영문 건강기능식품 법령집

English Version of Health Functional Food Acts and Subordinate Statutes, Notifications, etc.

식품의약품안전청

목 차

Health Functional Food Act

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Chapter Ⅰ General Provisions

Article 1 (Purpose) The purpose of this Act is to contribute to the improvement of national health and the consumer protection by ensuring safety, improving quality, and seeking sound distribution and sales of health functional food.

Article 2 (Responsibility) (1) The State and the local governments shall establish reasonable policies that the public is provided health functional food with good quality and proper information thereof, and direct and supervise persons who manufacture, process, import, or sell health functional food (hereinafter referred to as "business person").

(2) Any business person shall provide health functional food with good quality in a safe and sound manner pursuant to the related Acts and subordinate statutes.

Article 3 (Definitions) For the purpose of this Act, the definitions of terms shall be as follows:

1. The term "health functional food" means food manufactured or processed in a form of tablet, capsule, powder, granule, liquid or pill, etc. with ingredients or components, that possess the functionality useful for human body.
2. The term "functionality" means gaining useful effect on health purposes by the adjustment of nutrients or the physiological effect, etc. for human body structure and function.
3. The term "labeling" means letters, figures or diagrams described upon the container or the package of health functional food (including accompanying articles and contents; hereinafter the same shall apply).
4. The term "advertising" means any conduct which shows or announces information of health functional food by radio, TV, newspaper, magazine, voice, sound, image, internet, printed matter, signboard or other methods.
5. The term "business" means, as a business, the manufacturing (including any case of processing; hereinafter the same shall apply), importing or selling (including supplying for a large number of unspecified persons free of charge; hereinafter the same shall apply) of health functional food.

Chapter Ⅱ Business

Article 4 (Business types and facilities criteria) (1) Any person who intends to operate any the following business shall have the facilities suitable for such criteria as prescribed by the Ordinance of the Ministry of Health and Welfare:

1. Health functional food manufacture business
2. Health functional food import business
3. Health functional food sales business

(2) The detailed types and scope of the business as referred to in paragraph (1) shall be prescribed by the Presidential Decree.

Article 5 (Business permission, etc.) (1) Any person who intends to carry on the health functional food manufacture business as prescribed in Article 4(1)1 shall equip each business establishment with the facilities in accordance with the provisions of Article 4 under the Ordinance of the Ministry of Health and Welfare, and obtain a permission from the Commissioner of the Food and Drug Administration. The same shall also apply to a case for the modification of any matter as prescribed by the Presidential Decree.

(2) Where a person, who has obtained the business permission under paragraph (1), intends to discontinue the business or modify any matter as prescribed by the Ordinance of the Ministry of Health and Welfare from among permitted matters, the person shall report it to the Commissioner of the Food and Drug Administration.

(3) Matters necessary for the procedure, etc. of the business permission, the modification permission and the modification report as referred to in paragraphs (1) and (2) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 6 (Business report, etc.) (1) Any person who intends to carry on the health functional food import business as prescribed in Article 4(1)2 shall equip each business establishment with the facilities in accordance with the provisions of Article 4 under the Ordinance of the Ministry of Health and Welfare, and report to the Commissioner of the Food and Drug Administration.

(2) Any person who intends to carry on the health functional food sales business as prescribed in Article 4(1)3 shall equip each business establishment with the facilities in accordance with the provisions of Article 4 under the Ordinance of the Ministry of Health and Welfare, and report to the Special Metropolitan City Mayor, Metropolitan City Mayor, or *Do* governor (hereinafter referred to as "Mayor/*Do* governor"). Provided, That if a health functional food is sold at a pharmacy which is established and registered under Article 20 of the 「Pharmaceutical Affairs Act」, this shall not apply. <Amended on March 22, 2004, April 11, 2007>

(3) In case of the business closure or the modification of any matter as prescribed by the Ordinance of the Ministry of Health and Welfare, a person who has reported under paragraph (1) shall report to the Commissioner of the Food and Drug Administration and a person who has reported under paragraph (2) shall report to the Mayor/*Do* Governor.

(4) Matters necessary for the procedure, etc. of the business report and the modification report as referred to in paragraphs (1) through (3) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 7 (Item manufacture report, etc.) (1) Where a person, who has obtained the permission for health functional food manufacture business under Article 5(1), intends to manufacture a health functional food, the person shall report matters as prescribed by the Ordinance of the Ministry of Health and Welfare, such as the manufacturing method document of such item, etc. to the Commissioner of the Food and Drug Administration. The same shall also apply to a case where the person intends to modify any matter as prescribed by the Ordinance of the Ministry of Health and Welfare from among the reported matters.

(2) Matters necessary for the procedure, etc. of the item manufacture report and the modification report as referred to in paragraph (1) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 8 (Health functional food import report, etc.) (1) Any person who intends to import health functional food for business use shall report to the Commissioner of the Food and Drug Administration under the Ordinance of the Ministry of Health and Welfare.

(2) If there is any reason as prescribed by the Ordinance of the Ministry of Health and Welfare, the Commissioner of the Food and Drug Administration shall have relevant public officials or examination laboratories conduct the necessary examination of the health functional food as reported under paragraph (1) before the customs clearance procedure is completed.

(3) Notwithstanding paragraph (2), the Commissioner of the Food and Drug Administration may exempt from the whole or part of the examination in case where the health functional food as reported under paragraph (1) falls under any of the following subparagraphs:

1. Where the Commissioner of the Food and Drug Administration has confirmed in advance and publicly announced (hereinafter referred to as "imported health functional food pre-confirmed registration") that it satisfies with the facilities criteria and the standards and specifications as prescribed in Articles 4, 14, 15, and 17 and that it does not correspond to matters of the prohibition of advertising and sales as prescribed in Articles 18 and 23 through 25;
2. Where the examination is carried out by a food sanitation examination laboratory designated by the Commissioner of the Food and Drug Administration pursuant to Article 18 of the Food Sanitation Act (hereinafter referred to as "examination laboratory") or a foreign examination laboratory recognized and publicly announced by the Commissioner of the Food and Drug Administration, and the written result of such examination or the certificate thereof is submitted; and
3. Where it falls under any reason as prescribed by the Ordinance of the Ministry of Health and Welfare, which is other matters corresponding to subparagraphs 1 and 2.

(4) Matters necessary for the import report procedure as referred to in paragraph (1), the type, object and method of examination as referred to in paragraph (2), and the standards and designation procedures of the imported health functional food pre-confirmed registration as referred to in paragraph (3), etc. shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 9 (Restrictions on business permission, etc.) (1) In case falling under any of the following subparagraphs, no business permission shall be granted as prescribed in Article 5(1):

1. Where a person, for whom a period of six months has not elapsed since the business permission was revoked under any of subparagraphs of Article 32(1) (excluding subparagraph 9. Hereinafter this shall apply to this Article and Articles 34 and 35), intends to carry on the same kind of business as the revoked one at the same business establishment. Provided, That if the business permission has been revoked due to a removal of the entire business facilities, this shall not apply;
2. Where a person (including its representative in case of a juridical person), for whom a period of one year has not elapsed since the business permission was revoked under any of subparagraphs of Article 32(1), intends to carry on the same kind of business as the revoked one; and
3. Where a person (including its representative in case of a juridical person), who intends to obtain a business permission, is incompetent or is declared bankrupt and not yet reinstated.

(2) In case falling under any of the following subparagraphs, no business report shall be filed under Articles 6(1) and 6(2).

1. Where a person, for whom a period of six months has not elapsed since the order of business establishment closure was issued under any of subparagraphs of Article 32(1), intends to carry on the same kind of business as one subject to such order at the same business establishment. Provided, That if the order of business establishment closure has been issued due to a removal of the entire business facilities, this shall not apply;
2. Where a person (including its representative in case of a juridical person), for whom a period of one year has not elapsed since the order of business establishment closure was issued under subparagraphs of Article 32(1), intends to carry on the same kind of business as one subject to such order; and
3. Where a person (including its representative in case of a juridical person), who intends to file a business report, is incompetent or is declared bankrupt and not yet reinstated.

Article 10 (Compliance matters of business person) (1) For the purpose of ensuring safety and controling quality of health functional food, maintaining distribution order thereof, and promoting the public health, any business person shall:

1. Control the manufacturing facilities and products (including raw materials) in order to prevent hazards and to ensure safety for public health;
2. Not 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;
3. Exchange any product that is rotten, deteriorated, or disposed, or whose sell-by-date has been passed, unless there is any justifiable reason;
4. Not act to sell any product by stirring up speculative spirit, such as providing sales promotion gift or free gift, etc.; and
5. Comply with matters as prescribed by the Ordinance of the Ministry of Health and Welfare, which are other matters corresponding to subparagraphs 1 through 4, for the purpose of

ensuring safety and controling quality of health functional food, and promoting the public health.

(2) A health functional food manufacture business person shall notify the Commissioner of the Food and Drug Administration of the production records, etc. pursuant to the Ordinance of the Ministry of Health and Welfare.

Article 11 (Business succession) (1) Where a business person transfers his business or ceases to live, or juridical persons are merged, the transferee or the heir, or the juridical person surviving the merger or newly established by the merger shall succeed to the status of the previous business person.

(2) Any person who has acquired all of the business facilities and equipments by auction under the Civil Execution Act, transfer under the Debtor Rehabilitation and Bankruptcy Act, sale of property seized under the National Tax Collection Act, the Customs Act, or the Local Tax Act, or a procedure corresponding to it, shall succeed to the status, under this Act, of the previous business person. <Amended on March 31, 2005>

(3) Any person who succeeds to the status of the previous business person under paragraph (1) or (2) shall report to the Commissioner of the Food and Drug Administration or the Mayor/*Do* Governor within one month pursuant to the conditions as prescribed by the Ordinance of the Ministry of Health and Welfare.

(4) Articles 9(1) and 9(2) shall apply *mutatis mutandis* to the succession as referred to in paragraphs (1) and (2). Provided, That if the heir falls under Article 9(1)3 or 9(2)3, this shall not apply for three months from the day an inheritance has commenced.

Article 12 (Quality manager) (1) Any person who intends to carry on business with the health functional food manufacture business permission under Article 5(1) shall employ a quality manager pursuant to the Ordinance of the Ministry of Health and Welfare (hereinafter referred to as “quality manager”).

(2) A quality manager shall direct persons who engage in the health functional food manufacture in order to prevent the violation of this Act, or orders issued or sanctions imposed under this Act, and maintain products and facilities to be sanitary.

(3) Any person who carries on the health functional food manufacture business shall not obstruct a quality manager's works under paragraph (2), and, when the quality manager requests a cooperation in the execution of works, shall comply with such request unless there is any justifiable reason.

(4) Any person who carries on the health functional food manufacture business shall, in case of appointing a quality manager or dismissing him from his office, report to the Commissioner of the Food and Drug Administration pursuant to the Ordinance of the Ministry of Health and Welfare.

(5) Matters necessary for the qualification criteria, duties, etc. of quality manager shall be prescribed by the Presidential Decree.

Article 13 (Education) (1) The Minister of Health and Welfare may, if deemed necessary to

prevent hazards for national health, order a business person and the employees to receive an education on ensuring safety of the health functional food and the quality management thereof.

(2) Any person who intends to carry on the business under Article 4 shall receive in advance an education on ensuring safety of the health functional food and the quality management thereof. Provided, That in case where a person is unable to receive in advance such education due to any reason as prescribed by the Ordinance of the Ministry of Health and Welfare, the person may receive such education after the commencement of business under the conditions as determined by the Minister of Health and Welfare.

(3) Any person who has appointed as a quality manager under Article 12 shall regularly receive an education on ensuring safety of the health functional food, the quality management thereof, etc.

(4) Any person, from among those who have to receive an education under paragraph (1), who intends to carry on the business in more than two places or who is unable to receive an education due to any reason as prescribed by the Ordinance of the Ministry of Health and Welfare, may designate a person in charge, from among employees, to receive such education.

(5) Matters necessary for the education institution, the contents of education, the collection of required expenses, etc. as referred to in paragraphs (1) through (3) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Chapter Ⅲ Standards and Specifications, Labeling and Advertising, etc.

Article 14 (Standards and specifications) (1) The Commissioner of the Food and Drug Administration shall establish and publicly announce the standards and specifications for manufacture and use, storage, etc. of health functional food for sale.

(2) With respect to the standards and specifications of food, whose standards and specifications are not announced publicly under paragraph (1), the Commissioner of the Food and Drug Administration may recognize the standards and specifications of a health functional food through an examination by an examination laboratory after having a business person prescribed under Article 5(1) or 6(1) provide data on the standards and specifications, the safety, the functionality, etc. of such food.

(3) Notwithstanding the provisions of paragraphs (1) and (2), the standards and specifications of health functional food for the export purpose may be subject to those as required by the importers.

(4) Matters necessary for the standards and methods, the procedure, etc. for recognition as referred to in paragraph (2) shall be determined by the Commissioner of the Food and Drug Administration.

Article 15 (Recognition of ingredients, etc.) (1) The Commissioner of the Food and Drug Administration shall determine and publicly announce the ingredients or the components of health functional food intended for sale.

(2) With respect to the ingredients or the components of health functional food, which are not

announced publicly under paragraph (1), the Commissioner of the Food and Drug Administration may recognize the ingredients or the components of health functional food after having a business person prescribed under Article 5(1) or 6(1) provide data on the safety, the functionality, etc. of such ingredients or such components.

(3) Matters necessary for the standards and methods, the procedure, etc. for recognition as referred to in paragraph (2) shall be determined by the Commissioner of the Food and Drug Administration.

Article 16 (Deliberation of labeling and advertising of functionality) (1) Any person who intends to label and advertize the functionality of health functional food shall be deliberated in accordance with the standards of labeling and advertising deliberation of health functional food, and the methods and procedures thereof decided by the Commissioner of the Food and Drug Administration.

(2) The Commissioner of the Food and Drug Administration may entrust the works for the deliberation of labeling and advertising of functionality of health functional food as referred to in paragraph (1) to an association which is established under Article 28.

Article 17 (Standards of label) (1) Any container or package of health functional food shall bear a label containing-: <Amended on October 4, 2006>

1. letters of health functional food or diagram that stands for health functional food;
2. the functional components or the nutrients, and the ratio of the recommended daily amounts (limited to the case where the recommended daily amounts is set up);
3. the consumption amount, the consumption method, and the warning notice for consumption;
4. the sell-by-date and the storage method;
5. an disclaim that it is not a medicine for preventing and curing disease; and 6. other matters determined by the Commissioner of the Food and Drug Administration.

(2) The Commissioner of the Food and Drug Administration shall determine and publicly announce the matters necessary for the method of labeling, etc. as referred to in paragraph (1).

Article 18 (Prohibition of false or exaggerated labeling and advertising) (1) With respect to name, raw materials, manufacturing method, nutrients, components, usage method, quality, etc. of health functional food, no business person shall make false or exaggerated labeling or advertising falling under any of the following subparagraphs:

1. Labeling or advertising which may cause to mislead or confuse that it is efficient and effective in preventing and curing disease, or it is a medicine;
2. Labeling or advertising which is not truthful or exaggerated;
3. Labeling or advertising which may cause consumers to be deceived, misled, or confused;
4. Labeling or advertising with the name solely used for medicines (including prescriptions of Korean oriental medicine); and
5. Labeling or advertising whose contents have not been deliberated or which is different in contents from what was deliberated under Article 16(1).

(2) Matters necessary for the scope of false or exaggerated labeling and advertising, etc. as referred to in paragraph (1) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 19 (Official book of health functional food) The Commissioner of the Food and Drug Administration shall prepare and disseminate the official book of health functional food containing the standards and specifications of health functional food as prescribed under Article 14, the ingredients and the components as prescribed under Article 15, and the standards of label as prescribed under Article 17.

Chapter Ⅳ Inspection, etc.

Article 20 (Entry; inspection; collection; etc.) (1) The Commissioner of the Food and Drug Administration (including the heads of his subordinate agencies as prescribed by the Presidential Decree) or Mayor/*Do* governor may, if deemed necessary, have any business person or other person concerned make a necessary report, or have a relevant public official enter a business place, office, warehouse, factory, storehouse, retail store or similar place to inspect raw materials, product, container and package, intended for sale or used for business, or a manufacturing or business facilities, etc., collect a minimum quantity of raw materials, product, containers and packages, etc. as required for examination without compensation, and peruse books or documents related to the business as the occasion arises.

(2) Any relevant public official who intends to enter, inspect, collect or peruse under paragraph (1) shall carry an identification verifying his authority and present it to persons concerned.

Article 21 (Responsibility of self quality examination) (1) Any person who has obtained a permission for the health functional food manufacture business as referred to in Article 5 (1) shall examine whether or not his manufactured health functional food conforms to the standards and specifications described in Article 14 under the conditions as prescribed by the Ordinance of the Ministry of Health and Welfare, and keep the records.

(2) If it is improper that a person required to inspect under paragraph (1) carries out such self examination, the Commissioner of the Food and Drug Administration may entrust such examination to an examination laboratory.

(3) Matters necessary for the examination items, the examination procedure, etc. as referred to in paragraphs (1) and (2) shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

Chapter Ⅴ Good Manufacturing Practices, etc.

Article 22 (Good Manufacturing Practices, etc.) (1) For the purpose of manufacturing and

quality control of good health functional food, the Commissioner of the Food and Drug Administration may determine and publicly announce the standards of manufacturing and quality control of good health functional food (hereinafter referred to as "Good Manufacturing Practices").

(2) The Commissioner of the Food and Drug Administration may designate and publicly announce the Good Manufacturing Practices application business establishment, when a person with a permission for the health functional food manufacture business as referred to in Article 5 (1) complies with the Good Manufacturing Practices under paragraph (1).

(3) Matters necessary for the designation procedure of the Good Manufacturing Practices application business establishment, the education and training for business persons and the employees, etc. shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

(4) In case where a Good Manufacturing Practices application business establishment falls under any of the following subparagraphs, the Commissioner of the Food and Drug Administration may revoke the designation or order to rectify it:

1. Where it fails to comply with the Good Manufacturing Practices;
2. Where it is imposed a business suspension or heavier administrative measures under Article 32;
3. Where the business person and the employees fail to receive an education and training under paragraph (3); and
4. Where it fails to observe any other matter as prescribed by the Ordinance of the Ministry of Health and Welfare for the purpose of managing effectively the Good Manufacturing Practices application business establishment.

(5) No person, not designated as a Good Manufacturing Practices application business establishment, shall make labeling or advertising with the title of the Good Manufacturing Practices application business establishment or similar contents.

(6) The Commissioner of the Food and Drug Administration may exempt the Good Manufacturing Practices application business establishment from the entry and inspection under Article 20 within a certain period of time as prescribed by the Ordinance of the Ministry of Health and Welfare, or give financial supports to improve business facility, etc.

(7) The expenses required for the education and training, etc. under paragraph (3) may be charged to the recipients.

Chapter Ⅵ Prohibition of Sales, etc.

Article 23 (Prohibition of sales, etc. of health functional food injurious to health) No health functional food shall be sold or manufactured, imported, used, stored, transported or displayed for sale-

1. If it is rotten or spoiled so that it may injure the health of the human body;
2. If it contains or is adhered with any poisonous or detrimental substance, or if there is any possibility thereof, except that this subparagraph shall not apply in case where the Commissioner of the Food and Drug Administration deems that it is not injurious to health of the human body;

3. If it is or may be contaminated with any pathogenic microorganism so that it may injure the health of the human body;
4. If it may injure the health of the human body because it is filthy, any foreign substance is mixed or added, or there is any other reason;
5. If it is manufactured by a person without business permission in case where it is required to obtain a permission for business under Article 5 (1); or
6. If it is prohibited from importing or is imported without report in cases where it is required of import report under Article 8.

Article 24 (Prohibition of selling, etc. of the health functional food which violates the standards and specifications) (1) Any business person shall manufacture, use, or store the health functional food, whose standards and specifications are determined in Articles 14 (1) and (2), in accordance with such standards and specifications, and shall not sell or manufacture, import, use, store, transport or display for sale any health functional food which does not comply with such standards and specifications.

(2) No business person shall manufacture a health functional food with ingredients, solely used for medicines, or whose combination, mixture ratio or content is identical with or similar to medicine, or import, sell, or display such health functional food.

(3) The Commissioner of the Food and Drug Administration shall prescribe the detailed standards and scope of the ingredients solely used for medicines and the health functional food similar to medicines, etc. as referred to in paragraph (2).

Article 25 (Prohibition of sales etc. of health functional food violated the standards of label) No business person shall sell or manufacture, import, display, transport, or use for sale any health functional food violated the standards of label prescribed in Article 17.

Article 26 (Prohibition of analogous labeling, etc.) If it is not a health functional food, no one shall make labels upon its container or package, or advertising which may mislead public into thinking that it has food and nutritional · physiological functions and effects, etc. for the human body structure and function, or sell, store or display for sale anything that is labelled or advertised as one analogous to health functional food.

Chapter Ⅶ Establishment of Health Functional Food Deliberation Committee and Associations

Article 27 (Health Functional Food Deliberation Committee) (1) The Health Functional Food Deliberation Committee shall be established in the Ministry of Health and Welfare to research and deliberate on the following matters at the request of the Minister of Health and Welfare or the Commissioner of the Food and Drug Administration:

1. Matters relating to the policies on health functional food;

2. Matters relating to the standards and specifications for health functional food;
3. Matters relating to the labeling and advertising of health functional food; and
4. Other important matters relating to health functional food.

(2) The Health Functional Food Deliberation Committee may appoint research fellows to research and study on the standards and specifications, the labeling and advertising of health functional food, etc.

(3) Matters necessary for the organization and operation of the Health Functional Food Deliberation Committee as referred to in paragraphs (1) and (2) shall be prescribed by the Presidential Decree.

Article 28 (Establishment of associations) (1) Business persons may establish an association by type of business as determined by the Presidential Decree in order to contribute to ensuring safety and improving quality of health functional food, and improving the public health by promoting a sound development of such business.

(2) The association shall be a juridical person.

(3) In case where intending to establish an association, the promoters of more than 1/10 (20 persons in case of exceeding 20) of persons eligible for members shall prepare the articles of association under the conditions as prescribed by the Presidential Decree, and obtain an authorization for its establishment from the Minister of Health and Welfare.

Chapter Ⅷ Administrative Sanctions such as Order of Correction and Revocation of Permission, etc.

Article 29 (Order of correction) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may, if deemed necessary, issue an order of correction to a person who does not observe the provisions of this Act.

Article 30 (Sanction of disposal, etc.) (1) If a business person violates the provisions of Articles 23 through 26, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may have relevant public officials seize or dispose such health functional food, or order the business person to take measures necessary for eliminating any hazard to food sanitation.

(2) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may have relevant public officials seize or dispose such health functional food as manufactured or such apparatus, containers or packages, etc. as used for it, without obtaining permission in a case where it is required under Article 5 (1).

(3) When any hazard to sanitation has occurred or is deemed to occur, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may order the business person to recall or dispose such health functional food in circulation, or to change the ingredients, manufacturing method, components or mixture ratio thereof of health functional food.

(4) In the case of the seizure or disposal as referred to in paragraphs (1) and (2), the relevant

public official shall carry an identification verifying his authority and present it to the persons concerned.

(5) Matters necessary for the seizure or disposal as referred to in paragraphs (1) and (2), the standards applying to the health functional food to be recalled under paragraph (3), etc. shall be determined by the Ordinance of the Ministry of Health and Welfare.

Article 31 (Order to improve or repair facilities, etc.) (1) If business facilities do not conform to the standards as prescribed in Article 4 (1), the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may order the business person to improve or repair the facilities within a prescribed period.

(2) If the owner of a building is not the business person, the former shall cooperate fully with the latter in improving or repairing the facilities according to an order issued under paragraph (1).

Article 32 (Revocation of permission, etc.) (1) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may revoke the business permission, suspend the whole or part of the business with fixing a period not exceeding six months, or order a business establishment closure (limited to a business as reported under Article 6; hereafter the same shall apply in this Article) under the conditions as prescribed by the Presidential Decree, if a business person–:

1. violates the provisions of Article 5(1)(latter part), 7(1)(former part), 8(1), 10(1) (excluding subparagraphs 1 and 5), or 11(3);
2. violates the provisions of 12(1);
3. violates the provisions of 18(1);
4. fails to carry out the self quality examination under Article 21;
5. violates the provisions of 22(5);
6. violates the prohibitions of selling and analogous labeling, etc. under Article 23, 24(1) and (2), 25 or 26;
7. violates an order issued under Article 29, 30(1) and (3), 31(1) or 33(1);
8. continues to carry on the business in violation of the business suspension order; or
9. continues to suspend his business for six months or more without any justifiable reason.

(2) The detailed criteria for administrative sanction as referred to in paragraph (1) shall be determined by the Ordinance of the Ministry of Health and Welfare considering the types, degree, etc. of violation,

Article 33 (Suspension of item manufacturing, etc.) (1) If a business person violates the provisions of Article 18(1), 21(1), 23, 24(1) and (2), 25 or 26, the Commissioner of the Food and Drug Administration may order the business person to suspend the manufacturing of the item or items concerned (referred to all items manufactured under application of the same standards and specifications as those determined under Article 14; hereinafter the same shall apply), with fixing a period not exceeding six months, under the conditions as prescribed by the Presidential Decree.

(2) The detailed criteria for administrative sanction as referred to in paragraph (1) shall be

determined by the Ordinance of the Ministry of Health and Welfare considering the types, degree, etc. of violation.

Article 34 (Succession to effect of administrative sanction) In case where a business person transfers his business or juridical persons are merged, the effect of an administrative sanction taken against the previous business person for his violation of Article 32 (1) or 33 (1) shall be succeeded to the transferee or the juridical person surviving the merger for a year from the day on which the sanction period is terminated, and if the procedure for the administrative sanction is pending, it may proceed against such transferee or juridical person.

Article 35 (Closure measures, etc.) (1) If a person carries on a business without obtaining permission or reporting in violation of the provisions of Article 5(1)(former part) or 6(1) and (2), or continues to carry on the business after the permission is revoked or an order of business establishment closure is issued under Article 32(1), the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may have relevant public officials take the following measures for closing the business establishment in question:

1. To remove or delete a signboard or other business marks of such business establishment;
2. To post a notice, etc. announcing that such business establishment is not a legal establishment; and
3. To put the seal on facilities of such business establishment and other apparatus, etc. used for the business, for the prohibition of their use.

(2) If it is deemed unnecessary to continue sealing after administering it under paragraph (1)3, or the business person or his agent promises to close such business establishment or otherwise requests the release of sealing by presenting any justifiable reason, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may release such sealing. This provision shall also apply to a case of notice, etc. as referred to in paragraph (1)2.

(3) If the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor intends to take measures under paragraph (1), he shall, in advance, notice in writing to the business person or his agent in question, unless there is any reason determined by the Ordinance of the Ministry of Health and Welfare.

(4) The measures taken under paragraph (1) shall be limited to a minimum extent as required to close the business.

(5) In a case as referred to in paragraph (1), the relevant public official shall carry an identification verifying his authority and present it to the persons concerned.

Article 36 (Hearing) If the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor intends to impose a sanction of business permission revocation or order of business establishment closure under Article 32(1), he shall hold a hearing.

Article 37 (Penalty surcharge) (1) If a business person falls under any of subparagraphs of Article 32(1) (excluding subparagraphs 8 and 9) or 33(1), the Commissioner of the Food and Drug

Administration or the Mayor/*Do* governor may impose a penalty surcharge not exceeding two hundred million won in lieu of a sanction of business suspension or item or items manufacturing suspension under the conditions as prescribed by the Presidential Decree, except in a case where he falls under Article 32(1) or 33(1) for violating the provisions of Article 5(1)(latter part), 10(1), 18(1), 23, 24(1) and (2), 25 or 26, which is determined by the Ordinance of the Ministry of Health and Welfare.

(2) Matters necessary for the amount of penalty surcharge depending on the cases, degree, etc. of violation on which the penalty surcharge is imposed under paragraph (1), etc. shall be determined by the Presidential Decree.

(3) If the penalty surcharge as referred to in paragraph (1) is not paid by the due date, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall cancel the penalty surcharge as referred to in paragraph (1) and impose a sanction of business suspension, etc. under Article 32 or 33.

(4) Of the penalty surcharge collected under paragraphs (1), that imposed and collected by the Commissioner of the Food and Drug Administration shall be reverted to the State, and that imposed and collected by the Mayor/*Do* governor to the Food Promotion Fund of City/*Do* (referring to the Food Promotion Fund under Article 71 of the Food Sanitation Act).

(5) In a case where the Mayor/*Do* governor has delegated the authority to impose and collect the penalty surcharge as referred to in paragraph (1) to the head of *Si*/*Gun*/*Gu* under Article 41, the Mayor/*Do* governor may grant the required expenses to the head of *Si*/*Gun*/*Gu* under the conditions as prescribed by the Presidential Decree.

Chapter IX Supplementary Provisions

Article 38 (Relations with other Acts) (1) Except for providing in this Act, the standards and specifications for food additives prescribed in Article 7 of the Food Sanitation Act shall apply *mutatis mutandis* to food additives used for health functional food, the reexamination of food, etc. prescribed in Article 17-2 of the same Act shall apply *mutatis mutandis* to matters relating to the reexamination of health functional food, the designation of food sanitation examination laboratory prescribed in Article 18 of the same Act shall apply *mutatis mutandis* to matters relating to the designation of health functional food examination laboratory, the food sanitation inspectors prescribed in Article 20 of the same Act shall apply *mutatis mutandis* to the health functional food sanitation inspectors, the honorary food sanitation inspectors prescribed in Article 20-2 of the same Act shall apply *mutatis mutandis* to the honorary health functional food sanitation inspectors, the medical examination prescribed in Article 26 of the same Act shall apply *mutatis mutandis* to the medical examination, the voluntary recall of food, etc. prescribed in Article 31-2 of the same Act shall apply *mutatis mutandis* to matters relating to the voluntary recall of health functional food, the hazard analysis critical control point system prescribed in Article 32-2 of the same Act shall apply *mutatis mutandis* to matters relating to the hazard analysis critical control point system, the publication prescribed in Article 56-2 of the same Act shall apply *mutatis mutandis* to matters

relating to the publication, and the investigation and report on food poisoning prescribed in Article 67 of the same Act shall apply *mutatis mutandis* to matters relating to the investigation and report on food poisoning.

(2) If a person violates the provisions of the Food Sanitation Act applicable *mutatis mutandis* under paragraph (1), the order of correction under Article 55 of the same Act, the sanction of disposal, etc. under Article 56 of the same Act, the revocation of permission, etc. under Article 58 of the same Act, or the suspension of item manufacturing, etc. under Article 59 of the same Act, may be imposed, and the person may be punished under Articles 75, and 78 through 80 of the same Act.

Article 39 (State subsidy) The Minister of Health and Welfare or the Commissioner of the Food and Drug Administration may assist the whole or part of the following expenses within the limit of budget:

1. Expenses required for the collection of health functional food, etc. under Article 20(1);
2. Expenses needed for the finance support, etc. for the business facilities of the Good Manufacturing Practices application business establishment under Article 22(6);
3. Expenses required for the quality improvement of health functional food, the prevention of false or exaggerated labeling and advertising thereof, the promotion of research and development thereof, etc.; and
4. Expenses required for the private organization activities in order to improve safety of health functional food.

Article 40 (Payment of reward money) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may pay the reward money, under the criteria as determined by the Ordinance of the Ministry of Health and Welfare, to a person who reports to or informs a relevant administrative agency or criminal investigation agency on an offender who violates the provisions of Article 5(1), 6(1) and (2), or 23 through 26.

Article 41 (Delegation and entrustment of authority) (1) The Commissioner of the Food and Drug Administration may delegate part of his authority as prescribed in this Act to the Commissioner of the Regional Food and Drug Administration or entrust it to the head of the National Quarantine Service under the conditions as prescribed by the Presidential Decree.

(2) The Mayor/*Do* governor may delegate part of his authority as prescribed in this Act to the head of *Si*/*Gun*/*Gu* under the conditions as prescribed by the Presidential Decree.

(3) The Minister of Health and Welfare or the Commissioner of the Food and Drug Administration may entrust part of his authority as prescribed in this Act to the association, as referred to in Article 28, under the conditions as prescribed by the Presidential Decree.

Article 42 (Fees, etc.) Any person who intends to obtain a permission, file a report, file an application, or undergo an examination, falling under one of the following subparagraphs, shall pay the fees as determined by the Ordinance of the Ministry of Health and Welfare:

1. Business permission, modification permission under Article 5(1) or modification report under Article 5(2);
2. Business report or modification report under Article 6(1) through (3);
3. Item manufacturing report or modification report under Article 7;
4. Import report, examination or imported health functional food pre-confirmed registration application under Articles 8(1) through (3);
5. Examination for recognizing the standards and specifications, the ingredients, etc. under Article 14(2) or 15(2);
6. Application for deliberation of functionality labeling and advertising under Article 16 (1);
7. Entrusted self quality examination under Article 21(2); and
8. Application for designation of the Good Manufacturing Practices application business establishment.

Chapter X Penal Provisions

Article 43 (Penal provisions) Any person who violates the provisions of Article 5(1) or 23 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 44 (Penal provisions) Any person who falls under any of the following subparagraphs, 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:
1. A person who carries on business without filing such report required by Article 6(1) or 6(2);
2. A person who manufactures and sells a product without filling an item manufacturing report required by the former part of Article 7(1);
3. A person who sells a product in violation of Article 10(1)4;
4. A person who makes a false or exaggerated labeling or advertising in violation of Article 18(1);
5. A person who fails to make such self quality examination under Article 21(1);
6. A person who makes labels or advertising in violation of Article 22(5);
7. A person who sells, etc. in violation of Articles 24 through 26;
8. A person who fails to comply with any such order under Article 29 or 30(1) and (3); and
9. A person who violates such business suspension order under Article 32(1).

Article 45 (Penal provisions) Any person who falls under any of the following subparagraphs, shall be punished by imprisonment for not more than three years or a fine not exceeding thirty million won:
1. A business person who violates such facilities criteria prescribed under Article 4;
2. A person who fails to observe such matters to be complied by the business person under

Article 10(1)2 and 3;

3. A person who fails to file such business succession report prescribed by Article 11(3);
4. A person who fails to employ such quality manager prescribed by Article 12(1);
5. A person who refuses, interferes with or evades such entry, inspection or collection under Article 20(1);
6. A person who refuses, interferes with or evades such seizure or disposal under Article 30(2);
7. A person who violates such item manufacturing suspension order, etc. under Article 33(1); and
8. A person who removes or damages, without permission, such sealing or notice, etc., which was put by a relevant public official under Article 35.

Article 46 (Joint penal provisions) If the representative of a juridical person or an agent, employee or any other worker of a juridical person or individual has committed offenses as referred to in Articles 43 through 45 with respect to activities of such juridical person or individual, the fine as prescribed in respective Articles shall be imposed on such juridical person or individual, in addition to punishment of the offender.

Article 47 (Fine for negligence) (1) Any person who falls under any of the following subparagraphs shall be punished by a fine for negligence not exceeding three million won:

1. A person who fails to file such modification report of permitted matter required by Article 5(2);
2. A person who fails to file such modification report of reported matter required by Article 6(3);
3. A person who fails to file such modification report of item manufacturing reported matter required by the latter part of Article 7(1);
4. A person who fails to observe such matters to be complied by business person under Article 10(1) 1 and 5 or violates the provisions of Article 10(2);
5. A person who interferes with the works of quality manager under Article 12(3) or fails to file such report of appointment or dismissal of quality manager under Article 12(4);
6. A person who fails to receive such education required by Articles 13(1) through (3);
7. A person who fails to keep the records after such self quality examination or makes fraud records required by Article 21(1); and
8. A person who fails to comply with such order to improve or repair facilities under Article 31(1).

(2) The fine for negligence as referred to in paragraph (1) shall be imposed and collected by the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor under the conditions as prescribed by the Presidential Decree.

(3) Any person who is disagreed with the disposition of a fine for negligence under paragraph (2), may raise an objection to the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor within thirty days after he is informed of the disposition.

(4) When a person subject to the disposition of a fine for negligence under paragraph (2), has raised an objection under paragraph (3), the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall notify the competent court without delay, and such court tries the case of fine for negligence according to the NonContentious Case Litigation Procedure Act.

(5) If no objection is raised and no fine for negligence is paid within such a period as prescribed in paragraph (3), the fine shall be collected according to the case of disposition of national taxes or local taxes in arrears.

Article 48 (Special cases in application of provisions concerning fine for negligence) In application of the provisions of Article 47 concerning a fine for negligence, this shall not be imposed on an act against which a penalty surcharge is imposed under Article 37.

ADDENDA <Act No. 6727, August 26, 2002>

Article 1 (Enforcement date) This Act shall enter into force one year after the date of its promulgation.

Article 2 (Transitional measures concerning health functional food manufacture business permission, etc.) (1) Any person, who has filed such food manufacture business or food processing business required by Article 22(5) of the Food Sanitation Act and manufactures health functional food in accordance with the standards and specifications required by Article 14(1) at the time this Act enters into force, shall be considered as the business person, who carries on health functional food manufacture business, as prescribed in this Act. In this case, he shall obtain a permission from the Commissioner of the Food and Drug Administration under Article 5 within six months after this Act enters into force, but the fees shall be exempted.

(2) If the item that the business person under the former part of paragraph (1) has made a manufacture notification required by Article 22(6) of the Food Sanitation Act falls under health functional food in accordance with the standards and specifications required by Article 14(1) at the time this Act enters into force, it may continue to be manufactured and sold. In this case, the business person shall file a report with documents determined by the Ordinance of the Ministry of Health and Welfare, such as a manufacturing method document of the item, etc. to the Commissioner of the Food and Drug Administration under Article 7 within six months after this Act enters into force, but the fees shall be exempted.

Article 3 (Transitional measures concerning health functional food import business report) Any person, who has filed such report on imported food, etc. business required by Article 16(1) of the Food Sanitation Act, and imports and sells health functional food in accordance with the standards and specifications required by Article 14(1) at the time this Act enters into force, shall be considered as the business person, who carries on the health functional food import business, as prescribed in this Act. In this case, he shall file a report to the Commissioner of the Food and Drug Administration under Article 6(1) within six months after this Act enters into force, but the fees shall be exempted.

Article 4 (Transitional measures concerning a person whose business permission has been

revoked, etc.) The period for restricting any permission or report against a person whose license is revoked or who is ordered to close the business establishment under the Food Sanitation Act before this Act enters into force, shall be subject to the provisions of the Food Sanitation Act.

Article 5 (Transitional measures concerning penalty and fine for negligence) In applying the penalty or the fine for negligence to the acts committed before this Act enters into force, the provisions of the Food Sanitation Act shall apply.

Article 6 (Transitional measures concerning disposition, etc.) Any disposition, application, report, notification and other act to the administrative agency pursuant to the Food Sanitation Act before this Act enters into force shall be considered as one done under this Act.

Article 7 (Transitional measures concerning association) Any trade association which has been established under Article 44 of the Food Sanitation Act at the time this Act enters into force shall be considered as an association established under this Act when it falls within the purview of Article 28.

Article 8 (Relations with other Acts and subordinated statues) In cases where other Acts and subordinated statues refer the provisions of the Food Sanitation Act at the time this Act enters into force and this Act has provisions equivalent to them, this Act or such provisions of this Act shall be deemed to be referred in lieu of the previous provisions.

Article 9 (Amendment to other Acts) (1) The Food Sanitation Act shall be amended as follows:

"Article 65 and Article 37 of the Health Functional Food Act" shall replace "Article 65" in Article 71(2)2, "business person (including business person under the Health Functional Food Act)" shall replace "business person" in Article 71(3)1, and "food sanitation, national nutrition and health functional food" shall replace "food sanitation and national nutrition" in Article 71(3)7.

