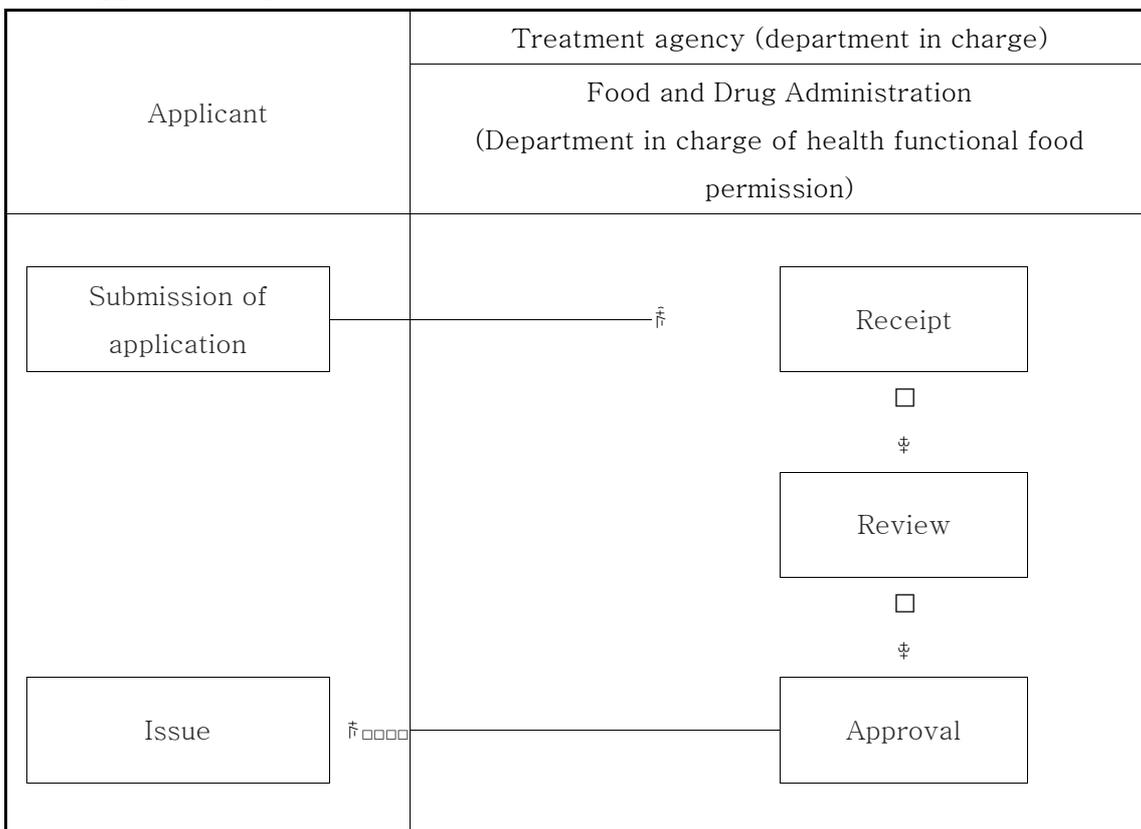
| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

[Annexed the Form (17-2)] <Newly inserted on November 20, 2006>

| | | | |
|---|-----------------------|--------------------------------|------------------|
| Item Manufacture Report Certificate Reissue Application | | | Treatment period |
| | | | Immediately |
| Applicant | Name | Resident registration No. | |
| | Address | (Tel:) | |
| | Trade name (title) | | |
| | Place | (Tel:) | |
| Items of product or recognition No. | | Business permission No. | No. |
| Name of product | | Item manufacture report No. | No. |
| Reissue reason | | | |
| <p>I apply a item manufacture report certificate reissue under Article 8(3) of the Enforcement Rule of the 「Health Functional Food Act」 .</p> | | | |

| | | |
|---|---------------------------------|---------------------|
| Date (YY/MM/DD): | | |
| Applicant | | (signature or seal) |
| To the Commissioner of the Food and Drug Administration | | |
| ※ Documents required | Fee stamps or electric approval | Fees |
| Item manufacture report certificate if the item manufacture report certificate is worn-out. | | 5,300 won |

This application is processed as below:



210 mm×297 mm(general paper 60g/m²(recycled product))

[Annexed the Form 18]

(front)

| Item Manufacture Report Matters Modification Report | | | Treatment period | |
|--|----------------------|---------------------|-----------------------------|-----|
| | | | 5 days | |
| Applicant | ① Name | | ② Resident registration No. | - |
| | ③ Address | | | |
| Business establishment | ④ Trade name (title) | | | |
| | ⑤ Place | | | |
| ⑥ Items of product or recognition No. | | | ⑦ Business permission No. | No. |
| ⑧ Classification | | Before modification | After modification | |
| Name of product | | | | |
| Contents of ingredients | | | | |

| | | |
|---|-------------------------------------|------------|
| or components | | |
| Sell-by date | | |
| ⑨ Modification reason | | |
| <p>I report a modification on the item manufacture report of health functional food under Article 7 of the 「Health Functional Food Act」 and Article 9 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter (signature or seal)</p> | | |
| To the Commissioner of the Food and Drug Administration | Revenue stamp | Fees |
| | | 10,000 won |
| Documents required | Item manufacture report certificate | |

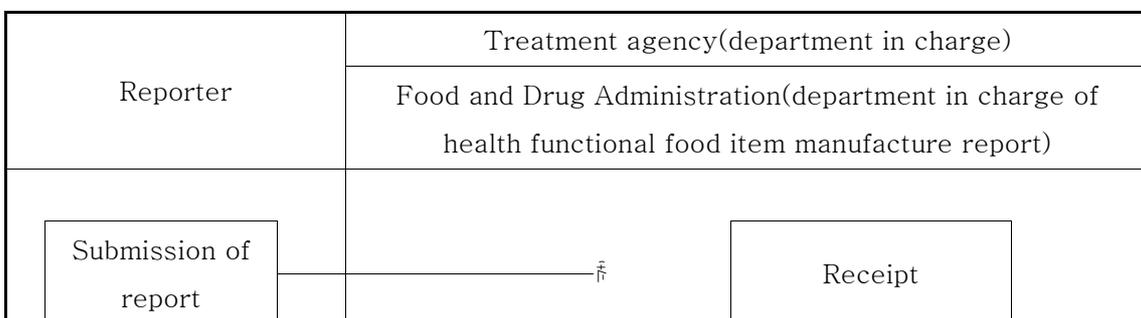
210 mm×297 mm(general paper 60g/m²(recycled product))

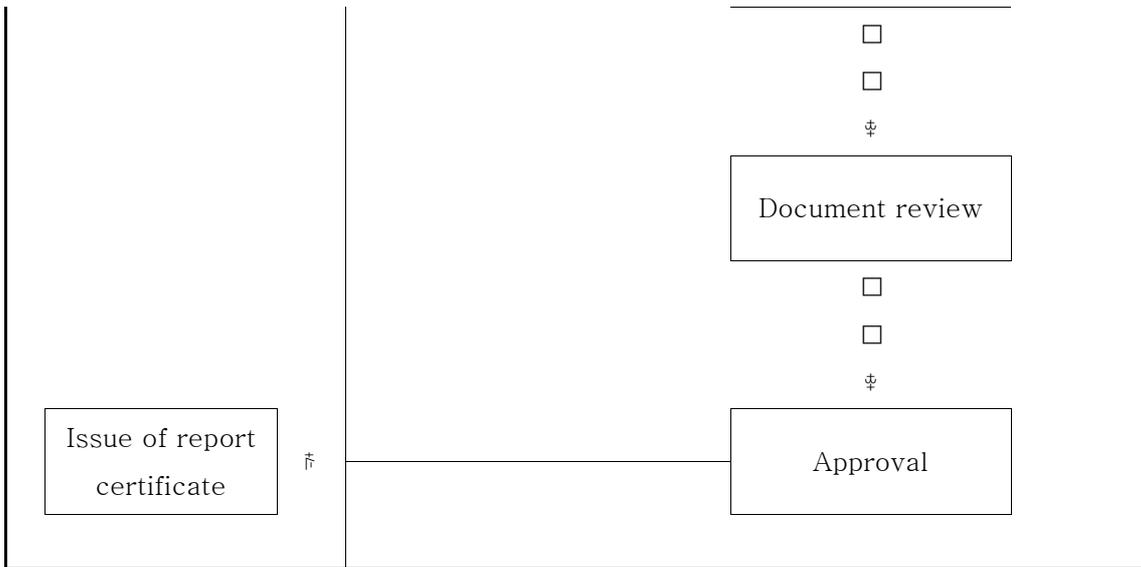
※ Report guidance

(back)

- | |
|---|
| <ol style="list-style-type: none"> 1. Report authorities : Food and Drug Administration. 2. An item manufacture report shall be filed again if the functionality of the product in question is changed due to the modification of content of the main ingredients or the major components that have the functionality. 3. A person who manufactures and sells a product without filing an item manufacture report required shall be punished by administrative measurement and fine for negligence not exceeding three million won under Article 47 of the health functional food Act. |
|---|