(2) Article 16(6)13-2 of the Industrial Placement and Factory Construction Act shall be provided as follows:

13-2 health functional food manufacture business permission under Article 5 of the Health Functional Food Act.

(3) Article 10(1)3-2 of the Distribution Industry Development Act shall be provided as follows:

3-2 health functional food manufacture business under Article 5 of the Health Functional Food Act or health functional food sales business under Article 6 of the same Act.

(4) The Act on Special Measures for the Control of Public Health Crimes shall be amended as follows:

In Article 2(1), "a person who manufactures or processes without the permission under the provisions of Article 5 of the Health Functional Food Act, previously permitted or reported food, food additives or health functional food" shall replace "previously permitted or reported food or food additives", and "Article 6 or 7(4) of the Food Sanitation Act or Article 24(1) of the Health Functional Food Act" shall replace "Article 6 or 7(4) of the same Act", and in Article 2(1)1 and 2,

"food, food additives or health functional food" shall replace "food or food additives".

ADDENDUM <Act No. 7211, March 22, 2004>

This Act shall enter into on the date of its promulgation.

ADDENDA (Debtor Rehabilitation and Bankruptcy Act) <Act No. 7428, March 31, 2005>

Article 1 (Enforcement date) This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 4 Omitted

Article 5 (Amendment to other Acts) (1) and (2) Omitted.
(3) The Health Functional Food Act shall be amended as follows:
"Debtor Rehabilitation and Bankruptcy Act" shall replace "Bankruptcy Act" in Article 11(2).
(4) through (145) Omitted.

Article 6 Omitted.

ADDENDUM <Act No. 8033, October 4, 2006>

This Act shall enter into force six months after the date of its promulgation.

ADDENDUM <Act No. 8365, April 11, 2007>

Article 1 (Enforcement date) This Act shall enter into on the date of its promulgation.<proviso omitted>

Articles 2 through 20 Omitted.

Article 21 (Amendment to other Acts) (1) The Health Functional Food Act shall be amended as follows:
"Article 16 of the Pharmaceutical Affairs Act" shall replace "Article 20 of the 「Pharmaceutical Affairs Act」" in the proviso of Article 6(2).
(2) through (12) Omitted.

Aticle 22 Omitted.

Enforcement Decree of the Health Functional Food Act

Enacted by Presidential Decree No. 18164, Dec. 18, 2003
Amended by Presidential Decree No. 19513, Jun. 12, 2006
Amended by Presidential Decree No. 19836, Jan. 18, 2007

Article 1 (Purpose) The purpose of this Decree is to provide matters delegated by the 「Health Functional Food Act」 and matters necessary for the enforcement thereof. <Amended on January 18, 2007>

Article 2 (Types of business) The detailed types and scope of business referred to in Article 4(2) of the 「Health Functional Food Act」 (hereinafter referred to as the "Act") are as follows <Amended on January 18, 2007>:

1. Health functional food manufacture business
   (a) Health functional food manufacture-specializing business: a business which specializes in manufacture health functional food.
   (b) Health functional food manufacture venture business : a business in which a venture business under the provisions of Article 2 of the 「Act on Special Measures for the Promotion of Venture Businesses」 entrusts a health functional food manufacture-specializing business person under item (a) with manufacturing a health functional food.
2. Health functional food import business: a business engaged in importing a health functional food
3. Health functional food sales business
   (a) Health functional food general sales business : a business which sells a health functional food in a business place, by the door-to-door sale, the multi-level sale or the telephone solicit sale under the provisions of Article 2 of the 「Door-to-Door Sales」 , etc. Act, or by the electronic commerce transaction or the mail order, etc. under the provisions of Article 2 of the 「Act on the Consumer Protection in the Electronic Commerce Transactions」 , etc.
   (b) Health functional food distribution-specializing sales business: a business in which a person distributes and sells under his trade mark such health functional food manufactured at his request by a health functional food manufacture-specializing business person under subparagraph 1 (a).

Article 3 (Modification permission of matter subject to permission) The modification matter subject to permission under the latter part of Article 5(1) of the Act shall be the modification of the location of business establishment.

Article 4 (Qualification criteria of quality manager) The qualification criteria of quality manager as provided in Article 12(5) of the Act shall be as follows:

1. A certified food engineer under the National Technical Qualifications Act;
2. A certified food technician under the National Technical Qualifications Act, who has engaged in

a manufacturing work of health functional food, its ingredients and components, general food or food additive (hereinafter referred as "health functional food, etc." in this Article) for one year or more;

3. 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, microbiology, genetic engineering, biotechnology etc. (hereinafter referred to as "food-related fields" in this Article) at a school under the provisions of the subparagraphs of Article 2 of the Higher Education Act (except a college under paragraph (4) of the same Article, hereinafter referred to as "a university, etc." in this Article) or a certified food technician under the National Technical Qualifications Act, who has engaged in a manufacturing work of health functional food etc. for three years or more;
4. A person who obtained a bachelor degree in food-related fields at a university etc., obtained a master degree in food-related fields at a graduate school under the provisions of Article 29 of the Higher Education Act (hereinafter referred to as "a graduate school" in this Article), and engaged in a manufacturing work of health functional food etc. for one year or more;
5. A person who obtained a bachelor degree not in food-related fields at a university etc., obtained a master degree in food-related fields at a graduate school, and engaged in a manufacturing work of health functional food etc. for three years or more;
6. A person who has graduated from a college under the provisions of Article 2(4) of the Higher Education Act (including the person who was recognized to have an academic background equivalent to this by laws and ordinances, and engaged in a manufacturing work of health functional food etc. for five years or more;
7. A person who has graduated from a highschool or technical highschool under the provisions of Article 2(4) of the Elementary and Secondary Education Act (including the person who was recognized to have an academic background equivalent to this by laws and ordinances, and engaged in a manufacturing work of health functional food etc. for eight years or more; and
8. A person recognized by the Minister of Health and Welfare that he has a qualification, academic background or career equivalent to and above subparagraphs 1 through 7.

[Wholly amended on January 18, 2007]

Article 5 (Duties of quality manager) The duties of quality manager as provided in Article 12(5) of the Act are as follows:

1. To secure safety of health functional food;
2. To manage qualities of products and ingredients through the self quality examination, etc. under the provisions of Article 21 of the Act;
3. To maintain manufacturing facilities and products to be sanitary; and
4. To direct and supervise the employees and to educate and train them.

Article 6 (Head of subordinated agencies) The term "his subordinate agencies as prescribed by the Presidential Decree" in Article 20(1) of the Act means the Commissioners of the Regional

Food and Drug Administrations referred to in the provisions of Article 20(1) of the 「Service Regulations of the Food and Drug Administration and Its Subordinate Agencies」. <Amended on January 18, 2007>:

Article 7 (Composition of health functional food Deliberation Committee) (1) The Health Functional Food Deliberation Committee referred to in the provisions of Article 27 of the Act (hereinafter referred to as the "Deliberation Committee") shall be composed of between thirty and eighty members including one chairman and two vice-chairmen.

(2) The chairman shall be elected from among its members, and the vice-chairmen shall be appointed by the chairman from among the members.

(3) The members shall be <Amended on June 12, 2006, January 18, 2007> -:

1. appointed by the Minister of Health and Welfare from the fifth-ranking and above public officials in charge of relevant health functional food affairs or the public officials in general service of the Senior Executive Service; or
2. commissioned by the Minister of Health and Welfare from-
   (a) persons with extensive learning and experience in foods, medicines, nutrition and health care; or
   (b) persons recommended by heads of health functional food related organizations, citizen's organizations (referring to the nonprofit non-governmental organization under Article 2 of the 「Assistance for Nonprofit Non-Governmental Organizations Act」), health functional food related academic societies, or universities.

(4) The members under paragraph (3)1 shall hold office as long as he holds his office, and the terms of office of the members under paragraph (3)2 shall be two years.

Article 8 (Operation of the Deliberation Committee) (1) The chairman shall represent the Deliberation Committee and exercise general control over the business of the Deliberation Committee.

(2) The vice-chairmen shall assist the chairman and the vice-chairman, designated by the chairman, acts on behalf of the chairman when the chairman is unable to perform his duties due to unavoidable reasons.

(3) The chairman shall convene meetings and preside over the meetings.

(4) The meeting of the Deliberation Committee shall start a deliberation with the attendance of a majority of the total members and make a decision with a concurring vote of a majority of those present.

(5) In the case where a request for the convocation of a meeting is filed by the Minister of Health and Welfare, the Commissioner of the Food and Drug Administration or not less than one-third of the members, the chairman shall convene the meeting without delay.

Article 9 (Subcommittees) (1) The Deliberation Committee may have subcommittees by specialized field in order to discharge its duties efficiently.

(2) Matters decided by a subcommittee shall be reported to the chairman and deliberated by the

Deliberation Committee. Provided, That if the chairman deems matters minor, he may substitute a decision by the Deliberation Committee upon the matters with one by a subcommittee upon them.

Article 10 (Research fellows) (1) The Deliberation Committee may appoint twenty or fewer research fellows for the purpose of researches and studies on the standards and specifications of the health functional food and the labeling and advertising thereof, etc.
(2) The research fellows shall be appointed by the Minister of Health and Welfare from persons with extensive learning and experience in the health functional foods, or the foods, etc.
(3) The research fellows may attend and have a say in meetings of the Deliberation Committee or a subcommittee.

Article 11 (Audience of opinions) The chairman may request for attendance of the persons concerned and ask their opinions, if he determines it necessary to do so in regard to matters on the agenda of the Deliberation Committee or a subcommittee.

Article 12 (Secretary) (1) One secretary shall be put in the Deliberation Committee to deal with general affairs of the Deliberation Committee.
(2) The secretary shall be appointed by the Minister of Health and Welfare from the competent public officials of the Ministry of Health and Welfare.

Article 13 (Report) The chairman shall report matters deliberated by the Deliberation Committee to the Minister of Health and Welfare without delay.

Article 14 (Allowances and travel expenses) (1) The members present at the meetings of the Deliberation Committee may be provided, within the budget limit, with allowances, travel expenses and other required expenses: Provided, That the same shall not apply to the public officials present at the meetings directly related to affairs under their jurisdiction.
(2) The Minister of Health and Welfare or the Commissioner of the Food and Drug Administration may, within the budget limit, provide the research fellows with research and study funds, and other related expenses for their researches, studies, etc.

Article 15 (Detailed regulations of operation) Other matters than those prescribed by this Decree, the matters for the operation of the Deliberation Committee and those necessary for the services of research fellows shall be prescribed by the Minister of Health and Welfare.

Article 16 (Establishment authorization of associations) (1) The term "type of business as determined by the Presidential Decree" in Article 28(1) of the Act means the type of business described in Article 2.
(2) Any person who intends to obtain an authorization of an association establishment pursuant to the provisions of Article 28(3) of the Act shall submit to the Minister of Health and Welfare the documents(including electronic documents) prescribed in the Ordinance of the Ministry of Health

and Welfare. <Amended on January 18, 2007>

Article 17 (Time limit of business permission revocation, etc.) In case where a hearing under Article 36 of the Act has been held or an opinion has been received under Article 27 of the 「Administrative Procedures Act」 in order to impose sanctions, such as the business permission revocation, the business suspension, the business establishment closure, the item or items manufacturing suspension, etc., the Commissioner of the Food and Drug Administration or the Special Metropolitan City Mayor, Metropolitan City Mayor, or *Do* governor (hereinafter referred to as "Mayor/*Do* governor") shall impose the sanction within fourteen days after the relevant procedures are finished unless there exist any special reasons. <Amended on January 18, 2007>

Article 18 (Types of offense to be imposed a penalty surcharge and the amount thereof) The amount of penalty surcharges imposed under the provisions of Article 37(2) of the Act shall be assessed, in consideration of the types, the degree, etc. of a violation in question, by applying the standards listed in annexed the Table 1 in accordance with the period of business suspension or item or items manufacturing suspension as prescribed by the Ordinance of the Ministry of Health and Welfare.

Article 19 (Procedures for imposing and paying penalty surcharges, etc.) (1) In case where intending to impose a penalty surcharge pursuant to the provisions of Article 37 of the Act, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall specify the type of offense and its corresponding amount of penalty surcharge in a written form and give a notice of the payment of the penalty surcharge.

(2) A person received a notice under paragraph (1) shall pay the penalty surcharge to a receiving agency designated by the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor within twenty days from the day he has received the notice. Provided, That if the person is not able to pay the penalty surcharge within the specified days due to *force majeure* or other unavoidable causes, the person shall pay it within seven days from the day the cause has ceased to exist.

(3) When it receives the penalty surcharge under the provisions of paragraph (2), the receiving agency shall issue a receipt and inform, without delay, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor that it has received the penalty surcharge.

(4) The procedures for the penalty surcharge levy shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

(5) The required expenses granted by the Mayor/*Do* governor under the provisions of Article 37(5) of the Act shall be equivalent to one-tenth of the amount levied by the head of *Si/Gun/Gu* (it means the head of autonomous *Gu;* hereinafter the same shall apply). In this case, the Mayor/*Do* governor shall give the required expenses from the penalty surcharges paid to the Food Promotion Fund to the head of *Si/Gun/Gu* concerned by the following month after monthly calculation.

Article 20 (Delegation and entrustment of authority) (1) The Commissioner of the Food and Drug Administration shall delegate his authority related to the following subparagraphs to the Commissioner of the Regional Food and Drug Administration under Article 41(1) of the Act: <Amended on January 18, 2007>

1. The business operation report and the modification report of the health functional food import business under Articles 6(1) and (3) of the Act;
2. The import report and the examination of the health functional food under Articles 8(1) through (3) of the Act, excluding the import report and the examination in a district which is under the jurisdiction of the head of the National Quarantine Service, from among districts under the jurisdiction of the Commissioner of the Regional Food and Drug Administration;
3. The business person status succession report of the health functional food import business under Article 11(3) of the Act;
4. The administrative sanctions under Articles 29 through 32, 35, 36, and 38(2) of the Act (excluding cases where the item manufacturing suspension measure under Article 59 of the 「Food Sanitation Act」 shall be applied *mutatis mutandis*), etc. against a business person of the health functional food import business under Article 4(1)2 of the Act ; and
5. The imposing and collecting a penalty surcharge and a fine for negligence under Articles 37 and 47 of the Act against a business person of the health functional food import business under Article 4(1)2 of the Act.

(2) From among the authority of the Mayor/*Do* governor, the authority related to the following subparagraphs shall be delegated to the head of *Si*/*Gun*/*Gu* pursuant to Article 41(2) of the Act<Amended on January 18, 2007>:

1. The business operation report and the modification report of the health functional food sales business under Articles 6(2) and (3) of the Act;
2. The business person status succession report of the health functional food sales business under Article 11(3) of the Act;
3. The administrative sanctions under Articles 29 through 32, 35, 36, and 38(2) of the Act (excluding cases where the item manufacturing suspension measure under Article 59 of the 「Food Sanitation Act」 shall be applied *mutatis mutandis*), etc. against a business person of the health functional food sales business under Article 4(1)3 of the Act ; and
4. The imposing and collecting a penalty surcharge and a fine for negligence under Articles 37 and 47 of the Act against a business person of the health functional food sales business under Article 4(1)3 of the Act.

(3) With respect to districts under the jurisdiction of the head of the National Quarantine Service, from among districts under the jurisdiction of the Commissioner of the Regional Food and Drug Administration, the Commissioner of the Food and Drug Administration shall, pursuant to Article 41(1) of the Act, entrust his authority related to the import report and the examination of health functional food under Article 8 of the Act to the head of the National Quarantine Service.

Article 21 (Procedures for imposing and collecting a fine for negligence) (1) In the case where intending to impose a fine for negligence pursuant to the provisions of Article 47(2) of the

Act, the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall investigate and confirm the violation in question and then notify the party subject to the disposition of fine for negligence with a fine for negligence payment notice specifying the fact of violation in question, the corresponding amount of fine for negligence, the due date for payment, the receiving agency, the appeal method, the period for raising the appeal, etc.

(2) In case where intending to impose the fine for negligence pursuant to the provisions of paragraph (1), the Commissioner of the Food and Drug Administration or the Mayor/*Do* governor shall give the party subject to the disposition of fine for negligence an opportunity to state his opinion in writing or orally specifying the time limit not less than 10 days: Provided, That the party subject to the disposition concerned shall be deemed to have no objection in case he fails to respond to such opportunity within the specified time limit.

(3) The standards of fine for negligence to be imposed shall be as listed in annexed the Table 2. Provided, That the detailed standards of fine for negligence related to matters as determined by the Ordinance of the Ministry of Health and Welfare, that shall be complied by the business person under Article 10(1)5 of the Act, shall be prescribed by the Ordinance of the Ministry of Health and Welfare.

(4) The Commissioner of the Food and Drug Administration or the Mayor/*Do* governor may reduce the amount within the limit of one half of the amount under paragraph (3) by taking account of the motives, the facts, the recall, etc. of the violation.

ADDENDA <Presidential Decree No. 18164, Dec. 18, 2003>

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

Article 2 (Transitional measures concerning the business report of health functional food sales business) Any person, who sells a health functional food or has filed a distribution specializing business under Article 13 of the Food Sanitation Act at the time this Decree enters into force, shall equip with the facilities by type of business in accordance with the Ordinance of the Ministry of Health and Welfare and file a report of business within six months after this Decree enters into force.

Article 3 (Amendment to other subordinated statues) The Enforcement Decree of the Food Sanitation Act shall be amended as follows:

Subparagraph 4-2 shall be prescribed in Article 13(2) as follows:

4-2. Where a person carries on the business after obtaining a business permission for or filing a report of the health functional food manufacturing business, the health functional food import business and the health functional food sales business under the provisions of Articles 5 and 6 of the Health Functional Food Act. “food sanitation, national nutrition and health functional food” shall replaces “food sanitation and national nutrition” in the subparagraphs of Article 42 (1), and subparagraph 7 shall be prescribed in the same Article as follows:

7. Assistance to the business person who complies with the Good Manufacturing Practices under the provisions of Article 22 of the Health Functional Food Act, or intends to install related facilities, etc. to comply with it.

ADDENDA (Personnel Regulation on the Senior Executive Service)

<Presidential Decree No. 19513, June 12, 2006>

Article 1 (Enforcement Date) This Decree shall enter into force on July 1, 2006.

Articles 2 and 3 Omitted.

Article 4 (Amendment to other subordinated statues) (1) Omitted.

(2) The Enforcement Decree of the Health Functional Food Act shall be amended as follows: "the fifth-ranked and above public officials or the public officials in general service of the Senior Executive Service" shall replaces "the fifth-ranked and above public officials" in Article 7(3)1.

(3) through (241) Omitted.

ADDENDA <Presidential Decree No. 19836, Jan. 18, 2007>

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

[Annexed the Table 1]

The standards to calculate penalty surcharge
(related to Article 18)

1. General standard

(a) The base period of one month of business suspension shall be 30 days.

(b) The standard annual sales for the calculation of penalty surcharge in lieu of the business suspension shall be the total sales of the previous year of the disposition. Provided, That if it is unable to calculate the total sales of the whole year due to the new business or the business close, etc., it shall be calculated by the quarterly, monthly or daily total sales.

(c) The standard annual sales for the calculation of penalty surcharge in lieu of the items manufacturing suspension shall be the item total sales, which falls under the items in question, of the previous year of the disposition. Provided, That if it is unable to calculate the item total sales, which falls under the items in question, of the whole year due to the new manufacture or the business close, etc., it shall be calculated by the quarterly, monthly or daily total sales.

(d) The standard annual sales for the calculation of penalty surcharge in lieu of the item manufacturing suspension shall be calculated by multiplying 4 by the total sales of the previous three months which are retroactive from the month of the disposition date. Provided, That if it is unable to calculate the total sales of the latest three months due to the new manufacture or the business close, etc., it shall be calculated by multiplying 365 by one day average sales of the previous month (when it is unable to identify the previous month sales, it shall be the said month).

2. The standard of penalty charge

Type of business / Grade	The annual sales(unit : million won)			The penalty surcharge on one day of the business or manufacturing suspension (unit : won)
	health functional food import business and sales business (exceeding~not exceeding)	health functional food manufacture business (exceeding~not exceeding)	the item or items manufacturing suspension (exceeding~not exceeding)	
1	~ 30			80,000
2	30 ~ 50	~ 100	~ 100	120,000
3	50 ~ 100	100 ~ 200	100 ~ 200	200,000
4	100 ~ 150	200 ~ 310	200 ~ 300	280,000
5	150 ~ 210	310 ~ 430	300 ~ 400	360,000
6	210 ~ 270	430 ~ 560	400 ~ 500	440,000
7	270 ~ 330	560 ~ 700	500 ~ 650	520,000
8	330 ~ 400	700 ~ 860	650 ~ 800	600,000
9	400 ~ 470	860 ~ 1,040	800 ~ 950	680,000
10	470 ~ 550	1,040 ~ 1,240	950 ~ 1,100	760,000
11	550 ~ 650	1,240 ~ 1,460	1,100 ~ 1,300	820,000
12	650 ~ 750	1,460 ~ 1,710	1,300 ~ 1,500	880,000
13	750 ~ 850	1,710 ~ 2,000	1,500 ~ 1,700	940,000
14	850 ~ 1,000	2,000 ~ 2,300	1,700 ~ 2,000	1,000,000
15	1,000 ~ 1,200	2,300 ~ 2,600	2,000 ~ 2,300	,060,000
16	1,200 ~ 1,500	2,600 ~ 3,000	2,300 ~ 2,700	1,120,000
17	1,500 ~ 2,000	3,000 ~ 3,400	2,700 ~ 3,100	1,180,000
18	2,000 ~ 2,500	3,400 ~ 3,800	3,100 ~ 3,600	1,240,000
19	2,500 ~ 3,000	3,800 ~ 4,300	3,600 ~ 4,100	1,300,000
20	3,000 ~ 4,000	4,300 ~ 4,800	4,100 ~ 4,700	1,360,000
21	4,000 ~ 5,000	4,800 ~ 5,400	4,700 ~ 5,300	1,420,000
22	5,000 ~ 6,500	5,400 ~ 6,000	5,300 ~ 6,000	1,480,000
23	6,500 ~ 8,000	6,000 ~ 6,700	6,000 ~ 6,700	1,540,000
24	8,000 ~ 10,000	6,700 ~ 7,500	6,700 ~ 7,400	1,600,000
25	10,000 ~ 12,000	7,500 ~ 8,600	7,400 ~ 8,200	1,660,000
26	12,000 ~ 15,000	8,600 ~ 10,000	8,200 ~ 9,000	1,720,000
27	15,000 ~ 20,000	10,000 ~ 12,000	9,000 ~ 10,000	1,780,000
28	20,000 ~ 25,000	12,000 ~ 15,000	10,000 ~ 11,000	1,840,000
29	25,000 ~ 30,000	15,000 ~ 20,000	11,000 ~ 12,000	1,900,000
30	30,000 ~ 35,000	20,000 ~ 25,000	12,000 ~ 13,000	1,960,000
31	35,000 ~ 40,000	25,000 ~ 30,000	13,000 ~ 15,000	2,020,000
32	~ 40,000	30,000 ~ 35,000	15,000 ~ 17,000	2,080,000
33		35,000 ~ 40,000	17,000 ~ 20,000	2,140,000
34		~ 40,000	~ 20,000	2,200,000

[Annexed the Table 2]

The standard of fine for negligence (related to Article 21)

NO.	Act	The type of violation	Fine for negligence(won)
1	Article 5(2)	A business person who has not reported the modification of the business permission	3 million
2	Article 6(3)	A business person who has not reported the modification of the business report	1 million
3	Article 7(1)	A business person who has not reported the modification of the item manufacture report	1 million
4	Article 10(1)	(a) A business person who has not controled the manufacturing facilities and products (including raw materials) in order to prevent sanitary hazard and to ensure safety	3 million
		(b) A person who has not complied with matters as prescribed by the Ordinance of the Ministry of Health and Welfare, which are other matters corresponding to subparagraph (a) for the purpose of ensuring safety and controling quality of health functional food, and promoting public health	1 million
5	Article 10(2)	A business person who has not notified of the production records or has notified a false production records	1 million
6	Article 12(3)	A business person who has obstructed the quality manager's work	3 million
7	Article 12(4)	A business person who has not reported the appointment or the dismissal of a quality manager	2 million
8	Article 13(1)	(a) A business person who has not received the education (b) A employee who has not received the education	1 million 300,000
9	Article 13(2)	A business person who has not received the education	2 million
10	Article 13(3)	A quality manager who has not received the education	500,000
11	Article 21(1)	A business person who has not kept the records or has made a false data after the self quality examination	3million
12	Article 31(1)	A business person who fails to improve or repair the facilities according to the order issued	3 million

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 rexamination 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. Heath 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 handing 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 *Si/Gun/Gu* (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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu*.

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 *Si/Gun/Gu*. <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 *Si/Gun/Gu,* 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 *Si/Gun/Gu*. <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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu* shall, without delay, notify the other heads of *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 *Si/Gun/Gu* 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 (Example : 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 equiped 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 handing 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 handing 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 Article2-2 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 of 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 sanitarily 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 recognised 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 therof, 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 concern 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 advertizing 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 recognised 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 advertizing 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 advertizing pre-deliberation certificate (limited to the case of receiving the functionality labeling and advertizing 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 labelling 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 *Si/Gun/Gu*, 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 disease, 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. Advertizing 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. Advertizing which indirectly makes product of other business establishment to be understands 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)

<table>
<tr><th>Type of
health functional food</th><th>Collection
amount</th><th>Reference</th></tr>
<tr><td>Liquid product</td><td>600g(㎖)</td><td rowspan="4">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.
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.
3. When two or more are collected, the container or the package and the date of manufacture shall be identical.
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.</td></tr>
<tr><td>Tablet · Capsule · powder
· Granule · pill</td><td>200g(㎖)</td></tr>
<tr><td>Other health functional food</td><td>400g(㎖)</td></tr>
<tr><td>Ingredients or components
◦natural product
◦components</td><td>1㎏
500g</td></tr>
</table>

[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 advertizing, 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 heal 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 Act	Article 32 of the Act	business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
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 12(1) of the Act	Article 32 of the Act	business suspension: 7 days	business suspension: 15 days	business suspension: 1 month
10. Violation Article 18(1) of the Act	Articles 32 and 33 of the Act			
a. When make labeling or advertising which may cause to mislead or confuse that it is efficient and effective in preventing and curing disease, or it is a medicine		<manufacturing business> items manufacturing suspension: 2 months <import business ·	business suspension: 2 months	business suspension: 3 months

		sales business> business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
b. When make labeling or advertising which is not truthful or exaggerated		<manufacturing business> item manufacturing suspension: 2 months	business suspension: 2 months	business suspension: 3 months
		<import business · sales business> business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
c. When make labeling or advertising which may cause consumers to be deceived, misled, or confused		<manufacturing business> item manufacturing suspension: 2 months	business suspension: 2 months	business suspension: 3 months
		<import business · sales business> business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
d. When make labeling or advertising with the name solely used for medicines (including prescriptions of Korean oriental medicine)		<manufacturing business> item manufacturing suspension: 2 months	business suspension: 2 months	business suspension: 3 months
		<import business · sales business> business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
e. When make labeling or advertising whose contents have not been deliberated or which is different in contents from what was deliberated under Article 16(1) of the Act. However, the case where the sanction is imposed due to the same violation under item a through d shall be excluded.		business suspension: 2 months	business suspension: 3 months	business suspension: 3 months business permission revocation or business establishment closure
11. Violation of Article 21(1) of the Act	Article 32 and 33 of the Act			
a. When fail to conduct the self quality examination		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	Article 32 of the Act	business suspension: 15 days	business suspension: 1 month	business suspension: 2 months

title of the Good Manufacturing Practices application business establishment or similar contents under Article 22(5) of the Act				
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 and disposal of product in question	business suspension: 2 months and disposal of product in question	business suspension: 3 months and disposal of product in question
		<import 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
b. It contains or is adhered with any poisonous or detrimental substance, or there is any possibility thereof, and it is or may be contaminated with any pathogenic microorganism so that it may injure the health of the human body.		business permission revocation or business establishment closure and disposal of product in question		
c. It may injure the health of the human body because it is filthy, any foreign substance is mixed or added, or there is any other reason.		<manufacturing business>		
		items manufacturing 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
		<import business · sales business>		
		business suspension: 7 days and disposal of product in question	business suspension: 15 days and disposal of product in question	business suspension: 1 month and disposal of product in question
d. It is manufactured by a person without business permission under Article 5 (1) of the Act.		<manufacturing business>		
		business suspension: 1	business suspension: 2	business suspension: 3 months and

		month and disposal of product in question <import business · sales business> business suspension: 15 days and disposal of product in question	months and disposal of product in question business suspension: 1 month and disposal of product in question	disposal of product in question business suspension: 2 months and disposal of product in question
e. It is prohibited from importing or is imported without the report under Article 8 of the Act.		<manufacturing business> business suspension: 1 month and disposal of product in question <import business · sales business> business suspension: 15 days and disposal of product in question	business suspension: 2 months and disposal of product in question business suspension: 1 month and disposal of product in question	business suspension: 3 months 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 Act	the 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 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 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
d. When manufacture the health functional food whose combination, mixture ratio or content is identical with or similar to medicine		item manufacturing 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
e. When import, sell, or display the health		business	business	business suspension:

functional food whose combination, mixture ratio or content is identical with or similar to medicine		suspension: 15 days and disposal of product in question	suspension: 1 month and disposal of product in question	2 months and disposal of product in question
15. Violation of Article 25 of the Act	Article 32 of the Act			
a. When manufacture, import or sell the health functional food that violates the standards of label under Article 17(1)1 through 5 of the Act		<manufacturing and import 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
		<sales business> business suspension: 7 days and disposal of product in question	business suspension: 15 days and disposal of product in question	business suspension: 1 month and disposal of product in question
b. When manufacture, import or sell the health functional food that violates the standards of label under Article 17(1)6 of the Act		<manufacturing and import business> order of correction	business suspension: 15 days and disposal of product in question	business suspension: 1month and disposal of product in question
		<sales business> order of correction	business suspension: 7 days and disposal of product in question	business suspension: 15 days and disposal of product in question
16. Violation of Article 26 of the Act	Article 32 of the Act			
a. When make labels upon its container or package, or advertising which may mislead 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		business suspension: 1 month and disposal of product in question	business suspension: 2 months and disposal of product in question	business suspension: 3 months and disposal of product in question
b. When sell, store or display for sale anything that is labelled or advertised as one analogous to health functional food		business suspension: 15 days and disposal of product in	business suspension: 1 month and disposal of product in	business suspension: 2 months and disposal of product in question

		question	question	
17. Violation of the order of correction under Article 29 of the Act	Article 32 of the Act	business suspension: 7 days	business suspension: 15 days	business suspension: 1 month
18. Violation of Article 30(1) and (3) of the Act	Article 32 of the Act			
a. When violate the order to take measures necessary for eliminating any hazard to food sanitation to the business person		business suspension: 7 days	business suspension: 15 days	business suspension: 1 month
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, 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		business suspension: 1 month	business suspension: 2 months	business suspension: 3 months
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 the Act	order of correction		

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

The penalty surcharge exemption (relating to Article 33)

If it is 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	
a. import report	20,000won
b. import examination	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
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)
6. application for recognition of the functionality ingredients or components	100,000won
7. application for the functionality labeling or the deliberation of advertising	100,000won
8. entrusted examination of self quality examination	Based on the fees regulation of food sanitation examination laboratories designated under Article 18 of Food Sanitation Act
9. Good Manufacturing Practices standards application business establishment designation	
a. initial application	200,000won
b. modification application	100,000won
10. business person status succession report	9,300won
11. English certificate application	2,000won each

[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 recognised 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 of inferior quality	1,000,000won
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 advertizing 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) that have a bad effect on the public health in relation to the health functional food	500,000won
7	Business person who fails to keep the business report certificate, the standards and specifications recognition certificate and the functionality labeling and advertizing 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 advertizing 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

[Annexed the Form 1] (front)

Business Permission Application ☐ Health functional food specializing manufacture business ☐ Health functional food venture manufacturing business ※ Refer to application guideline				Treatment period 14 days
Applicant	① Name		② Resident registration No.	
	③ Address	(Tel.:)		
	④ Trade name (title)			
	⑤ Place	(Tel.:)		

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.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration

Fee stamp	Fees
	50,000 won

※Documents required

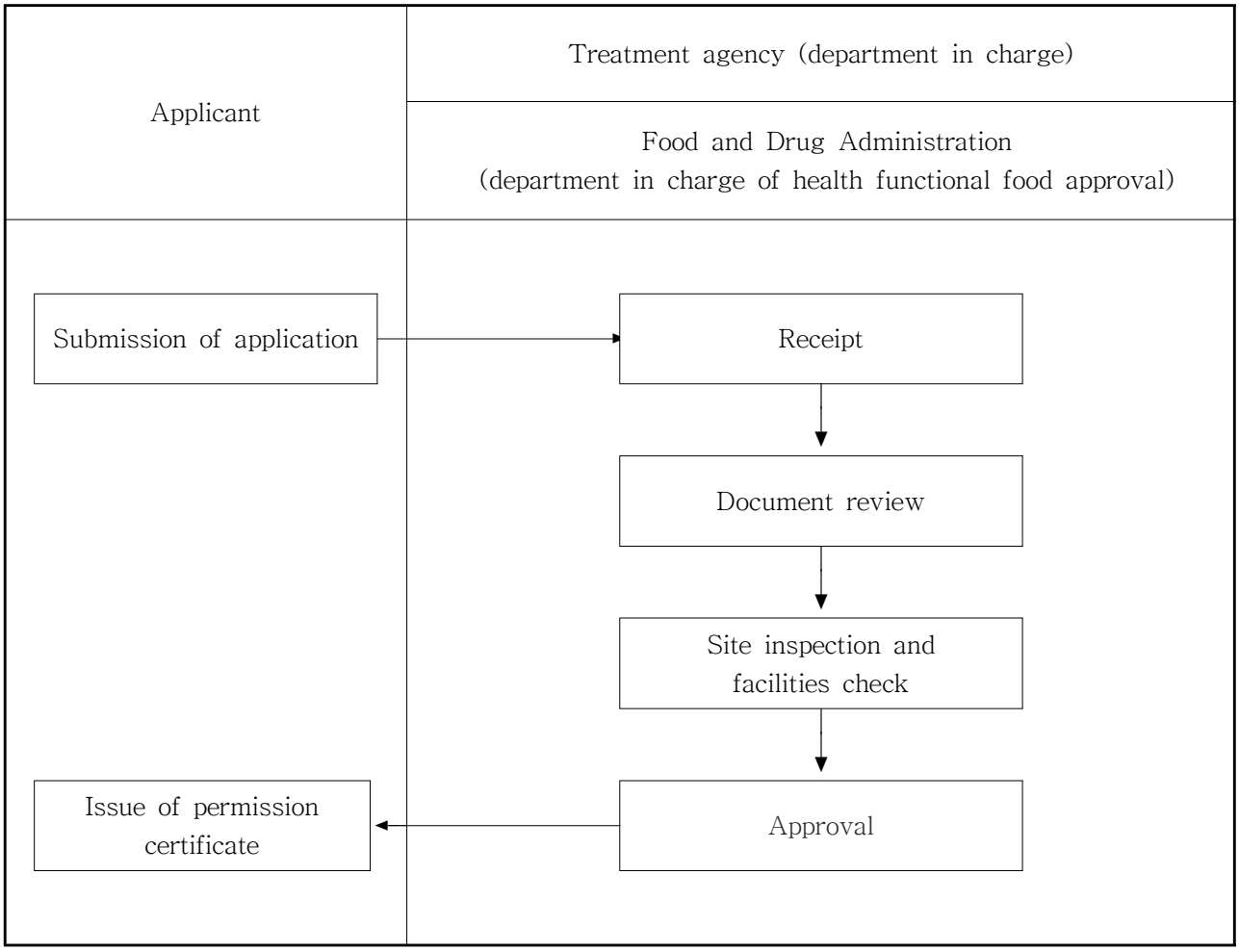
1. Health functional food specializing manufacturing business
   a. The type of product to manufacture and the manufacturing method document
   b. Arrangement plan of manufacturing facilities and list of main machinery and apparatus
   c. Land use plan confirmation and certified copy of building administrative 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㎜×297㎜(general paper 60g/㎡(recycled product))

※ Application guidance (back)

Agency submitted	Food and Drug Administration
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 permission agency. 2. The mattes shall not be in the violates on 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. 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).

This application is processed as below:



[Annexed the Form 2] <Amended on November 20, 2006>

(front)

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)

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

(back)

Permission No (No.)

1. Arrangement plan of facilities

2. Modification contents

Date	Contents	Recorder position · name (signature or seal)

[Annexed the Form 3] <Amended on November 20, 2006> (page 1)

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

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

3. Scale of business establishment

Scale of factory			Number of employees		
① Ground area		㎡	④ Whole personnel		persons
② Building area		㎡	⑤ Head office		persons
③ Business place area	subtotal	㎡	⑥ Factory	Office	persons
- pre-treatment of raw materials		㎡		Sales	persons
- manufacturing room		㎡		Production	persons
- packaging room		㎡		Others	persons
- quality controling room		㎡			
- others		㎡			
Classification of building ownership	own · lease (security money won, monthly rent won)				

4. Quality management appointment · modification report matters

Classification (appointment · modification)	Date		Name	Resident registration No.	Qualification	Position
	Appointment	Modification				

5. Remarks

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 Application ☐ Health functional food specializing manufacture business ☐ Health functional food venture manufacturing business				Treatment period Immediately
Applicant	① Name		② Resident registration No.	
	③ Address	(Tel:)		
	④ Trade name (title)			
	⑤ Place	(Tel:)		
Reissue reason				

I apply business permission certificate reissue under Article 3(4) of the Enforcement Rule of the 「Health Functional Food Act」.