This application is processed as below:





[Annexed the Form 19] <Amended on November 20, 2006>

| | | | | | | | | | | | | | | | | | | | |
|---|-------------------|---|------------------------------|---|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| <h2 style="text-align: center;">Health Functional Food Import Report</h2> | | Treatment period | | 2 days for document examination; 3 days for Sensory examination ; 5 days for random sampling; 10 days for close examination; (14 days for food subject to heating-preservation examination) | | | | | | | | | | | | | | | |
| | | ①Report Type | A. Report B. Prior-report | ③Reception No. | | | | | | | | | | | | | | | |
| ②Product Type | | 1. Health functional food 2. Functionality ingredients or components | | ④Reception Date | (YY/MM/DD) | | | | | | | | | | | | | | |
| ⑤ Reporter | Business Reg. No. | | | | | | | | | | | | | | | | | | |
| | Trade Name | | | | | | | | | | | | | | | | | | |
| | Address | | | | | | | | | | | | | | | | | | |

| | | |
|---|-----------------------------|--|
| <30>Date of bringing in | (YY/MM/DD) | |
| <31>Examination Agency | | |
| <32>Genetically modified labeling | Labeling(), No Labeling() | |
| <p>I report under and Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter (signature or seal)</p> <p>To the Commissioner of the Regional Food and Drug Administration or To the head of the National Quarantine Service</p> | | |

210mm×297mm(general paper60g/m²(recycled product))

(page 2)

| No. | Material Code | Name of raw Materials | Composition (%) | No. | Material Code | Name of raw Materials | Composition (%) |
|-----|---------------|-----------------------|-----------------|-----|---------------|-----------------------|-----------------|
| 1 | | | . | 15 | | | . |
| 2 | | | . | 16 | | | . |
| 3 | | | . | 17 | | | . |
| 4 | | | . | 18 | | | . |
| 5 | | | . | 19 | | | . |
| 6 | | | . | 20 | | | . |
| 7 | | | . | 21 | | | . |
| 8 | | | . | 22 | | | . |
| 9 | | | . | 23 | | | . |
| 10 | | | . | 24 | | | . |
| 11 | | | . | 26 | | | . |
| 12 | | | . | 26 | | | . |

| | | | | | | | |
|--|--------------------------|-----------------|---|----------|------------------------|--------------------|---------------------------|
| | | | | Date | | | |
| ⑥ Close examination | Examination laboratories | | Date of Consignment (YY/MM/DD) | | Scope of examination | | |
| | | | Date of Results Announcement (YY/MM/DD) | | Results No. | | Compliance non-compliance |
| ⑦ Post-examination Measure | | | | | | | |
| ⑧ Administrative Disposition | Reason | | | | Notice Date (YY/MM/DD) | | |
| | Reason | | | | Notice Document No | | |
| | Note | | | | | | |
| ⑨ Report Received | Date (YY/MM/DD) | | | | Quantity (Unit :) | Weight (Unit : kg) | Amount (Unit : US\$) |
| | No. | | | | | | |
| ⑩ Final result of non-compliance handing | | Date (YY/MM/DD) | | | Reason of Informity | | |
| ⑪ Person in Charge (working-level) | | | | ⑫ Remark | | | |

(page 3)

| | | | | |
|-----|--------------------------|--|------------------|--------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US\$) |

| | | | | |
|-----|--------------------------|--|------------------|--------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US\$) |

| | | | | |
|-----|--------------------------|--|------------------|--------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US\$) |

| | | | | |
|-----|----------------|--|----------------|----------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |

| | | | | |
|--|--------------------------|--|------------------|---------------|
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |
|--|--------------------------|--|------------------|---------------|

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

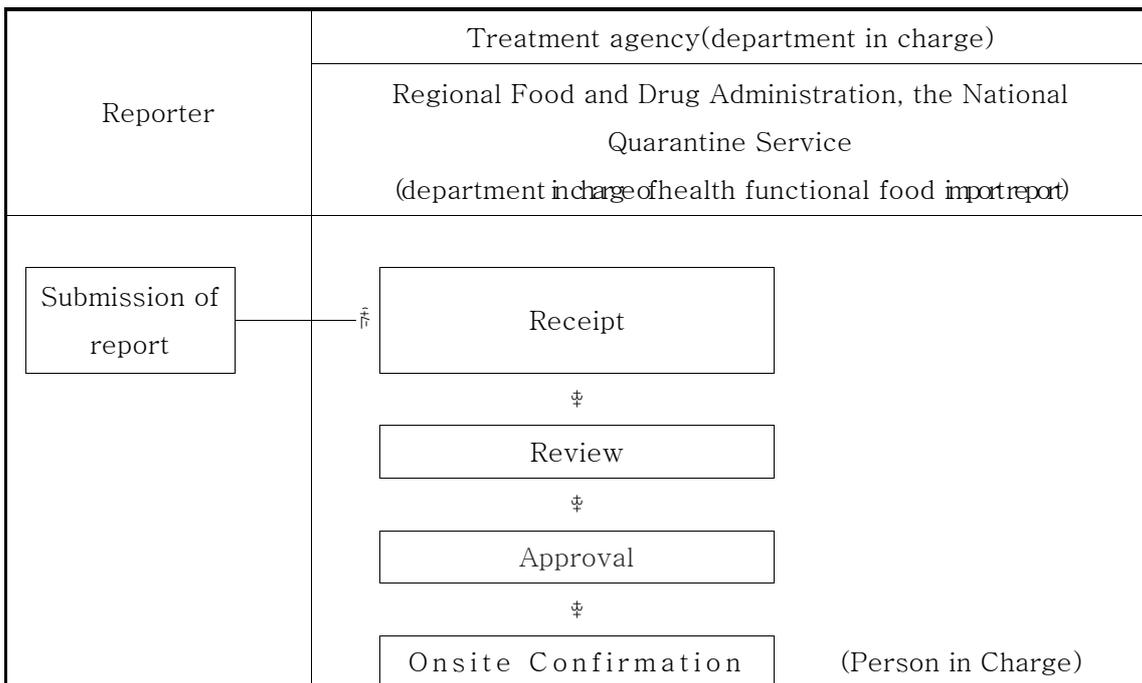
| | | | | |
|-----|--------------------------|--|------------------|---------------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |

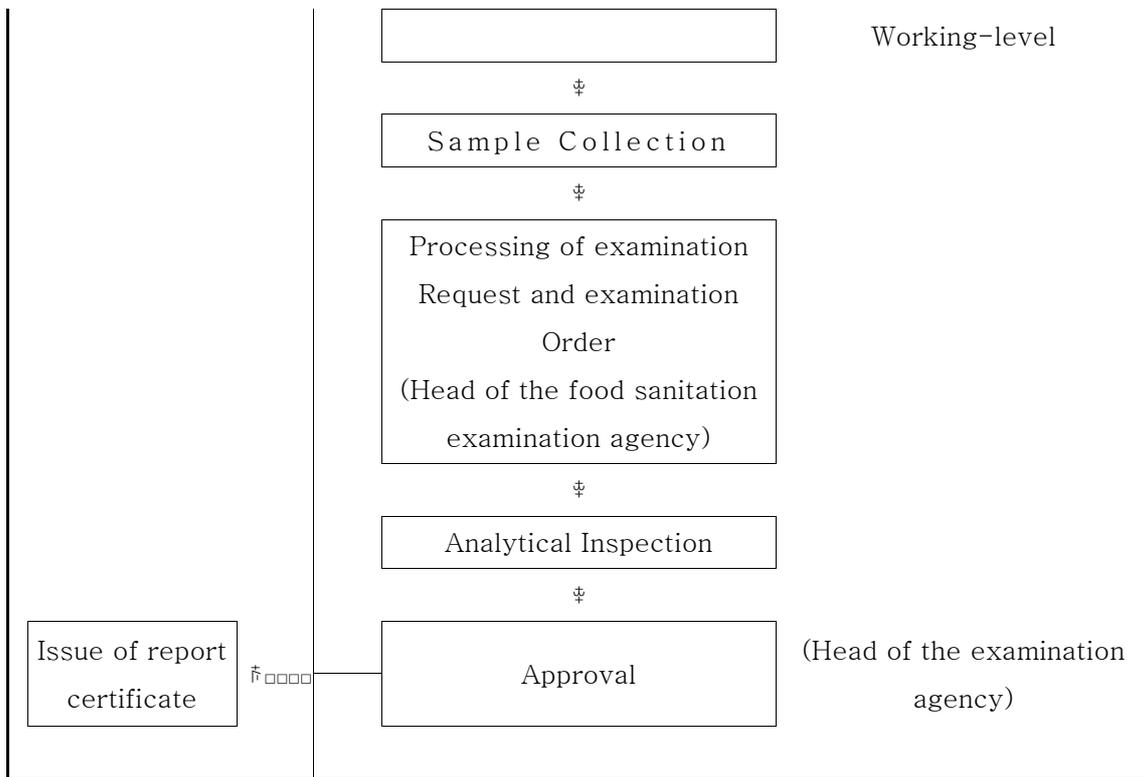
| | | | | |
|-----|----------------|--|----------------|----------|
| No. | ⑦ Product name | | ⑩ Total counts | (Unit:) |
| | ⑧ Name(Korean) | | ⑪ Net weight | kg |

| | | | | |
|--|--------------------------|--|------------------|---------------|
| | ⑭ Freight management No. | | ⑫ Taxation value | (Unit: US \$) |
|--|--------------------------|--|------------------|---------------|