Date (YY/MM/DD):

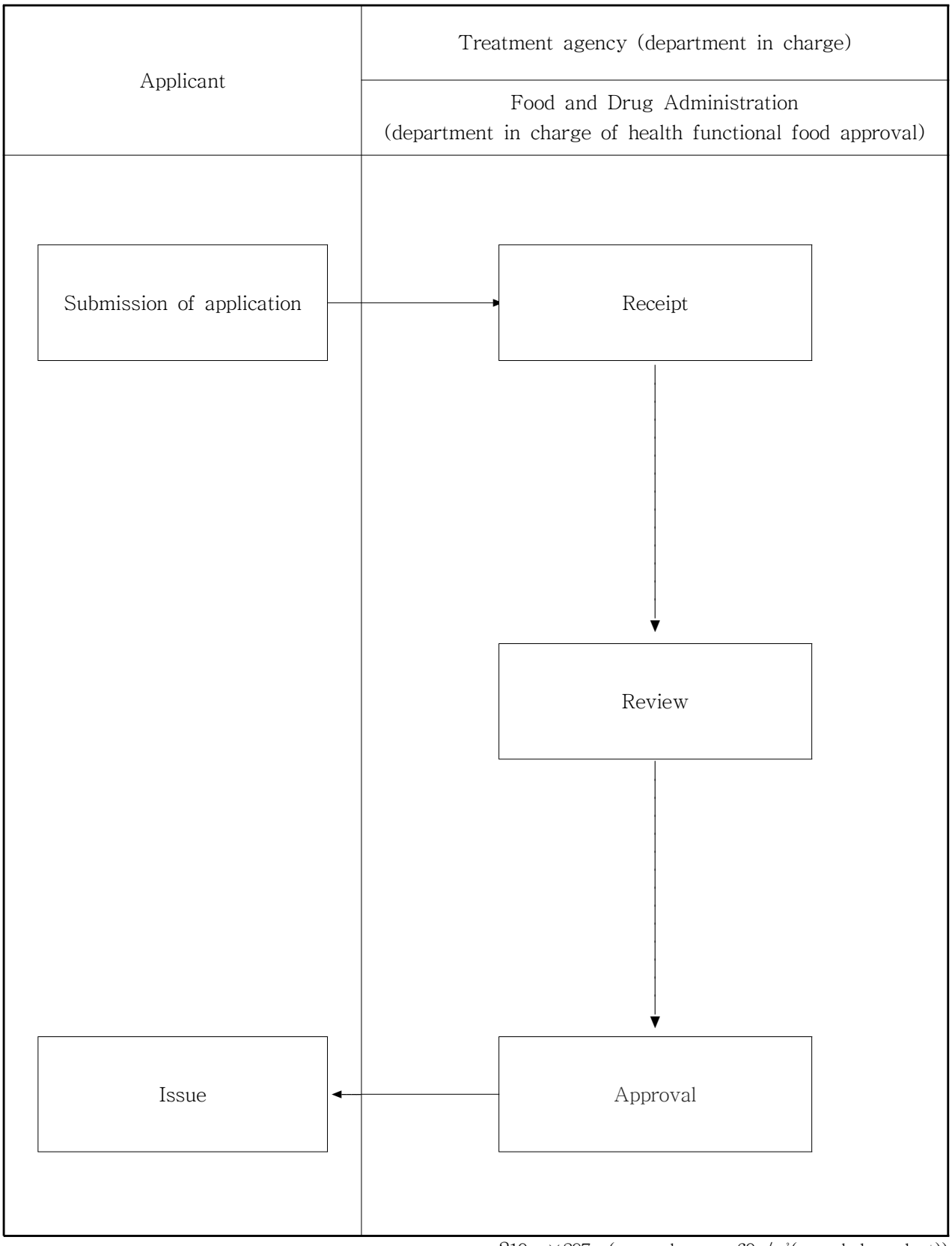
Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration

※ Documents required Permission certificate if the permission certificate is worn-out.	Fees 5,300 won

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

This application is processed as below:



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

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

(front)

Modified Matters on Health Functional Food (Specializing·Venture) Manufacturing Business Permission

Treatment period
back

☐ Permission application
☐ 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 handing 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		

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.

Date (YY/MM/DD):

Applicant (Reporter) (signature or seal)

Fee stamp	Fees
	30,000 won

To the Commissioner of the Food and Drug Administration

※ Documents required

1. Modification permission of permission matters (limited to place of the business establishment 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 handing 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㎜×297㎜(general paper 60g/㎡(recycled product))

(back)

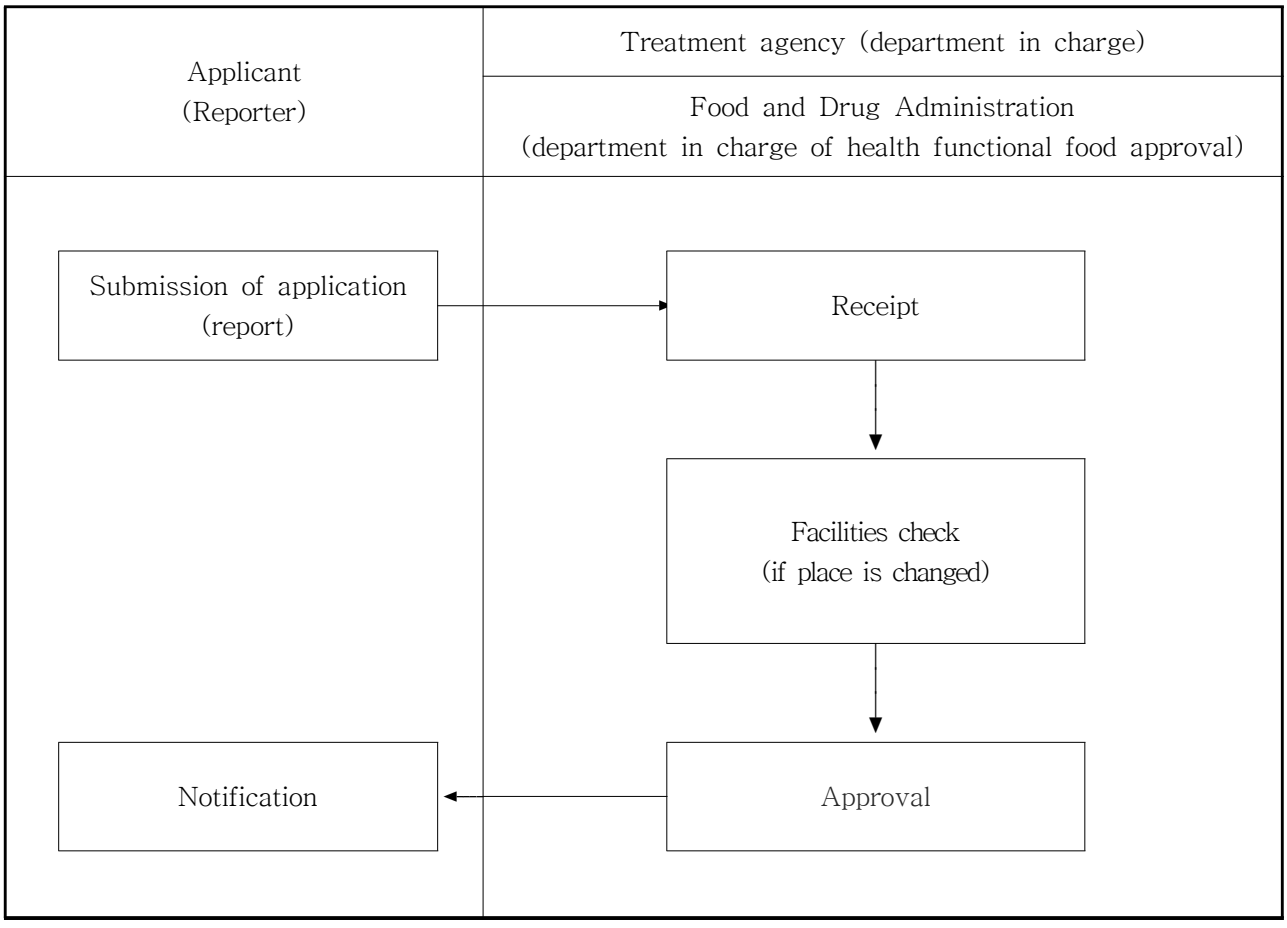
※ Application (report) guidance

Agency submitted	Food and Drug Administration	Treatment period	1. modification permission 14 days 2. modification report: 7 days

※ Notice

1. Among permission matters, when the place of business establishment is changed, a modification permission shall be granted.
2. Among permission matters, when the following matters are changed, the modification matters shall be reported:
   a. the name of the representative (limited to a juridical person);
   b. title or trade name of the business establishment;
   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
   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)
3. The modification report for the succession status of business status under Article 11 of the Act is excluded.

This application (report) is processed as below:



[Annexed the Form 6] (front)

Business Report

☐ health functional food import business
☐ health functional food sales business

※ Refer to report guidance

Treatment period
Immediately

Applicant	① Name		② Resident registration No.	
	③ Address	(Tel.:)		
	④ Trade name (title)		⑤ Detailed types of business	
	⑥ Place	(Tel.:)		

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.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Regional Food and Drug Administration
or To the Head of *Si/Gun/Gu*

Fee stamp or import certificate stamp	Fees
	28,000won

※ Documents required
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㎜×297㎜(general paper60g/㎡(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

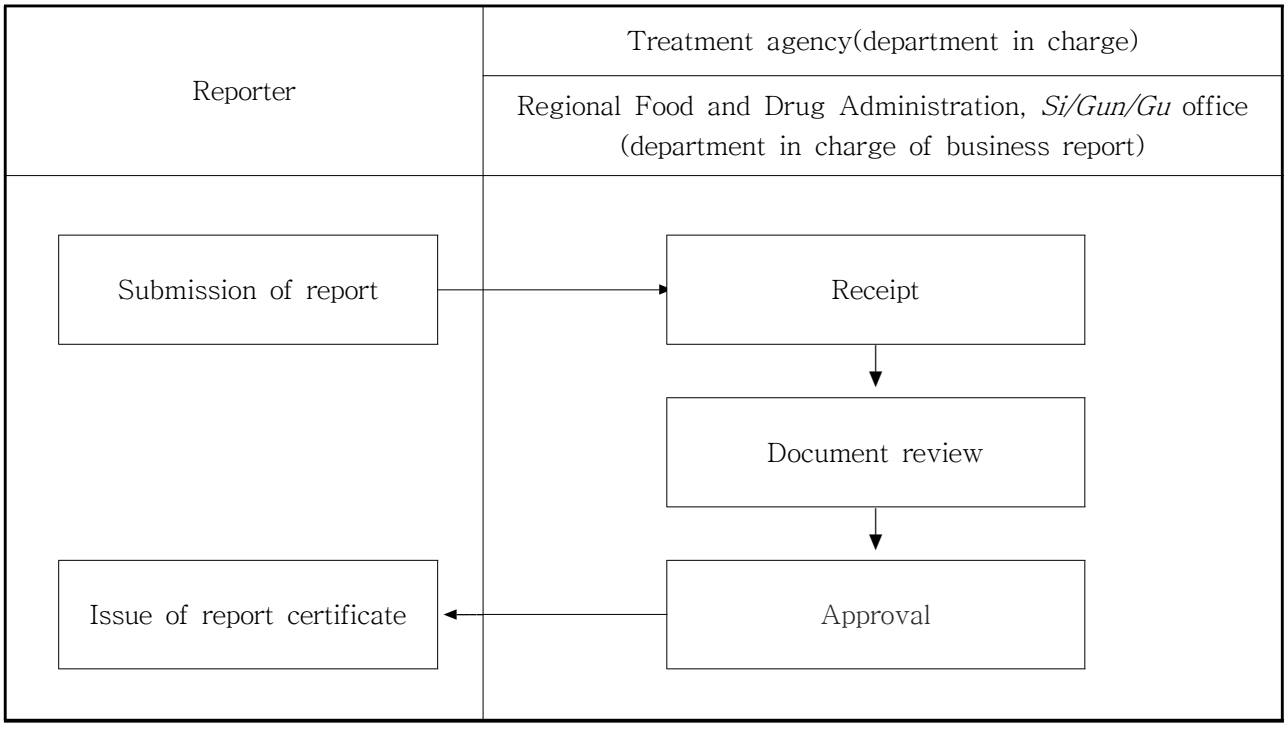
<Business that shall be reported to the Head of *Si/Gun/Gu*>

○ 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:



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

(back)

Report No (No.)

1. Arrangement plan of business facilities

2. Modification contents of report matters

Date	Contents	Recorder position · name (signature or seal)

[Annexed the Form 8] <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 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 *Si/Gun/Gu* (seal)

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

(back)

Report No (No.)

1. Arrangement plan of business facilities

2. Modification contents of report matters

Date	Contents	Recorder position · name (signature or seal)

[Annexed the Form 9] (page 1)

Health Functional Food
Import Business Report Administrative Register

1. Business report matters

① Name of business establishment				Joint seal	
② Business report No.	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 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㎜×297㎜(preservative paper(1 class)120g/㎡)

3. Scale of business establishment

Scale of business place			Number of employees		
① Ground area		㎡	④ Whole personnel		persons
② Building area		㎡	⑤ Head office		persons
③ Business place area	subtotal	㎡	⑥ Business place	Office	persons
-business establishment		㎡		Sales	persons
-warehouse		㎡		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

[Annexed the Form 10]

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

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

3. Scale of business establishment

<table>
<tr><td colspan="2">Scale of business place</td><td colspan="3">Number of employees</td></tr>
<tr><td>① Ground area</td><td>㎡</td><td colspan="2">④ Whole personnel</td><td>persons</td></tr>
<tr><td>② Building area</td><td>㎡</td><td colspan="2">⑤ Head office</td><td>persons</td></tr>
<tr><td rowspan="3">③ Business place area
-business establishment
-warehouse</td><td rowspan="3">subtotal ㎡
㎡
㎡</td><td rowspan="3">⑥ Business place</td><td>Office</td><td>persons</td></tr>
<tr><td>Sales</td><td>persons</td></tr>
<tr><td>Others</td><td>persons</td></tr>
<tr><td>⑦ Classification of building ownership</td><td colspan="4">own · lease (security money won, monthly rent won)</td></tr>
</table>

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 11]

Recipient: the Commissioner of the Food and Drug Administration

Via:

Subject: **Current Status of Business Report Management**

No.	Trade name(title) of business establishment	Representative	Place (Tel)	Reported business	Type of handling items	Remarks

(The head's name of dispatch agency)

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

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

Business Report Certificate Reissue Application ☐ health functional food import business ☐ health functional food sales business					Treatment period Immediately
Applicant	Name		Resident registration No.	-	
	Address	(Tel.:)			
	Trade name(title)		Type of business		
	Place	(Tel.:)			
Reason					

I apply a business report certificate reissue under Article 5 of the 「Enforcement Rule of the Health Functional Food Act」.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Regional Food and Drug Administration or To the Head of *Si/Gun/Gu*

※ Notice 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 *Si/Gun/Gu*. ※ Documents required Permission certificate if the permission certificate is worn-out.	Fees 5,300 won

This application is processed as below:

Applicant	Treatment agency(department in charge) Regional Food and Drug Administration, *Si/Gun/Gu* office (department in charge of business report certificate issue)
Submission of application →	→ Receipt → Review → Approval
← Issue of report certificate	

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

[Annexed the Form 13] (front)

Business Report Matters Modification Report

☐ health functional food import business
☐ health functional food sales business

Treatment period
Immediately

Applicant	① Name		② Resident registration No.	-
	③ Name of business establishment	(Tel:)		
	④ Place			

⑤ Modification matters	Before modification	After modification
Name of juridical person representative		
Trade name(title) of business establishment		
Place of business establishment		
Place of storage facility		
Title or trade name of manufacturing establishment that is entrusted with manufacturing health functional food		
⑥ Modification reason		

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

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Regional Food and Drug Administration or To the Head of *Si/Gun/Gu*

Fee stamp or import certificate stamp	Fees
	26,500won

※ Documents required
A business report certificate

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

(back)

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

○ Health functional food import business

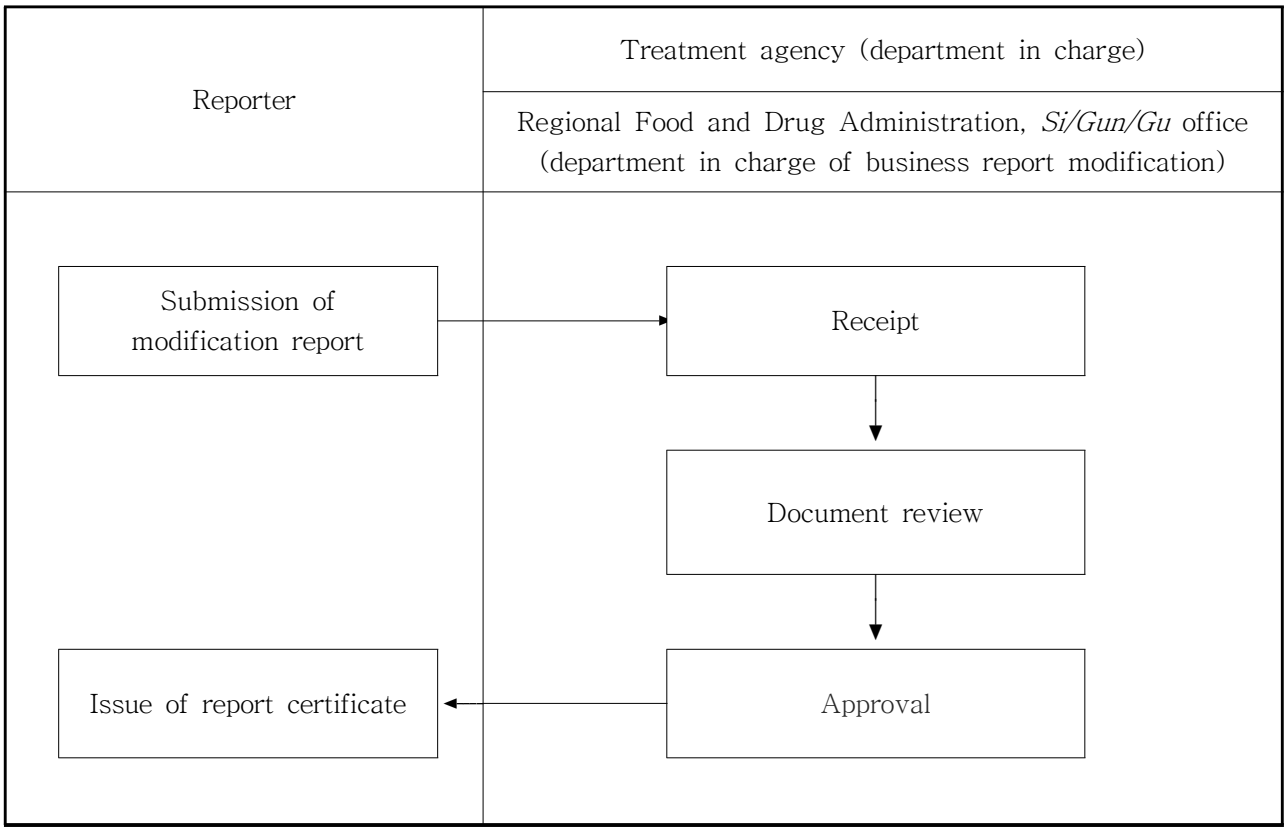
<The business type that the modification shall be reported to the head of *Si/Gun/Gu*>

○ 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				

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.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Food and Drug Administration
or To the Commissioner of the Regional Food and Drug Administration
or To head of *Si/Gun/Gu*

※ 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:

Reporter	Treatment agency(department in charge)
	Food and Drug Administration, Regional Food and Drug Administration, *Si/Gun/Gu* office(department in charge of health functional food business report)
Submission of report	→ Receipt
	↓ Review
	↓ Approval
Issue of report certificate	←

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

[Annexed the Form 15] (front)

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				

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.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Food and Drug Administration	Fee stamp	Fees
		20,000won

※ Documents required

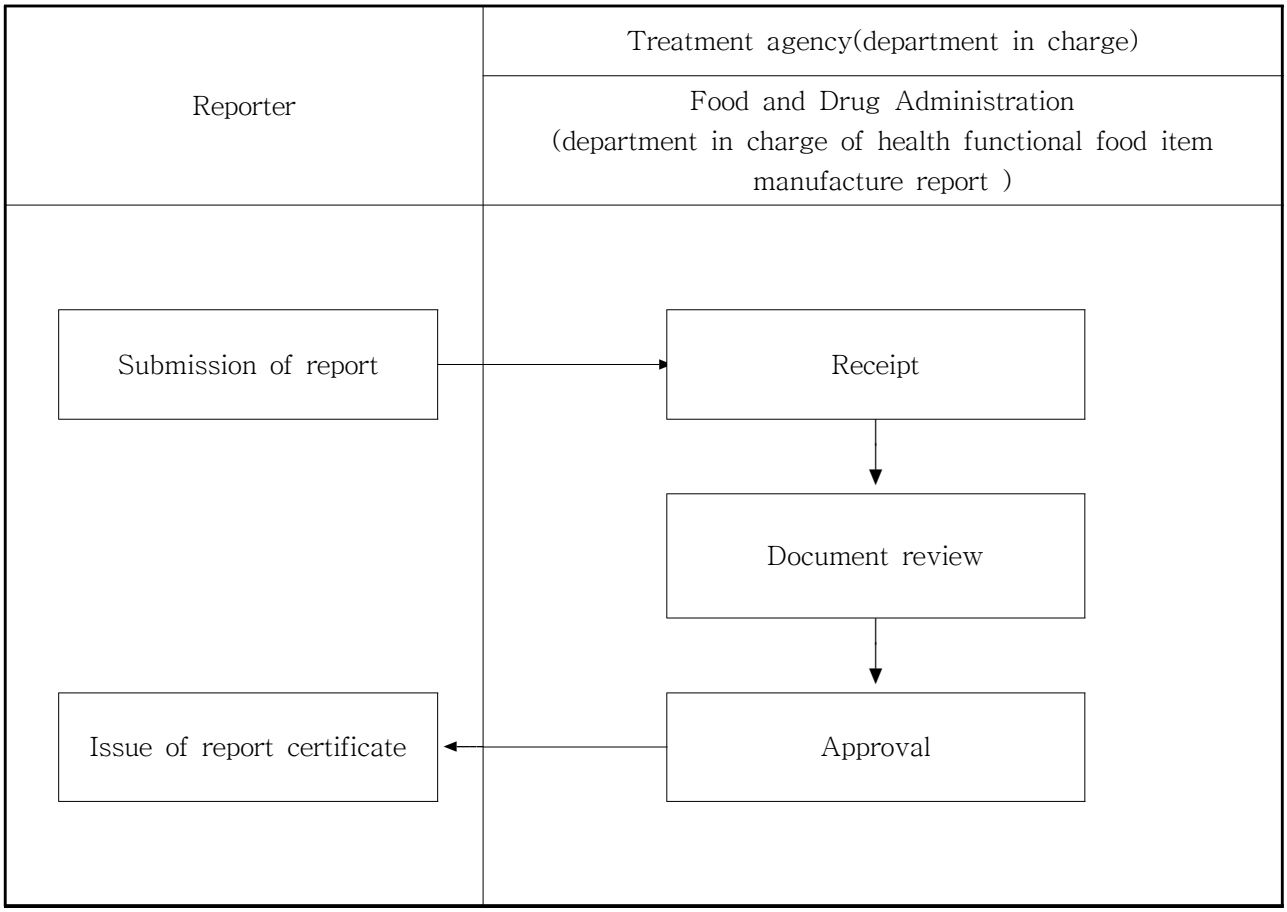
1. A manufacturing method document (including the document for the establishment of sell-by date)
2. Name and contents of ingredients or components
3. The examination result of the standards and specifications (limited to the health functional food product complied with the standards and specifications)

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

※ Report guidance (back)

Agency submitted	Food and Drug Administration	Treatment period	7 days
Notice	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. 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.		

This application is processed as below:



[Annexed the Form 16] <Amended on November 20, 2006>

(front)

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)

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

(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)

[Annexed the Form 17] (front)

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㎜×297㎜(preservative (1class)120g/㎡)

(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				

I apply a item manufacture report certificate reissue under Article 8(3) of the Enforcement Rule of the 「Health Functional Food Act」.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration

※ Documents required Item manufacture report certificate if the item manufacture report certificate is worn-out.	Fee stamps or electric approval	Fees
		5,300 won

This application is processed as below:

Applicant	Treatment agency (department in charge) Food and Drug Administration (Department in charge of health functional food permission)
Submission of application	Receipt
	Review
Issue	Approval

210㎜×297㎜(general paper 60g/㎡(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		

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.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Food and Drug Administration

Revenue stamp	Fees
	10,000 won

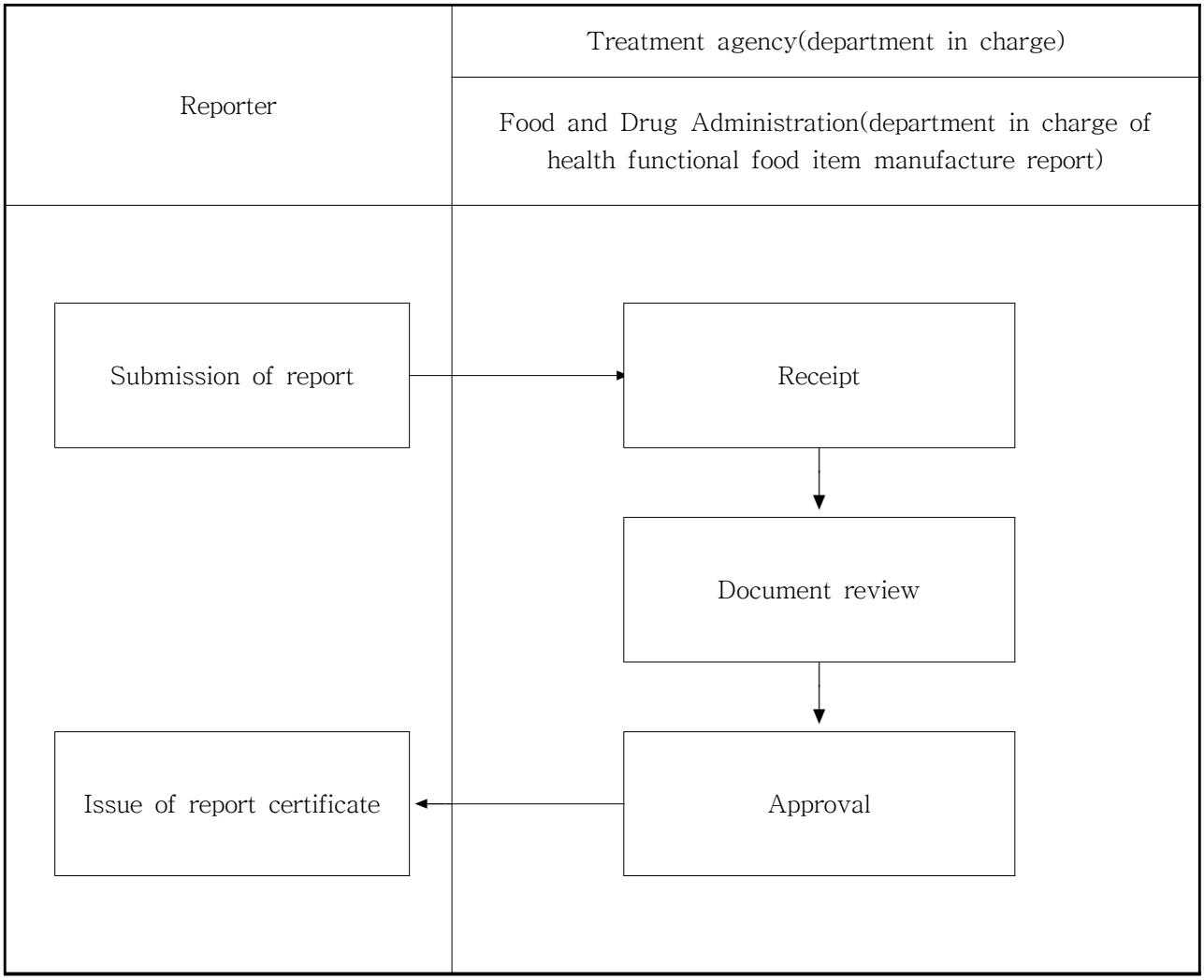
Documents required	Item manufacture report certificate

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

※ Report guidance (back)

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>

Health Functional Food Import Report

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.		Name	
	Trade Name			
	Address			
⑥ Manufacturer	Business Reg. No.		Name	
	Trade Name			
	Address			

⑦Products name		⑩Total Quantity Reported	(Unit:)
⑧Products name (in Korean)		⑪weight	kg
⑨Total No.		⑫Value for Taxation	(Unit:US$)
⑬ No.	⑭ Baggage control No	⑮Model · specifications	
<16> No. of HSK		<17> Usage	
<18>Ingredients · Manufacturing process	Recorded on page 2		
<19>Sell-by date	From (manufacturing date) To		(YY/MM/DD)

<20>Production (Manufacturing Country)		<21>Exporting Country	
<22>Manufacturing Company	Company name		
	Address		
<23>Exporting Country	Company name		
	Address		
<24>Place of Package			
<25>Port of Entry		<26> Entry Date	(YY/MM/DD)
<27>Transport Type			
<28>Transport name			
<29>Place of examination(bringing in)		(☎ - -)	
<30>Date of bringing in	(YY/MM/DD)		
<31>Examination Agency			
<32>Genetically modified labeling	Labeling( ), No Labeling( )		

I report under and Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Regional Food and Drug Administration
or To the head of the National Quarantine Service

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

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			•
13			•	27			•
14			•	28			•

Manufacturing process	

※ Document Required

1. Certificate of examination or Written results of examination (1 copy)(In accordance with Article 8(3)2 of the Health Functional Food Act, only for exemption that all or partial examination)
2. A packing paper that bears a Korean label (In case of the submission of package is difficult with transportation packing, etc, a document that contains a Korean label)
3. In accordance with Article 11(1)7 of the Enforcement Rule of the Food Sanitation Act, IP Handling Certificate or a Certificate through which the government of the manufacturing country recognizes the same validity as IP Handing Certificate (only for the food that falls under the category of GM Food labeling but does not bear any GM Food)

Fees
20,000 won

※ Notice

1. In case of import report by electronic data(document) interchange, document, annexed the Form 19, may not be submitted and all required documents may be attached by image file(PDF file, etc.).
2. Name of raw materials mentioned in page 2 refer to the food or food additives that are included in the product. All the name of raw materials shall be listed. For those food additives whose composition and amount of major raw materials are specified, their composition and amount of main raw materials shall be recorded in order to classify the type of the product. As for apparatus or container · package, their portions that come into direct contact with food or food additive shall be recorded by material code and name.
3. The inspection fee shall be determined according to the table of fees established by the Korea Food and Drug Administration and the National Institute of Health.

Import Report Processing Status

(Recorded by the Regional Food and Drug Administration & the National Quarantine Service)

①Item Classification							
②Examination Type					③Import Report Certificate Issuance		
④ Sensory examination	First Date	(YY/MM/DD)	⑤ Improvement Required	First Date	(YY/MM/DD)	Reason	
	Final Date	(YY/MM/DD)		Final Date	(YY/MM/DD)	Reason	
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	
⑦Post-examination Measure							
⑧ Administrative Disposition	Reason			Notice Date	(YY/MM/DD)		
	Reason			Notice Document No			
	Note						
⑨Report Received	Date	(YY/MM/DD)	Quantity (Unit :)	Weight (Unit : kg)	Amount (Unit : US$)		
	No.						
⑩Final result of non-compliance handing	Date	(YY/MM/DD)	Reason of Informity				
⑪Person in Charge (working-level)		⑫Remark					

(page 3)

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

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

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

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

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

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

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

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

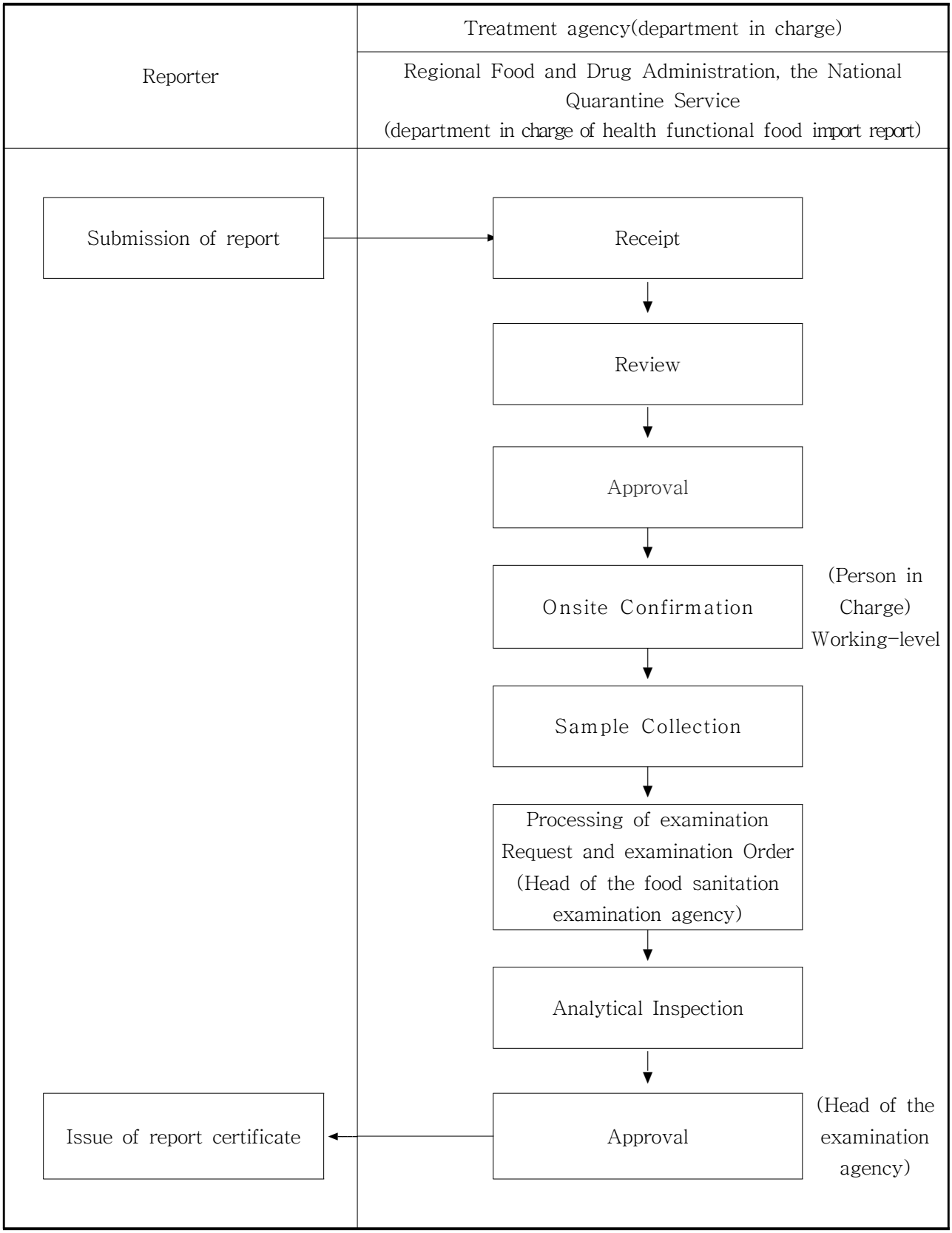
No.	⑦Product name		⑩Total counts	(Unit:)
	⑧Name(Korean)		⑪Net weight	kg
	⑭Freight management No.		⑫Taxation value	(Unit: US$)

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

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

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

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:)		
Manufacture 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$)

I certify this report under Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

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

210mm×297mm(general paper60g/㎡(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 (manufacturing country)			Exporting 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)	

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.

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㎜×297㎜(general paper60g/㎡(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(㎏) Amount($)	Country of origin Exporting Country	HSK No. (Importing Date)	Type of examination Result of examination	Import establishment Manufacture establishment

364㎜×257㎜(preservative paper(1 class)70g/㎡)

[Annexed the Form 23]

Recipient: the Commissioner of the Food and Drug Administration
Subject: **Status Report for Import Report of Health Functional Food(Year)**

1. Examination Status for Import Report Items of Health Functional Food

[Unit : Number of case ,Kg,$]

Type of examination / Items	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

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 / Items	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

B. Non-compliance sanction Status

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

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㎜×297㎜(general paper60g/㎡(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.		

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.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration	Fees
	28,000won (Overseas travel expense not included)

※ Documents required

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 provisons 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.

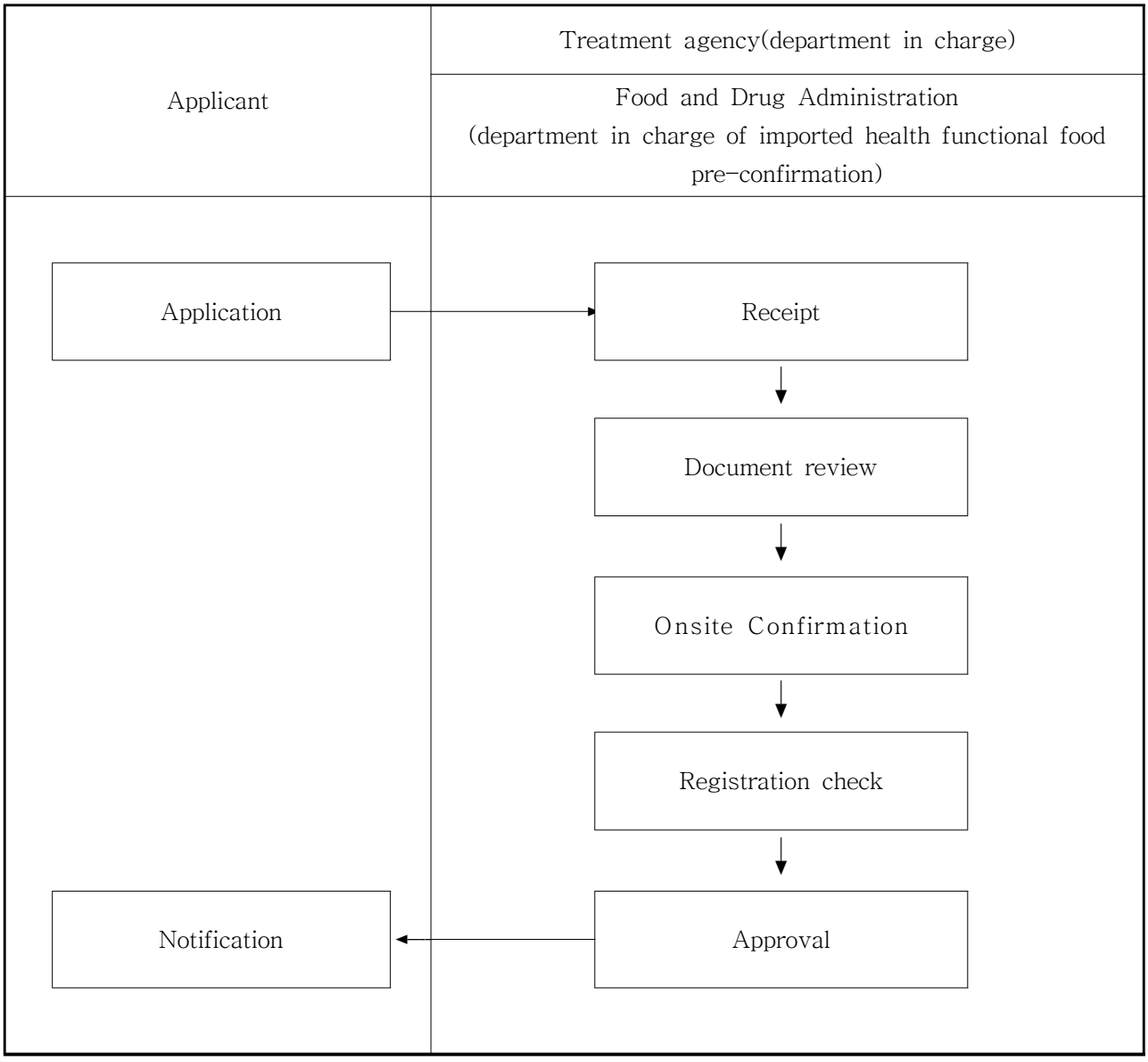
210㎜×297㎜(general paper 60g/㎡(recycled product))

(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

297㎜×210㎜(Preserved paper(class 2)70g/㎡)

[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					

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.

Date (YY/MM/DD):

Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration	Fees
	17,000 won

※ Documents required

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.