(page 4)

This application is processed as below:





[Annexed the Form 20]

| Import Report Certificate of Health Functional Food | | | |
|---|--------------------------------|----------|----------------------------|
| Receipt No. | | | Receipt Date (YY/MM/DD) |
| Acceptance No. | | | Acceptance Date (YY/MM/DD) |
| Reporter | Name of business establishment | | Representative |
| | Place | (Tel:) | |
| Manufacturer business person | Name of business establishment | | Representative |
| | Place | (Tel:) | |
| Name of product | | | Name of product(Korean) |
| Total Quantity | | (unit:) | Total weight (unit: kg) |

| Total amount | (unit: US\$) | Freight management No. | | | |
|---|-----------------|------------------------------|-------------------|-------------------|---------------------|
| Producing country (manufacturing country) | | Exporting country | | | |
| Manufacturing company | | Exporting establishment | | | |
| HSK No. | | Type of examination | | | |
| Usage | | Sell-by date expiration date | | | |
| Genetically modified labeling | Labeling () | No labeling() | Nothing() | | |
| Import report certificate issue condition | | | | | |
| The contents of product | | | | | |
| No. | Name of product | Freight management No. | Quantity (unit:) | Weight (unit: kg) | Amount (unit: US\$) |
| | | | | | |
| <p>I certify this report under Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">the Commissioner of the Regional Food and Drug Administration, the Head of the National Quarantine Service (seal)</p> | | | | | |

210mm×297mm(general paper60g/m²(recycled product))

[Annexed the Form 21]

| Notification of non-compliance | | | |
|--------------------------------|--------------|------------------------------|--------------|
| Recipient | | | |
| Receipt No. | | Receipt date (YY/MM/DD) | |
| Notification No. | | Notification date (YY/MM/DD) | |
| Reporter | Title | Representative | |
| | Place | (Tel.:) | |
| Name of product | | Name of product(Korean) | |
| Total counts | (unit:) | Total weight | (unit:: kg) |
| Total amount | (unit: US\$) | Freight management No. | |
| Producing country | | Exporting country | |

| | | | | | |
|--|-----------------|------------------------|------------------|------------------|--------------------|
| (manufacturing country) | | | | | |
| Manufacturing company | | | | | |
| Exporting establishment | | | | | |
| Date of arrival | | Warehouse | | | |
| Contents of non-compliance | | | | | |
| Contents of product | | | | | |
| No. | Name of product | Freight management No. | Quantity(unit:) | Weight(unit: kg) | Amount(unit: US\$) |
| | | | | | |
| Measures contents (call for cooperation) | | | | | |
| <p>I notify the result of non-compliance in accordance with ○○ examination under Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">the Commissioner of the Regional Food and Drug Administration, the Head of the National Quarantine Service (seal)</p> | | | | | |

Drafter(position/class) Reviewer(position/class) Approver(position/class)

signature

signature

signature

Cooperator(position/class) signature

Enforcement: name of department and serial number (enforcement date) Receipt: name of department and serial number (receipt date)

Zip code

Address

/Homepage Address

Tel()

Fax()

/Official's e-mail address/Public

notice

210 mm×297 mm(general paper60g/m²(recycled product))

[Annexed the Form 22]

Health Functional Food import Report Acceptance Register

| Acceptance No. Date of acceptance | Receipt No. Date of receiving | Name of items classification Name of Product | Weight(kg) Amount(\$) | Country of origin Exporting Country | HSK No. (Importing Date) | Type of examination Result of examination | Import establishment Manufacture establishment |
|--------------------------------------|----------------------------------|--|--------------------------|--|-----------------------------|--|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| | | | | | | | | | | | | | |
|-------|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Items | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |

2. Non-compliance sanction Status for Import Report Items of Health Functional Food

A. Non-compliance Status for Items

[Unit : Number of case ,Kg, \$]

| Type of examination | Total | | | Document examination | | | Sensory examination | | | Close examination | | |
|---------------------|----------------|--------|--------|----------------------|--------|--------|---------------------|--------|--------|-------------------|--------|--------|
| | Number of case | Weight | Amount | Number of case | Weight | Amount | Number of case | Weight | Amount | Number of case | Weight | Amount |
| Items | | | | | | | | | | | | |
| | | | | | | | | | | | | |

B. Non-compliance sanction Status

| Date of receipt | Receipt No. | Weight (Kg) | Name of Product | Item Classification | Country of origin | Close examination agency | Remark |
|-----------------|--------------|-------------|----------------------|---------------------|-------------------|---|--------|
| Sanction Date | Document No. | Amount (\$) | Import establishment | Type of examination | Exporting Country | Non-compliance reason Non-compliance content | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

the Commissioner of the Regional Food and Drug Administration
the Head of the National Quarantine Service (Seal)

Drafter(position/class)
signature

Reviewer(position/class)
signature

Approver(position/class)
signature

Cooperator(position/class) signature

Enforcement: name of department and
serial number (enforcement date)

Receipt: name of department
and serial number (receipt date)

Zip code

Address

/Homepage Address

Tel()

Fax()

/Official's e-mail

address/Public notice

210 mm×297 mm(general paper60g/m²(recycled product))

[Annexed the Form 24]

(front)

| | | | |
|---|--------------------------------|-------------------------------|--------------|
| Imported Health Functional Food Pre-confirmed Registration Application | | Treatment period | |
| | | 60 days | |
| Applicant (Health functional food manufacture business) | Name of Country | | |
| | Name of business establishment | | |
| | Representative | Contact address | Tel: Fax: |
| | Place | | |
| Health functional food | Classification | 1. Health functional food () | |

| | | | |
|---|-----------------|---|---|
| | | 2. functional ingredients or components () | |
| | Name of product | Items of product or recognition No. | |
| <p>I apply an imported health functional food pre-confirmed registration under Article 8 of the 「Health Functional Food Act」 and Article 11 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Applicant (signature or seal)</p> | | | |
| | | | Fees |
| To the Commissioner of the Food and Drug Administration | | | 28,000won (Overseas travel expense not included) |
| | | | |
| <p>※ Documents required</p> <ol style="list-style-type: none"> 1. Documents for the names of raw materials, composition ratio, manufacturing method, names and amount of food additives, etc. 2. The type of health functional food, product name and manufacturing method document 3. Package or label contents in Korean 4. The original copies of the written results of examination or the examination certificate issued by officially recognized domestic and/or foreign examination laboratories that verifies the health functional food in question complied with the standards and specifications, etc. under the provisions of the Articles 14 and 15 of the Health Functional Food Act. 5. Documents for place of manufacturing factory, building arrangement plan (including instrument.machinery arrangements), workplace plan, etc. | | | |