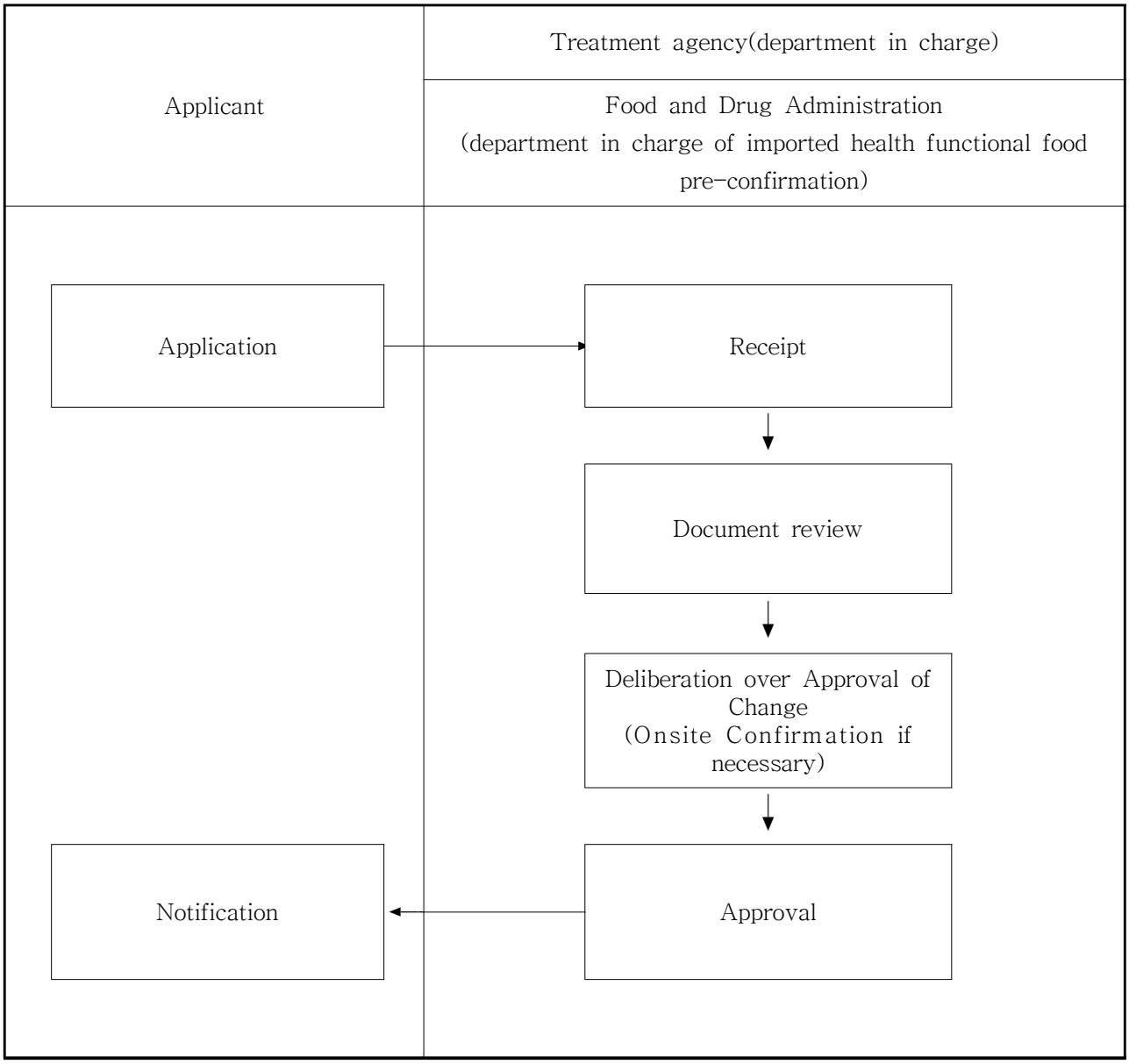
210㎜×297㎜(general paper 60g/㎡(recycled product))

(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 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	⑥Address *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

⑳ 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㎜×297㎜(general paper60g/㎡(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 ☐					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.:)			
④ Permission(report) No.			⑤ Succession reason	☐ Transfer and acquisition ☐ Inheritance ☐ Other( )	

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 *Si/Gun/Gu*

※ 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

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

(back)

Notice of administrative sanction contents etc. and confirmation of aggravated business establishment

1. The transferor dose inform the transferee that the administrative sanction has been taken and the procedure for administrative sanction is in progress (if no administrative sanction was taken, then the fact of no sanction) under Articles 29 through 32 of the Health Functional Food Act, Article 31 of the Enforcement Rule of the same Act and annexed the Table 9 within one year.

a. Administrative sanctions witch is received by transferor within one year.

Disposal date	Administrative sanction content	Administrative sanction reason

b. Procedure of administrative sanctions

Exposure date	Violation content	Working contents

(1) If no administrative sanctions was taken within one year, “none” shall be written in left field of the above table.

(2) The officer responsible for transfer permission (report) shall confirm whether the above content is agreed with the register of administrative sanction. If it is not correct, he shall notify both the transferor and transferee the result and order to correct the above table.

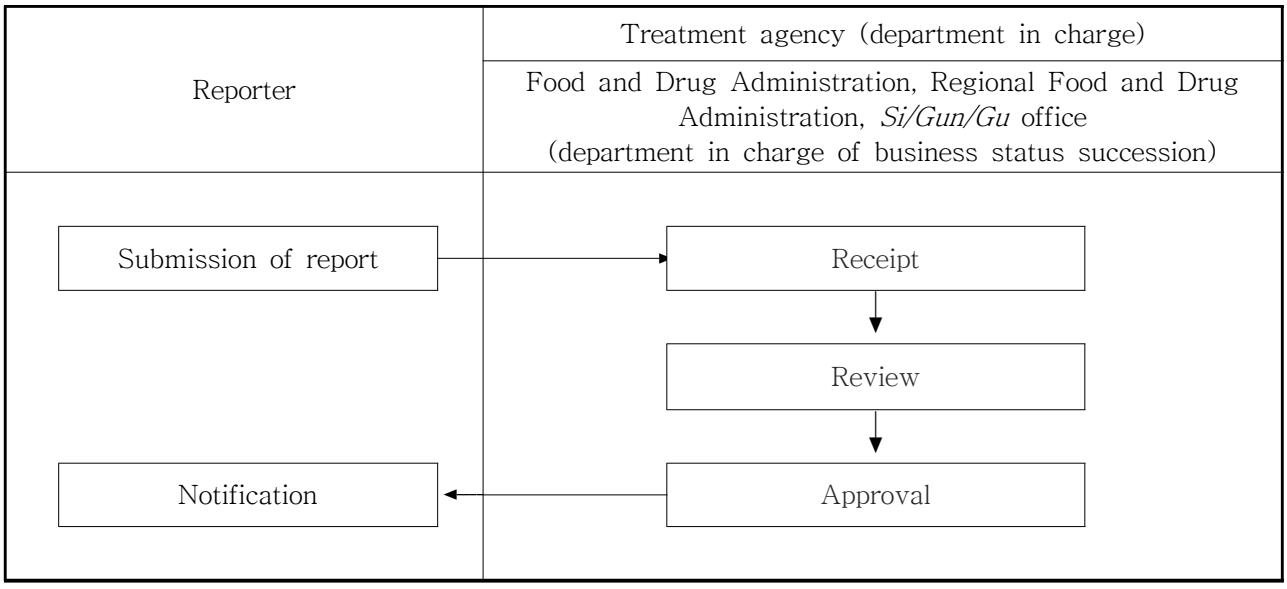
2. If the transferee does not fulfill the administrative sanction within the designated date or re-expose the same violation, the administrative sanction given to transferor was succeeded to the transferee and aggravated the sanction under Article 31 of the Enforcement Rule of the Health Functional Food Act and annexed the Table 9.

Date (YY/MM/DD):

Transferor: Name (signature or seal)
Address

Transferee: Name (signature or seal)
Address

This report is processed as below:



[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	Appoint-ment	Name			
		Resident registration No.			
		Qualification			
		Position			
		Date			
	Dis-missal	Name			
		Resident registration No.			
		Qualification			
		Position			
		Date			

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.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Food and Drug Administration

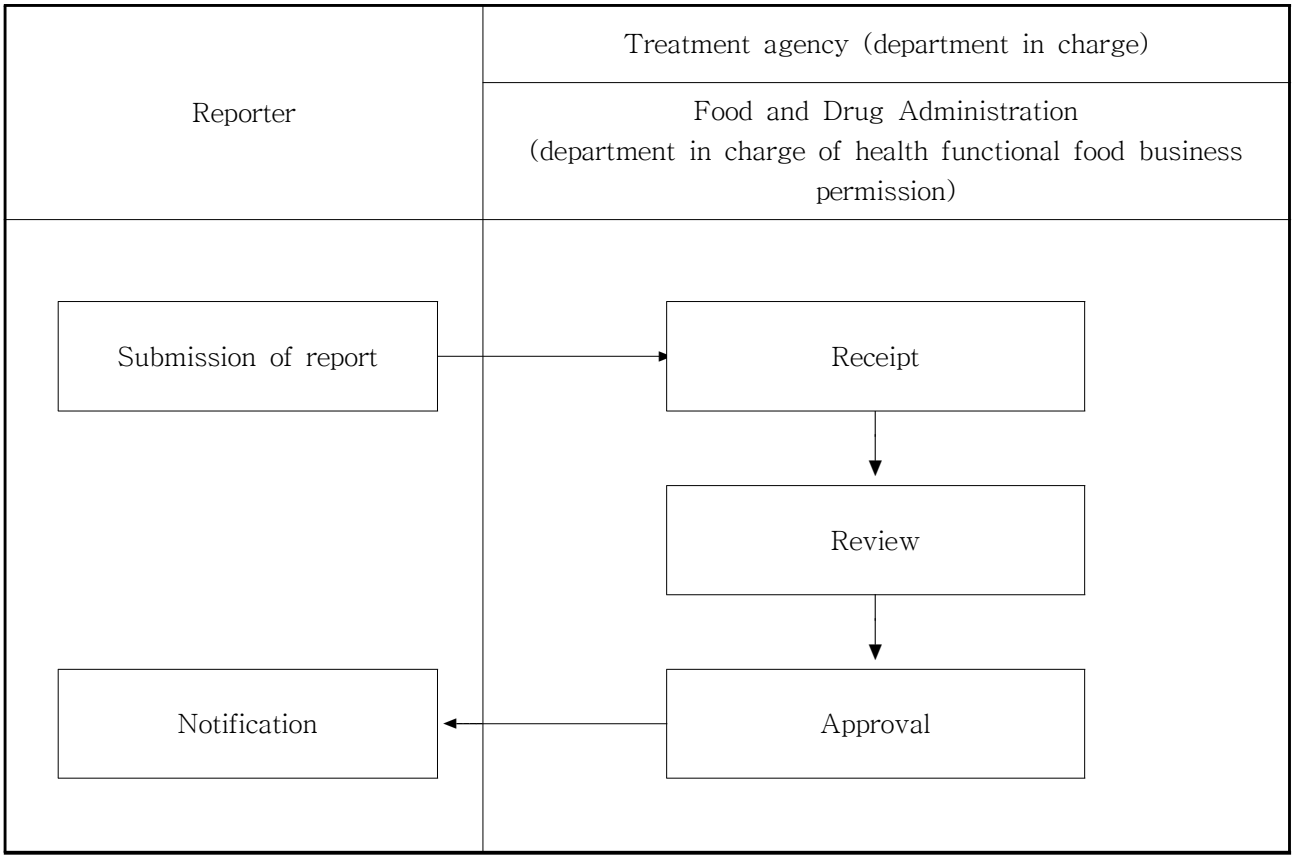
※ Documents required	Fees
Documents that verifies the qualification of the quality manager (limited to the case of appointment)	free

210㎜×297㎜(general paper 60g/㎡(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

NO.	Date	Purpose of inspection	Contents of main guidance	Inspector				Entrant or Confirmer		
				Department	Position (class)	Name	Signature (seal)	Position (class)	Name	Signature (seal)

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

[Annexed the Form 31]

No.	Domestic	Imported
Collection (Seizure) Certificate		

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)			

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.

Date (YY/MM/DD):

Collector (seizor) department :
name (signature or seal)

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

[Annexed the Form 32]

Collection Examination Administrative Register

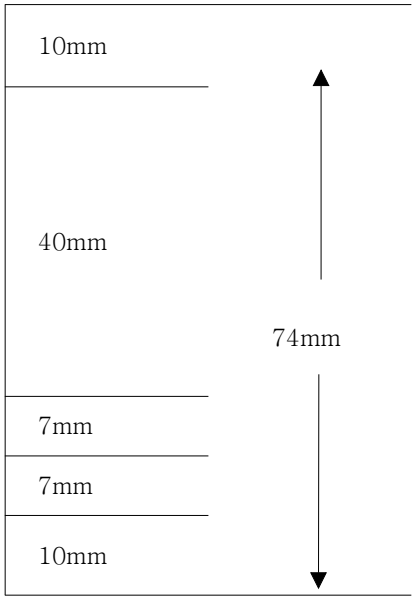
Director of bureau	Division head	Chief clerk	Charge	No.	Collection certificate No.	Name of product	Specification and quantity	Place of collection	Date of collection	Date of request	Date of notification	Judgement	Treatment result	Examination laboratory	Classification of inspection	Treatment of collection product	Remark (import. domestic)

325mm×290mm(preservative paper(1class)70g/㎡)

[Annexed the Form 33]

(front)

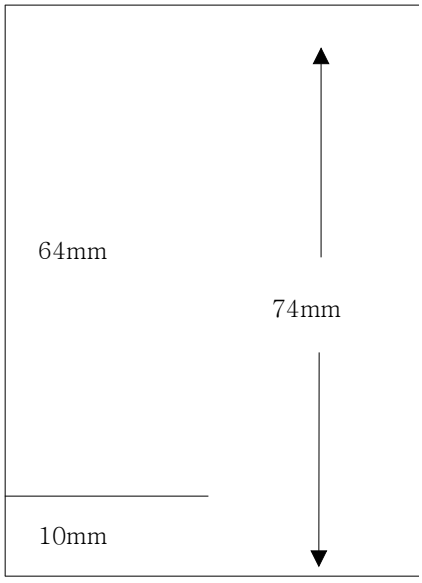
The Health Functional Food sanitation Inspectors certificate
①   ⑤
②
③
④

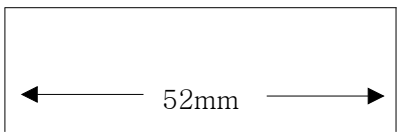


52㎜×74㎜(preservative paper(1class)120g/㎡)

(back)

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(YY/MM/DD) 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 si/gun/gu** (seal)
If you got this certificate, put in near a post box.





※ Footnote

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

① Picture (30㎜×40㎜)

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
[illegible]	10 point	Ming-style printing
[illegible]	8 point	Ming-style printing

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

4) Color is sky blue

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

(front)

<table>
<tr><td colspan="5">Application for Designation as GMPs Applied Business Establishment</td><td>Treatment period
60 Days</td></tr>
<tr><td rowspan="8">Applicant</td><td colspan="2">① Business permission No.</td><td>No.</td><td>② Business permission Date</td><td>(YY/MM/DD)</td></tr>
<tr><td colspan="2">③ Name of business establishment</td><td></td><td>④ Telephone No.</td><td></td></tr>
<tr><td rowspan="2">⑤ Place</td><td>Head office</td><td colspan="3"></td></tr>
<tr><td>Factory (business place)</td><td colspan="3"></td></tr>
<tr><td colspan="2">⑥ Name of representative</td><td></td><td>⑦ Resident registration No.</td><td></td></tr>
<tr><td colspan="2">⑧ GMP team manager</td><td></td><td>⑨ Resident registration No.</td><td></td></tr>
<tr><td colspan="2">⑩ The product name of GMP application (Type)</td><td colspan="3"></td></tr>
<tr><td colspan="6">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.

Date (YY/MM/DD):
Applicant (signature or seal)

To the Commissioner of the Food and Drug Administration

Revenue stamps: Fees 200,000 won</td></tr>
</table>

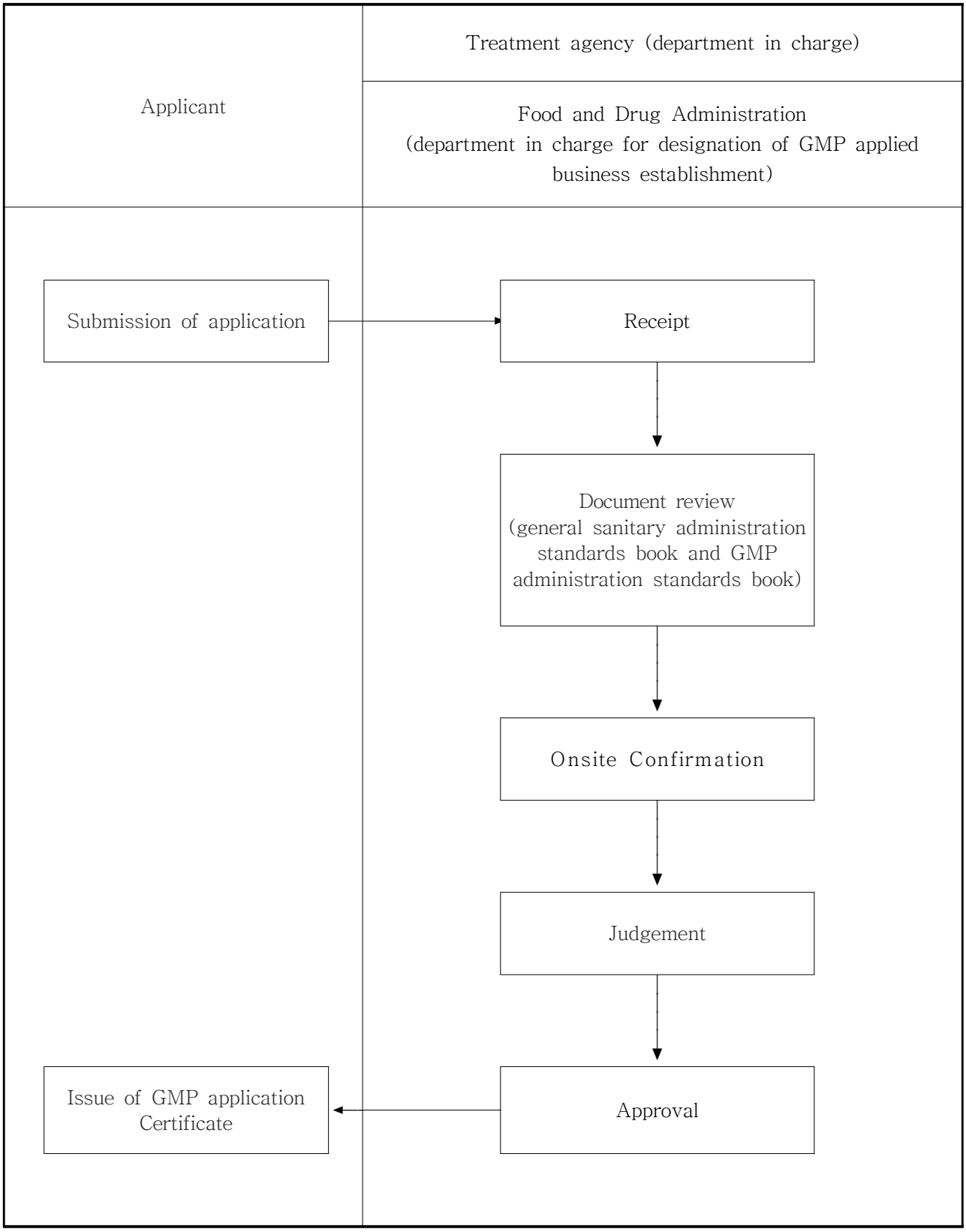
※ Documents required

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

(back)

This application is processed as below:



[Annexed the Form 35] <Amended on November 20, 2006>

(front)

No.

Designation Certificate of Good Manufacturing Practices Applied Business Establishment

Name of business establishment:

Place:

Representative: Resident registration number :

Conditions :

I designate a GMP application business establishment designation under Article 22(2) of the 「Health Functional Food Act」 and Article 26 of the Enforcement Rule of the same Act.

Date (YY/MM/DD):

the Commissioner of the Food and Drug Administration (seal)

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

(back)

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

[Annexed the Form 36] <Amended on November 20, 2006>

(front)

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		

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」.

Date (YY/MM/DD):

Reporter (signature or seal)

To the Commissioner of the Food and Drug Administration

Revenue stamps	Fees
	100,000원

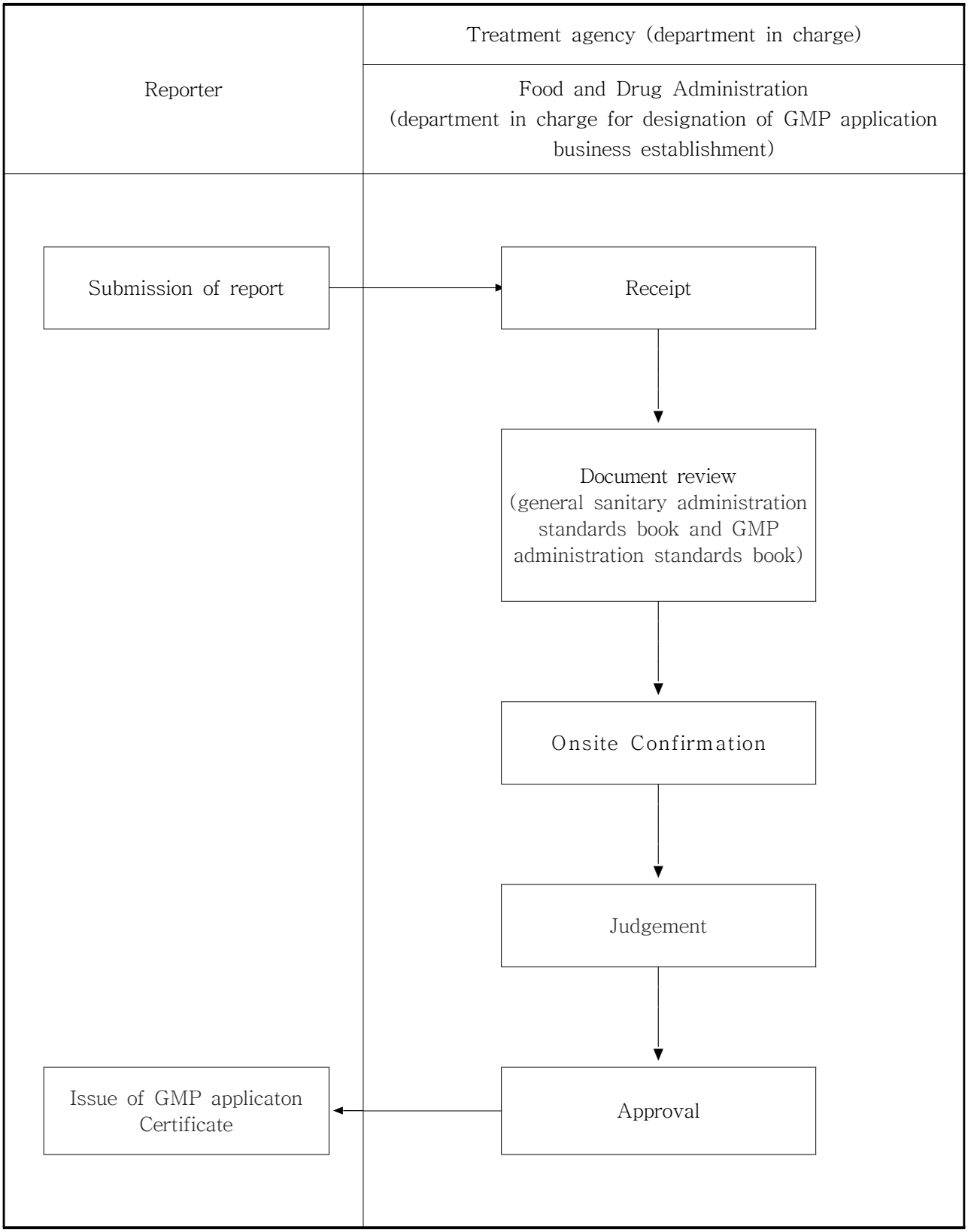
※ Documents required

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)

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

(back)

This application is processed as below:



[Annexed the Form 37]

Administrative Sanction and Hearing Register

No.	Document No. (sending date)	Name of business establishment	Place	Representative	Violation matters	Hearing date	Sanction criteria	Sanction contents and period

297㎜×210㎜(preservative paper(2 class) 70g/㎡)

[Annexed the Form 38]

Recipient: Commissioner of the Food and Drug Administration

Subject: **Administrative Sanction Matters Report**

Name of the business establishment (business type)	Business permission (report) No.	Representative (resident registration No.)	Place	Violation Content	Administrative sanction content	Period of the administrative sanction	Item name of the administrative sanction

Sender's name (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㎜×297㎜(general paper 60g/㎡(recycled product))

[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	☐ Health certificate ☐ Certificate of free sales ☐ Certificate of good manufacturing practieces 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 controled under the Health Functional Food Act and was being sold without limit in Korea.

※ Documents required

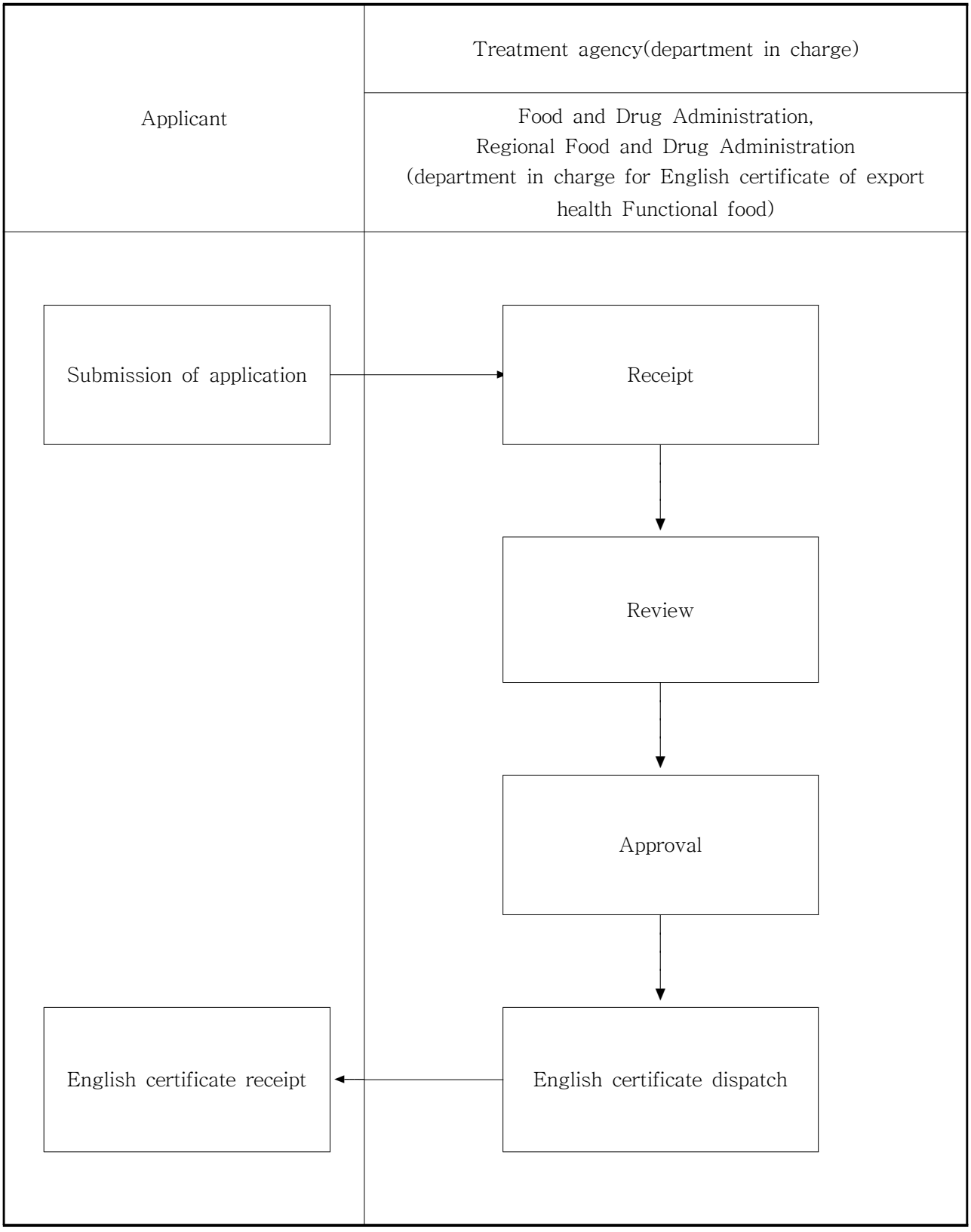
① A copy of verification documents for export or official letter for import request by importing country

② An english certificate to be issued

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

(back)

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㎜×297㎜(general paper 60g/㎡(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㎜×297㎜(general paper 60g/㎡(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

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

[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㎜×297㎜(general paper 60g/㎡(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

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

[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

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

Regulation on Deliberation of Labeling and Advertising of Health Functional Food

Enacted by Korea Food & Drug Administration Notification No. 2004-5, Jan. 31, 2004
Amended by Korea Food & Drug Administration Notification No. 2004-95, Dec. 29, 2004

Article 1 (Purpose) The purpose of this regulation is to provide standards, methods, procedures, etc. for the deliberation of labeling and advertising of functionality of health functional food under Article 16 of the 「Health Functional Food Act」.

Article 2 (Subject of deliberation) The labeling and advertising of functionality subject to deliberation under Article 16(1) of the 「Health Functional Food Act」 (hereinafter referred to as the "Act") shall be as follows. Provided, in case where it is labeled the functionality as publically announced by the standards and specifications of health functional food or as recognized under Article 14 or 15 of the Act, it shall be deemed as deliberated when the labeling content has been submitted to, confirmed by, and accepted by the competent authority at the time of filing item manufacture report or import report:

1. Labeling of functionality of health functional food under Article 3(3); and
2. Advertising of functionality of health functional food under Article 3(4).

Article 3 (Deliberation standard) The deliberation standard for labeling and advertising of functionality of health functional food shall be as follows:

1. It shall be complied with the national policy of health functional food regarding improvement of national health and the consumer protection;
2. It shall be declared the useful effects on the health purpose by physiological roles, etc. for human body structure and function;
3. It shall be expressed based on objective and scientific data;
4. It shall be clearly expressed, using sentences or words that are easy to understand and correct;
5. It shall be complied with the standards and specifications, or the ingredients or the components of health functional food on safety and functionality publically announced or recognized under Article 14 or 15 of the Act;
6. It shall be complied with the standards of label under Article 17 of the Act; and
7. It shall not be fallen under the scope of false or exaggerated labeling and advertising under Article 18 of the Act.

Article 4 (Application for deliberation) Any person who intends to apply for the deliberation of labeling and advertising of functionality of health functional food(hereinafter referred to as "applicant") shall submit an Application for Deliberation of Labeling and Advertising of Functionality, annexed the Form (1), along with the documents described in the following subparagraphs to the Korea Health Supplement Association (hereinafter referred to as the

"Deliberation Agency") under the provision of Article 16(2) of the Act:

1. Contents of labeling and advertising of functionality; and
2. Copy of Item Manufacture Report Certificate (Import Report Certificate for the imported health functional food) or product explanation.

Article 5 (Deliberation, result notification, etc.) (1) The Deliberation Agency received the application for deliberation of labeling and advertising of functionality of health functional food under the provision of Article 4 shall notify the applicant of the result in written form, after deliberation by the Deliberation Committee for Labeling and Advertising of Functionality of Health Functional Food (hereinafter referred to as the "Deliberation Committee") under Article 9, within ten days (excluding public holidays) from the date of the application received. Provided, That if the deliberation can not be completed within such period due to unavoidable reasons, the Deliberation Agency shall inform the applicant in advance of the deliberation delay.

(2) In case of deleting a part of the deliberated contents under paragraph (1) or simply modifying contents without changing the deliberated contents, or shifting advertising media or agency, etc. without changing the deliberated contents, it may not have to be deliberated separately. In this case, the applicant who has modified the deliberated contents shall notify the Deliberation Agency of the modified contents before labeling and advertising.

(3) The Deliberation Agency that is notified of the modified contents as referred to in the latter part of paragraph (2) shall undertake a re-deliberation under Article 4, in case where the modified contents are recognized as different labeling and advertising from the previously deliberated ones.

(4) The Deliberation Agency shall notify the business permission authorities or the business report authorities having jurisdiction over the business establishment of the results under paragraph (1) or the re-deliberation results under Article 6.

Article 6 (Re-deliberation) (1) The applicant may request a re-deliberation within one month after receiving the deliberation result, in case there are objections to the deliberation result under Article 5.

(2) The Deliberation Agency requested the re-deliberation under paragraph (1) shall notify the applicant of the result in written form, after deliberation by the Deliberation Committee under Article 3.

Article 7 (Recommendation for re-deliberation) (1) The business permission authorities or the business report authorities notified of the deliberation or re-deliberation result under Article 5(4) shall report to the Commissioner of the Food and Drug Administration when deciding that the result does not comply with the deliberation standard under Article 3.

(2) When receiving the report under paragraph (1), the Commissioner of the Food and Drug Administration may recommend a re-deliberation to the Deliberation Agency. In this case, the Deliberation Agency shall conform it unless there is any particular reason.

Article 8 (Statement of the deliberation result) (1) In cases where the deliberated contents under Articles 5 and 6 are intended to be advertised, in the advertising it may be stated that it is deliberated.

(2) The Chairman of the Deliberation Committee shall prescribe the detailed matters related to the statement that it is deliberated under paragraph (1), method, etc. of such statement considering the characteristics of the advertising media, upon the Commissioner of the Food and Drug Administration's approval.

Article 9 (The Deliberation Committee) The Deliberation Agency under Article 4 shall establish and administer the Deliberation Committee for Labeling and Advertising of Functionality of Health Functional Food in order to perform efficiently the deliberation of labeling and advertising of functionality.

Article 10 (Composition etc. of the Deliberation Committee) (1) The Deliberation Committee shall be composed of within fifteen members, including one chairman and one vice-chairman.

(2) The Deliberation Committee shall elect the chairman and the vice-chairman.

(3) The president of the Deliberation Agency shall commission the members from among the persons falling under the following subpargraphs upon the Commissioner of the Food and Drug Administration's approval. In this case, persons belonging to industry shall be less than one-third of the members and women shall be 30 % or more of the total members.

1. Persons with extensive learning and experience in the health functional food or the advertising; or
2. Persons recommended by heads of health functional food related organizations, citizens' organizations (referring to non-profit non-governmental organization under Article 2 of the Assistance for Nonprofit Non-Governmental Organizations Act), health functional food related academic societies, or universities.

(4) The terms of office of the member shall be one year. Provided, That the terms of office of the substitute member shall be the remainder of the predecessor.

(5) The chairman shall represent the Deliberation Committee and exercise general control over the business of the Deliberation Committee. The vice-chairman shall assist the chairman and act on behalf of the chairman when the chairman is unable to perform his duties.

(6) One secretary shall be put in the Deliberation Committee to deal with the general affairs of the Deliberation Committee.

Article 11 (Meeting and proceeding) (1) The chairman shall convene meetings and preside over the meetings.

(2) The meeting of the Deliberation Committee shall be convened -

1. in the case where a request for the convocation of a meeting is filed by the Commissioner of the Food and Drug Administration;
2. in the case where a request for the convocation of a meeting is filed by not less than one-third of the members; or

3. in the case where the chairman decides that a meeting is necessary.

(3) The meeting of the Deliberation Committee shall start an deliberation with the attendance of a majority of the total members, and make a decision with a concurring vote of two-third or more of those present.

Article 12 (Minutes) The Deliberation Committee shall record and keep minutes of each meeting. Provided, That the written opinion of the deliberation may substitute for the minutes of deliberation or re-deliberation under Articles 5 and 6.

Article 13 (Allowances and travel expenses) The members present at the meetings of Deliberation Committee may be provided with allowances and travel expenses as decided by the Deliberation Agency.

Article 14 (Fees for deliberation) The provisions of Article 42(6) of the Act shall apply to the fees for deliberation.

Article 15 (Deliberation report) The president of the Deliberation Agency shall report quarterly the results of deliberation or re-deliberation under Articles 5 and 6 according the format of annex the Form (2) to the Commissioner of the Food and Drug Administration within fifteen days after the completion of a quarter year.

Article 16 (Detailed provisions) The chairman may decide any matters related to the operation of the Deliberation Committee and detailed matters necessary for the deliberation other than the provisions as prescribed in this Regulation, upon the Commissioner of the Food and Drug Administration's approval.

ADDENDA (Jan. 31, 2004)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures) At the time this Notification enters into force, in case of the product that is deliberated as advertising prior deliberation under the Food Sanitation Act and the subordinate statutes or that is not subject to the advertising prior deliberation, it is deemed that it is deliberated for the labeling and advertising of functionality under this Notification within the period of transitional measures under Articles 2 and 3 of the Addenda of the Act.

ADDENDA (Dec. 29, 2004)

(1) (Enforcement Date) This Notification shall enter into force on the date of its announcement.

[Annexed the Form 1]

<table>
<tr><td colspan="5">Application of Labeling and Advertisement of Functionality (Deliberation · Re-deliberation)</td><td>Treatment period
10 days</td></tr>
<tr><td rowspan="2">Applicant</td><td>Name</td><td></td><td>Resident registration No.</td><td colspan="2">-</td></tr>
<tr><td>Address</td><td colspan="4">(☎) (Fax)</td></tr>
<tr><td rowspan="2">Business</td><td>Title or trade name</td><td></td><td>Address</td><td colspan="2"></td></tr>
<tr><td>Type of business</td><td></td><td>Business permission (report) No.</td><td colspan="2"></td></tr>
<tr><td>Product for deliberation</td><td>Product name</td><td colspan="4"></td></tr>
<tr><td rowspan="3">Deliberation content</td><td>Phrase for functionality claim</td><td colspan="4"></td></tr>
<tr><td rowspan="2">Advertisement</td><td>Media</td><td></td><td>Company for advertisement production</td><td></td></tr>
<tr><td colspan="4">Advertising phrase for deliberation : (attached)</td></tr>
<tr><td colspan="6">I apply for the deliberation (re-deliberation) of functionality labeling and advertisement for the above product under Articles 4 and 6 of Regulation on Deliberation of Labeling and Advertising of Health Functional Food.

Date (YY/MM/DD):

Applicant (Sign or Seal)

To the Head of Deliberation Agency</td></tr>
<tr><td colspan="5">※ Documents
1. Labeling and advertisement contents for functionality
2. A copy of item manufacture report or import report (including the mixing ratio of components) (Only for the products completed the item manufacture report or import report)
3. A copy of product explanation (including product name, mixing ration of components, type and manufacturing methods, consumption amount and method, warning notice for consumption, packing method and unit) (Only for the products to be manufactured or imported)
4. Additional document for deliberation (if necessary)</td><td>Fees
100,000Won (no fees for re-deliberation)</td></tr>
</table>

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

[Annexed the Form 2]

Report of Deliberation Result for Labeling and Advertisement of Functionality

1. Overall of deliberation result

(unit : item No.)

Classification / Product kind	No. of application / No. of non-compliant application									Etc.
	Total	Label	Newspaper	Magazine	Print	Internet	Home shopping	Cable TV	misc.	
Total										

※ The product kinds are the name pre-described in the Official Book of Health Functional Food.

2. Detailed deliberation by business

No.	Deliberation date (MM/DD)	Name of business	Name of product	Media	Deliberation result			Functionality content
					Passed	Correction required	Non-Compliance	
total(item no)								

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

Labeling Standard of Health Functional Food

Enacted by Korea Food & Drug Administration Notification No. 2004-6, Jan. 31, 2004
Amended by Korea Food & Drug Administration Notification No. 2005-65, Nov. 11, 2005
Amended by Korea Food & Drug Administration Notification No. 2007-16, Mar. 22, 2007

Article 1 (Purpose) The purpose of this Notification is to contribute toward the quality improvement of health functional food and provide the consumers with correct information by establishing the standards for information, methods, etc., which shall be declared on the labels of health functional food as prescribed in Article 17 of the 「Health Functional Food Act」 (hereinafter referred to as the "Act").