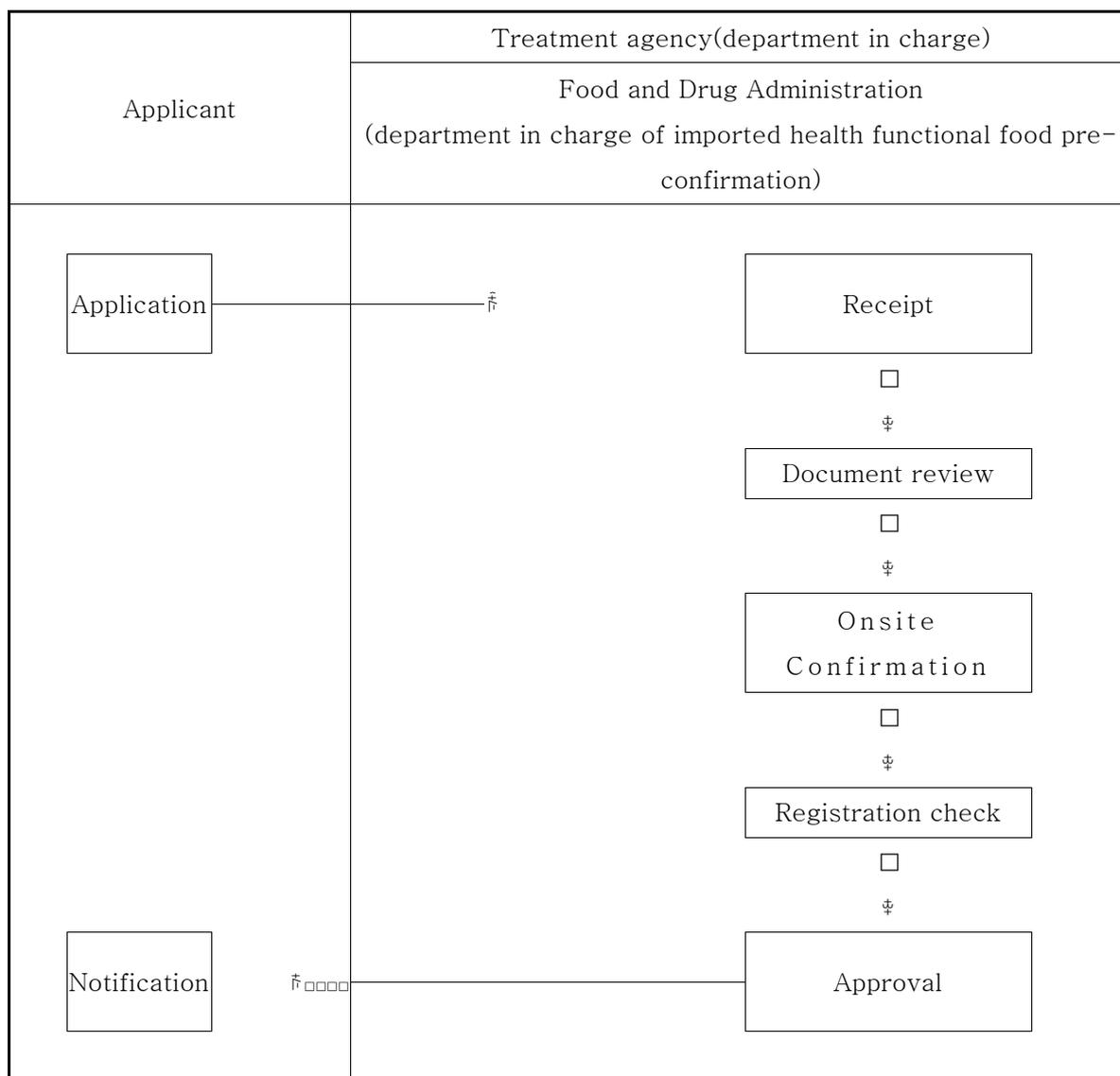
210 mm×297 mm(general paper 60g/m²(recycled product))

(back)

※ Notice

1. The product filed as imported health functional food pre-confirmed registration may be exempt from a close examination.
2. Among the matters for imported health functional food pre-confirmed registration, if any matter described below is changed, the modification of imported health functional food pre-confirmed registration shall be applied.
 - a. The type of health functional food, product name and manufacturing method document
 - b. The package or label contents in Korean
 - c. Place of manufacturing factory

This application is processed as below:



[Annexed the Form 25]

Imported Health Functional Food Pre-confirmed Registration

Register

| Registration date (YY/MM/DD) | Registration No. | Name of Product | Manufacturer (Representative) | Place of factory (name of country) | Items of Product. Recognition No. | Remark |
|---------------------------------|---------------------|-----------------------|----------------------------------|---|--|--------|
| | | | | | | |
| | | | | | | |
| | | | | | | |

[Annexed the Form 26]

(front)

| | | | |
|--|--------------------------------|------------------------------|--------------|
| Imported Health Functional Food Pre-confirmed Registration Modification Application | | Treatment period | |
| | | 30 days | |
| Applicant | Name of Country | | |
| | Name of business establishment | | |
| | Representative | Contact address | Tel: Fax: |
| | Place | | |
| Health functional food | Classification | 1. Health functional food() | |

| | | | |
|---|-----------------|---|--------------------|
| | | 2. Functional ingredients or components () | |
| | Name of Product | Items of Product or Recognition No. | |
| Registration No. | | Registration Date | |
| Modification Matters | | Before modification | After modification |
| Type of health functional food, product name and manufacturing method document | | | |
| Package or label contents in Korean | | | |
| Place of manufacturing factory | | | |
| <p>I apply an imported health functional food pre-confirmed registration modification under Article 8 of the 「Health Functional Food Act」 and Article 11 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Applicant (signature or seal)</p> | | | |
| To the Commissioner of the Food and Drug Administration | | | Fees |
| | | | 17,000 won |
| <p>※ Documents required</p> <p>The original copies of the written result of examination or examination certificate issued by officially recognized domestic and/or foreign examination laboratories that examined the modified health functional food.</p> | | | |

210 mm×297 mm(general paper 60g/m²(recycled product))

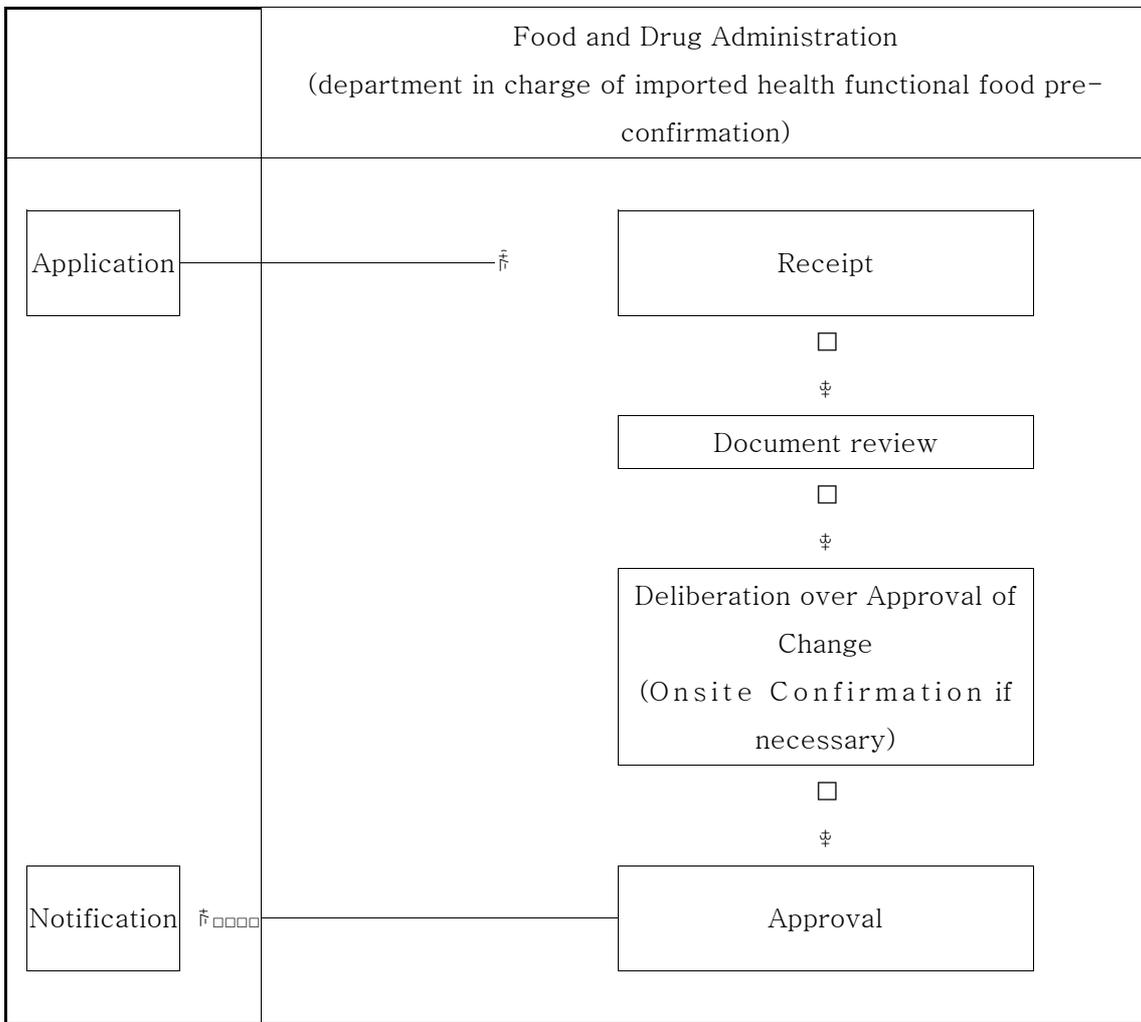
(back)

※ Notice

1. The product filed as imported health functional food pre-confirmed registration may be exempt from a close examination.
2. Among the matters for imported health functional food pre-confirmed registration, if any matter described below is changed, the modification of imported health functional food pre-confirmed registration shall be applied.
 - a. The type of health functional food, product name and manufacturing method document
 - b. The package or label contents in Korean
 - c. Place of manufacturing factory

This application is processed as below:

| | |
|-----------|--|
| Applicant | Treatment agency(department in charge) |
|-----------|--|



[Annexed the Form 27]

Document registration No.