Article 2 (Definitions of terms) For the purpose of this Notification, the definitions of terms shall be as follows:

1. The term "product name" means the unique name indicating the true nature of each individual food.
2. The term "sell-by-date" means the period of time the last date of offer to sale to consumer from the date of manufacture under any stated storage instructions.
3. The term "date of manufacture" means the date on which no further manufacturing or processing other than packaging becomes necessary (for those products that, after packaging, undergo additional manufacturing process such as sterilization or pasteurization, etc., it refers to the point when the final process is completed). Provided, for capsule type, it means the date on which filling and molding processes are completed; for the types of tablet, fluid, etc. it means the date on which manufacturing process is finished except filling and packaging steps.
4. The term "raw material" means any material used in the manufacture of health functional food and present in the final product. Provided, any food (including a purified water) or any food additive which is used in manufacturing or processing but not remained in the final product is excluded.
5. The term "component" means any chemical substance, mixture, or single substance separated from food, etc. or composed of raw material present in the final product.
6. The term "serving size" means an amount customarily consumed per eating occasion by a person representing the main consumer group depending on the nature of food.
7. The term "nutrition information display" means the declaration of the nutrient content and the percentage of daily reference value, etc. contained in a certain amount of product.
8. The term "daily reference value" means the average daily intake of nutrients by single Korean established for the food labelling.
9. The term "recommended daily allowances" mean the recommended amounts of nutrients to intake by single Korean, which each amount of nutrients necessary per day is determined according to sex and age groups.
10. The term "function information display" means the degree of functional component or marker compound present in a certain amount of product, the health claims and others.

11. The term “health claim” means the labeling of functionality as prescribed in Article 3(2) of the 「Health Functional Food Act」 (hereinafter referred to as the “Act”). In this case, health claims include nutrient function claims, other function claims and reduction of disease risk claims.
12. The term “main ingredient” means any main ingredient or major component representing the functionality of health functional food.
13. The term “principal display panel” means the side panel generally shown to consumers when purchasing a health functional food.
14. The term “information display panel” means that part of the label easy to read by consumers, which contains the information not in principle display panel of the product.

Article 3 (Subject of label) The health functional foods subject to labeling according to this labeling standard shall be as follows:

1. The health functional food manufactured by health functional food manufacturing business permission under Article 5 of the Act (including any functional ingredient or component; hereinafter the same shall apply); and
2. The health functional food reported for import under Article 8 of the Act.

Article 4 (Label requirements) The information declared on the label under Article 17(1) of the Act shall be as follows:

1. letters of “health functional food” or diagram that stands for “health functional food” (Provided, claims of “health functional food ingredient” for ingredient product of health functional food);
2. the product name;
3. the name and place of business establishment;
4. the shell-by-date and the storage method;
5. net contents;
6. nutrition information (including the nutrient and its content, and the percentage of daily reference values or recommended daily allowances);
7. function information (including functional component or marker compound of functional ingredient, and its content);
8. the consumption amounts, the consumption method and the warning notice for consumption;
9. the name and content of raw materials;
10. an disclaim that it is not a medicine for preventing and curing diseases; and
11. miscellaneous matters as prescribed in the detailed labeling standards of health functional food

Article 5 (Labeling methods) The labeling methods of label statements under Article 4 shall be as follows:

1. General matters
   a. Labels shall be written in Korean, but Chinese characters or foreign languages can be written in tandem with Korean for better consumer understanding; in this case, the type size of Chinese characters or foreign languages shall not be larger than that of Korean letters. Provided, for imported health functional foods and trademarks registered under the Trademark

Act, the type size of foreign languages in label may be larger than that of Korean letters.

b. Labels shall be printed on the each container or package of minimal sales unit sold to consumers. Provided, for collection of a whole granular item packaged product, the product name and the name of business establishment shall be declared on the individual wrap.

c. Label shall be printed with a color distinguished from the background color that is conspicuous and easy to read by consumers. Provided, That if a carving seal or a stamp, etc. is used to recognize the label information, in order to prevent the alteration of part of label statements, etc. such as the sell-by-date, etc., this shall not be apply.

d. Labeling shall be printed with unerasable ink, or used by a seal or a stamp, etc. Provided, if a print, a seal or a stamp, etc. can not be used for label due to the nature of packaging materials such as the tank truck (lorry), the drum, the bottle product or th plastic container, the paper or the processing paper or the plastic package for materials purpose not sold to consumers directly, etc., a Label, etc. on which label statements are printed or written, can be used.

e. A container or a package that bears the label of a different manufacture business shall not be used. Provided, if the container does not have harmful effects on health functional food and is only used to supply the raw materials to another business establishment, this may not apply.

2. The location of label

The label shall be placed where is most likely to be seen by the consumer. Provided, the label statements prescribed in Article 4(1), (2) and (5) shall be labeled on the principal display panel and information under Article 4(3), (6), (7) and (10) and miscellaneous matters prescribed in subparagraph (11) shall be declared en bloc on the information display panel.

3. The type size

a. The type size under Article 4(1) and (5) shall be 12 points or larger. Provided, if the type size prescribed in subparagraph 2 is smaller than 22 points, the type size may be 7 points or more.

b. The type size under Article 4(2) shall be at least half of the largest type size used in label and shall be at least 7 points or more.

c. The type size under Article 4(3), (4), (7), (8) and (10) shall be 7 points or more and other type size shall be above 6 points.

Article 6 (Detailed labeling standards and methods) Detailed labeling standards and methods of health functional food shall be as follows:

1. Letters of health functional food or diagram that stands for health functional food

a. The health functional food shall contain the letters of “health functional food” or the diagram that stands for health functional food shown below on principal display panel; and

b. For the ingredients or components of health functional food, letters of “health functional food ingredient” shall be declared on principal display panel.

2. The product name

a. The product name shall be the unique name indicating the true nature of the product and be the name recorded in business permission, or item manufacture report or import report;

b. The name defined by the standard and specifications under Article 14(1) of the Act (A part of the name indicating the true nature of the product may be used) or the name recognized by the Commissioner of the Food and Drug Administration under Article 14(2) of the Act shall be used. In this case, the trade name, or the brand or virtual name may be used together;

c. If the treatment condition, etc. during manufacturing may be used together due to the nature of the product, the additional terms (drying, concentration, restoration, smoking, etc.) necessary for consumers not to mislead or confuse shall be used together with the product name or declared around the product name;

d. The expression corresponding to the false or exaggerated labeling and advertising under Article 18 of the Act, or any expression misleading or confusing with other health functional food shall not be used; and

e. When the product name of imported health functional food is written in Korean, and the original name in foreign language may be translated into Korean and labeled. In this case, it shall comply with the provisions of a) through d).

3. The name and place of business establishment

a. Title and place of health functional food manufacture business establishment shall be the name and place recorded in the business permission certificate. In this case, the place may be replaced by a location that is responsible for exchanging the returned products;

b. Title and place of health functional food import business establishment shall be the name and place recorded in the business report certificate and the names of exporting country and manufacture business establishment shall be labeled in tandem. In this case, if the names of exporting country and manufacture business establishment are written in foreign language, the additional label in Korean may not be necessary; and

c. When the health functional sales business wants any additional label for its business name and place of business establishment, trademark or logo, etc., the type size for shall be equal to or smaller than that used for the name and place of manufacturing business establishment, trademark or logo, etc.

4. The sell-by-date and storage instructions

a. The sell-by-date shall be labeled as follows:

1) The sell-by-date shall be labeled as “until ○○year○○month○○day” or “until yy.mm.dd”,

or “until ○○○○year○○month○○day” or “until yyyy.mm.dd” and if it is difficult ed hoc to label the sell-by-date on the principal display panel, the position where it is labeled instead shall be declared on the principal display panel;

2) In the case of imported health functional foods, if the order of the sell-by-date used in exporting country is different from the above 1), the order of year, month and day shall be illustrated in order to consumers understand easily; and

3) If date of manufacture is labeled together, the sell-by-date shall be labeled as “within ○○ days from the date of manufacture” for less than 1 month, “within ○○ months from the date of manufacture” for less than 12 months or “within ○○years from the date of manufacture” for 1 yea or more. In this case, the date of manufacture shall be labeled as “○○year○○month○○day” or “until yy.mm.dd”, or “○○○○year○○month○○day” or “ yyyy.mm.dd.”

b. If different products with different sell-by-date are packaged together, only the shortest sell-by-date among the products shall be labeled.

c. If there are specified conditions for use or storage of the product, they shall be labeled together with the sell-by-date. In this case, the products required to maintain freezing or refrigeration condition continuously shall be labeled as 『keep frozen』 or 『keep refrigerated』 and the freezing or refrigeration temperatures necessary to maintain the quality of the product shall be declared.

5. The net content

a. It shall be declared with weight, volume or counts according to its property. If the content is solid or semi-solid, it shall be declared by weight; for liquid, by volume; for mixture of solid and liquid, either by weight or volume. If net content is declared with counts, the weight or volume shall be added in parenthesis together;

b. In the case of tablet-type products, the number of tablets and the total weight within a container or a package for sales shall be declared. In the case of capsule-type products, the number of capsules and the net contents excluding the weight of the coating materials shall be declared.

6. The nutrition information

a. The name, content per serving size, and percentage of daily reference values (%, excluding the calories) in Annexed the Table 1, Daily Reference Values (or relevant Koreans' recommended daily allowances for each of specific groups) for calories, carbohydrate, protein, fat and sodium shall be labeled as follows: Provided, vitamins, minerals (excluding sodium) and other nutrients may be labeled arbitrary. In this case, the name, content and percentage (%) in Annexed the Table 1, Daily Reference Values or relevant Koreans' recommended daily allowances for each of specific groups) of the nutrient in question shall be labeled. while the name and content shall be labeled if daily reference value is not established.

1) Calories shall be expressed in kilocalorie (kcal) units. It shall be expressed to nearest 5 kcal increment and less than 5 kcal may be expressed as zero. Calories shall be the sum of values multiplied 4, 4, 9, 7, 3 and 2.4 kcal by per gram (g) of carbohydrate, protein, fat, alcohol, organic acid and sugar-alcohol, respectively. Provided, if the content of dietary fiber

in carbohydrate is to be declared, the content of carbohydrate not including dietary fiber can be used for calculation.

2) Carbohydrate shall be expressed in gram (g) units and expressed to nearest 1 g increment. Carbohydrates less than 1 g may be expressed as “less than 1 g” and less than 0.5 g as zero. In this case, the content of carbohydrates refers to the value of health functional food weight not including the contents of crude protein, crude fat, moisture and ash. If dietary fiber or sugars are to be declared, the name and its content shall be added in parenthesis right below carbohydrate according to the labeling methods of carbohydrate.

3) Proteins shall be expressed in gram (g) units and expressed to nearest 1 g increment. Protein less than 1 g may be expressed as “less than 1 g” and less than 0.5 g as zero.

4) Fat shall be expressed in gram (g) units. It shall be expressed to nearest 0.5 g increment up to and including 5 g, and 1 g increment above 5 g, except that amount less than 0.5 g may be expressed as zero.

a) If saturated fatty acid or unsaturated fatty acid is to be declared, the name and its content shall be added in parenthesis right below fat according to the labeling methods of fat.

b) If cholesterol is to be declared, the name and its content in ㎎ shall be labeled right below fat, and be expressed to nearest 5 ㎎ increment. If the content is 2 ㎎ or more up to less than 5 ㎎, it may be expressed as “less than 5 ㎎” and less than 2 ㎎ as zero.

5) Sodium shall be expressed in ㎎ units, and expressed to nearest 5 ㎎ increment for 5 ㎎ or more up to 120 ㎎ or less and 10 ㎎ increment for more than 120 ㎎, and as zero for less than 5 ㎎.

6) If the content of carbohydrate, protein, fat and sodium is expressed as zero, the labeling may be omitted.

b. The allowable tolerance limit between the labeled and measured values of nutrient shall be as follows:

1) The measured values of calorie, sugars, fat, saturated fat, cholesterol and sodium shall be less than 120% of each of the labeled values; the measured values of vitamin, mineral, protein, carbohydrate and dietary fiber shall be 80% or more of each of the labeled values. Provided, if the specification of component according to the standards and specifications of health functional food in Article 14 of the Act is described as “the labeled value or more,” the measured value shall be the labeled value or more; if it is described as “the labeled value or less,” the measured value shall be the labeled value or less; and if it is described “~ or more ~ or less,” the measured value shall be within the range of the labeled value.

2) Even when the measured value is beyond the range prescribed in 1), it shall be recognized as the allowable tolerance limit within the labeled range per unit value according to provision a).

c. The nutritional information display with the function information display in subparagraph 7 shall be declared in the information display panel according to annexed the Table 2, Outline and Methods of Nutrition and Function Information Display.

7. The function information

a. The label of functional component shall be declared with a representative functional component or a marker compound of functional ingredient and its content of the relevant product. In this case, the content of functional component or marker compound shall be expressed as the value containing per serving size. If it is difficult to identify the functional component or marker compound, the functional ingredient and its content may be declared. Provided, the product for processing not sold to consumers directly may declare the final content containing per unit value of functional component or marker compound.

b. If the health claim is to be declared, it shall be classified as the nutrient function claim that shows the physiological activity of nutrient on growth, promotion and normal function of human body; the other function claim, excluding the nutrient function, that has specific effects on normal function of human body or biological activity so that shows health contribution or function enhancement, or health maintenance or improvement; and the reduction of disease risk claim that reduces the disease risk or health problem by consuming of food through the total meals, and declared to conform the followings:

1) The product shall be notified or recognized according to the standards and specifications or ingredients components in Article 14 or 15 of the Act.

2) It shall be recognized by generally known scientific data that sufficiently prove the declared effect of functionality and health-related condition.

3) The nutrient function claim shall be limited to the nutrients established the daily reference values in Annexed the Table 1.

4) It shall not contain the relevant functional component, ingredient or nutrient those amount may increase the risk of disease or make the unhealthy condition worse.

5) The health claim shall not be the misleading content that may foster the excessive consumption of specific food such as excess intake of daily reference value or criticise the good food habits such as the daily balanced diet.

6) The component or marker compound of functional ingredient subject to health claim shall be officially recognized or may quantitative test recognized by the Commissioner of the Food and Drug Administration.

7) It shall be received a prior deliberation according to the Labeling and Advertising Deliberation Regulation of Health Functional Food in Article 16 of the Act.

8. The consumption amount, consumption method, and warning notice for consumption

a. The amount recommended for consumption per eating occasion by each of consumption group, consumption frequency and consumption method for the relevant product shall be labeled.

b. If there exist any group concerning the abnormal symptom or side effect when consumed the relevant product, or any warning notice for the possible side effect and the amount, etc. due to excess intake, it shall be declared.

9. The name of raw material and content

a. The name of raw material which represents the functionality of the relevant product shall be declared first and others in descending order of amount used. Provided, the name of raw material which is not remaining in the final products may not be declared.

b. When any compound raw material (a product manufactured by using at least two raw

materials) is used, the name of compound raw material shall be declared and the names of raw materials in descending order of amount used shall be declared in parenthesis. Provided, the name of relevant raw material may not be declared if the compound raw material consists of less than 5% of the product or the names of raw material is identified clearly in the name of compound raw material.

c. Notwithstanding the provision of item b, if the product contains egg (limited to poultry), milk, buckwheat, peanut, soybean, wheat, mackerel, crab, pork, peach or tomato, known to cause allergy among Koreans or the raw ingredients that are the processing product manufactured by using those foods as raw materials, the names of those raw materials shall be declared [for example: in case of using chicken egg – “chicken egg,” in case of using yolk – “yolk (chicken eggs)”].

d. The purified water used for manufacture shall be declared as raw material. Provided, if the purified water used is not remaining in the final product or is declared as salt water, syrup or meat stock, the purified water used may not be declared.

e. The genetically modified food, etc. manufactured with the raw materials of agricultural, livestock, fishery products, etc. grown or raised by DNA recombinant techniques, etc. that select the useful DNAs among DNAs of organism and combine them with DNAs of other organism shall be declared as “genetically modified” or “(containing) genetically modified ○○” in parenthesis just beside the name of raw material or component in accordance with the Labeling Standard for Genetically Modified Foods as referred to the provision of Article 10\(1) of Food Sanitation Act,

f. Notwithstanding the provision of item b, if food additive prescribed the usage limit in the Official Book of Food Additives is used or added (It limits those originated from the ingredient product that the food additive is used intentionally.), the name of food additive added and its intended use shall be declared.

g. If the content of soluble component (or extract) used as raw material is declared, the solid content (percentage) of each of raw materials contained in the product shall be declared.

10. Any disclaim that it is not a medicine for preventing and curing disease shall be labeled on the lower portion of primary display panel or information display panel in parallel with bottom side so it is easy to read by consumers.

11. Miscellaneous matters as prescribed in the detailed labeling standards of health functional food

a. If the component originated from animal (including food additive) is used, the name of component, originated animal and used part shall be declared. Provided, the item that does not have the potential contamination of BSE in manufacturing process such as empty capsule may be exempted.

b. If it is any irradiated health functional food (including ingredient of health functional food) or manufactured with any irradiated raw material, the name of irradiation business and dose of irradiation shall be declared, and the indication for irradiated product and the irradiation logo shall be declared so it is easy to read by consumers.

c. The packing material shall be declared on the synthetic resin container or wrapping sheet used for the product. In this case, it may be labeled according to the material of synthetic resin such as polyvinylchloride(PVC), polyethylene(PE), fluorinated polyethylene and polypropylene(PP), polystyrene(PS), polychlorovinylidene(PVDC), polyethyleneterephthalate(PET), phenolformaldehyde (PF), etc. or with the English abbreviation which it is used generally.

d. If recommended before and after drinking, hangover cure, etc. is to be labeled, the warning statement, "excessive drinking compromises your health," etc. shall be labeled together.

e. The term "natural" shall be labeled only for the health functional food that does not contain any artificial (combined) flavoring agent, synthetic color, synthetic preservative or any other artificial or post-harvest-added synthetic component, and that has not gone through additional processes other than a process of eliminating inedible part or minimal physical processes.

f. The term "100%" may be labeled only when no other materials than the raw materials subject to label are added.

g. The product that is added and used aspartame shall bear the indication, "phenylalanine is contained."

h. For ginseng or red ginseng product, the following statements may be used:

1) Ginseng or other name indicating ginseng (including the product name), design and figure may be labeled or used only for the product complied with the standards and specifications for ginseng and red ginseng product. Provided, this shall not apply the case that is prescribed in other the acts and subordinate statues.

2) The compound ratio (percentage) of raw ginseng used for ginseng and red ginseng product shall be categorized into and declared as ginseng hair root and ginseng root.

3) When the ginseng design is labeled on the package of ginseng product, the label shall be referred to the standard design of ginseng product in annexed the Table (3)(1). Provided, this shall not apply when any design to symbolize ginseng is labeled.

4) If the origin of ginseng is to be declared in product description or on product package, the Standard Sentence for the Origin of Ginseng in Annexed the Table 3 (2) shall be applied *mutatis mutandis*

5) The product name may be labeled in Chinese characters.

6) "Special product of Korea" in Korean or Chinese characters may be labeled in the products for domestic market while "Special product of Korea" in English or the importing country's language may be labeled in the products for export.

i. The letters of "GMP application business" or the diagram showing that it is a GMP application business (hereinafter referred to as "GMP certification diagram") may be shown on the product of good manufacturing practices (GMP) application business. Provided, That if

the GMP certification diagram is shown, it shall be shown in accordance with the GMP certification diagram, annexed the Table 4.

Article 7 (Allowable tolerance of weight, etc.) To indicate the net content as prescribed in Article 4(5), allowable tolerance between the labeled content on the container or package and the measured content shall be as prescribed in annexed the Table 5.

Article 8 (Special cases of application) Notwithstanding the provisions of Articles 4 and 5, it may be labeled as follows by considering the nature of health functional food:

1. In case of ingredient product of health functional food, the label statements prescribed in Article 4 (6), (8), (10), and (11) may not be applicable.
2. If it is difficult to label the bundle statement declared on information display panel except principal display panel in accordance with the provision of Article 5 (2) with prescribed size due to lack of display panel area, only the requirements in Article 4 (3), (4) and (8) (consumption amount and consumption method) may be declared on each container or package of minimal sales unit and other requirements may be written on the product description packaged with the product. In this case, "Referred to product description" shall be labeled.
3. The exporting health functional food may be labeled according to the request of importer.
4. If the statement required to label on principal display panel in accordance with the provision of Article 5 (2) is to declare on information display panel due to unavoidable reason, it shall be declared with the type size of at least 12 points.
5. When the health functional food manufacture business establishment imports raw material or component (hereinafter, "own ingredient for health functional food") to manufacture its own product, the label statements in Article 4 (6), (8), (10) and (11) may not be declared and the label requirements in Korean may be omitted if there is a label used by exporting country among the label statements of own ingredient for health functional food.
6. When the product name is declared in accordance with the provision of Article 6 (2) b, the name prescribed on the standards and specifications may not be included in the product name if the name prescribed on the standards and specifications, etc. is clearly labeled around the product name (just above, below or beside) with the type size of at least half of the biggest type size of product name.

Article 9 (Application of *Mutatis Mutandis*) The Labeling Standards of Food, etc. under the provision of Article 10 of the Food Sanitation Act shall apply *mutatis muntandis* for any food additive, apparatus or container and package, and organic processed food and organic agricultural product or use of analogous terminology, etc. that the labeling standards are not prescribed by the provisions of this Notification.

ADDENDA (Jan. 31, 2004)

Article 1 (Enforcement date) This Notification shall enter into force on the date of its

announcement.

Article 2 (Transitional measures) The labeling of the health functional food manufactured or imported by a person who has business report under Food Sanitation Act at the time this Notification enters into force may be complied with the Labeling Standards of Food, etc. under the provision of Article 10 of the Food Sanitation Act until August 26, 2004.

Article 3 (Amendment of other notifications) (1) Among the Labeling Standards of Food, etc. under Food Sanitation Act and subordinate statues, the labeling standards of each of the products relevant to the standards and specifications of health functional food under the Articles 14 and 15 of this Act such as health supplement food, nutrition supplement food in special nutrition food, ginseng and red ginseng product (excluding ginseng and red ginseng drinks, and other ginseng and red ginseng products) shall be deleted.

(2) The Labeling Standards of Genetically Modified Food, etc. shall be amended as follows:"under Article 7 of the Food Sanitation Act and Article 14 of the Health Functional Food Act" shall replace "under Article 7 of this Act" in each subparagraph of Article 3", "nutrition supplement product in health functional food" shall replace "nutrition supplement food in special nutrition food" in Article 3(17)," and "business person for import and sales business of food, etc. and business person for health functional food manufacturing business or health functional food import business under the provision of Article 2 of the Enforcement Decree of the Health Functional Food Act" shall replace "business person for import and sales business of food, etc." in Article 4.

ADDENDA (Nov. 11, 2005)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures) The health functional food manufactured or imported by a person who has business permission or business report at the time this Notification enters into force may be labeled by the previous regulation until May 31, 2007,

ADDENDA (Mar. 22, 2007)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

[Annexed the Table 1]

Daily Reference Value

Nutrients	Default value	Nutrients	Default value	Nutrients	Default value
Carbohydrate(g)	328	Iron(㎎)	15	Pantothenic acid(㎎)	5
Dietary fiber(g)	25	Vitamin D(㎍)	5	Phosphorus(㎎)	700
Protein(g)	60	Vitamin E(㎎α-TE)	10	Iodine(㎍)	75
Fat(g)	50	Vitamin K(㎍)	55	Magnesium(㎎)	220
Saturated fat(g)	15	Vitamin B_1(㎎)	1.0	Zinc(㎎)	12
Cholesterol(㎎)	300	Vitamin B_2(㎎)	1.2	Selenium(㎍)	50
Sodium(㎎)	3,500	Niacin(㎎ NE)	13	Copper(㎎)	1.5
Potassium(㎎)	3,500	Vitamin B_6(㎎)	1.5	Manganese(㎎)	2.0
Vitamin A(㎍ RE)	700	Folic acid(㎍)	250	Chromium(㎍)	50
Vitamin C(㎎)	55	Vvitamin B_{12}(㎍)	1.0	Molybdenum(㎍)	25
Calcium(㎎)	700	Biotin(㎍)	30		

- Vit A, Vit D and Vit E can be additionally indicated with IU unit in parenthesis while following the above reference table.

[Annexed the Table 2]

Outline and Methods of Nutrition and Functional Information Display

1. Nutrition, function information display content (illustration)

< illustration 1 >

① Nutrition and function information

② serving size

③per serving size	content	④% daily reference value
⑤calories	150kcal	
⑥carbohydrate	23g	7%
⑦protein	2g	3%
⑧fat	6g	11%
⑨sodium	55㎎	2%
⑩vitamin C	11㎎	20%
⑪calcium	20㎎	7%
⑫functional component or marker compound	○㎎	

⑬※% daily reference value: ratio of nutrient reference value

< illustration 2 >

① Nutrition and function information

② serving size

③per serving size	content	④% daily reference value
⑤calories	150kcal	
⑥carbohydrate	23g	7%
dietary fiber	3g	12%
sugars	10g	
⑦protein	2g	3%
⑧fat	6g	11%
saturated fatty acid	2g	
unsaturated fatty acid	3g	
cholesterol	10㎎	3%
⑨sodium	55㎎	2%
⑩vitamin C	11㎎	20%
⑪calcium	20㎎	7%
⑫functional component or marker compound	○㎎	

※% daily reference value: ratio of nutrient reference value

< illustration 3 >

① Nutrition and function information

② serving size

③per serving size	content	④% daily reference value	③per serving size	content	④% daily reference value
⑤calorie	150kcal		⑦protein	2g	3%
⑥carbohydrate	23g	7%	⑧fat	6g	11%
dietary fiber	3g	12%	⑨sodium	55㎎	2%
⑩vitamin C	11㎎	20%	⑪calcium	20㎎	7%
⑫functional component or marker compound	○㎎				

※% daily reference value: ratio of nutrient reference value

< illustration 4 >

Nutrition and function information

Total 12 servings Serving size (35g)

content per serving: calories kcal, carbohydrate ○g(○%), protein ○g(○%), fat ○g(○%), sodium ○㎎(○%), vitamin C ○㎎(○%), calcium ○㎎(○%), functional component or marker compound ○㎎

※Numbers in parenthesis are the ratio of nutrient reference value.

2. Labeling method

a. Common requirements

① When it is labeled on product, only labeling items shall be labeled except for labeled number by item.

② It shall be labeled with Gothic or HumanGothic type of letter.

③ For calories, carbohydrate, protein, fat and sodium, it shall be labeled with thick Gothic or HumanGothic type of 7 points or bigger.

④ It shall be labeled with the methods given at illustrations 1) through 3) according to product packaging form. Provided, That if labeling as illustrations 1) through 3) is impossible due to the small area of labeling, then it may be labeled as illustration 4).

b. Labeling methods by each label items shall be as follows:

① Nutrition and function information: Labeling with thick Gothic or HumanGothic type of 8 points or bigger as possible;

※ In case of health claim, the functionality shall be labeled in dotted line.

② Serving size: Labeling with the weight or count, etc. per serving size of the product;

※ Since the upper portion of labeling requirements is designated for mandatory nutrients label, it shall be labeled with thick line (about 1.0~1.5㎜) to distinguish lower portion of same panel from the upper portion.

③ Content per serving size: Labeling with 6 points or bigger;

④ % daily reference value: Labeling with 6 points or bigger;

⑤~⑨: The content and percentage of daily reference value by each kind of nutrients shall be labeled with 6 points or bigger. In this case, ⑥ for carbohydrate, it may be categorized into and labeled as dietary fiber and sugars, ⑧ for fat, it may be categorized into and labeled as saturated fatty acid, unsaturated fatty acid, cholesterol, etc.

※ Below the upper portion of labeling requirement (⑤~⑨), voluntary nutrients label and nutrients of nutrition supplement product shall be labeled, and it shall be labeled with medium thick line (about 0.5~0.8㎜) to distinguish those from mandatory label requirements.

⑩ Vitamins: If the vitamins contained or added in product are to be emphasized, the names, its content per serving size and daily reference value of each vitamin shall be labeled.

⑪ Minerals: If the minerals (calcium, iron, etc.) contained or added in product are to be emphasized, the names, its content per serving size and daily reference value of each mineral shall be labeled.

※ The content of functional component or marker compound of functional ingredient shall be labeled at the lower portion of labeling requirements and it shall be labeled with medium thick line (about 0.5~0.8㎜) to distinguish those from voluntary label requirements.

⑫ Functional components other than nutrients: The label of functional component shall be declared the representative functional component or marker compound of functional ingredient and its content of such product. In this case, content of functional ingredient or marker compound shall be labeled with content per serving size and If it is difficult to identify the functional component or marker compound, the functional ingredient and its content may be

declared.

⑬ The notice that “% daily reference value” is the ratio of daily reference value shall labeled.

[Annexed the Table 3]

1. The standard design of ginseng

2. The standard sentence for origin of ginseng

1) Korean

高麗人蔘의 由來

人蔘은 數千年前부터 中國의 民間醫에 依하여 널리 補身用으로 使用되었다고 합니다. 文獻上의 記錄으로는 中國의 前漢元帝時代(西曆紀元前33～48)의 史遊의 著「急就章」에 人蔘의 이름이 처음 記載되었고 後漢 獻帝建安年度(西紀196～220)의 張仲景의 著「傷寒論」에는 總處方 113方中 人蔘配劑 21方이 收錄되었으며 그後의「名醫別錄」,「神農本草經」等 많은 漢方醫書의 記錄에 依하면 人蔘이 貴重한 補身材料로서 使用되어 東洋 諸民族의 保健에 寄與한 바 컸으며 家庭常備品으로 까지 登場하였음을 알 수 있습니다.

高麗人蔘은 元來 韓國 및 韓國과 隣接한 中國地方의 深山에 自生하였던 것이나 많이 採取되어 消盡됨에 따라 人工的으로 栽培하게 되었고 韓國에서는 朝鮮 宣祖(西紀1567～1608)때부터 그 記錄이 있는 것으로 보아 實際 人蔘의 人工栽培는 더 오랜 歷史를 가진 것으로 보입니다.

2) English

ORIGIN OF KOREAN GINSENG

The medicinal use of Ginseng was already well known to chinese civil herb doctor several thousands years ago. The name of Ginseng can be found in various chinese historical records many of which were written as early as B.C 100.

According to many chinese medicinal books ever published, Ginseng has been generally used as a medicine for human health in most of the oriental countries.

Korean Ginseng originally grew in deep mountains both of Korea and China. However, this wild Korean Ginseng was so scarcely found to obtain that its supply could not meet ever increasing demand, and therefore from 16th century, it has been cultivated on the farm as a mass supply in Korea.

3) Japanese

高麗人蔘の 由來

人蔘は 數千年前より 中國の 民間醫に 依り, 廣く 補身用として 使用されました。文獻上の 記錄には 中國の 前漢元帝時代(西曆紀元前 33～48年)の 史遊の著 「急就章」に 人蔘名が 始めて 記載され 後漢獻帝建安年代(西紀 196～220年)の 張仲景の著「傷寒論」には 總處方 113方中 人蔘配劑 21方が收錄されており其後の「名醫別錄」「神農本草經」等 多くの 韓方醫書の 記錄に依れば人蔘が 貴重な 補身材料として 使用され 東洋諸民族の 保健に 寄與した ること 大なるにして 家庭常備品にまで 登場されたことは

周知の通りですが、又 高麗人蔘は 元來韓國竝び 韓國と 隣接した 中國地方の 深山に 自生されたものが多く採取され 消盡されるに 從い 人工的に栽培するようになり 韓國では 朝鮮宣祖(1567～1608)時代より其の記錄に 書かれているのに 依れば 實際人蔘の 人工栽培は 最も長い歷史を 持っていることと看做されます。

4) Chinese

高麗人蔘的 由來

距今 數千年前, 人蔘在中國醫學史上, 己被採用爲補身 强壯之靈葯 中國 「前漢」元帝時代(公元前 33～48年) 吏遊著之「急就章」中, 初見 蔘名, 此爲文獻上首 次記載「後漢」 獻帝建安時代(公元196～220年) 張仲景著之「傷寒論」中, 總處方內, 列有 113種, 其中配劑人蔘者 計有 21種, 此後 「名醫別錄」「神農本草經」等 許多醫書, 無不記載人蔘的功效, 且對黃色人種保健, 具有莫大貢獻等 語 高麗人蔘, 原爲韓國及隣近之中國東北深山之天然植物, 然因採蔘者過多, 不願滅種之虛, 故始有人工栽培之輿論, 吾國朝鮮宣祖時代(公著 1567～1608年) 始發 現人工栽培地文獻 然而其人蔘栽培之史蹟, 赤不可推測地

[Annexed the Table 4]

GMP certification diagram

1. Ratio and color code of the diagram

가. Ratio : width : length = 1 * 0.83

나. Color code : Phantom color 355C

[Annexed the Table 5]

Allowable Tolerance (Range) between Labeled and Measured Content

Items	Labeled content	Allowable tolerance
Ginseng and red ginseng products	3g or less	5%
	more than 3g and 100g or less	3%
	more than 100g and 1,000g or less	2%
	more than 1,000g	1%
Health functional food other than ginseng and red ginseng products	50g[㎖]or less	4%
	more than 50g[㎖] and 100g[㎖] or less	3%
	more than 100g[㎖] and 1,000g[㎖] or less	2%
	more than 1,000g[㎖]	1%

Appendix

Recommended Daily Allowances for Korean by Ages

Age	weight (kg)	height cm	energy kcal	protein g	vitamin A μgRE	vitamin D μg	vitamin E mgα-TE	vitamin C mg	vitamin B_1 mg	vitamin B_2 mg	niacin mgNE
infant											
0~4(mo) *	5.6	58	500	15(20)	350	5(10)	3	35(50)	0.2(0.3)	0.3(0.4)	2(3)
5~11	9.3	73	750	20	350	10	4	35	0.4	0.5	5
toddler											
1~3(yr)	14	92	1200	25	350	10	5	40	0.6	0.7	8
4~6	19	111	1600	30	400	10	6	50	0.8	1.0	11
7~9	27	127	1800	40	500	10	7	60	0.9	1.1	12
boy											
10~12(yr)	38	144	2200	55	600	10	8	70	1.1	1.3	15
13~15	54	162	2500	70	700	10	10	70	1.3	1.5	17
16~19	64	172	2700	75	700	10	10	70	1.4	1.6	18
20~29	67	174	2500	70	700	5	10	70	1.3	1.5	17
30~49	68	170	2500	70	700	5	10	70	1.3	1.5	17
50~64	68	168	2300	70	700	10	10	70	1.2	1.4	15
65~74	64	167	2000	65	700	10	10	70	1.0	1.2	13
more 75	60	166	1800	60	700	10	10	70	1.0	1.2	13
girl											
10~12(yr)	38	144	2000	55	600	10	8	70	1.0	1.2	13
13~15	51	158	2100	65	700	10	10	70	1.1	1.3	14
16~19	54	160	2100	60	700	10	10	70	1.1	1.3	14
20~29	54	161	2000	55	700	5	10	70	1.0	1.2	13
30~49	55	158	2000	55	700	5	10	70	1.0	1.2	13
50~64	57	157	1900	55	700	10	10	70	1.0	1.2	13
65~74	54	154	1700	55	700	10	10	70	1.0	1.2	13
more 75	52	152	1600	55	700	10	10	70	1.0	1.2	13
pregnant											
first half			+150	+15	+0	+5	+0	+15	+0.3	+0.3	+1.0
second half			+350	+15	+100	+5	+2	+15	+0.4	+0.4	+2.0
lactation			+400	+20	+350	+5	+3	+35	+0.4	+0.5	+4.0

Age		weight (kg)	height cm	energy kcal	protein g	vitamin B_6 mg	folic acid μg	calcium mg	phosphate mg	iron** mg	zinc mg
infant	0~4(mo)*	5.6	58	500	15(20)	0.1(0.2)	60(100)	200(300)	100(200)	2(6)	2(4)
	5~11	9.3	73	750	20	0.4	70	300	300	8	4
toddler	1~3(yr)	14	92	1200	25	0.5	80	500	500	8	6
	4~6	19	111	1600	30	0.6	100	600	600	9	8
	7~9	27	127	1800	40	0.8	150	700	700	10	9
boy	10~12(yr)	38	144	2200	55	1.1	200	800	800	12	12
	13~15	54	162	2500	70	1.4	250	900	900	16	12
	16~19	64	172	2700	75	1.5	250	900	900	16	12
	20~29	67	174	2500	70	1.4	250	700	700	12	12
	30~49	68	170	2500	70	1.4	250	700	700	12	12
	50~64	68	168	2300	70	1.4	250	700	700	12	12
	65~74	64	167	2000	65	1.4	250	700	700	12	12
	more 75	60	166	1800	60	1.4	250	700	700	12	12
girl	10~12(yr)	38	144	2000	55	1.1	200	800	800	16	10
	13~15	51	158	2100	65	1.4	250	800	800	16	10
	16~19	54	160	2100	60	1.4	250	800	800	16	10
	20~29	54	161	2000	55	1.4	250	700	700	16	10
	30~49	55	158	2000	55	1.4	250	700	700	16	10
	50~64	57	157	1900	55	1.4	250	700	700	12	10
	65~74	54	154	1700	55	1.4	250	700	700	12	10
	more 75	52	152	1600	55	1.4	250	700	700	12	10
pregnant											
first half				+150	+15	+0.5	+250	+300	+300	+4**	+3
second half				+350	+15	+0.5	+250	+300	+300	+8**	+3
lactation				+400	+20	+0.6	+100	+400	+400	+2	+6

* recommended daily intake for nourishing infant with breast-feeding (recommended daily intake for nourishing infant with bottle feeding)

** recommend amount for iron supplement

[The Korean Nutrition Society : recommended nutrition intake for Korean (7th revision, 2000)]

Good Manufacturing Practices

Enacted by Food and Drug Adminstration Notification No. 2004-7, Jan. 31, 2004

Article 1 (Purpose) The purpose of this Notification is to manufacture and supply the health functional food by providing necessary matters related to operations such as good manufacturing practices, designation and management, education and training, etc. under Article 22 of the 「Health Functional Food Act」 , and Articles 26(4) and 27(4) of the Enforcement Rule of the same Act.

Article 2 (Definitions) For the purpose of this Notification, the definitions of terms shall be as follows:

1. The term "manufacturing" means any operation to produce health functional food including packaging and labeling.
2. The term "batch" or "lot" means certain amount the date on which no further manufacturing or processing other than packaging becomes necessary to obtain uniformity under the same manufacturing process of health functional food (for those products that, after packaging, undergo additional manufacturing process such as sterilization or pasteurization, etc., it refers to the point when the final process is completed). Provided, That if it is difficult determine whether batch or lot unit as a result of continuous processes, the manufactured product of the same date may be considered the same batch or the same lot unit.
3. The term "batch No."or "lot No." means the comprehensive management by number, letter, etc. in order to identify all matters relating to manufacturing date, management, shipping, etc. for amount of a certain batch (or lot unit).
4. The term "packaging material" means any container, labeling material and packaging material used for packaging and labeling.
5. The term "in-process product" means any product manufactured in middle of processes, that requires further necessary processes to become a finished product.
6. The term "finished product" means any functional health food finished all the manufacturing processes so it can be sold to consumer as the product.
7. The term "examination" means any technical operation such as sensory, physiochemical and microbial examination or measurement for raw material, in-process product, finished product, etc. according to the method of the standards and specifications of health functional food, under Articles 14 and 15 of the 「Health Functional Food Act」 (hereinafter referred to as the "Act").
8. The term "clean zone" means any area which manufacturing process is operated under non-contaminated condition by air filtration, control of temperature and humidity, etc. to prevent contamination of pathogenic bacteria, hazardous chemical substance, etc., and deterioration and spoilage during health functional food manufacturing.

Article 3 (Application scope) The application subjects of this Notification shall be as follows:

1. Any health functional food manufacture business establishment that has obtained the business

permission under Article 5(1) of the Act, and applies or intends to apply (hereinafter referred to as "GMP application assessment business establishment") for the designation of the standard of manufacturing and quality control of food health functional food (hereinafter referred to as "Good Manufacturing Practices" or "GMP") prescribed in Article 22(2) of the Act.