Enforcement date

Recipient : Food and Drug

Administration

Sender

authorities (trade name)

Representative

(signature or seal)

Quality manager

(signature or seal)

Subject: **Health Functional Food Production Result Report (Annual Report)**

I report under Article 10(2) of the 「Health Functional Food Act」 and Article 13 of the enforcement rule of the same Act as follows:

1. Current status of business establishment

| | | | | | |
|----------------------------------|-----------------------------------|------------------|------------------------------|---------|--------------------------|
| ① Name of business establishment | | | ② Telephone No. | | |
| ③ Place | ④ Si/Do code | ⑤ Si/Gun/Gu code | ⑥ Address | | |
| | | | Si | Gu | Dong No. |
| | | | Si | Eyup | Ga |
| | | | Do | Gun | Myun Li |
| ⑦ Type of business | ⑧ Type of business code | | ⑨ | | |
| | | | | | |
| ⑩ Business permission | ⑪ Business permission number code | | ⑫ Permission date (YY/MM/DD) | | ⑬ Permission authorities |
| | | | | | |
| ⑭ Employer | ⑮ Total | ⑯ Officer | ⑰ Technician | ⑱ Labor | ⑲ Others |
| | | | | | |

2. Production result of health functional food manufacture by items

| ㉔ Production item code | (21) Production name of item | (22) Year production capacity (kg, ℓ) | (23) Production quantity (kg, ℓ) | (24) Production amount (thousand won) | (25) Domestic sale | | (26) Oversea sale | | Remark |
|------------------------------|---------------------------------|---|---|---|-----------------------|-----------------------------|----------------------|------------------|--------|
| | | | | | Quantity (kg, ℓ) | Amount (thousand won) | Quantity (kg, ℓ) | Amount (\$) | |
| | | | | | | | | | |

210 mm×297 mm(general paper60g/m²(recycled product))

[Annexed the Form 28] <Amended on November 20, 2006>

(front)

| Business Status Succession Report | | | | Treatment period |
|--|-------------------|------------------------|---|---------------------|
| ※ Refer to the guidance of report, mark √ in <input type="checkbox"/> | | | | Immediately |
| ① Person who intends to give a succession | Name | | Resident registration No. | |
| | Address | (Tel.:) | | |
| ② Person who intends to receive a succession | Name | | Resident registration No. | |
| | Address | (Tel.:) | | |
| ③ Business establishment | Trade name(title) | Before modification | After modification | |
| | Type of business | | | |
| | Place | (Tel.:) | | |
| | | ⑤ Succession reason | <input type="checkbox"/> Transfer and acquisition <input type="checkbox"/> Inheritance <input type="checkbox"/> Other() | |
| ④ Permission(report) No. | | | | |
| I report under Article 11(3) of the Health Functional Food Act and Article 14 of the Enforcement Rule of the same Act as above. | | | | Fees 9,300 won |

| |
|--|
| Date (YY/MM/DD): Reporter (signature or seal) To the Commissioner of the Regional Food and Drug Administration or To the Head of <i>Si/Gun/Gu</i> |
| ※ Documents required 1. A certificate of permission or report 2. For the case of transfer, verification documents of the transfer and acquisition, and a certificate of personal seal impression of the transferor 3. For the case of inheritance, a copy of family register, verification documents as a the successor 4. In other cases, verification documents for the succession of business person status |

| | |
|------------------|---|
| Agency submitted | Permission authorities or report authorities |
| Notice | 1. A person who fails to file such business succession report shall be punished by imprisonment for not more than three years or a fine not exceeding thirty million won under Article 45 of the Health Functional Food Act. 2. Any person who succeeds the status of the business person shall submit the application to the permission or report authorities within one month. 3. In the case where a certificate of personal seal impression of the transferor is unable to be submitted because the transferor is missing (including a case of moving-out without notification required by the Resident Registration Act), etc. a certificate of personal seal impression may not be submitted when the permission or the report authorities can endorse the transfer and acquisition through verification of fact, etc. or when the transferor and the transferee visit the permission or the report authorities together and file a business person status succession report, |

210 mm×297 mm(general paper60g/m²(recycled product))

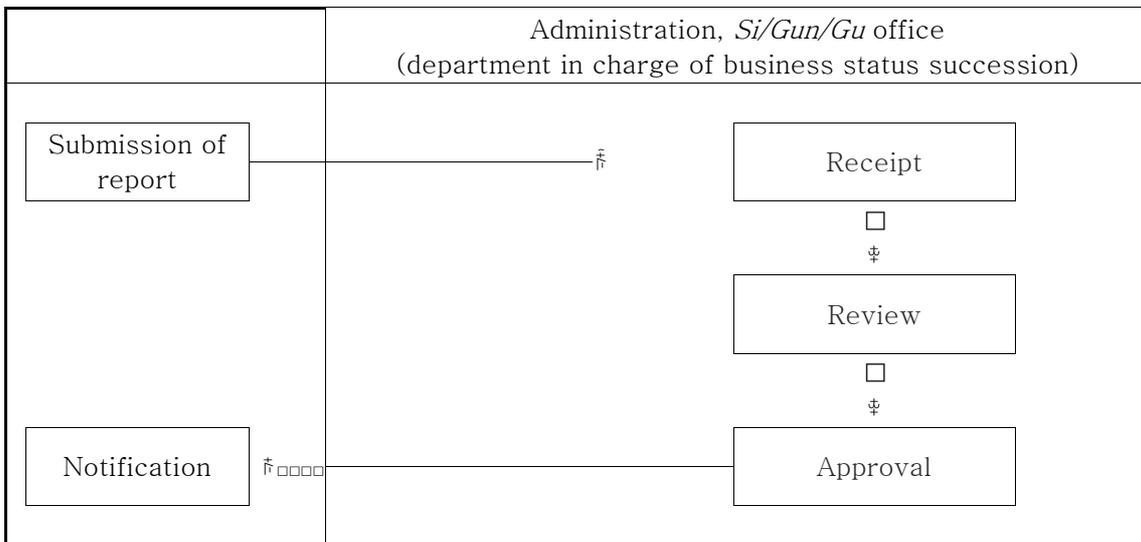
※ Report guidance

| | |
|------------------|---|
| Agency submitted | Permission authorities or report authorities |
| Notice | 1. A person who fails to file such business succession report shall be punished by imprisonment for not more than three years or a fine not exceeding thirty million won under Article 45 of the Health Functional Food Act. 2. Any person who succeeds the status of the business person shall submit the application to the permission or report authorities within one month. 3. In the case where a certificate of personal seal impression of the transferor is unable to be submitted because the transferor is missing (including a case of moving-out without notification required by the Resident Registration Act), etc. a certificate of personal seal impression may not be submitted when the permission or the report authorities can endorse the transfer and acquisition through verification of fact, etc. or when the transferor and the transferee visit the permission or the report authorities together and file a business person status succession report, |

210 mm×297 mm(general paper60g/m²(recycled product))

(back)

| |
|--|
| Notice of administrative sanction contents etc. and confirmation of |
|--|



[Annexed the Form 29]

(front)

| | |
|---|------------------|
| Quality Management Appointment or Dismissal Report | Treatment period |
| | 3 days |

| | | | | |
|--|-------------|---------------------------|-----------------------------|------|
| Reporter | ① Name | | ② Resident registration No. | - |
| | ③ Address | | (Tel.:) | |
| ④ Name of business establishment | | | ⑤ Business permission No. | No. |
| ⑥ Place | | | | |
| ⑦ Quality manager | Appointment | Name | | |
| | | Resident registration No. | | |
| | | Qualification | | |
| | | Position | | |
| | | Date | | |
| | Dismissal | Name | | |
| | | Resident registration No. | | |
| | | Qualification | | |
| | | Position | | |
| | | Date | | |
| <p>I report an appointment (dismissal) of quality manager under Article 12(4) of the 「Health Functional Food Act」 and Article 16 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter (signature or seal)</p> | | | | |
| To the Commissioner of the Food and Drug Administration | | | | |
| ※ Documents required | | | | Fees |
| Documents that verifies the qualification of the quality manager (limited to the case of appointment) | | | | free |

210 mm×297 mm(general paper 60g/m²(recycled product))