2. Any health functional food manufacture business establishment designated as GMP application business establishment under Article 22(2) of the Act (hereinafter referred to as "GMP application designated business establishment").

Article 4 (Workplace) The workplace (It means place where manufacturing process is carried out; hereinafter the same shall apply) shall be complied with the standards described in the following subparagraphs, together with the facilities criteria under Article 4 of the Act:

1. Clean zone and general zone (It means non-clean zone; hereinafter the same shall apply) shall be separated to prevent cross contamination by wall, etc. and shall be compartmentalized by workroom;
2. Clean zone shall be installed with HVAC system to maintain adequate temperature, humidity and air purity according to type and manufacturing method of the product. The entrances and windows shall be shut tightly so that outside air does not come in directly;
3. The floor shall be treated for waterproof with such material as concrete, etc. and made so it is not caved in or water does not well up;
4. The drain channel shall be installed so that drain and cleaning are easy, and the wastewater shall not flow backward or the filth shall not accumulate;
5. Inner wall and ceiling shall be smooth surface and waterproof to clean easily;
6. Lighting and illumination shall have proper brightness, and protector shall be installed to prevent pollution from lighting and illumination facilities, etc.;
7. Ventilation facilities shall be installed with sufficient for ventilating odor, toxic gas, sooty smoke, steam, etc.;
8. Workplace shall be equipped with moth- and rat- proof facilities;
9. The restroom, locker room and hand-washing facility shall be equipped enough so that workers can use hygienically and they shall be separated from the workplace;
10. The restroom shall be installed with water closet, the wall and floor shall be made of waterproof material, and ventilation facility shall be installed to vent the restroom outside;
11. The restroom entrance and necessary workroom shall be installed with disinfection facilities;
12. The facilities shall be installed to remove dust from the workplace where powder is floats and scattered all about;
13. The plumbing in workroom shall be installed so that cleaning is easy, and there is no aperture in case it passes through wall;
14. The pathway in the workplace shall be designed to use by workers only;
15. The waste and the wastewater treatment facilities shall be installed far from the workplace together with facilities to prevent risk caused from food or drinking water pollution;
16. In case of using underground water, etc. which is not tap water, it shall be installed with facilities that can supply water complied with the drinking water quality standards under

Article 5 of the Management of Drinking Water Act; and

17. In case of using underground water, the water resource shall be located in far from the place where there is possible contamination such as the restroom, waste disposal facilities, animal farm, etc. and water storage tank shall be installed not to be contaminated from outside and installed lock system to prevent from incoming of contaminant.

Article 5 (Special workplace) Special workplace (It means the workplace that is manufacturing health functional food by using or culturing, etc. microorganism; hereinafter the same shall apply) shall be complied with the standards described in the following subparagraphs, together with the workplace facilities criteria under Article 4 of the Act:

1. It shall be separated from other workplace of health function food;
2. Entrance and window are able to be tightly closed;
3. Clean zone shall be established with HVAC system having removing bacteria facility;
4. It may be prevented pollution from other manufacturing room using irradiation system such as sterilization, etc., and additional exhausting system, etc.; and
5. Additional exclusive locker room and working clothes shall be prepared to prevent cross contamination from other room by living microorganisms.

Article 6 (Storage facility) Storage facility (it means the place to store ingredients, resources, finished product and examination sample; hereinafter the same shall apply) shall be complied with the followings:

1. Depository of ingredients, resources, finished product and examination samples shall be separately each other;
2. It may be stored hygienically without affecting quality; and
3. Storage facility for ingredients and products shall be separated and stored under the related Acts and subordinate statutes.

Article 7 (Manufacturing facilities) manufacture facilitates (it is called the facilities for which is necessaries for manufacturing. same shall apply) shall be complied with the standards described in the following subparagraphs, together with the facilities criteria under Article 4 of the Act:

1. Manufacture facility shall be appropriately arranged according to manufacturing process flow of relevant item;
2. Manufacture facilities and equipment shall be easy to clean and arrange so that it is not polluted from other manufacturing processes;
3. The part of manufacturing facility and equipment which comes in direct contact with the health functional food shall not be deteriorate the product nor be hazardous to the human body; and
4. The in-processing product during manufacturing processes may be stored without affecting quality.

Article 8 (Quality control equipment) Quality control equipment shall be complied with the standards described in the following subparagraphs, together with the facilities criteria under

Article 4 of the Act:

1. Microorganism examination laboratory shall be established with general test room etc. and clean room or aseptic equipment that is equipped with aseptic condition; and
2. In case clean room, buffering room shall be established.

Article 9 (Species of standards book) Any health functional food manufacture business person shall make and maintain master formula, administration standards book of manufacturing, administration standards book of manufacturing hygiene, administration standards book of quality control to perform properly about manufacturing management and quality control.

Article 10 (Master formula) Master formula shall be prepared for each item and shall include the followings:

1. The product name, type and appearance of the product;
2. The date of item report;
3. Person and date of preparation;
4. Functionality, consumption method, consumption amount and warning notice of consumption;
5. Ingredients or components and their contents (or combination ratio of ingredients or components);
6. Manufacturing process, manufacturing method and examination of in-processing;
7. Batch and theoretical production quantity of each process;
8. Critical control point and control measures in order to improve quality and remove hazards.;
9. Standards and specifications, and examination methods of ingredients, in-processing product and finished product(packaging unit);
10. Standards and specifications, and examination methods of materials(apparatus · container · packaging), if necessary;
11. Facilities and equipment required for manufacturing and quality control;
12. Storage conditions and shelf life; and
13. Labeling requirements and other necessary matters.

Article 11 (Administration standards book of manufacturing) The administration standards book of manufacturing shall include the followings:

1. Items related to management of manufacturing processes;
   a. Preparation of manufacturing record including the followings;
      (1) The name, type and appearance of the product;
      (2) The batch number, lot unit and date of manufacturing;
      (3) Ingredients or components and their contents (or combination ratio of ingredients or components);
      (4) Batch number and examination number for ingredients used;
      (5) Comparison of amount between real and theoretical production by each process.;
      (6) Precautions and special observation (monitoring) matters in process;
      (7) Measures for noncompliant results of checking and testing in process;

(8) Name of worker and manufacturing date; and

(9) Other necessary matters.

b. The floor plan of workplace (The floor plan indicating separation or compartment by working property, the arrangements of machinery and facilities, manufacture process flowchart, location of washing and sanitary tank, moving route of worker, entrance door and window, etc.).

c. The HVAC system flowchart (flowchart of air flow such as filtration, temperature and humidity, inlet and exhaust by workplace. etc.).

d. The flowchart of water supply (drawing, filtration, deposit and supply, etc. of water) and drain.

e. The methods of checking (monitoring), testing, and verification in production process for improvement of quality and effective control of hazards.

f. Establishment of specifications for appropriate measuring devices that can measure weight or volume.

g. Confirmation methods for the decision that ingredients intended to use are compliant.

h. Education and training for the employees (especially, emphasis for education and training for new employee)

i. Other necessary matters.

2. Matters related to facility and utensil management

a. Regular check and confirmation methods of cleaning

b. Indication methods about Equipment and facilities at working

c. The action when the accident breakout as breakdown

d. other necessary matters

3. Ingredients and item about materials control

a. Methods about name, amount and standard and specifications when the ingredients and resources purchase.

b. Conformation about the breakdown the vessels and the processing method for mending

c. Place of storage and storage method

d. Processing method about incongruous product according to test result

e. Amount confirmation method of material and resources which was returned after using.

f. Action when the modification about changing the label

g. Countermeasure to prevent confusion

h. others, if needed.

4. Item about finish product management

a. Control method that the inlet and ship approval when the control method

b. Storage place and storage method.

c. others, if needed.

5. In case of production of entrusting. Item about production control

a. Storage method and transportation of in-process products

b. Method of evaluating the test records who contract user

Article 12 (Production Hygiene Control Standards) Production Hygiene Control Standards shall be included the following particular.

1. Areas and intervals of cleaning.
2. Methods of cleaning agents and tools used for cleaning.
3. Methods of evaluating cleanliness.
4. Specifications for working garments and instructions for their use.
5. Methods of checking the health conditions of employees.
6. Methods of washing employees hands and disinfecting when necessary.
7. Precautions on the hygiene in the operation.
8. Checking method and checking number about the sanitizing facilities and sanitizing agent.
9. Method of mothproof, ratproof and checking method of insect invasion.
10. Adequate control method of air-conditioning system about the temperature · humidity and air flow of workplace etc..
11. Control method of using manufacture water.
12. Item about the restroom facilities and using. 13. others, if needed.

Article 13 (Quality Control Standards) Quality control standard shall include the following particular:

1. Keeping the test record writing next following
   a. The product name and lot number and manufacturing date
   b. Test number.
   c. Dates of receipt, test and evaluation.
   d. Items, specifications and results of tests.
   e. The evaluation of test results and date.
   f. Signatures of analyst and the person responsible for approval.
2. The quantity, the place and the method of sampling and treatment.
3. Method of informing the test results to related departments.
4. Method of checking and maintaining to equipment and instruments for the tests.
5. Maintaining of the reference samples.
6. Methods of maintaining and handling of the standard for test and the reagent, etc..
7. In case of the product of entrust, the method of evaluating the test records which contract uses.
8. Other necessary matters

Article 14 (Structure of operating organization) (1) GMP application business establishment business person should appoint general quality manager of GMP, establish the departments of production and of quality control independently each other under Article 12, Provided, That in case where a person pay due regard to manufacture type and method, general supervisor of GMP is able to take position concurrently as the responsible manager of production and quality control department.

(2) For the purpose comply with GMP, The business person should post adequate employees each

workplace, necessary organization, Employee and employee role each, In case changing work, determining the acquire and transfer method.

Article 15 (Mission of general quality manager of GMP) (1) General quality manager of GMP should educate and train periodically for effectively play a role his work about which good functional health food manufacturing control, facilities control, quality control and if needed
(2) manager of GMP shall store and maintain of its record which is perform guidance information about prohibition of false or exaggerated labeling and advertising and hygienic storage of product to business person and employee.

Article 16 (Mission of the manager of production department) The manager of production department, who is responsible for the manufacturing process control, the production hygiene control and the storage control, should carry out the following particulars:

1. To maintain the master formula, production control standards and production hygiene control standards in order to carry out the production control appropriately.
2. To maintain the production instructions including the following particulars, and to ensure whether the processes are carried out as specified.
   a. The product name, type of product and appearance
   b. Lot number and production date.
   c. Components and amounts(mixing ration of ingredient and component.)
   d. Theoretical yield per step of the processes.
   e. Precautions during the operation.
   f. Others, if needed.
3. To ensure whether the production hygiene and the storage control are carried out according to the specifications.
4. Specify the personnel for the storage control of ingredients, packaging materials and finished products.

Article 17 (Mission of the manager of quality control department) The manager of quality control department, who is responsible for the quality control of ingredients, intermediate products and finished products, should carry out the following particulars:

1. To maintain the master formula and the quality control standards so as to carry out the quality control appropriately.
2. To maintain the test instruction including the following particulars, and to ensure whether the tests are carried out as specified.
   a. Test items
   b. The time and the place of sampling.
   c. The amount and the method of sampling.
   d. The names of the sampler and the analyst.
3. To evaluating the test results and to inform them to the related department through written documents.

Article 18 (In-Process Control) Any Good Manufacturing Practices GMP application business establishment should observe the In-Process Control as follows:

1. The admittance to the production area should be restricted the related personnel only.
2. Before operating, the cleanliness of the equipment and the instruments to be used should be checked.
3. On the equipment and instruments in operation, the name and the lot number of the product should be marked.
4. To assure the homogeneity of finished products, proper checks should be made in the necessary process.
5. Any labels remaining after labeling and packaging should be counted, and then either returned or destroyed.
6. The production records, in accordance with the Production Control Standards, should be written per lot.
7. When other operations are carried out in the same or adjacent area, it is necessary to control them so as to prevent the confusion between different packaging materials and different health functional food.
8. The aseptic operation is required, special precautions should be taken to prevent microbial contamination, and the microbe number in the air of the area should be monitored periodically.
9. Half-product products should be kept separately and processed as soon as possible to avoid the deterioration of quality.

Article 19 (Production Hygiene Control) The Production Hygiene Control should be done as following:

1. The facilities and equipment in the production area should be kept clean all times.
2. The facilities and equipment needed for sanitation management should be kept sanitation conditions.
3. Personnel working on workplace should wear garment needed for the relevant task while maintaining personal cleanliness.
4. No Personnel should be directly participate manufacture production because of affecting harmful effect to functional health food etc.
5. Disposal, sewage treatment facilities should be located far from workplace and its managing record should be kept and written
6. Sewage disposal do not allowed carrying out consecutively every day and sewage disposal container shall sanitate and wash often.
7. Relief of mouse and insect should be permitted in limited area after adopt do reserve to keep away contamination for health function food in workplace.
8. Poisonous and flammability material such as insecticide shall manage and store safely separated area with precaution indication.
9. Employee shall be trained and educated about hygiene of manufacturing.

Article 20 (Storage Control) The Storage Control should be done as following:

1. Ingredients and packaging materials should be stored separately classified by the item, which is marked to show whether or not it has been tested.
2. Ingredients and packaging materials requiring test should be transferred to the production areas only when approved by quality control.
3. Rejected ingredients and packaging materials should be isolated from the other materials and handled as soon as possible.
4. Ingredients, packaging materials and finished products should be stored under the conditions which do not lead to any bad effects on their qualities.
5. Returned products should be isolated from other products and handled as soon as possible.

Article 21 (Quality Control) The Quality Control should be done as following:

1. The tests should be carried out on ingredients, intermediate products, finished product, returned products, packaging materials and other materials requiring test, and the test records according to Quality Control Standards should be written.
2. Sampling for test should be carried out so as to prevent contamination or deterioration.
3. The storage conditions of health functional food should be evaluated.
4. On the health function food of questionable morphology change, deteriorate and decay etc. the stability tests should be performed and the sell-by-date should be established.
5. Sufficient quantities of finished products per lot for tests should be kept for the shelf life.
6. Labels should be checked with the specifications at each time a change is made, and their sample should be kept for reference.
7. The packaging materials which contact directly with functional health foods should be checked for assuring if they may cause the deterioration to the drugs if they may be hazardous to human beings.

Article 22 (GMP application business designation and control) (1) In case where the business person who want to designate GMP application business establishment submit the result paper which contains composition of GMP operation organization and representative and pre-operation for three month then self-assessment with GMP application check table under annex the table 1.

(2) When the Commissioner of the Food and Drug Administration according to Act Article 22 and Act enforcement 26(1) may request the GMP application business establishment, He order to a relevant public official investigation record and assessment according to GMP application assessment table under table annex the table 1 by inspecting the actual manufacturing situation of the factory, in case appropriate, designate GMP application business.

(3) The Commissioner of the Food and Drug Administration may deliver GMP indication board according to paragraph 2 designated GMP application business establishment under Annex the table 2.

(4) The Commissioner of the Food and Drug Administration order to a relevant public official investigation and assessment according to GMP application assessment table under annex the Table 1 over one time per year.

Article 23 (GMP Instructor) (1) The Commissioner of the Food and Drug Administration appoint the GMP Instructor in KFDA and regional KFDA to designate and manage of GMP application business establishment under article, appoint Inspection servant for assist Inspection Authorities.

(2) The Commissioner of the Food and Drug Administration shall appoint public officials, Inspection officer for assist Inspection Authorities who have trained education and training among the qualification of functional health food hygiene inspector as following particular:

1. GMP Instructor who engage in functional health food department fourth-ranking or seventh-ranking belong to KFDA and regional KFDA; and
2. GMP officer who engage in functional health food department eight-ranking and ninth-ranking belong to KFDA and regional KFDA.

Article 24 (Self application audit and assessment) (1) Business person who GMP application business establishment shall keep the checking and recording about wether or not the GMP operation according to quality control standard each part of employee.

(2) Business person who GMP application business establishment shall self inspect according to GMP application assessment over one time per year.

(3) If there is any needs for improvement or correction by GMP operation check or self, external professional office inspection. shall be peformed adequate action.

Article 25 (Corrective action for consumer complaint etc.) Whenever complaints on the quality of health functional food are received about quality and safety of health functional food, the business person corresponding to range of GMP application under Article 3, should be made and it is necessary to find the cause of the complaint to take the appropriate actions as soon as possible, and its records should be made.

Article 26 (Record keeping) GMP application business establishment keep all management record which is written and written date according to standard exclude subordinated statues over two years.

Article 27 (Education and training etc) (1) Korea Health Industry Development Institute(KHIDI) designate as professional education institute according to Act Enforcement 27(3).

(2) According to GMP professional education institute work out a plan about education and training schedule every year. will summit Commissioner of the Food and Drug Administration 20 days before beginning of year, and establish the education by its approval. In case where the plan is change, as same shall apply.

(3) GMP professional education institute issue the certification each curriculum of education and training and record for education like as enrollment report certification will keep 2 years or more.

(4) Report of education results notify within on month to Food and Drug Administration and shall report 31 January next year to Commissioner of the Food and Drug Administration.

Article 28 (Self education and training) GMP application business establishment shall set up self education program and effectively execute regular education and training program about manufacturing control, quality control and training others, if needed.

ADDENDA

This notification shall enter into on the date of its announcement.

[Annexed the Table 1]

GMP APPLICATION INSPECTION TABLE

☐ Name of business establishment :

☐ Representative : (☎)

☐ Place of business establishment : (☎)

This table is inspection report for Good Manufacturing Practices on above health functional food manufacturing business establishment by Good Manufacturing Practice standard under Article 22(1) of the 「Health Functional Food Act」.

date:(YY/MM/DD)

Confirmer (Signature)

Inspector (Signature)

Good Manufacturing Practices (GMP) application inspection table

1. Circumstance of manufacture establishment

Business establishment	Name of manufacture establishment			
	Presentative			
	Quality manager		General quality manager	
	Manager of production department		Manager of quality control department	
Area	Workplace		Special workplace	
	Laboratory		Storage facility	
	Etc.		Total	
Number of employee	Production department		Quality department	
	Etc.		Total	

2. Item report and production

Name of product	Date of report (YY/MM/DD)	Result of last year production (Amount of production)	Etc.

3. Report on production of entrusting authority and circumstance of production

Name of product	Date of report (YY/MM/DD)	Result of last year production (Amount of production)	Etc.

※ That in case where is not any production record last year, it will report 3 months production before inspection.

4. Inspection of facilities

4-1. Workplace

Classifi-cation / Rank	Content of inspection	(○/x)	Etc.
1	Is the workplace separated into clean zone and general zone and compartmentalized by workroom?		
2	Is HVAC system for adequate temperature, humidity and ventilation of clean zone workplace installed, and are entrances and windows shut tightly so that outside air doesn't flow indoors?		
3	Is floor treated for waterproof with such materials as concrete, etc. and made so it is not caved in or water doesn't well up?		
4	Is the drain channel installed so that the wastewater does not flow backward or the filth does not accumulate?		
5	Are inner wall and ceiling smooth surface and waterproof to clean easily?		
6	Are lighting and illumination appropriate and is protector installed to prevent pollution from lighting and illumination facilities?		
7	Are ventilating facilities sufficient for ventilating odor, toxic gas, smoke, and steam?		
8	Are there equipped with moth- and rat- proof facilities?		
9	Are there equipped enough restroom, locker room, and hand-washing facility (including disinfection facilities) for workers and are they separated from the workplace?		
10	Are there dustproof facilities installed in the workplace where powder is floats and scattered all about?		
11	Is the plumbing in workroom installed so that cleaning is easy, and there is no aperture?		
12	Is pathway in the workplace designed to use by workers only?		
13	Are the waste and the wastewater treatment facilities installed far from the workplace?		
14	Are facilities can supply water complied with the drinking water quality standards installed in case of using underground water, etc. which is not tap water?		
15	In case of using underground water, is the water resource located in the place where there is no possible contamination, and is the water storage tank installed not to be contaminated from outside?		

4-2. Special workplace

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Is it segregated from other workshop of health functional food?		
2	Are entrance and windows able to be tightly closed?		
3	Is clean zone air established with HVAC system having removing bacteria facility?		
4	Are irradiation system such as sterilization, etc., and additional exhausting system installed?		
5	Are there prepared additional exclusive locker room and working clothes of other health functional food workplace?		

4-3. Storage facilities

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Are depositories of ingredients, resources, and products each separated? (When depository is installed so that there are no concern of mistakes, it doesn't have to be separated)		
2	Can it store hygienically without affecting quality?		
3	Is storage facility for ingredients and products are legally prescribed separated?		

4-4. Production and quality control facilities

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Are there prepared necessary facilities and equipments for the relevant manufacturing item?		
2	Is manufacture facility appropriately arranged according to the manufacturing process flow of relevant item?		
3	Are facilities and equipment easy to clean and arranged so that it is not polluted from other manufacturing processes?		
4	Are manufacture facility and equipment which comes in direct contact with the product composed of material deteriorate the product or is hazardous to the human body?		
5	Is there laboratory and testing equipment required for performing standard and specification examination on raw materials, sub materials and products?		
6	If microorganism experiment is required, is there aseptic rooms or aseptic facilities installed?		

5. Standard

Classifi-cation / Rank	Content of inspection	(○/x)	Etc.
1	Does the master formula prepare for each item and include the following particular? 1) The product name, type and appearance of the product (including the form of product) 2) The date of item report 3) Person and date of preparation 4) Functionality, consumption method, consumption amount and warning notice of consumption 5) Components and their contents (or combination ratio of ingredients or components) 6) Manufacturing process, manufacturing method and examination of in-processing 7) Batch and theoretical production quantity of each process 8) Critical control point and control measures in order to improve quality and remove hazards 9) Standards and specifications, and examination methods of ingredients, in-processing product and finished product (packaging unit) 10) Standards and specifications, and examination methods of materials (apparatus · container · packaging), if necessary. 11) Facilities and equipment required for manufacturing and quality control 12) Storage conditions and shelf life 13) Other necessary matters		
2	Does the administration standards book of manufacturing include the following particular? 1) Items related to management of manufacturing processes 2) Matters related to facility and utensil management and The action when the accident breakout as breakdown 3) Ingredients and item about materials control 4) Item about finish product management 5) In case of production of entrusting. Item about production control 6) Other necessary matters related to production control		

3	Does the production hygiene control standards include the following particular? 1) Areas and intervals of cleaning 2) Methods of cleaning agents and tools used for cleaning 3) Methods of evaluating cleanliness 4) Specifications for working garments and instructions for their use 5) Methods of checking the health conditions of employees 6) Methods of washing employees hands and disinfecting when necessary 7) Precautions on the hygiene in the operation 8) Checking method and checking number about the sanitizing facilities and sanitizing agent 9) Method of mothproof, ratproof and checking method of insect invasion 10) Adequate control method of air-conditioning system about the temperature · humidity and air flow of workplace etc. 11) Control method of using manufacture water 12) Item about the restroom facilities and using. 13. others, if needed 13) Other necessary matters		
4	Does the quality control standard include the following particular? 1) Keeping the test record writing next following 2) The quantity, the place and the method of sampling and treatment 3) Method of informing the test results to related departments 4) Method of checking and maintaining to equipment and instruments for the tests 5) Maintaining of the reference samples 6) Methods of maintaining and handling of the standard for test and the reagent, etc. 7) In case of the product of entrust, the method of evaluating the test records which contract uses 8) Other necessary matters		

6. Composition and Manager

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Does the general quality manager have sufficient knowledge about GMP?		
2	Does it have an independent production department and assigned a person in charge?		
3	Is the quality control department independent from the production department and is there a person in charge separately assigned?		
4	Does the manager of production department maintain the master formula, production control standards and production hygiene control standards?		
5	Does the manager of production department maintain the production instructions and ensure whether the processes are carried out as specified?		
6	Does the manager of production department ensure whether the production hygiene and the storage control are carried out according to the specifications?		
7	Does they specify the personnel for the storage control of ingredients, packaging materials and finished products?		
8	Does they assign appropriate personnel so there is no setbacks in the production department operation?		
9	Does manager of quality control department manage the quality control of ingredients, intermediate products and finished products?		
10	Does manager of quality control department maintain the master formula and the quality control standards?		
11	Does manager of quality control department maintain the test instruction and ensure whether the tests are carried out as specified?		
12	Does manager of quality control department evaluate the test results and inform them to the related department through written documents?		
13	Does they assign appropriate personnel so there is no setbacks in the quality control operation?		

7. Management

7-1. Process Control

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Are the admittance to the production area restricted the related personnel only?		
2	Are the cleanliness of the equipment and the instruments checked before the operation?		
3	Are the name and the lot number of the product marked on the equipment and instruments in operation?		
4	Is appropriate process examination performed in the process required for securing the homogeneity of finished products?		
5	Is the production record in accordance with the Production Control Standards written per lot?		
6	Are appropriate measures taken in order to prevent confusion between products, cross contamination, confusion between different packaging materials when other operations are carried out in the same or adjacent area?		
7	Is the number of microorganism regularly measured at the workplace manufacturing the product managing the contamination level of microorganisms?		
8	Is the half-product products quickly processed as soon as possible to avoid the deterioration of quality?		
9	Is the half-product products put into a container and is they segregated and stored with a label until the test is over?		
10	Are proper checks to assure the homogeneity of finished products made in the necessary process?		
11	Are any labels remaining after labeling and packaging counted, and then either returned or destroyed?		
12	Are proper checks to assure whether or not labelling such as the batch number of manufacturing and the sell-by-date, etc. corresponds to the record on the test records?		
13	Is the indicated material checked whether it corresponds to the master formula?		
14	Are packaging container set with dry conditions after cleansing?		

7-2. Production Hygiene Control

Classifi-cation / Rank	Content of inspection	(○/x)	Etc.
1	Are sanitation conditions(disinfection or sterilization if needed) maintained by equipping facilities and equipments needed for sanitation management?		
2	Are personnel working on workplace wearing disinfected overgarment, disinfected cap and hygienic gloves needed for the relevant task while maintaining personal cleanliness?		
3	Are measures taken for personnel having the possibility of adversely affecting the product due to disease?		
4	Are disposable and sewage treatment facilities operated and is managing record for this maintained?		
5	Are there regular training and education about hygiene of manufacturing for employee?		
6	Is food forbidden at workplace and storage facilities?		

7-3. Storage Control

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Are storage facilities of ingredients, packaging materials, intermediate products and finished products dry, clean and well organized?		
2	Are ingredients, packaging materials, intermediate products and finished products clearly classified and stored, and classified and stored by labelling before testing and after the testing.		
3	Is ingredients, packaging materials, intermediate products and finished products stored under conditions where the quality is not adversely affected?		
4	When problems occur during storage of ingredients, packaging materials, intermediate products and finished products, is it immediately notified and is the problem and the measures taken recorded?		
5	Are ingredients, packaging materials, intermediate products and finished products stored so that it is not close to the floor and wall?		
6	Are ingredients and packaging materials determined as inappropriate due to test results quickly processed by classifying it as inappropriate?		
7	Are returned products or defective products segregated and stored?		
8	Are labeled material classified and stored for each item and are there labels indicated the item name in the stored location?		
9	Are storage and incoming · outgoing record sheet of ingredients, packaging materials, intermediate products and finished products prepared and managed?		
10	When there are changes in the entry of label materials, are measures taken to quickly dispose of label materials before changes?		
11	Are only materials requiring raw material & test which is determined as appropriate after test results being sent to the work site?		
12	When sending out finished products, are product names & manufacture no. recorded by major suppliers?		
13	When warehousing or delivering labeled materials, are the types, quantity & entries checked?		
14	When estimating ingredients, it the weight(or capacity) double checked?		
15	Is the subdivided raw material put into a clean container and labelled with raw material name, weight, test no. & usage?		
16	Is finished products delivered after approval from the quality management department?		
17	Is ingredients, packaging materials and finished products delivered in a FIFO(First-In-First-Out) basis?		
18	Are returned products processed according to regulations, and are those records kept?		

7-4. Quality Control

Classifi-cation / Rank	Content of inspection	(○/x)	Etc.
1	With regard to ingredients, raw material, half-finished product and returned product, is an examination recorded prepared according to the quality control administration standards book?		
2	Is sample collected and handled in such a way that it is not contaminated or deteriorated and is sterile sample collected so that its sterile status is maintained?		
3	Are the storage criteria and conditions of health function food being evaluated?		
4	With regard to health functional food which may cause temporal variation, is safety test perform and sell-by-date established?		
5	Is the end product taken classified by serial number and stored up to the expiry of the sell-by date at least.		
6	Are ingredients on label checked for suitability with the provisions whenever the description of label is changed and samples stored?		
7	Are raw materials with product checked whether or not if they cause deterioration and are harmful to human body?		

7-5. Facility control

Classifi-cation / Rank	Content of inspection	(○/x)	Etc.
1	Are facilities and equipments maintained cleanly?		
2	Are facilities and equipments managed and maintained so there are no setback during the operation by periodically checking it?		
3	Is the measuring equipment periodically checked and the record of it kept?		

7-6. Common item control

Classification / Rank	Content of inspection	(○/x)	Etc.
1	Are the execution and management of GMP checked and verified?		
2	Is there close examination of the causes and appropriate measures being taken when improvement measures related to the quality and safety of the product is needed?		
3	Are training conducted on workers about production control, production hygiene control and quality control?		
4	Are task process records prescribed by the related law kept for the duration of the prescribed period?		
5	Are task process records not prescribed on the related law kept for over 2 years?		

7-7. Protection of consumer

Classification / Rank	Content of inspection	(○/x)	Etc.
1	When there is a customer consultation and dissatisfaction notification on the quality and safety of the functional food, are they immediately looking into it and closely examining the causes and taking appropriate measures and recording and keeping the following? 1) Name of consultation(dissatisfactory) subject product, type of product, packaging & manufacture no. 2) Consultation(occurrence) date/month/year, location of occurrence, address & name of declarer 3) Content of consultation(dissatisfaction) & details of the report 4) Investigation results on the stored product, manufacturing record, quality management results of the consultation (dissatisfaction) subject product. 5) Decision by investigation results 6) Measures taken		

8. Final assessment

Classification	Content of inspection	(○/x)	Etc.
Overall evaluation		○ passed(○) : unit ○ failed(×) : unit	

※ Decision criteria

1. Fail
   a. if item 4-1-1is “×”
   b. if items 5-1, 5-2, 5-3 and 5-4 “×”
   c. excluding a) and b), if “×” is 11 or more
2. Correction or Supplementation
   ○ excluding a) and b), if “×” is 10 or less

[Annexed the Table 2]

Plate for GMP Applied Business Establishment

우수건강기능식품제조업소
(GMP 지정업소)

식품의약품안전청
Korea Food & Drug Administration

※ Specification : width; 30㎝, length; 23㎝
Font : 75 point
material : copper plate

Detailed Handling Regulation on Import Health Functional Food Report and Examination

Enacted by Korea Food & Drug Administration Notification No. 2004-8, Jan. 31, 2004
Amended by Korea Food & Drug Administration Notification No. 2004-94, Dec. 27, 2004
Amended by Korea Food & Drug Administration Notification No. 2007-43, Jun. 27, 2007

Article 1 (Purpose) The purpose of this regulation is to contribute toward the speediness and efficiency of examination matters by establishing detailed handling regulation on report and examination of import health functional food for business uses under Article 8 of the 「Health Functional Food Act」 and Article 10 of the Enforcement Rule of the Act.

Article 2 (Handling of pre-import report) (1) The document inspection for any health functional food filed an import report before five days ahead of the expected arrival date under Article 10(1) of the Enforcement Rule of the Health Functional Food Act (hereinafter referred to as the "Enforcement Rule") shall be completed by taking the report date as the initial day for civil petitions treatment (Provided, for those reported two to five days prior to the expected arrival date, the initial day for reckoning shall be one day before). For those subject to the document inspection, an import report certificate shall be issued immediately after confirming the entrance into a bonded area, and for those subject to the sensory inspection, close examination and random sampling examination, the sample necessary for on-site examination or examination shall be collected.

(2) Any import reporter shall notify the report authority of the entrance under paragraph (1) via telephone, fax, or document, etc.

Article 3 (Distribution control, etc.) (1) Any import health functional food subject to distribution control under Article 10(8) of the Enforcement Rule shall be as follows:

1. Health functional food for study and research; and
2. Other health functional food that the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service deems to be necessary of the follow-up management.

(2) The Commissioner of the Regional Food and Drug Administration notified a report under Article 10(9) of the Enforcement Rule shall confirm and check whether the import health functional food in question is used suitably for the purpose and usage of the import report, and, if any violation are detected, administrative measures, etc. shall be taken and the results shall be notified to the Commissioner of the Food and Drug Administration or the head of the National Quarantine Service who requested distribution control.

Article 4 (Examination of the import health functional food, etc.) (1) According to the sampling plan by the Commissioner of the Regional Food and Drug Administration, the random sampling examination under annexed the Table (2)(1)(d) related to Article 10 of the Enforcement

Rules shall be carried out to confirm the examination items based on domestic and foreign information or the standards and specifications of such product. Provided, in case where the Commissioner of the Regional Food and Drug Administration deems to be necessary, examinations may be carried out together.

(2) <Deleted> (on June 27, 2007)

Article 5 (Examination request to other laboratories) (1) The close examination of the import health functional food shall be carried out at the Regional Food and Drug Administration or The National Quarantine Service. Provided, where any import reporter requests, such examination may be carried out at a food sanitation examination laboratory under Article 8(3)2 of the Act (hereinafter referred to as "examination laboratory").

(2) Any import reporter who intends to request the close examination at the examination laboratory other than the Regional Food and Drug Administration or the National Quarantine Service under the proviso of paragraph (1) (hereinafter referred to as "examination at other laboratory") shall submit the import report stated the name of laboratory.

(3) The Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service who received a request for examination at other laboratory under the proviso of paragraph (2) shall designate the examination items for such product, and request the examination to the examination laboratory that the import reporter stated in the import report.

Article 6 (Confirmation of labeling standard and false or exaggerated labeling, etc.) (1) The Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service shall confirm whether the import health functional food is complied with the standard under Article 17 of the Act, and the scope of false or exaggerated labeling and advertising under Article 18 of the Act.

Article 7 (Handling of noncompliant health functional food, etc.) (1) Any import reporter intends to convert health functional food notified as noncompliant under Article 10(4) of the Enforcement Rule to other than edible use under Article 10(4)(2) of the Enforcement Rule shall submit the Modification Application for Other than Edible Use of Noncompliant Import Health Functional Food, annexed the Form (1), to the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service that has notified of the noncompliant, together with the certificate stating that it is possible to use as the converted purpose issued by the examination laboratory that is responsible for the test of converted purpose and sales contract document.

(2) When it is deemed not to be used as edible purpose after reviewing the Modification Application for other than edible use of non-compliant import health functional food under paragraph (1), the content of the Modification Application for other than edible use shall be notified to the import reporter, the competent head of the customs office, and the Commissioner of the Regional Food and Drug Administration that has the jurisdiction over the place of business establishment.

(3) Any import reporter who has been notified of the modification for other than edible use under paragraph (2) shall report the results within three days after the clearance to the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service.

Article 8 (Minimum import quantity) (1) The minimum import quantity determined by the Commissioner of the Food and Drug Administration under annexed the Table (2)(2)(a)(2) related to Article 10 of the Enforcement Rule shall be one hundred kilograms of the import health functional food reported.

(2) ~ (3) <Deleted> (on December 27, 2004)

Article 9 (Handling of Import health functional food for study and research purpose, etc.) (1) <Deleted> (on June 27, 2007)

(2) In order to import health functional food for study and research purpose, the proposal including the manufacturing method document of the product for study and research, period thereof, etc. shall be submitted to the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service.

(3) When the study and research is completed according to the proposal under paragraph (2), the results shall be submitted within one week from the completed date to the Commissioner of the Regional Food and Drug Administration or the head of the National Quarantine Service who has received import report.

Article 10 (Relations with other notifications) "Regulation on recognition standards of foreign public examination laboratory, etc." publically announced by the Commissioner of the Food and Drug Administration under Article 16 of the Food Sanitation Act and Article 11 of the Enforcement Rule of the same Act, shall apply *mutatis mutandis* to the administration of health functional food import by the domestic and foreign examination laboratory and written result of examination or certificate of examination, that this notification is not prescribed.

ADDENDUM

This Notification shall enter into force on the date of its announcement.

ADDENDA (Dec. 27. 2004))

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

ADDENDA (Jun. 27. 2007)

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

(2) **(Transitional measures related to import food, etc. in the middle of examination)** In case where import report was submitted before this Notification enters into force and examination is in progress, the previous Notification shall be applied.

[Annexed the Form 1]

(front)

Modification Application for Other than Edible Use of Non-compliant Import Health Functional Food

Import reporter	Import report no.		Date of non-compliance	
	Name of product			
	Representative		Amount of non-compliant	
	Name of business establishment		Examination agency	
	Place of business			
	Tel.		Fax.	
Consumer (contractor)	Representative		Name of business establishment	
	Place of business			
	Tel.		Amount of contract	
	Fax.			
	Type of business		Modified usage	

I apply the modification for Other than Edible Use of the above Non-compliant Import Health Functional Food under Article 7 (1) of the Detailed Handling Regulation on Import Health Functional Food Report and Examination.

Date (YY/MM/DD):

Applicant (sign or seal)

To Commissioner of the ○○ Regional KFDA,
Head of the National ○○ Quarantine Station

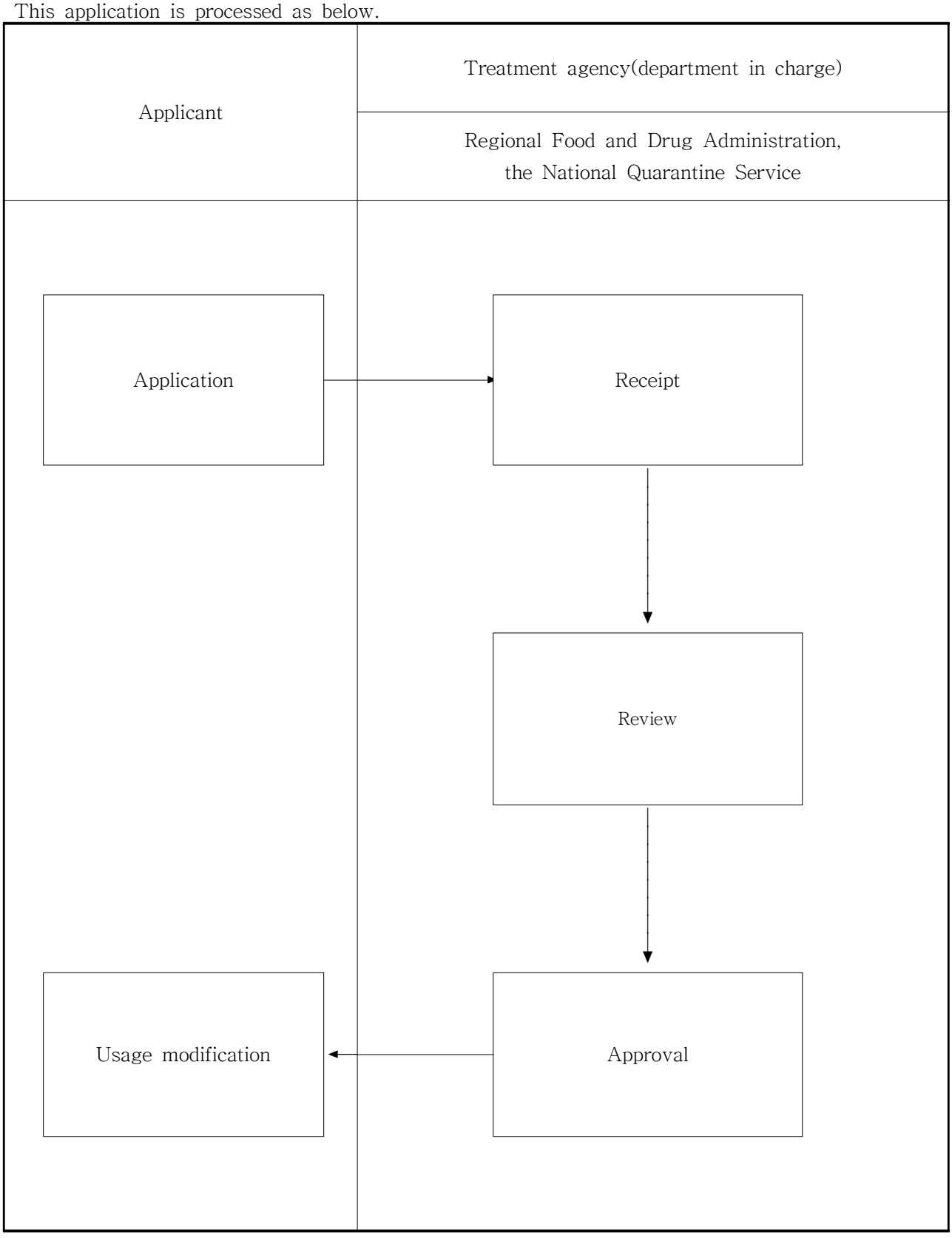
※ Documents required

1. Materials for necessary to apply the modified usage

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

(back)

This application is processed as below.



Self Quality Examination Work Handling Standard

Enacted by Korea Food & Drug Administration Notification No.2004-9, Jan. 31, 2004
Amended by Korea Food & Drug Administration Notification No. 2005-43, Jul. 29, 2005

Article 1 (Purpose) This standard is to establish detailed matters relating to Self Quality Examination Work under Article 21 of the 「Health Functional Food Act」 and annexed the Table 7 (2) relating to Article 25 (1) of the Enforcement Rule of the same Act.

Article 2 (Definition) For the purpose of this standard, the definitions of terms shall be as follows:

1. The term "self quality examination" means that person who carries on business of manufacturing and processing health functional food (including raw materials and components ; hereinafter the same shall apply) (hereinafter referred to as "business person") examines whether or not the manufactured and processed health functional food by himself conforms to the standards and specifications of health functional food under Articles 14 and 15 of the 「Health Functional Food Act」 (hereinafter referred to as the "Act").
2. The term "batch" or "lot" means certain amount the date on which no further manufacturing or processing other than packaging becomes necessary to obtain uniformity under the same manufacturing process of health functional food (for those products that, after packaging, undergo additional manufacturing process such as sterilization or pasteurization, etc., it refers to the point when the final process is completed). Provided, That if it is difficult determine whether batch or lot unit as a result of continuous processes, the manufactured product of the same date may be considered the same batch or the same lot unit.
3. The term "batch No."or "lot No." means the comprehensive management by number, letter, etc. in order to identify all matters relating to manufacturing date, management, shipping, etc. for amount of a certain batch (or lot unit).
4. The term "Examination laboratory" means the examination laboratories under Article 8(3)2 of the Act.

Article 3 (Self quality examination items and execution methods) (1) Self quality examination items and execution methods shall be carried out pursuant to Self Quality Examination Standard in annexed the Table 7 relating to Article 25 under the Enforcement Rule of the Health Functional Food Act (hereinafter referred to as the "Enforcement Rule"). Provided, as for the product that is manufactured seasonally or during specific period because of supply and demand of raw materials, etc. in terms of the characteristics of product, the self quality examination may conduct during the manufacturing life pursuant to examination cycle.

(2) The self quality examination method shall follow the test methods and procedures prescribed by the standards and specifications of health functional food under Articles 14 and 15 of the Act. Provided, the test on appearance and foreign substance may be substituted by a sensory test that determines the propriety based on the color, flavor(scent), texture(taste), the exterior, etc. and in case of products for export, the method may follow the standards and specifications, and test

methods that the importer requires.

(3) For the examination under paragraph (2), where the food additive items of synthetic preservatives, tar dyes, synthetic sweeteners, antioxidants, synthetic disinfectants and bleaching agents are established as the standards and specifications of health functional food under Articles 14 and 15 of the Act, the self quality examination on the relevant item may be omitted if the additives have not been added or used artificially in the manufacturing process of the such health functional food. Provided, That if raw materials have such food additives so that there is a possibility to carry over to the product in question even though the food additives have not been directly used for manufacturing the health functional food, it shall not apply.

Article 4 (Request of self quality examination, etc.) (1) A business person who intends to entrust the self quality examination to an examination laboratory due to lack of examination facilities and examination capacity, etc. under Article 21(2) of the Act may select the whole or the part of items to conduct examination in annexed the Form (1) excluding appearance, foreign substance, moisture, coliform, etc. among examination items of the standards and specifications of health functional food under Articles 14 and 15 of the Act, and request the entrusted examination.

(2) The examination laboratory requested to the entrusted examination under paragraph (1) shall issue a written result of examination by conducting examination only for requested examination items within ten days (fourteen days for test product preserved in heating) and determining the propriety of the results. Provided, That if it is difficult for the examination laboratory to complete the examination within the handling period for unavoidable reasons, the handling period may be extended within one half of the handling period only for one more time, and in this case the reason shall be notified to the ordering person.

Article 5 (Amount of samples, etc.) (1) Where a business person intends to entrust the self quality examination and examine under Article 4(1), the amount of samples shall be collected from the same manufacturing unit according to the collection amount under annexed the Table 6 relating to Article 23 of the Enforcement Rule.

(2) The quality manager shall collect samples under paragraph (1) according to the methods prescribed by the standards and specifications of health functional food under Articles 14 and 15 of the Act, and request to the examination laboratory after sealing and affixing a seal.

(3) Of the samples under paragraphs (1) and 2, the samples necessary to microbiological examination shall be kept and transported under refrigeration to prevent proliferation of microorganism, spoilage or deterioration. In this case, samples shall be transported under refrigeration to the examination laboratory within four (4) hours as soon as possible after the collection.

Article 6 (Handling of noncompliant products) (1) Where the result of the self quality examination does not conform to the standards and specifications of health functional food under Articles 14 and 15 of the Act, the business person shall prohibit the delivery of the products in question without delay, and take measures, such as disposal or reprocessing of the product, and

take necessary measures, such as correction, improvement, etc. by clarifying noncompliant factors.

(2) Measures necessary for the products that the result of the self quality examination under above paragraph (1) is found to be noncompliant, shall be as follows:

1. Where all products of the same manufacturing unit are not delivered and noncompliant items are not harmful to health, only for products with insignificantly noncompliant items such as appearance, moisture, etc. that are not directly related to sanitation and safety may be reprocessed.
2. Where noncompliant matters are found in the manufacturing process as a result of the self quality examination for in-processing products prior to final packaging, necessary measures such as improvement of manufacturing process, disposal, reprocessing, etc. shall be taken, and the self quality examination shall be carried out to the final product.
3. Among health functional food delivered before completion of the self quality examination and the examination results found to be noncompliant, the product In question and all products of the same manufacturing unit shall be recalled without delay; necessary measures such as disposal, etc. shall be taken; and the evident documents shall be made and kept for two years from the date of record.

(3) Where the product in question is determined as noncompliant, the examination laboratory to be requested the self quality examination shall notify the result without delay by phone or fax, etc. to the business person who has requested the examination in order to take necessary measures under paragraph (2).

Article 7 (Preparation and management of self quality examination record) (1) The head of examination laboratory shall make and maintain the record on self quality examination that is entrusted and carried out under Article 24(5) of the Enforcement Rule, and the business person shall make and maintain the record on self quality examination under Article 25(2) of the Enforcement Rule.

(2) The record on self quality examination under paragraph (1) shall include the date and time of sampling, the date and time of test, the examiner and the supervisor, the name of sample, the amount of sample used, the test methods, the test results, the particulars of standard sample and reagent, etc. (including outputs of analysis instrument, etc.), the determination of examination results, and the date and time of notification, etc.

Article 8 (Prohibition of public announcement and advertising of examination results, etc.) The business person and the examination laboratory entrusted with and carried out the self quality examination shall not use the examination results for announcement or advertisement, etc. and not declare those on product, container or package other than examination reference.

ADDENDUM (Jan. 31, 2004)

This notification shall enter into force on the date of its announcement.

ADDENDUM (Jul. 29, 2005)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

[Annexed the Form 1]

<table>
<tr><td colspan="4">Request of Self Quality Examination</td><td>Treatment period</td></tr>
<tr><td colspan="4"></td><td>10 days
(14 days for test product preserved in heating)</td></tr>
<tr><td rowspan="3">Applicant</td><td>Name of business establishment</td><td></td><td>Representative</td><td></td></tr>
<tr><td>Place of business</td><td colspan="3">(☏)</td></tr>
<tr><td>Business permission no.</td><td></td><td>Item manufacture report no.</td><td></td></tr>
<tr><td colspan="2">Name of product</td><td colspan="3"></td></tr>
<tr><td colspan="2">Batch no.
(Lot no.)</td><td></td><td>Manufacturing date
(or sell-by-date)</td><td></td></tr>
<tr><td colspan="2">Sample amount</td><td></td><td>Packing unit</td><td></td></tr>
<tr><td colspan="2">Type of transportation</td><td>room temperature · refrigeration · freezing</td><td>Transportation temperature</td><td></td></tr>
<tr><td colspan="2">Items requested for test</td><td colspan="3">○ Whole of items ( )
○ Part of items :
○ Miscellaneous items :</td></tr>
<tr><td colspan="2">Remarks</td><td colspan="3"></td></tr>
<tr><td colspan="5">I request the above self quality examination under Article 4(1) of Self Quality Examination Work Handling Standard.

Date (YY/MM/DD):
Ordering person (sign or seal)
Quality manager(sample collector) (sign or seal)</td></tr>
<tr><td colspan="3">To Head of ○○ Examination Laboratory</td><td colspan="2">Fees</td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
</table>

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

Guidance on Administration of Reward Money for Violation Report on Health Functional Food Act

Enacted by Korea Food & Drug Administration Notification No. 2004-10, Jan. 31, 2004

Article 1 (purpose) The purpose of this guidance is to establish the amount of reward money, the payment method and procedure, etc. under Article 40 of the Health Functional Food Act and Article 34 of Enforcement Rule of the same Act.

Article 2 (Amount of reward money) The amount of reward money specified by violation type on person who reports the violation (hereinafter referred to as the "reporter") under Article 40 of the Health Functional Food Act (hereinafter referred to as the "Act") and Article 34 of Enforcement Rule of the same Act shall be listed in annexed the Table.

Article 3 (The payment method and procedure) (1) The reward money shall be paid to the reporter on the type of violation of the Act by relevant administrative disposition authority. Provided, That if the authority which accepted the report of violation directly inspects, the agency may pay the reward money.

(2) If the number of violation on the same item is more than two, the reward shall be paid by more important sanction imposed.

(3) In case of the same reporter, the annual reward money shall be paid, not exceeding five hundred thousand won by the Regional Food and Drug Administration, and a million won by each *Si/Do*.

(4) The reward money shall be paid after confirming the violation. Provided, That if the violation is explicit, the reward money may be paid before the administrative disposition.

(5) When the Commissioner of the Regional Food and Drug Administration, Mayor/*Do* Governor or head of *Si/Gun/Gu* notify the reporter of the results of the acquired report, they shall specify the payment method of the reward money (example: deposit bank account).

Article 4 (Exempted from the payment) In case of the public officials of Food and Drug administration, *Si/Do*, or *Si/Gun/Gu* in charge of food or Health Functional Food and the honorary food sanitation inspectors, self inspectors, the officer of Consumer groups etc. who notify violations on the basis of the acquired information, the reward money shall not be paid.

Article 5 (Payment budget) (1) The reward money shall be paid pursuant to the budget which is determined by the general account of the Regional Food and Drug Administration, *Si/Do* or *Si/Gun/Gu*, or the budget of Food Promotion Fund.

(2) In case of the budget of reward money is short, the reward money may be paid by a revised supplementary budget within the fiscal year.

Article 6 (Report on the records of reward) (1) The Commissioner of the Regional Food and Drug Administration, Mayor/*Do* Governor shall quarterly submit to the Commissioner of the Food and Drug Administration a report on the payment of reward within fifteen days after the completion.

(2) When head of *Si/Gun/Gu* pay the reward money, they shall report the details of the reward money to Mayor/*Do* Governor.

ADDENDA

(1) (Enforcement date) This guidance shall enter into force on the 27th, Aug., 2004.

(2) (Transitional Measures) When this guidance enters into force, if payment procedure of reward money is in progress, the reward money is paid under the previous provision.

[Annexed Table]

The specification standard of reward by the type of violation

NO.	Act	The type of violation	Reward
1	Article 5 (1)	Where a person who operates business of Health Functional Food manufacture without permission	50,000 (won)
2	Article 6 (1)	Where a person who operates business of Health Functional Food manufacture without report	200,000 (won)
3	Article 6 (2)	Where a person who operates business of Health Functional Food sales business without report	100,000 (won)
4	Article 23	Where any Health Functional Food is sold or manufactured, imported, used, stored, transported or displayed for sale under any of the following subparagraphs-	
		a. If it is rotten or spoiled so that it may injure the health of the human body;	50,000 (won)
		b. If it contains or is adhered with any poisonous or detrimental substance, or if there is any possibility thereof, except that this subparagraph shall not apply in case where the Commissioner of the Food and Drug Administration deems that it is not injurious to health of the human body;	300,000 (won)
		c. If it is or may be contaminated with any pathogenic microorganisms so that it may injure the health of the human body;	200,000 (won)
		d. If it may injure the health of the human body because it is filthy or is mixed with any foreign substance, or there is any such reasons;	200,000 (won)

NO.	Act	The type of violation	Reward
		e. If it is manufactured by a person without business permission in case where it is required to obtain a permission for business under Article 5 (1); or	500,000 (won)
		f. If it is prohibited from importing or is imported without report in cases where it is required of import report under Article 8.	100,000 (won)
5	Article 24	a. Where any Health Functional Food which does not comply with the standards and specifications are determined in Articles 14 (1) and (2) is manufactured, imported, used, stored, transported or displayed for sale	50,000 (won)
		b. Where any Health Functional Food with ingredients, solely used for medicines, or whose combination, mixture ratio or content is identical with or similar to medicine is manufactured, imported, used, stored, transported or displayed for sale	50,000 (won)
6	Article 25	Where any Health Functional Food violated the standards of label prescribed in Article 17 is manufactured, imported, used, stored, transported or displayed for sale	50,000 (won)
7	Article 26	a. Where any food which is not a Health Functional Food, make labels or advertising upon its container or package, which mislead public into thinking that it has nutritional or physiological functions and effects, etc. for the human body structure and function	50,000 (won)
		b. Where any food that is labelled or advertised as one analogous to Health Functional Food is stored or displayed for sale	50,000 (won)

Regulation on Approval of Health Functional Food

Enacted by the Commissioner of the Food and Drug Administration Notification No. 2004-11, Jan. 31, 2004
Amended by the Commissioner of the Food and Drug Administration Notification No. 2005-81, Dec. 23, 2005
Amended by the Commissioner of the Food and Drug Administration Notification No. 2006-37, Aug. 29, 2006
Wholly amended by the Commissioner of the Food and Drug Administration Notification No. 2007-50, Jul. 11, 2007

Article 1 (Purpose) The purpose of this Regulation is to provide the matters concerning approval criteria, procedure, methods, etc. in order to approve of criteria and specification for health functional food which is not notified by the provisions of Article 14 of the 「Health Functional Food Act」 (hereinafter referred to as the "Act").

Article 2 (Approval criteria) Health functional food intended to obtain approval of criteria and specifications under this Regulation shall be manufactured and processed using functional ingredients approved by the Commissioner of the Food and Drug Administration according to the 『Regulation on Approval of Functional Ingredient for Health Functional Food』 (hereinafter referred to as "the functional ingredient approval regulation") publicly announced under the provisions of Article 14 (2) and Article 15 (2) of the Act.

Article 3 (Approval procedure) (1) In case where a business person under the provisions of Article 5 (1) or Article 6 (1) of the Act (hereinafter referred to as "a business person") intends to obtain approval of criteria and specifications under the provisions, the business person shall submit a health functional food approval application, annexed the Form 1, and data on the reason of mixture of ingredients, manufacturing method, standards and specifications used for the item applied.

(2) Notwithstanding the provision of paragraph (1) in case where a business person manufactures tablet, capsule, powder, granule, liquid or pill, etc. by mixing one of the following subparagraphs with functional ingredient under the provision Article 2 so that the approved matter under the regulation on approval of functional ingredient does not vary, the business person may not follow the approval application procedure under this provision.

1. Functional ingredient (however, less than the consumption amount shall be used.)
2. Vitamin
3. Mineral
4. Food in the Food Code
5. Food additive in the Food Additive Code
6. Mixture of any or all of subparagraphs 1 through 5

(3) The Commissioner of the Food and Drug Administration shall issue the Certificate of Health Functional Food, annexed the Form 2, to the business person after reviewing the data submitted by the business person within thirty (30) days. However, in case where the item corresponds to paragraph (2), the approval certificate of functional ingredient for health functional food issued under the regulation on approval of functional ingredient may substitute the health functional food

certificate.

Article 4 (Approval method) (1) With regard to an item under the provision of Article 3 (1), the Commissioner of the Food and Drug Administration shall send the examination request, annexed the Form 3, and the examination sample to the domestic health function food examination laboratory designated by the applicant, and if the item is suitable for the content of health function food criteria and specifications, annexed the Table 1, through the specification examination of the applied item, shall approve the item. However, if a written result of examination by a domestic health function food examination laboratory is submitted, the examination may be omitted;

(2) With regard to an item under Article 3 (2), a business person may establish specifications according to the content of standards and specifications of health function food, annexed Table 1, and after examination by a domestic health function food examination laboratory, may use the specification as the specification of the report item at the time of item manufacture report under Article 7 of the Act and import report under Article 8 of the Act.

ADDENDA

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures related to product in the middle of examination of approval) In case where the approval application was submitted before this Notification enters into force and the examination of approval is in progress, the previous Notification shall be applied.

[Annexed the Form 1]

Content of health functional food criteria and specifications (Related to Article 4)

1. Scope of application

a. Function ingredient shall be suitable for the manufacturing standards and product requisites of the certificate issued under the "Regulation on Approval of Functional Ingredient for Health Functional Food"

b. The predetermined daily consumption amount, content of functionality and precautions shall be suitable.

c. Other ingredients shall be suitable for the standards and specifications of food and food additive.

d. Suitability shall be confirmed using labeled information, written result of examination, component specification, etc.

2. Applications of specifications

		<Applied specification>
1. Specification applied for each dosage form	Capsule, tablet, pill and granule	→ ◦Disintegration
	Liquid	→ ◦Number of germs
2. Application of specifications by health functional food types ① Characteristic: shall have unique color with no undesirable taste or smell. ② Functional ingredient content: 80~120% of displayed amount ③ Coli group: Negative		◦Characteristic ◦Functional ingredient content → ◦Coli group
3. Application of functional ingredient manufacturing standards ※ The specification of pesticide residue and solvent residue is applied to ingredient only.		→ ◦Heavy metal ◦Solvent residue ◦Others Pesticide residue, fungal toxin, etc.
4. Application of vitamin and mineral content specification ※ In case where vitamin and mineral daily consumption amount is contained more than 30% of the nutrient reference value.		→ ◦Displayed amount

1) Chewing product may not be subject to the specification of disintegration.

2) In case separately approved by the Commissioner of the Food and Drug Administration, such specification may be applied.

[Annexed the Form 1]

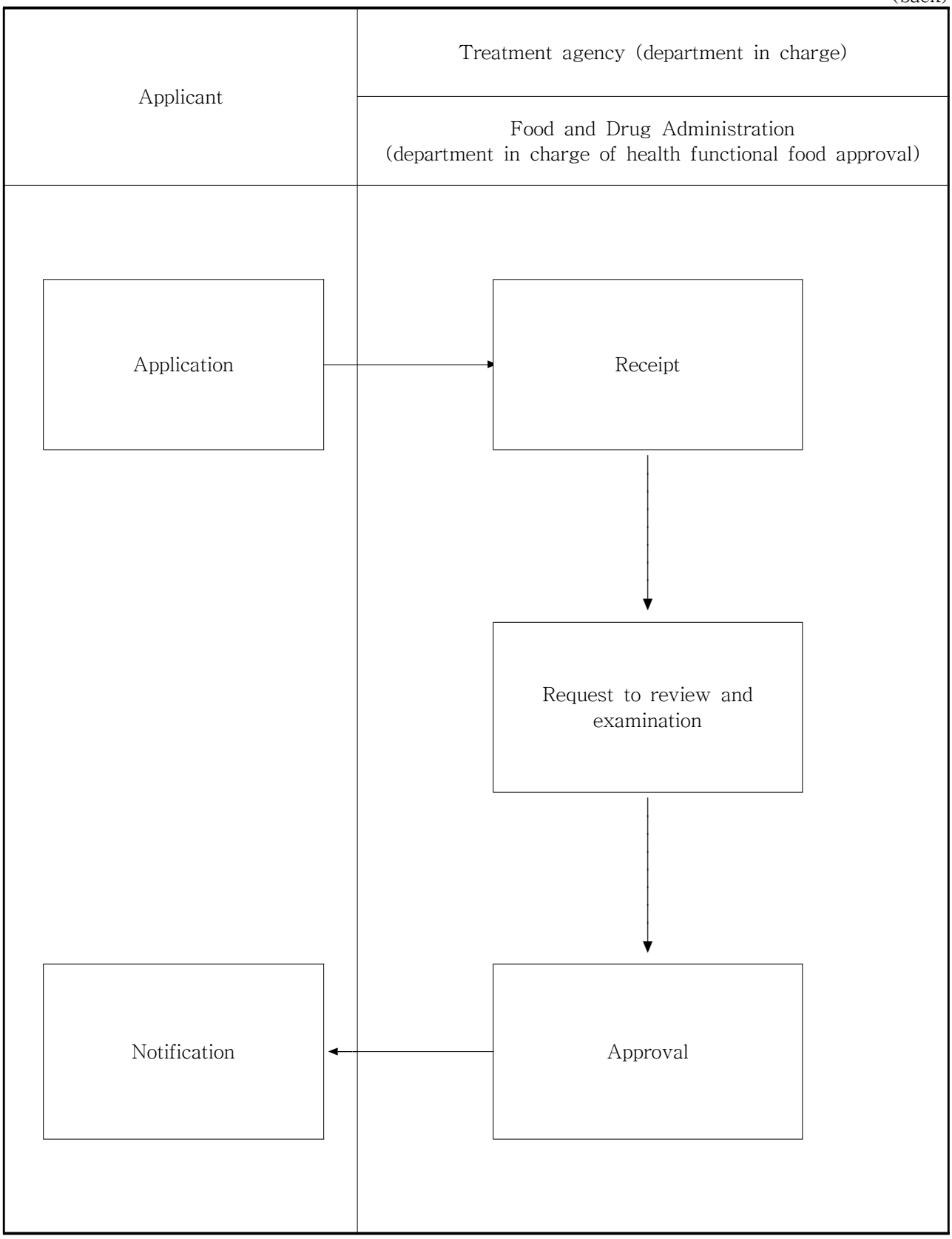
(Front)

<table>
<tr><td colspan="5">Health Functional Food Approval Application</td><td>Treatment period
60 days</td></tr>
<tr><td rowspan="7">Applicant</td><td colspan="2">Representative</td><td colspan="4"></td></tr>
<tr><td colspan="2" rowspan="2">Name of business establishment</td><td rowspan="2"></td><td rowspan="2">Business permission/ report No.</td><td>Manufacture business</td><td></td></tr>
<tr><td>Import business</td><td></td></tr>
<tr><td colspan="2">Place of business</td><td colspan="4">(Tel) (Fax)</td></tr>
<tr><td rowspan="4">Imported health functional food</td><td>Receipt No.</td><td colspan="4"></td></tr>
<tr><td>Exporting country</td><td colspan="4"></td></tr>
<tr><td>Business establishment of manufacture</td><td colspan="4"></td></tr>
<tr><td>Place of business</td><td colspan="4"></td></tr>
<tr><td colspan="3">Approval number of functional ingredients</td><td colspan="4"></td></tr>
<tr><td colspan="3">Name of product</td><td colspan="4"></td></tr>
<tr><td colspan="3">Examination laboratory</td><td colspan="4"></td></tr>
<tr><td colspan="7">Applying to approval of health functional food under Article 5 of the Regulation on Approval Health Functional Food.
Date(YY/MM/DD):
Applicant: (Signature)
To the Commissioner of the Food and Drug Administration</td></tr>
<tr><td colspan="6">※ Requisites of submission
1. Two copies of documents
2. Five samples of final product of minimal packaging unit (in the case of imported health functional food, including with label statement of manufacturer or recorded document) and standard substance. However, if a written result of examination by a domestic health function food examination laboratory is submitted, the examination may be omitted
3. In case of imported health functional food, one copy of manufacturing process and methods (including name of enzyme, extraction solvent, etc.), raw material name and a ratio of mixture, etc. shall be submitted.</td><td>Fees
100,000 won</td></tr>
<tr><td colspan="7">※ Submission documents
1. The reason of mixture of ingredients
2. Manufacturing methods and related data for such establishment
3. Data on standards and specifications</td></tr>
</table>

210㎜×297㎜(regular paper 60g/㎡(Recycle))

This application is processed as below.

(back)



[Annexed the Form 2]

(Front)

Domestic	Import

No:

Certificate of Health Functional Food

Representative :

Name of business establishment :

Place of business :

Name of product :

Standards and specifications :

Exporting country :

Name of business establishment in an exporting country :

Place of business establishment in an exporting country :

Approving this as health functional food under Article 3(1) of the Regulation on Approval Health Functional Food.

Date(YY/MM/DD):

The Commissioner of Food and Drug Administration (Signature)

※ Attachment (in case of requirement)

1. Name of product
2. Name and content of mixture of ingredients
3. Manufacturing methods
4. Specifications(including test methods)
5. Functionality contents
6. Consumption amount, consumption method, warning notice for consumption

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

[Attachment]

(Approval No.:)

Section	Approval contents
Name of product	
Name and content of mixture of ingredients	
Manufacturing methods	
Specifications	※ Including test methods
Functionality contents	
Daily consumption amount	
Warning notice for consumption	

[Annexed the Form 3]

Health Functional Food Examination Request

<table>
<tr><td rowspan="3">Applicant</td><td>Representative</td><td colspan="4"></td></tr>
<tr><td rowspan="2">Name of business establishment</td><td rowspan="2"></td><td rowspan="2">Business permission/ report No.</td><td>Manufacture business</td><td></td></tr>
<tr><td>Import business</td><td></td></tr>
<tr><td>Place of business</td><td colspan="4">(Tel.) (Fax.)</td></tr>
<tr><td>Name of product</td><td colspan="5"></td></tr>
</table>

Requesting examination on standards and specifications of following products to your examination laboratory under Article 4(1) of the Regulation on Approval Health Functional Food.

Date(YY/MM/DD):

The Commissioner of Food and Drug Administration (Signature)

To_____

Attachment 1. Standards and specifications, test methods

2. Two test samples and a standard substance (if necessary)

210㎜×297㎜(regular paper 60g/㎡(recycle))

Regulation on Approval of Functional Ingredient for Health Functional Food

Enacted by the Commissioner of the Food and Drug Administration Notification No. 2004-12, Jan. 31, 2004
Amended by the Commissioner of the Food and Drug Administration Notification No. 2006-36, Aug. 29, 2006
Amended by the Commissioner of the Food and Drug Administration Notification No. 2007-51, Jul. 11, 2007

Chapter 1. General Provisions

Article 1. (Purpose) The purpose of this Regulation is to provide the appropriate approval work relating to the standards and specifications, safety, functionality and consumption amount, etc. of ingredient by prescribing matters relating to approval criteria, approval procedure, scope and requisites of submitted documents, etc. necessary for the approval of functional ingredient for health functional food (hereinafter referred to as "ingredient") under Articles 14(2) and 15(2) of the 「Health Functional Food Act」 (hereinafter referred to as the "Act")

Article 2. (Definition): (1) For the purpose of this Regulation, the definitions of terms shall be as follows:

1. The term "functional ingredient" means any ingredient with functionality used in manufacturing of health functional food such as raw materials from animal, plant or raw material originated from microorganism; its extracts and purified substances; vitamins and minerals; or their synthetics or composites, etc.;
2. The term "functional component" means a component responsible for the functionality in ingredient;
3. The term "marker compound" means a component determined for the purpose of quality control among those chemically identified components;
4. The term "raw material" means a original substance used in manufacturing the ingredient;
5. <Deleted> (on July 11, 2007)
6. The term "detrimental substance" means any hazardous material to human body because of the possibility of its contamination or residue from ingredient or remained from manufacturing processes such as microorganism, heavy metal, pesticide residue, solvent residue and others.

(2) The definitions of terms not defined in this Regulation shall follow the Act or the Official Book of Health Functional Food.

Article3 (Review subject scope) The scope of review subject under this Regulation shall be as follows:

1. Ingredient not notified, or modification or addition of the content in accordance with Articles 14(1) and 15(1) of the Act (excluding specially intended food); or
2. Modification or addition of contents recognised in accordance with Articles 14(2) and 15(2) of the Act

Article 4. (Approval criteria) The approval criteria of ingredient shall be as follows:

1. It shall be complied with the Health Functional Food Act; and
2. Safety and functionality shall be ensured and scientifically proved.

Chapter 2. Approval procedure

Article 5 (Approval application) Any person who intends to obtain an approval for the ingredient among business persons under Article 5(1) or 6(1) of the Act shall submit health functional food approval application (including electronic application form), annexed the Form 1, along with the following documents(including electronic documents) to the Commissioner of the Food and Drug Administration:

1. Two copies of documents (including an original copy) under Article 12(1);
2. A CD containing the submitting documents; and
3. Product or test product and the standard of function component (or marker compound)
   In case of an import item which has never been distributed as food or food additive domestically, the item shall be used for research and investigation under annexed the Table 2 No. 1 (a)(2) related to Article 8 of the Act and Article 10 of the Enforcement Rule
4. Written result of examination issued by a domestic health functional food examination laboratory.

Article 6 (Treatment period) (1) The treatment period necessary for the approval of ingredient shall be within 120 days from the date of receiving.

(2) In case where there is the supplementary request on the documents under Article 7, the Commissioner of the Food and Drug Administration shall decided the supplementary period under the Civil Petitions Treatment Act.

Article 7 (Supplementary documents etc.) (1) The Commissioner of the Food and Drug Administration shall express the necessary matters in detail and request supplement of documents to the applicant if the submitted documents fall under any of the followings:

1. If type, scope, contents, requisites, etc. of submitted documents are not complied with the provisions of Articles 12 and 13; or
2. Additional documents etc. are especially required for appropriate evaluation.

(2) The Commissioner of the Food and Drug Administration may hear the opinion on the data submitted by the applicant in case where verification of fact is necessary because the item is not suitable for the provision of paragraph (1).

Article 8 (Return of application documents) The Commissioner of the Food and Drug Administration shall return the application documents to the applicant with the expressed reasons, if application falls under any of the followings:

1. In case where the ingredient is not complied with Article 4; and
2. In case where the applicant dose not submit relevant document within the supplementary period under Article 6 (2).

Article 9 (Approval and deliberation) The Commissioner of the Food and Drug Administration shall review the submitted documents by the applicant according to the provisions of Articles 14 through 16, and recognize as ingredient if it is suitable as a result of the deliberation of the Health Functional Food Deliberation Committee under the Article 27 of the Act.

Article 10 (Notification of approval etc.) The Commissioner of the Food and Drug Administration shall issue the "Certificate of Functional Ingredient for Health Functional Food," annexed the Form 2, to the applicant when recognizing the ingredient.

Article 11 (Modification of approval matters, etc) (1) Any person who intends to modify the contents of the certificate under Article 10 shall submit the 'Application of Modification on Certificate of Functional Ingredient for Health Functional Food,' annexed the Form 3, to the Commissioner of the Food and Drug Administration.

(2) When receiving the application of modification under paragraph (1), the Commissioner of the Food and Drug Administration shall determine whether he accepts the modification under the condition without changing ingredient after reviewing the validity of modification reasons.

Chapter 3 Submission documents

Article 12 (Scope of submission documents) (1) The documents submitted by the applicant to be recognized as the ingredient shall be as follows and may be submitted by entering the documents in "the Health Functional Food Approval Application Program":

1. Executive summary of whole submitted documents;
2. <Deleted> (on August 29, 2006);
3. Origin, developing history, current status of approval and use in domestic or foreign countries etc.;
4. Manufacturing methods and related data;
5. Characteristics of the ingredients;
6. Specification on functional component (or marker compound) and data on test method;
7. Specification of detrimental substance and related data for test method;
8. Safety;
9. Functionality contents and related data ;
10. Consumption amount, consumption method, warning notice for consumption and related data for such establishment;
11. <Deleted> (on July 11, 2007)
12. Confirmation data that ingredients are not identical with or similar to medicine.

(2) The preparation method for submitted documents shall be as follows:

1. Submitted documents shall be complied with the requisites under Article 13 and marked with the table of contents, index number and number by document according to the listed sequence by each of section. Provided, That if the submitted documents are exempted or omitted

according to the provisions of each Article, or are unable to be prepared, the reasons shall be described in detail and attached in the relevant section;

2. The executive summary shall be attached to understand the overview of whole documents, and index number by document shall be given to the end of the each content in order to figure out the links between the contents in the executive summary and each specific document;
3. Where there are excessive documents depending on sections, the brief section summary shall be attached to the starting page of document in relevant sections to facilitate understanding;
4. Both original copy and executive summary shall be submitted and Korean translation documents shall be submitted in case of documents written in foreign language other than English; and
5. The applicant shall acquire the confidence of submitted documents.

Article 13 (Contents and requisites of submitted documents) The contents and requisites of submitted documents under Article 12 shall be as follows:

1. Executive summary of whole submitted documents (Brief summary for contents of subparagraphs 3 through 12);
2. <Deleted> (on August 29, 2006);
3. Origin, developing history, current status of approval and use in domestic or foreign countries etc.;
   (a) Origin and developing history
   It shall be listed when, in which country, and how ingredients are developed. Especially in case that natural products is used as the raw material, the origin, the scientific name, the place of origin and the part used, etc. shall be listed in detail.
   (b) Current status of recognition and permission in domestic or foreign countries
   The contents related to the status of recognition and permission, and standards and specifications for use etc. in domestic or foreign countries, and international organization shall be listed precisely. If ingredients are under review by the international organization such as Codex Alimentary Commission (CAC), etc., data related to safety evaluation, standard of use and specification, etc. shall be researched and attached to submission.
   (c) Current status of use in domestic or foreign countries
   If ingredients have been used for foods, etc. in domestic or foreign countries, data related to the purpose of use, the amount of distribution, manufacturer, and actual condition of consumption shall be attached to submission.
4. Manufacturing methods and related data;
   Manufacturing methods shall be listed in detail, especially all matters related to evaluation of safety and functionality such as kinds of extraction solvent, enzyme, microorganism, etc. in manufacturing processes. In case of imported health functional foods, documents issued from manufacturer shall be submitted. In addition, in case of mixing more than two raw materials, the content and name of each ingredient shall be listed.

5. Characteristics of the ingredients;
   (a) Data on appearance and property of matter, etc. which may characterize the corresponding

ingredient.

(b) Data on functional component (or marker compound) for the confirmation of standardization of the corresponding raw material and evidence data on functional component (or marker compound)

In such a case the content unit of functional component (or marker compound) shall be established on the basis of results of multiple tests considering the characteristics of ingredient such as the manufacture of ingredient, the production and processing of ingredient, stability, etc. However, if it is unsuitable to establish content, it is allowed to establish through potency test or identity test.

(c) Change in productivity and the content functional component (or marker compound) following production steps.

6. Specification on functional component (or marker compound) and data on test method

(a) The specification of functional component (or marker compound) shall be established by the upper and lower limits in percentage for the value desired to be displayed considering analysis error. Generally, in case of a single component, it is established in terms of the displayed or value or more and in case of an extract, it is established in terms of 80~120% of the displayed value in principle. However, if there is a reasonable reason, it may be established otherwise.

(b) The test method of functional component (or marker compound) shall be suitable for the analysis of specification of functional component (or marker compound). For test method, a method publicly recognized domestically and overseas is recommended such as the health functional food code, the food code, the food additive code, CAC regulation and AOAC method, etc. However, if there is no publicly recognized method or the method presented by the applicant is recognized as more appropriate, the applicant's method may be used. In such a case, the applicant shall prove the suitability of the test method presented, referring to annexed the Table 1.

(c) Written results of examination by a domestic health functional food examination laboratory.

The written results of examination and analysis data by a domestic health functional food examination laboratory shall be submitted so that the suitability of the specification and test method of established functional component (or marker compound) and can be reviewed.

(d) In case where two or more ingredients are mixed, the specification and test method of functional component (or marker compound) of each component shall be established.

(e) ~ (g) <Deleted> (on July 11, 2007)

7. Specification of detrimental substance and related data for test method;

(a) The specification and test method for necessary items shall be established referring to annexed the Table 2, in order to secure safety from detrimental substance with possible contamination or residue from raw materials and manufacturing processes.

(b) For the test method of detrimental substance, a method publicly recognized domestically and overseas is recommended such as the health functional food code, the food code, the food

additive code, CAC regulation and AOAC method, etc. However, if there is no publicly recognized method or the method presented by the applicant is recognized as more appropriate, the applicant's method may be used. In such a case, the applicant shall prove the suitability of the test method presented, referring to annexed the Table 1.

(c) Written results of examination by a domestic health functional food examination laboratory.
The written results of examination and analysis data by a domestic health functional food examination laboratory shall be submitted so that the suitability of the specification and test method of established detrimental substance and can be reviewed.

8. Safety;

(a) Scientific data verifying that ingredient is not harmful to human body when taken as presented shall be submitted.

(b) Referring to annexed the Table 2, the evidence data of consumption, safety information on functional component or related components, evaluation of consumption amount, nutritional evaluation, bioavailability, human study data (interventional study, epidemiological study, etc.), and toxicological data may be used for safety data.

(c) Safety documents shall fall under one of the followings:

a. The evidence data of consumption shall be the historic record of use to verify the safety of such ingredient and the scientific data that describe manufacturing methods, usage, consumption amount, etc.

b. Safety documents on functional component or related substances shall be articles published or issued publication certificate in domestic or foreign academic journals, domestic or foreign government reports, or reports by international organization, related database search results, etc.

c. Documents on evaluation of consumption amount shall be prepared with various scientific data (survey data on actual condition of consumption, statistical data, etc.).

d. Documents on nutritional evaluation, bioavailability, human study, etc. shall be articles published or issued publication certificate in domestic or foreign academic journals. Provided, That if the report under Article 9(C)(1) may be used for human study.

e. Toxicological data shall be one of the following subparagraphs:

1) The report may be used if it is conducted by the institution operated under the Good Laboratory Practice (GLP) in accordance with OECD Test Guideline provided by Organization for Economic Cooperation and Development (OECD) or the equivalent test guidelines.

2) <Deleted> (on July 11, 2007)

9. Functionality contents and related data;

(a) Functionality contents

Useful effect on health purposes from consumption of such ingredient shall be listed.

(b) Human study, animal study, *in vitro* study, review, meta-analysis, evidence data oftraditional use, etc. may be used as functionality data.

a. Data on human study such as intervention or observation study, etc. shall be submitted to confirm the functionality of such ingredient on human body.

b. Documents on animal study, *in vitro* study, review, meta-analysis, evidence oftraditional use, etc. shall be submitted for scientific support on human study results.

c. In case of mixing two or more raw materials, the functionality of mixed ingredient shall be proved, and the valid reason for mixing and scientific evidence shall be submitted.