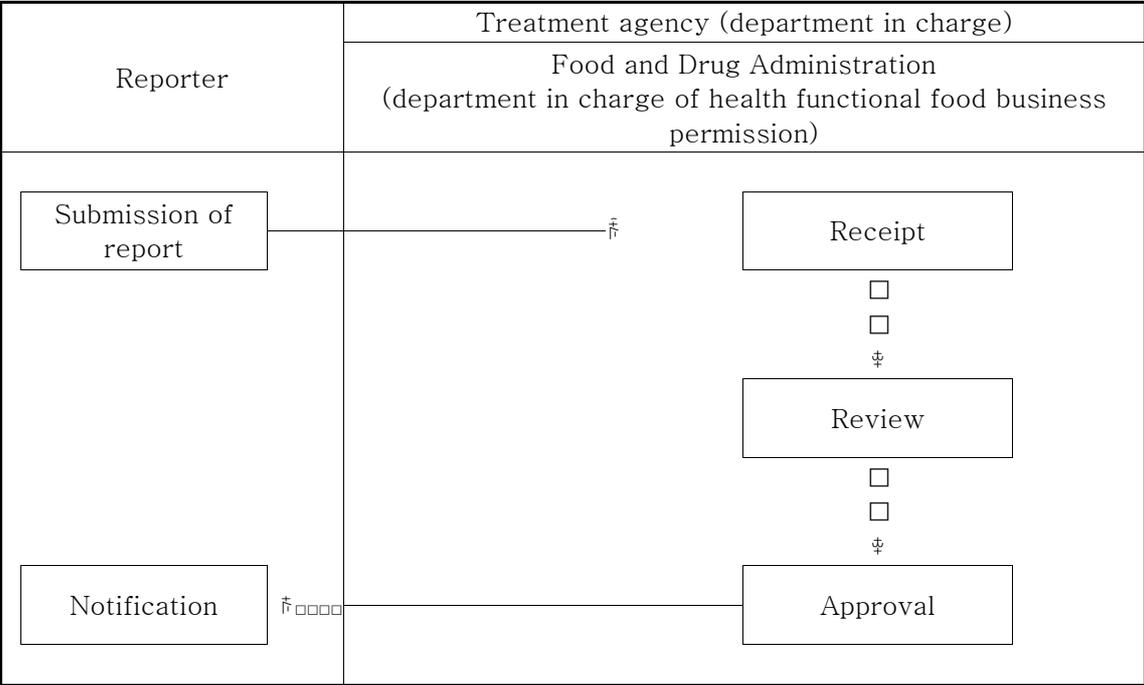
※ Appointing guidance

(back)

| |
|--|
| 1. The qualification criteria for quality manager shall be as follows: |
|--|

- a. A certified food engineer under the National Technical Qualifications Act;
 - b. A certified food technician under the National Technical Qualifications Act, who has engaged in a health functional food manufacturing work for one year or more;
 - c. A person who has graduated from a department or faculty in the fields related to food, such as food processing science, food chemistry, food manufacturing science, food engineering, sitology, food nutrition science, sanitary science, zymologic engineering, agricultural chemistry, etc. at a university under the provisions of subparagraph 1 of Article 2 of the Higher Education Act, and has engaged in a health functional food manufacturing work for three years or more; and
 - d. A person recognized by the Minister of Health and Welfare that he has a qualification, academic background and career equivalent to and above paragraphs a through c.
2. A business person who does not employ quality manager shall be punished by administrative measures and imprisonment not more than three years or a fine for not exceeding thirty million won under Article 45 of the Act.
 3. A business person who does not report the appointment or dismissal of a quality manager shall be punished by administrative measures and a fine for negligence not exceeding three million won under Article 47 of the Act.

This application is processed as below:



[Annexed the Form 30]

Entry . Inspection Registration

| | | | | | |
|---|---------------------|--------|--|--|--|
| Code | | | | | |
| Number | | | | | |
| ① Title, place of manufacture establishment for collection (seizure) product | Name | Title | | | |
| | Place | | | | |
| ② Title, place of sale business establishment, imported business establishment etc. for collection(seizure) product | Name | Title | | | |
| | Place | | | | |
| ③ Name of collection(seizure) item | | | | | |
| ④ Quantity of collection (seizure) | | | | | |
| ⑤ Collection (seizure) reason | | | | | |
| ⑥ Collection (seizure) time | hour | minute | | | |
| ⑦ Item manufacturing date or sell-by date | | | | | |
| ⑧ Place of collection(seizure) | | | | | |
| ⑨ A person who is collected (seizure) | (signature or seal) | | | | |
| <p>I prove the collection (seizure)of the product under Articles 20 and 30 of the 「Health Functional Food Act」 and Articles 23 and 31 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Collector (seizor) department :</p> <p style="text-align: center;">name (signature or seal)</p> | | | | | |

128mm×182mm(preservative paper(1class)120g/m²)

[Annexed the Form 32]

Collection Examination Administrative Register

[Annexed the Form 33]

The Health Functional Food sanitation
Inspectors certificate

(front)

| |
|---|
| ① |
| ⑤ |
| ② |
| ③ |
| ④ |

52 mm×74 mm(preservative paper(1class)120g/m²)

(back)

| | | |
|--|------|------|
| | 10mm | |
| | 40mm | 74mm |
| | 7mm | |
| | 7mm | |
| | 10mm | |

52 mm×74 mm(preservative paper(1class)120g/m²)

| |
|--|
| Department ⑥ Position Name Resident registration number This person is designated a The Health Functional Food Sanitation Inspector under Article 38 of the 「Health Functional Food Act」 . date(Y Y/M M/D D) ⑦ the Commissioner of the Food and Drug Administration, the Commissioner of the Regional Food and Drug Administration mayor of metropolitan government city and head of s/su/su (seal) |
| If you got this certificate, put in near a post box. |
| 52mm |

(back)

| | | |
|--|------|--|
| | 64mm | |
| | 74mm | |
| | 10mm | |

※ Footnote

1) The upper ①②③ etc. is prescribed as follows.

- ① Picture (30 mm×40 mm)
- ② The health functional food sanitation inspectors certificate No.
- ③ Name
- ④ Name of issue authorities (printed by issue authorities unit)
- ⑤ Seal
- ⑥ Department, job classification, name, resident registration number
- ⑦ Name of representative of issue authorities

2) The text size is as follows.

| Classification of text | Size of text | Type of text |
|--|--------------|---------------------|
| The Health Functional Food Sanitation Inspectors certificate | 16 point | Gothic type |
| Issue authorities(④) | 16 point | Gothic type |
| Name of representative of issue authorities(⑦) | 14 point | Ming-style printing |
| Department, job classification, name, resident registration number | 10 point | Ming-style printing |
| This person.....is designated. | 10 point | Ming-style printing |
| This certificateis hoped | 8 point | Ming-style printing |

3) Texture is preservative paper(1class) 120g/m²

4) Color is sky blue

[Annexed the Form 34] <Amended on November 20, 2006>

(front)

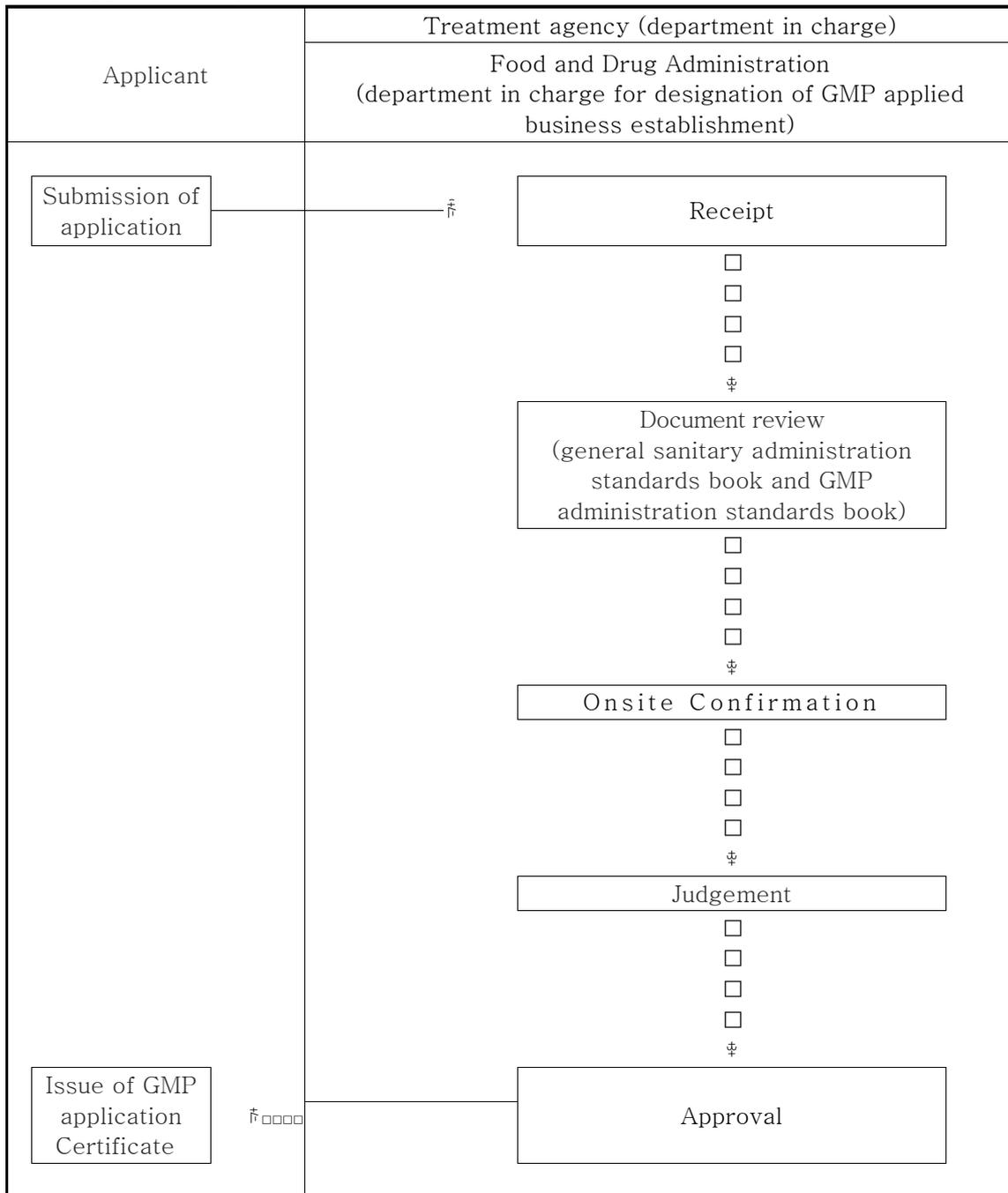
| | |
|--|---------------------|
| Application for Designation as GMPs Applied | Treatment period |
|--|---------------------|

| Business Establishment | | | | 60 Days | |
|---|----------------------------------|--------------------------|-----------------------------|------------|--|
| Applicant | ① Business permission No. | No. | ② Business permission Date | (YY/MM/DD) | |
| | ③ Name of business establishment | | ④ Telephone No. | | |
| | ⑤ Place | Head office | | | |
| | | Factory (business place) | | | |
| | ⑥ Name of representative | | ⑦ Resident registration No. | | |
| | ⑧ GMP team manager | | ⑨ Resident registration No. | | |
| ⑩ The product name of GMP application (Type) | | | | | |
| <p>I apply for the designation of GMP applied business establishment under the Article 22(2) of the 「Health Functional Food Act」 and the Article 26 of the Enforcement Rule of the same Act.</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Applicant (signature or seal)</p> | | | | | |
| To the Commissioner of the Food and Drug Administration | | Revenue stamps | Fees | | |
| | | | 200,000 won | | |
| <p>※ Documents required</p> <ol style="list-style-type: none"> 1. A copy of manufacturing process flowchart by item; 2. The arrangement plan of building and the floor plan of workplace (including the arrangements of machinery and facilities); 3. The list of machinery and facilities in quality control room; 4. The production records of previous year. Provided, That if the person does not have the records for the whole year, it may substitute the monthly production records of the last three months or more; 5. A copy of the certificate of completion of the initial education under Article 27(3); and 6. The self assess results and related documents of the application and operation for three months or more according to the Good Manufacturing Practices under Article 22(1) of the Act. | | | | | |

210 mm×297 mm(general paper60g/m²(recycled product))

(back)

This application is processed as below:

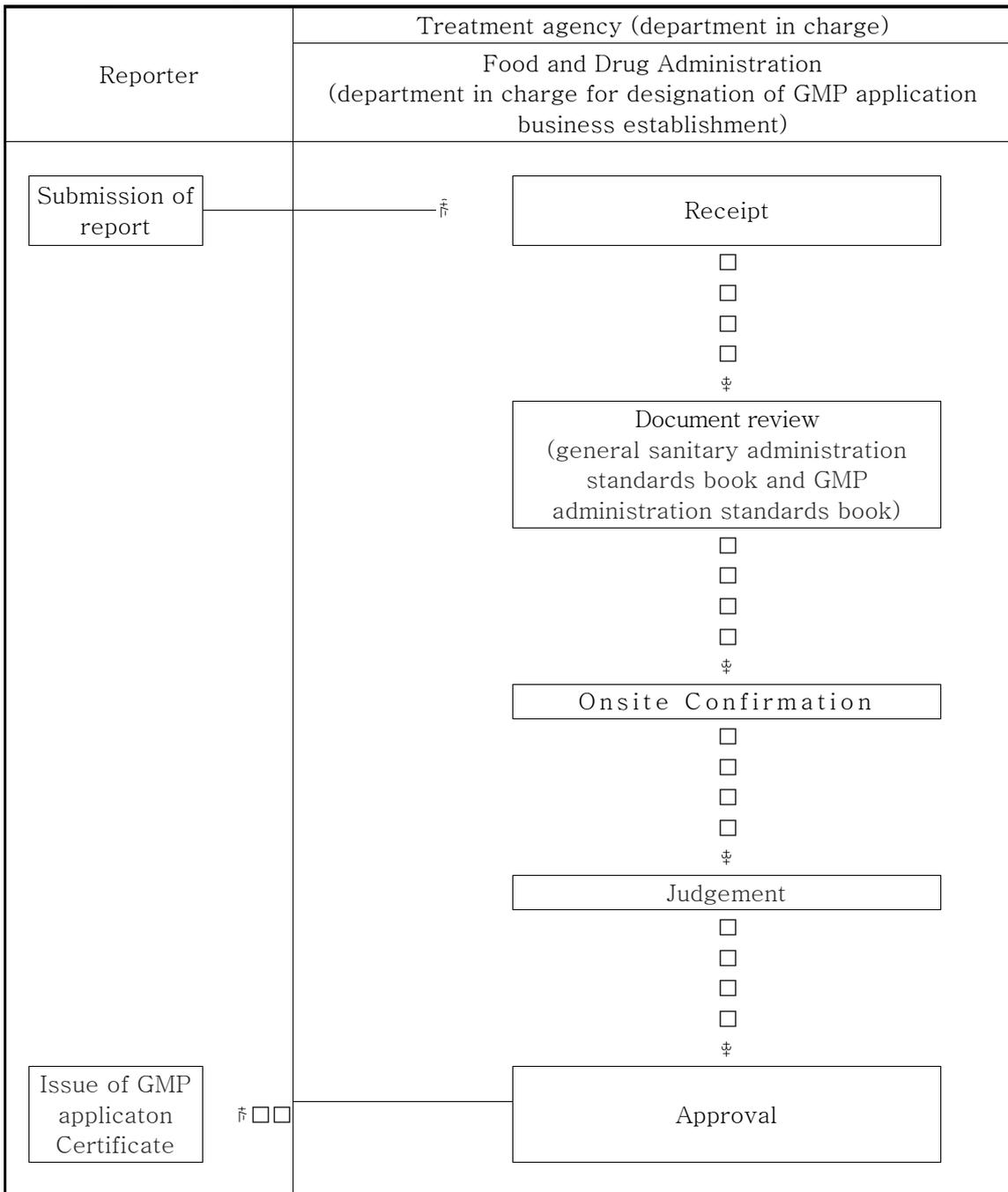


(back)

| Modification and Sanction matters | | |
|-----------------------------------|---------|-----------------------------|
| Date | Matters | Recorder(signature or seal) |
| | | |

| Modification Application for the Designation Matters of GMP Applied Business Establishment | | | Treatment period |
|---|-------------------------|-----------------------------|--------------------|
| | | | 15 Days |
| Reporter | ① Name | ② Resident registration No. | - |
| | ③ Address | | |
| Business establishment | ④ Name of establishment | ⑤ Designated No. | |
| | ⑥ Place | | |
| ⑦ Modification matters | | | |
| Classification | | Before modification | After modification |
| The place of designated business establishment | | | |
| Workplace, handing facilities for health function food or quality control room among manufacturing facilities | | | |
| ⑧ Modification reason | | | |
| <p>I apply for the modification related to the designation matters of the GMP applied business establishment under Article 26(3) of the Enforcement Rule of the 「Health Functional Food Act」 .</p> <p style="text-align: center;">Date (YY/MM/DD):</p> <p style="text-align: center;">Reporter (signature or seal)</p> | | | |
| To the Commissioner of the Food and Drug Administration | | Revenue stamps | Fees |
| | | | 100,000 원 |
| <p>※ Documents required</p> <ol style="list-style-type: none"> 1. The designation certificate of GMP application business establishment 2. A copy of business permission certificate (limited to the case of the designation business establishment location modification) 3. The administration standards book of the Good Manufacturing Practices and the administration standards book of the general sanitation, and related forms (it means the standards book amended according to the location and the facilities, and related forms) | | | |

This application is processed as below:

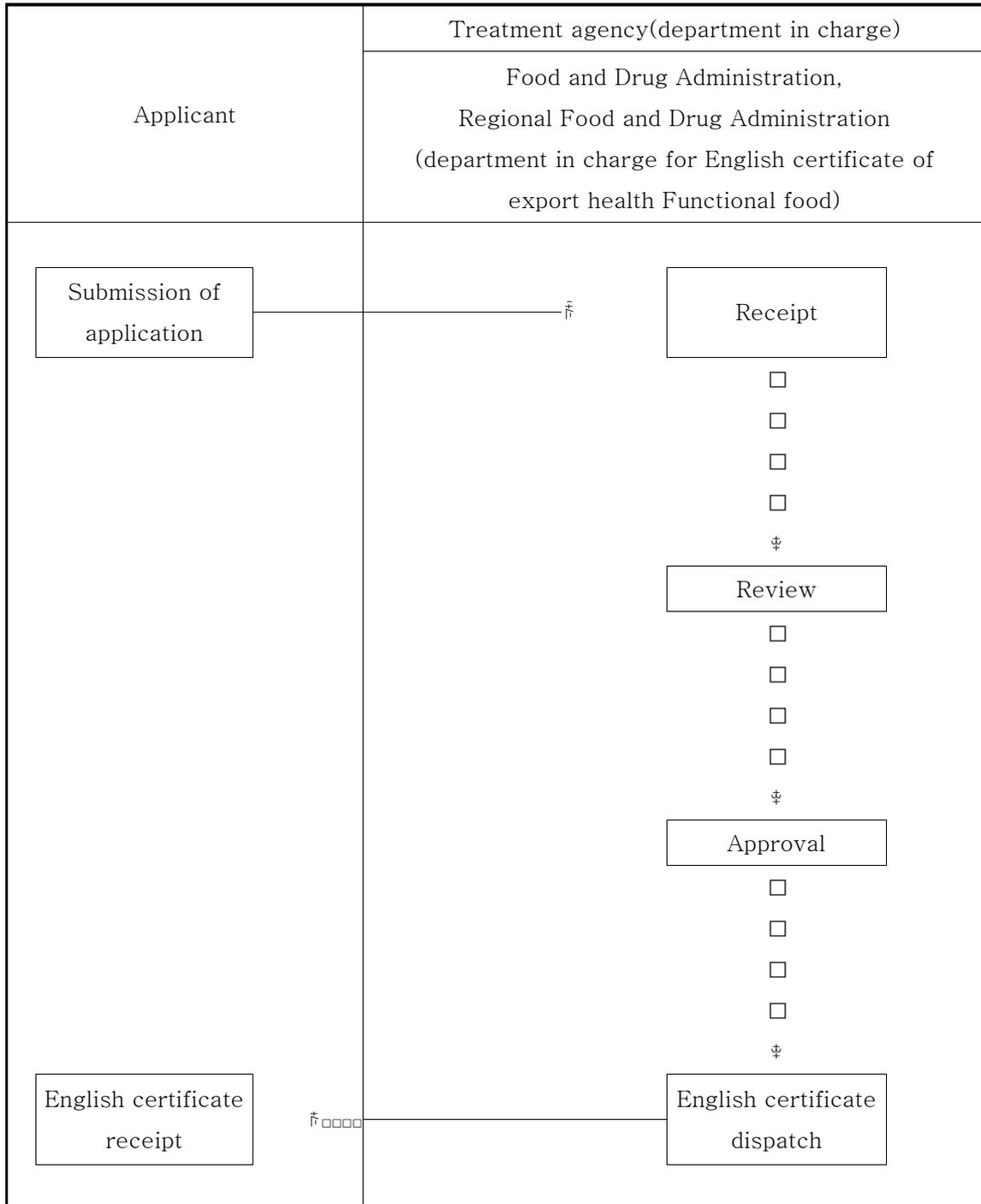


[Annexed the Form 39] <Newly inserted on November 20, 2006>

| Application of English Certificate for Export Health Functional Food | | | | Treatment period |
|--|--|---------------------------|-----------------------|------------------|
| | | | | 3 days |
| Applicant | Name | Resident registration No. | - | |
| | Address | | Tel. | |
| Business establishment | Representative | Trade name(title) | | |
| | Place | | | |
| ① Division | <input type="checkbox"/> Health certificate <input type="checkbox"/> Certificate of free sales <input type="checkbox"/> Certificate of good manufacturing practice applied establishment | | | |
| ② Name of product | | | | |
| ③ Quantity | | | | |
| ④ Notification No | | | | |
| ⑤ Name and address of manufacturing establishment | | | | |
| ⑥ Country of destination | | | | |
| ⑦ Name and address of consignor | | | | |
| ⑧ Name and address of consignee | | | | |
| ⑨ Additional certification | | | | |
| ⑩ Remarks | | | | |
| I apply for an English certificate of export health functional food under 29(2) of the Enforcement Rule of the 「Health Functional Food Act」 . Date (YY/MM/DD): Applicant (signature or seal) | | | Fees each 2,000won | |
| To the Commissioner of the Food and Drug Administration or To the Commissioner of the Regional Food and Drug Administration | | | | |
| ※ Definitions ① Health Certificate: Document verifying that the product was manufactured and distributed in accordance with the provisions of the Health Functional Food Act. ② Certificate of Free Sales: Certificate verifying that the product was controlled under the Health Functional Food Act and was being sold without limit in Korea. | | | | |
| ※ Documents required ① A copy of verification documents for export or official letter for import request by importing country ② An english certificate to be issued | | | | |

210 mm×297 mm(general paper 60g/m²(recycled product))

This application is processed as below:



[Annexed the Form 40-1] <Newly inserted on November. 20, 2006>



#5 Nokbun-dong, Eunpyung-Gu, Seoul, Korea, Tel : 82-2-380-1311, Fax : 82-2-382-6380

Certificate No. :

Health Certificate

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following product(s) is(are) manufactured, distributed and fit for human consumption in compliance with the Health Functional Food Act of the Republic of Korea.

Name of the Product(s) :

Product(s) Description :

Quantity :

Date of Manufacture or Lot No :

Name and Address of Manufacturing Establishment :

Country of Destination :

Name and Address of Consignor :

Name and Address of Consignee :

Additional Certification :

Remarks :

Sincerely Yours,

(Signature)

Name

Director of Health Functional Food Team
Nutrition & Functional Food Headquarters
Korea Food & Drug Administration
Republic of Korea

210 mm×297 mm(general paper 60g/m²(recycled product))

[Annexed the Form 40-2] <Newly inserted on November 20, 2006>



(Address, Tel: -)

Certificate No. :

Health Certificate

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following product(s) is(are) manufactured, distributed and fit for human consumption in compliance with the Health Functional Food Act of the Republic of Korea.

Name of the Product(s) :
Product(s) Description :
Quantity :
Date of Manufacture or Lot No :
Name and Address of Manufacturing Establishment :
Country of Destination :
Name and Address of Consignor :
Name and Address of Consignee :
Additional Certification :
Remarks :

Sincerely Yours,

(Signature)

Name
Director of Food Safety Management Team
○○ Regional Food & Drug Administration
Republic of Korea

210 mm×297 mm(general paper 60g/m²(recycled product))

[Annexed the Form 41-1] <Newly inserted on November 20, 2006>



#5 Nokbun-dong, Eunpyung-Gu, Seoul, Korea, Tel : 82-2-380-1311, Fax : 82-2-382-6380

Certificate No. :

CERTIFICATE OF FREE SALES

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following product(s) is(are) freely sold without any restriction in compliance with the Health Functional Food Act of the Republic of Korea.

Name of the Product(s) :

Product(s) Description :

Notification No :

Name and Address of Manufacturing Establishment :

Additional Certification :

Remarks :

Sincerely Yours,

(Signature)

Name

Director of Health Functional Food Team
Nutrition & Functional Food Headquarters
Korea Food & Drug Administration
Republic of Korea

[Annexed the Form 41-2] <Newly inserted on November 20, 2006>



(Address, Tel: -)

Certificate No. :

CERTIFICATE OF FREE SALES

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following product(s) is(are) freely sold without any restriction in compliance with the Health Functional Food Act of the Republic of Korea.

Name of the Product(s) :

Product(s) Description :

Notification No :

Name and Address of Manufacturing Establishment :

Additional Certification :

Remarks :

Sincerely Yours,

(Signature)

Name

Director of Food Safety Management Team

○○ Regional Food & Drug Administration

Republic of Korea

210 mm×297 mm(general paper 60g/m²(recycled product))

[Annexed the Form 42-1] <Newly inserted on November 20, 2006>



#5 Nokbun-dong, Eunpyung-Gu, Seoul, Korea, Tel : 82-2-380-1311, Fax : 82-2-382-6380

Certificate No. :

CERTIFICATE OF
GOOD MANUFACTURING PRACTICES
APPLIED ESTABLISHMENT

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following is designated as GMP applied establishment in accordance with the Article 22.2 of the Health Functional Food Act and the Article 26 the Enforcement Rule of the Health Functional Food Act.

Name of Manufacturer :
Address :
Name of Representative :
Name of Registered Production Manager :
Name of Registered Quality Control Manager :
Notified Products :
Approval Date :
Remarks :

Sincerely Yours,

(Signature)

Name
Director of Health Functional Food Team
Nutrition & Functional Food Headquarters
Korea Food & Drug Administration
Republic of Korea

[Annexed the Form 42-2] <Newly inserted on November 20, 2006>



(Address, Tel: -)

Certificate No. :

CERTIFICATE OF
GOOD MANUFACTURING PRACTICES
APPLIED ESTABLISHMENT

Date :

TO WHOM IT MAY CONCERN :

This is to certify that the following is designated as GMP applied establishment in accordance with the Article 22.2 of the Health Functional Food Act and the Article 26 the Enforcement Rule of the Health Functional Food Act.

Name of Manufacturer :
Address :
Name of Representative :
Name of Registered Production Manager :
Name of Registered Quality Control Manager :
Notified Products :
Approval Date :
Remarks :

Sincerely Yours,

(Signature)

Name
Director of Food Safety Management Team
○○ Regional Food & Drug Administration
Republic of Korea