(c) Documents on functionality shall fall under one of the followings:

a. Functionality data shall be articles published or issued publication certificate in domestic or foreign academic journals, domestic or foreign government reports, or reports by international organization. Provided, in case of human study, the report may be used if it is conducted by domestic or foreign specialized institutions, such as hospital, university, or research institute, etc. under the Guideline for Good Clinical Practice by the International Conference on Harmonization (ICH GCP) or equivalent guidelines to protect the human right of subjects as well as guarantee the creditability of experimental results. Provided, That if it is submitted as report, protocol and final report approved by the Institutional Review Board (IRB) shall be submitted.

b. The evidence data of consumption shall be the historic record of use to verify the safety of such ingredient and the scientific data that describe manufacturing methods, usage, consumption amount, etc.

10. Consumption amount, consumption method, warning notice for consumption and related data for such establishment;

(a) Minimum and maximum daily intake that can show functionality shall be established to ensure the safety of ingredient based on the safety and functionality data. Provided, That if it is difficult to establish the minimum and maximum daily intake, the appropriate range of consumption amount may be established.

(b) Based on functionality data, consumption method shall be listed to achieve the most effectiveness of functionality of such ingredient.

(c) The warning notice for consumption shall be listed by considering the excessive consumption of such ingredient, interaction with foods or medicinal components, susceptible population (pregnant and lactating women, children, the elderly, etc.), etc.

11. <Deleted> (on July 11, 2007)

12. Confirmation that ingredient is identical with or similar to medicine.

It shall be confirmed that ingredient is not identical or similar to the medicine according to Regulation on Prohibited Ingredients, etc. for Health Functional Food (Food and Drug Administration Notification).

Chapter 4 Principle of evaluation

Article 14 (Standards and specifications) (1) The commissioner of Food and Drug Administration shall evaluate whether the origin, the scientific name, the place of origin, and part used, etc. of ingredient applied are described in detail, and in case of compound ingredient, whether the

contents of each raw material are described well.

(2) The Commissioner of the Food and Drug Administration shall evaluate whether solvent, enzyme, etc. used in the manufacturing processes of the applied ingredient are used appropriately according to the health function food code, the food code and the food additive code.

(3) The Commissioner of the Food and Drug Administration shall evaluate whether the content, specification and test method of functional component (or marker compound) of ingredient are suitably established and the results of test by the domestic health function food examination laboratory is appropriate. He shall also evaluate whether change in contents of functional component (or marker compound) by manufacturing steps are properly analyzed from raw materials through the ingredient applied.

(4) The Commissioner of the Food and Drug Administration shall evaluate whether the specification of detrimental substance in ingredient is established so that safety can be secured and shall evaluate whether the results of test by the domestic health function food examination laboratory is appropriate.

(5) <Deleted> (on July 11, 2007)

Article 15 (Safety) The Commissioner of Food and Drug Administration shall evaluate whether it ensures safety of such ingredient by reviewing overall data submitted on origin, development history, current status of approval and use in domestic or foreign countries, manufacturing methods, characteristics of ingredient, traditional use, consumption amount evaluation, nutritional evaluation, bioavailability, results of human study, results of toxicological test, etc.

Article 16 (Functionality) (1) To confirm the functionality of such ingredient, the Commissioner of Food and Drug Administration shall individually evaluate the submitted functionality documents according to research type and quality and totally evaluate the quantity, consistency and applicability of research.

(2) Functionality shall be recognized under paragraph (1) as follows:

1. If the functionality data show the reduction of disease risk occurrence and the level of scientific evidence data is high enough to reach scientific agreement, 'reduction of disease risk' shall be recognized; and
2. From the submitted functionality data, if it has the specific effects on normal function of human body or biological activity so that shows health contribution or function enhancement, or health maintenance or improvement, 'other function' shall be recognized.

ADDENDA

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures related to ingredient in the middle of examination of approval) In case where the approval application was submitted before this Notification enters into force and the examination of approval is in progress, the previous Notification shall be applied.

(3) (Period of validity) The provisions of Article 13(8)C(5)(2) will be valid until Dec. 31, 2006.

ADDENDA (Jul. 11, 2007)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures related to ingredient in the middle of examination of approval) In case where the approval application was submitted before this Notification enters into force and the examination of approval is in progress, the previous Notification shall be applied.

(3) (Transitional measure on functional ingredient which is not approved of standards and specifications) Functional ingredient which is approved of safety and functionality according to "Regulation on Approval of Health Functional Food Functional Approval" (Food and Drug Administration Notification No. 2004-12, enacted on January 31, 2004) but whose standards and specifications are not established may apply for criteria and specifications under this Notification.

[Annexed the Table 1]

Definition and Application of Check Items for Test Method Validation

Item	Definition	Application		
		Functional Component		Detrimental Substance (Quanti-tative)
		Quantitative test	Identity test	
Specificity	1. Capability for selectively measuring target analysis substance when it is mixed with impurities, decomposed substances, mixture components, etc.	Yes	Yes	Yes
Accuracy	Degree of agreement between test results and know true values and standard values	Yes	No	Yes
Precision	Degree of distribution among measured values when samples that are obtained from homogeneous material many times are measured in a predetermined condition	Yes	No	Yes
Quantitation Limit	The minimum quantity of target analysis substance among samples that can be expressed with proper accuracy and precision	No	No	Yes
Linearity	Capability for obtaining linear measured values among samples in a predetermined range against the quantity (or concentration) of target analysis material	Yes	No	Yes
Range	Region between the upper and lower limits of target analysis material among samples that can sufficiently present proper precision, accuracy and linearity	Yes	No	No

[Annexed the Table 2]

Items for Establishment of Detrimental Substance Specifications

Category	Item		Specification	Remark
A	Heavy metal	Lead	< 10.8㎍/day*	
		Total arsenic	< 150㎍/day*	
		Cadmium	< 3.0㎍/day*	
		Total mercury	< 2.1㎍/day*	
	Micro-organism	Coli group	Negative	
		Number of germs	≤ 100/g (Liquid product only)	
	Solvent residue	Hexane	< 0.005g/kg	If used
		Isopropyl alcohol	< 0.05g/kg	
		Ethyl acetate	< 0.05g/kg	
		Acetone	**	
		Methyl alcohol	**	
B	Animal medicine	Antibiotic	Following the allowable residue limit of the raw material	
		Synthetic antimicrobial		
		Vermifuge		
		Synthetic hormone		
	Fungal toxin	Aflatoxin		
		Patulin		
		Ochratoxin		
		Other fungal toxin		
	Radioactive contamination	^{131}I	≤ 300Bq/Kg, L	
		$^{134}Cs+^{137}Cs$	≤ 370 Bq/Kg, L	
C	Pesticide residue	Endrin	Following the allowable (residue) limit of the raw material	
		Dieldrin		
		Aldrin		
		BHC		
		DDT		
		Other pesticide		

* Average body weight is assumed to be 60kg. If the subject of consumption has a different average body weight, the standars may be changed considering the average body weight of Korean dietary reference intake.

** If residue remains inevitably in the course of manufacturing, the substance shall be established to be managed at the minimum quantity achievable in the manufacturing processes.

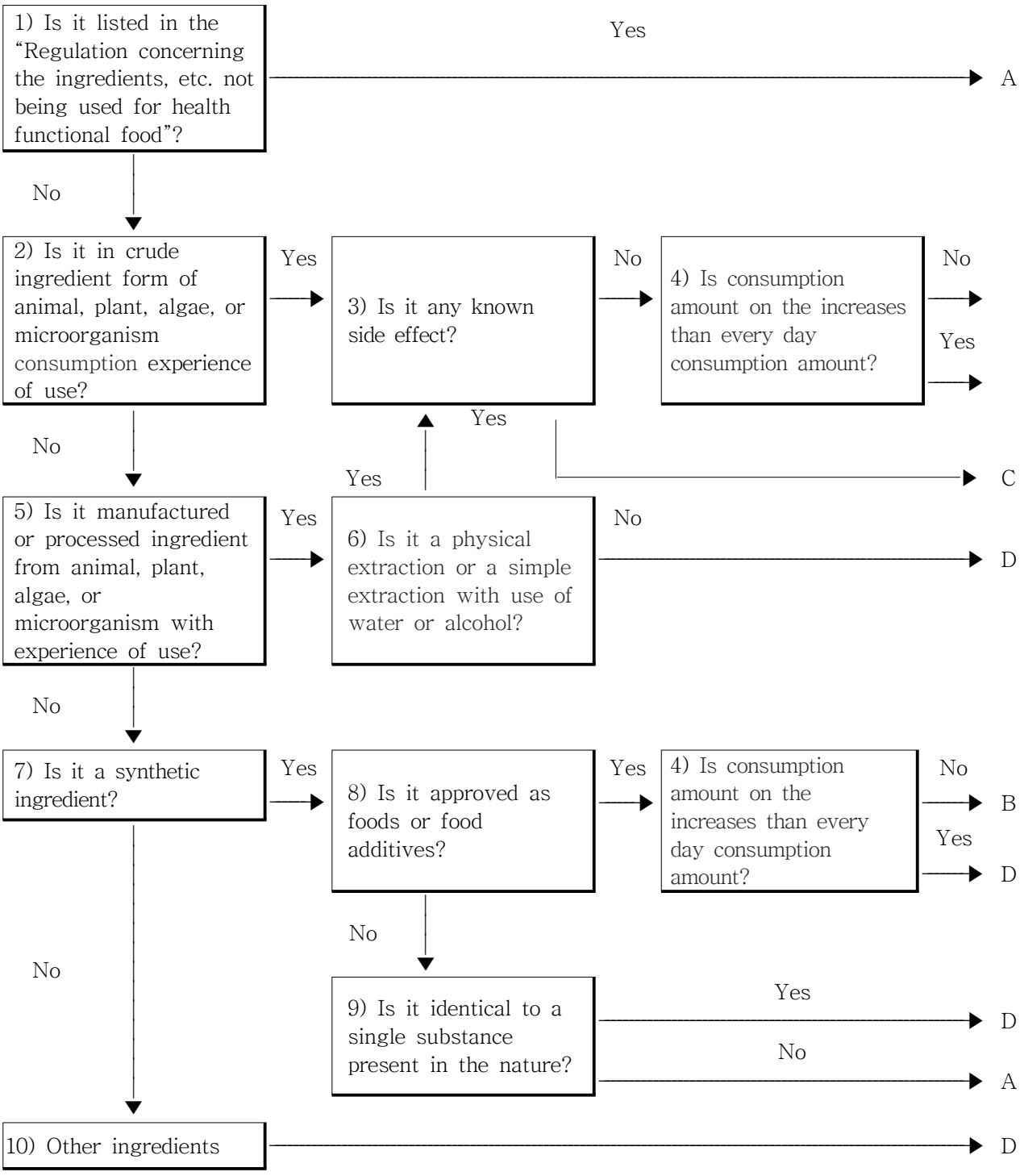
A: Item for which specification shall be established at all time and whose results of examination shall be submitted.

B: Item for which specification shall be established and whose results of examination shall be submitted depending on ingredient.

C: Item whose results of examination shall be submitted, but specification may not be established.

[Annexed the Table 3]

Decision Tree for Safety Evaluation of Functional Ingredient for Health Functional Food (relating to Article 13(8))



<1. Scope of submitted document on safety>

Scope of submitted documents on safety	A	B	C	D
Cannot be applied as health functional food	√			
Evidence of consumption [1)]		√	√	√
Safety data on functional ingredient or related substances [2)]		√	√	√
Documents on evaluation of intake level [3)]		√	√	√
Documents on nutritional evaluation, bioavailability, human study [4)]			√	√
Documents on toxicological study [5)]				√

---

1) Evidence documents on consumption based on Official book of Health Functional Food, Official book of Food, Official book of Food additives, Scientific documents on historical/traditional use/ documents on recognition from domestic or foreign government institution, etc.

2) Documents on safety/toxicity of functional ingredient or related substances can be collected from databases.

3) Documents on the average intake and recommendation intake analyzed by national nutrition survey or survey on consumption behavior.

4) Documents on the effect of ingredient intake on adsorption, distribution, metabolism, and excretion of other nutrients bioavailability; interventional study, epidemiological study.

5) Toxicity studies shall include the single dose-toxicity (rodents, non-rodents), 3 month repeated dose toxicity (rodents), and genotoxicity (reverse mutation test, chromosomal aberration test, and micronucleus test). Depending on the characteristics of the ingredient or constituent, reproductive toxicity, antigenicity, immunotoxicity, carcinogenicity, or others. Provided the safety can be demonstrated by other safety documents, exemption may be applied.

<2. Significant points needed to be considered in making a decision>

1) Determined if the ingredient is specified at the “Regulation on Prohibited Ingredients, etc. for Health Functional Food.” in the Manufacture of Drug products (KFDA Notification)

2) Determined if the ingredient is derived from historically used animals, plants, microorganism without processing such as extraction or fermentation (e.g. powder of raw materials). Historical use indicates ingredient listed in Official Book of Health Functional Food, Official book of Food, Official book of Food additives, scientific documents on historical/traditional use/ documents on recognition from domestic or foreign government institution, etc.

3) Determine by searching the databases if the ingredient may contain detrimental substances can that cause toxicity or adverse health effects.

4) Determined if the recommended intake is over three times of average daily intake or extreme amount (95 percentile) in care of food ingredient. Determine if recommended intake is over average daily intake in case of medicinal ingredient. Provided lacking in evidence of intake, it shall be judged that intake is changed.

5) Determined if the ingredient or substances is derived from historically used animals, plants, microorganism processing such as extraction, fermentation, separation, decomposition.

6) Determined if the ingredient is obtained from extraction through compression or osmosis, or a simple extraction made of extraction or leaching with water or alcohol followed by separating pellet from supernatant. If manufacturing methods meet one of following subparagraphs, it is applied to this category.

- Ingredient extracted using solvents, other than water and alcohol, approved by “Official Book of Health Functional Food, Chapter 2. Standard and Specification of Health Functional Food”.

- Ingredient from separation of specific component, purified ingredient, or modified

- ingredient after separation.

7) Determine if the ingredient or substances is composed of synthetic chemicals.

8) Determine if the ingredient is recognized as food ingredient or food additive.

9) Determine if the ingredient is not recognized as food ingredient or food additive but identical to natural substance.

10) Applicable to all ingredients except those of 1), 2), 3), 6), and 9).

※ In case of compound ingredients, the “decision tree” shall be applied to the individual raw material to determine the level of the safety documents. Additional documents demonstrating that interaction between ingredients used in combination does not cause adverse effect shall be submitted (additional documents shall be based on evidence of historical use, safety and functionality, etc.). Provided toxicity study on compound ingredients was conducted, those additional documents on safety of interaction may be exempted.

※ In case of ingredients subjected to the Regulation on “Safety evaluation of Genetically Modified Organisms” (KFDA Notification), its safety shall be evaluated in accordance with this Regulation.

[Annexed the Form 1]

(Front)

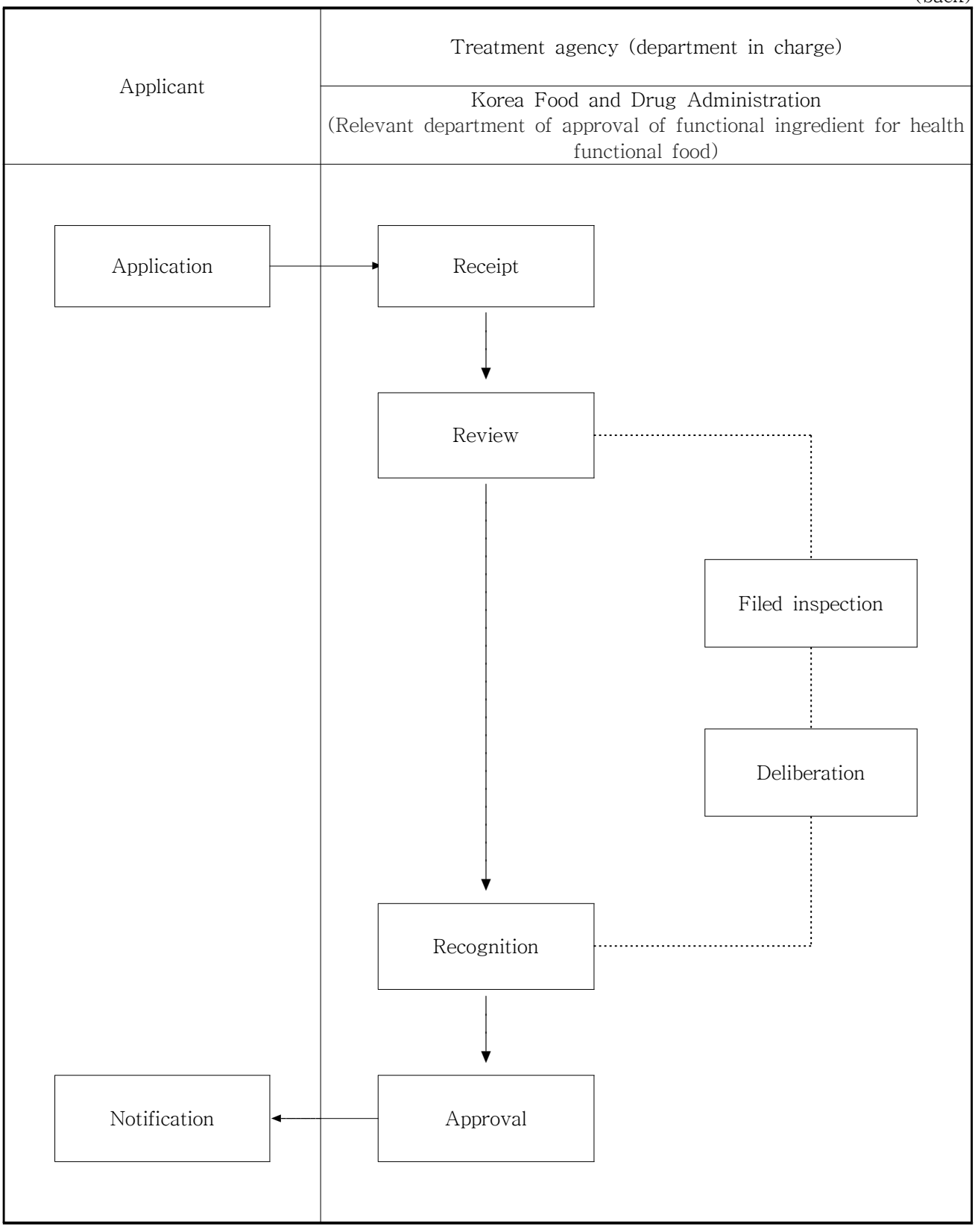
<table>
<tr><td colspan="6">Approval Application of Functional Ingredient for Health Functional Food</td><td>Treatment period
120 days</td></tr>
<tr><td rowspan="8">Applicant</td><td colspan="2">Representative</td><td colspan="4"></td></tr>
<tr><td colspan="2" rowspan="2">Name of business establishment</td><td rowspan="2"></td><td rowspan="2">Business permission/ report No.</td><td>Manufacture business</td><td></td></tr>
<tr><td>Import business</td><td></td></tr>
<tr><td colspan="2">Place of business</td><td colspan="4">(Tel) (Fax)</td></tr>
<tr><td rowspan="4">Imported health functional food</td><td>Receipt No.</td><td colspan="4"></td></tr>
<tr><td>Exporting country</td><td colspan="4"></td></tr>
<tr><td>Business establishment of manufacture</td><td colspan="4"></td></tr>
<tr><td>Location of business establishment</td><td colspan="4"></td></tr>
<tr><td colspan="3">Ingredient name</td><td colspan="4"></td></tr>
<tr><td colspan="7">Applying to approval of functional ingredient for health functional food under Article 5 of the Regulation on Approval of Functional Ingredient for Health Functional Food.

Date(YY/MM/DD):
Applicant (Signature)
To the Commissioner of the Food and Drug Administration</td></tr>
<tr><td colspan="6">※ Requisites of submission
1. Two copies of documents (Including an original copy)
2. A CD containing submitting documents
3. Product or test product and the standard of function component (or marker compound)
4. Written result of examination issued by a domestic health functional food examination laboratory</td><td>Fees
100,000 won</td></tr>
<tr><td colspan="7">※ Submission documents
1. Executive summary of whole submitted documents
2. Origin, developing history, approval and use status in domestic or foreign country etc.
3. Manufacturing methods and related documents for such establishment
4. Characteristics of the ingredients
5. Specification on functional component (or marker compound) and data on test method
6. Specification of detrimental substance and related data for test method;
7. Safety
8. Functionality contents and related documents for such establishment
9. Consumption amount, consumption method, warning notice for consumption and related documents for such establishment
10. Confirmation that ingredients are not identical with or similar to medicine</td></tr>
</table>

210㎜×297㎜(regular paper 60g/㎡(Recycle))

This application is processed as below.

(back)



[Annexed the Form 2]

(Front)

Domestic	Import

No:

Certificate of Functional Ingredient for Health Functional Food

Representative :

Name of business establishment :

Place of business :

Ingredient name :

Exporting country :

Name of business establishment in an exporting country :

Place of business establishment in an exporting country :

Approving this as functional ingredient for health functional food under Article 10 of the Regulation on Approval of Functional Ingredient for Health Functional Food.

Date(YY/MM/DD):

The Commissioner of Food and Drug Administration (Signature)

※ Attachment

1. Name of ingredient
2. Manufacturing standards (raw material, manufacturing methods, functional component (or maker compound), notice for manufacturing (specification of detrimental substance, etc.))
3. Requisites of product (functionality contents, daily consumption amount, notice for consumption, etc.)

210㎜×297㎜(Conservation paper 120g/㎡)

(back)

Modification contents		
Date (YY/MM/DD)	Contents	Name/Position of the person in charge(signature)

210㎜×297㎜(Conservation paper 120g/㎡)

[Attachment]

(Approval No.:)

Section		Approval contents
Name of ingredient		
Manufacturing standards	Raw material	
	Manufacturing methods	
	Functional component (or maker compound)	※ Including test methods
	Notice for manufacturing (specification of detrimental substance, etc.)	※ Including test methods
Requisites of product	Functionality contents	
	Daily consumption amount	
	Notice for consumption	
	Etc.	

[Annexed the Form 3]

Application of Modification on Certificate of Functional Ingredient for Health Functional Food					Treatment period
					5days
Applicant	Representative				
	Name of business establishment		Business permission/ report No.	Manufacture business	
				Import business	
	Place of business	(Tel) (Fax)			
Ingredient name					
Approval No.					

Contents of modification

Item of modification	Contents of modification		Reasons for modification
	before	after	

Applying to modification of item mentioned in ‘Certificate of Functional Ingredient for Health Functional Food’ under Article 11 of the Regulation on Approval Functional Ingredient for Health Functional Food.

Date (YY/MM/DD):

Applicant (Signature)

To The Commissioner of Food and Drug Administration

※ Requisites of submission

A copy of ‘Certificate of Functional Ingredient for Health Functional Food’

210㎜×297㎜(regular paper 60g/㎡(recycle))

Regulation Concerning the Ingredients, etc. Not Being Used for Health Functional Food

Enacted by Korea Food & Drug Administration Notification No. 2004-13, Jan. 31, 2004
Amended by Korea Food & Drug Administration Notification No. 2006-38, Aug. 29, 2006

Article 1 (Purpose) The purpose of this regulation is to protect the consumer through ensuring the safety of health functional food, and preventing the confusion with medicines by prescribing the detailed standards and the scope of the ingredients solely used for the medicines and the heath functional food identical or similar to medicines under Article 24(3) of the Health Functional Food Act.

Article 2 (Ingredients not being used for health functional food) (1) Any of the followings cannot be used as the ingredient of health functional food.

1. Ingredients originated from plant

Ingredients	Botanical origin	Synonyms, components, etc.
Gelsemine	Gelsemine sempervirens	-
Pharbitis Seed	Pharbitis nil Choisy	Pharbitidis Semen
Pregnum	Pregnum harmala Linné	-
Datura	*Datura stramonium* Linné *Datura metel* Nees	Datura Leaf, Daturae Folium, Atropine
Hanbury's garcinia	*Garcinia hanburyi* Hooker f.	Gutti
Digitalis	*Digitalis purpurea* Linné	Digitalis leaf Digitalis Folium
Ephedra	*Ephedra sinica* Stapf *Ephedra intermedia* Schrenk et C.A.Meyer	Ephedra Herb Ephedrae Herba Ephedrae Radix
Sacred lily	*Rhodea japonica* Roth	Lobelia Lobeline or its salts
Male fern	*Dryopteris crassirhizoma* Nakai	Aspidium, Crassirhizomae Rhizoma
Pinellia	*Pinellia ternata* Breitenbach	Pinelliae Tuber, Pinellia Tuber
Sinimenium	*Sinomenium acutum* Rehder et Wilson	Sinomenium Stem, Sinomeni Caulis et Rhizoma
Saposhnikovia	*Saposhnikovia divaricata* Schiskin	Saposhnikovia Root, Saposhnikoviae Radix
Dictamnus	*Dictamnus dasycarpus* Turcz	Dictamni Radicis Cortex

Veratrum	*Veratrum nigrum* Linné var. *ussuriense* Loes. fil.	White Hellebore, Veratri Rhizoma
Belladonna	*Atropa belladonna* Linné	Belladonna Root, Belladonnae Radix, Atropine
Ignatia	*Strychnos ignatii* Bergius	Strychni Ignatii Semen
Adonis	*Adonis amurensis* Regel et Radde	
Aconite	*Aconitum carmichaeli* Debeaux	Oriental Aconite) Aconiti Tuber, Pulvis Aconiti Tuberis Purificatum
Henbane leaf	*Hyoscyamus niger* Linné	Hyoscyami Folium
Pomegranate bark	*Punica granatum* Linné	Granate Bark), Granati Cortex
Poke root	*Phytolacca esculenta* Houttuyn	Phytolaccae Radix
Strophanthus	*Strophanthus kombe* Oliver	Strophanthus Seed, Strophanthi Semen
Opium	*Papaver somniferum* L.	Papaveris semen
Jalapa	*Ipomoea purga* Hayne	Jalapa Root, Jalapae Tuber
Lily of the valley	*Convallaria keiskei* Miquel	Lily of valley herb, Convallariae Herba
Rauwolfia	*Rauwolfia serpentina* Bentham	Rauwolfia Lindians Snake Root, Rauwolfia Radix Ajmaline(Rauwolfine) or its salts
Tree of heaven bark	*Ailanthus altissima* Swingle	Ailanthi radicis Cortex
Kava kava	Piper methysticum	–
Ipecac	*Uragoga ipecacuanha* Baillon	Ipecacuanhae Radix
Tubocurarine	Chondrodendron tomentosum	Pareira
Croton	*Croton Tiglium* Linné	Tiglium Seed, Tiglii Semen
Squill	*Urginea scilla* Steinheil	Scillae Bulbus
Nux Vomica	*Strychnos nux-vomica* Linné	Strychni Semen Brucine or its salts Strychnin or its salts

2. Ingredients originated from animals

Ingredients	Remarks
Dried thyroid	
Bile & gall bladder	
Ergot	
Blister beetle	Cantharides, Cantharis
Snake venom	
Human placenta	
Human blood)	
Musk	Moschus
Toad Venom	Bufonis Venenum

3. Isolated compound, etc.

Ingredients
Galanthamine or its salts
Neostigmine or its salts
Nicotine or its salts
Lobeline or its salts
Bulbocapnine or its salts
Brucine or its salts
Vinblastin or its salts
Vincristin or its salts
Sabina oil
Cepharanthin
Strychnin or its salts
Sparteine or its salts
Agaritine or its salts
Arecoline or its salts
Ajmaline or its salts
Atropine
Apomorphine or its salts
Yohimbine or its salts
Usnic acid or its salts
Kainic acid
Calcitonin
Cotarnine or its salts

Colchicine or its salts
Tropacocaine or its salts
Papaverine or its salts
Physostigmine or its salts
Pilocarpine
Homatropine or its salts
Volatile mustard oil
Hydrastine or its salts
Hyoscyamine

4. Miscellaneous

Ingredients	Remarks
Narcotics	Dihydrocodeine, Morphine, Thebaine Ethylmorphine, Ecgonine, Codeine, etc.
Radioactive substance	
Vaccines	
Antibiotics	Items approved as the medicines
Hormones	Items approved as the medicines

(2) Among ingredients not listed in paragraph (1), any of the followings cannot be used as the ingredient of health functional food.

1. Being necessary for expert knowledge of consumption method or amount;
2. Being recognized to possess severe toxicity or side-effect due to the characteristics of ingredient; or
3. Having risk to structure and function of human body.

Article 3 (Heath functional food identical or similar to medicines) (1) Any of the followings is identical to medicine, therefore they cannot be recognized as health functional food:

1. Ingredient and its amounts identical to the items (including the modified recipe added or subtracted under basis of Korean oriental medicine book concerned) recorded in the existing Korean oriental medicine books (*Bangyakhapyon, Dongeuibogam, Hyangyakzipsungbang, Gwangzebikeup, Jejungshinpyon, Yaksungga, Sasangeuiyak, Euiyayipmun, Gyongakjeonseo, Susebowon* and *Bonchogangmok,)* approved by "Interium provision on the existing Korean oriental medicine book" established by the Ministry of Health and Welfare, and the guide book on the preparation of Korean oriental medicine approved by "regulation on the items of Korean oriental medicinal recipe and its preparation methods publicly announced by the Ministry of Health and Welfare". Provided, That if the recipe is constituted with three or less ingredients, items of this recipe shall be excluded.
2. Ingredients approved to as the medicine (Provided, in the case of concerned crude drugs,

identical each other with manufacturing method, dosage and usage). Provided that, when the medicinal ingredients is intended to select for health functional food, it may possibly used for health functional food through the consultation with concerning officer about the validity.

(2) Any of the followings is similar to medicine, therefore they cannot be recognized as health functional food:

1. The kind of ingredient (including water or ethanol extracts) identical to the items (including the modified recipe added or subtracted under basis of Korean oriental medicine book concerned) recorded in the existing Korean oriental medicine books and the guide book on the preparation of Korean oriental medicine. Provided, That if the recipe is constituted with three or less ingredients, items of this recipe shall be excluded.

ADDENDA

Article 1 (Enforcement Date) This notification shall enter into force on the date of its announcement.

Article 2 (Transitional measures) Ingredients approved as the health functional food ingredients before enforcement of this notification shall be except.

Regulation on Using the Manufacturing Facilities of Medicine for Health Functional Food

Enacted by Korea Food & Drug Administration Notification No. 2005-55, Oct. 10, 2005
Amended by Korea Food & Drug Administration Notification No. 2007-39, Jun. 19, 2007

Article 1 (Purpose) The purpose of this Regulation is to establish necessary detailed procedure and standards of using the manufacturing facilities of medicine for Health Functional Food under Article 4 of the Health Functional Food Act and Article 2 of the Enforcement Rule of the Act, annexed the Table 1,1,h(4).

Article 2 (Standard for approval) The approval condition requirement of using the manufacturing facilities of medicine for health functional food shall be as follows:

1. Health functional food to be manufactured in the intended manufacturing facility of medicine shall not be contaminated with the medicinal component manufactured in the same facility;
2. Manufacturing facilities used for the production of biological agents, antibacterial, antifungal agent, sex hormone drugs, narcotic drugs, radiopharmaceuticals, injection, ointment and such shall not be used for the production of health functional food; and
3. The management standards (including Cleaning Validation method) of cleaning or sanitation, etc. for the machinery or equipments, etc. shall be established and operated to prevent cross-contamination between health functional food and medicine.

Article 3 (Approval Procedure) (1) Any person who intends to manufacture health functional food with medicine manufacturing facilities shall submit the Commissioner of the Food and Drug Administration. an approval application form, annexed the Form 1, along with the documents according to the following subparagraphs :

1. A copy of medicine item manufacturing permission or report certificate;
2. Type and a manufacturing method document of health functional food which intends to manufacture;
3. Draw of lay out (list of medicine manufacturing facilities intended to use); and
4. Standard Operating Procedure to prevent cross-contamination between health functional food and medicine in accordance with the provisions of Article 2(3).

(2) Upon receipt of an approval application referred to in paragraph (1), after examination of the documents and on-site verifications etc., the Commissioner of the Food and Drug Administration shall notify the results to the applicant within 30 days. When approval is determined, the Commissioner of the Food and Drug Administration may request consulting to expert.

(3) When Any person who received the approval under paragraph(2) applies the manufacture business permission as referred to in Article 5 of the Health Functional Food Act and Article 3 of the Enforcement Rule of the Health Functional Food Act , he or she shall submit the documents with the approval notice according to the paragraph (2).

Article 4 (Follow-up management etc.) (1) Whenever the business person intends to manufacture the Health Functional Food by using the medicine manufacturing facilities according to Article 4 , he or she shall keep and maintain records under Article 11, subparagraph 1(a) of the Good Manufacturing Practice for three years.

(2) A business person under Article(1) shall examine the contamination of Health Functional Food with medicine whenever Health Functional Food is manufactured through medicine manufacturing facilities and shall maintain the records for three years.

(3) The records of cleaning or sanitation and the prevention of the cross-contamination operated by Standard Operating Procedure under Article 3(1)4 shall be maintained for three years.

Article 5 (Investigation) The Commissioner of the Food and Drug Administration have the Commissioner of the Regional Food and Drug Administration inspect the compliance by this article more than once per one year and report the results to the Commissioner of the Food and Drug Administration.

ADDENDUM

(Enforcement date) This Notification shall enter into force on the date of its announcement.

[Annexed the Form 1]

(front)

Application on Using the Medicine Manufacturing Facilities for Health Functional Food Production	Treatment periods
	30days

Applicant	Name of business	(Tel :)
	Place of work	

☐ The medicine manufacturing facilities which intend to use

○ Machineries ○ Apparatuses ○ Dressing room and cleaning room

○ Warehouse etc. and storage facilities

The permission number of manufacture business		The date of permission		
Manufacturing item	Year	Product name	Main ingredients	Type(shape)	Usage

☐ Health Functional Food which intend to manufacture

Product name	Type of product	Main ingredients or composition	Type(shape)	others

I apply this form under Article 4(1)4 in order to use the medicine manufacturing facilities for Health Functional Food production.

Date(YY/MM/DD):

Applicant(representative) (signature)

To the Commissioner of the Food and Drug Administration

※ Documents required

1. A copy of medicine item manufacturing permission or report certificate;
2. Type and instruction of manufacturing method of health functional food which intends to manufacture;
3. The arrangement plan of medicine manufacturing facilities(including facilities which intend to be used for Health Functional Food production)
4. The Standard Operating Procedures to prevent cross-contamination between Health Functional Food and medicine

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

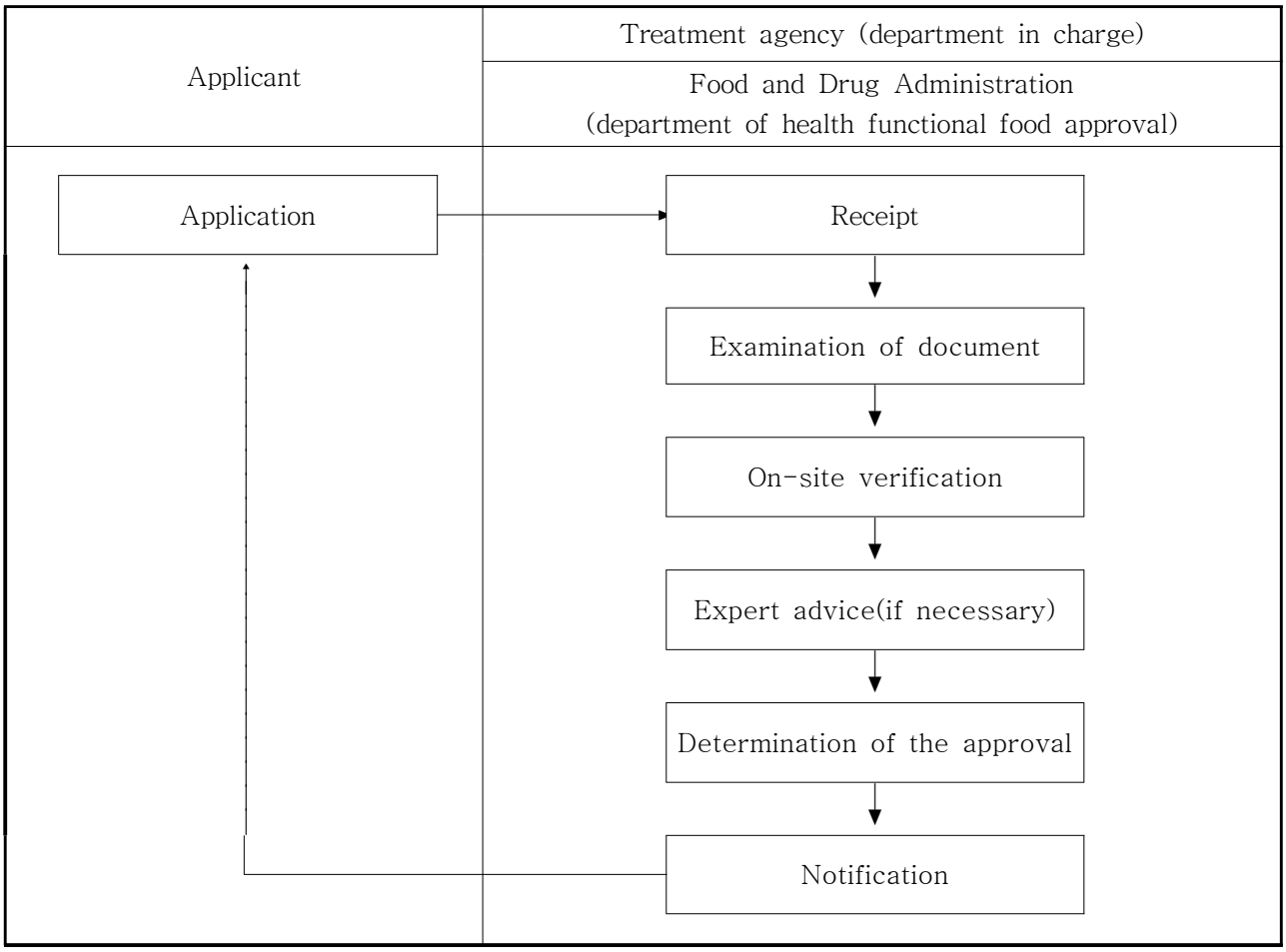
(back)

※ Notice

○ Where Health Functional Food is manufactured and processed through medicine manufacturing facilities without approval, if it is contaminated with biological agent, antibacterial, antifungal agents, sex hormone drugs, narcotic drugs etc., shall be punished the administrative sanction on revocation of business permission, closure order and the disposition of such product because of the violation of Article 23. And under Article 43 of the Act, the violator shall be punished by imprisonment for not more than seven years or by a fine of not more than one hundred million won or by both such fine and imprisonment.

○ If the Health Functional Food is manufactured with ingredients not being used for health functional food, even if the manufacturing facilities of medicine is approved, under Article 44 of the Act the health functional food manufacturer shall be punished by imprisonment for not more than five years or by a fine not more than fifty million won or by both such fine and imprisonment because of the violation of Article 24 of the Act.

This application is processed as below:



[Annexed the Form 2]

Written Investigation of facilities

☐ Establishment subject to investigation			
Name of business establishment		Representative	
Place	(Tel:)		
Medicine manufacture permission No.		Item permission (report) No.	

☐ Medicine/ Component of ingredient of Health Functional Food

○ Medicine

Name of product	Usage:	Amount	Date of item permission (report)	
Purpose of compound	Name of ingredient	Specification	Amount of permission	Reference

○ Health Functional Food

Name of product	Type of product	Amount	Date of item manufacturing report

<the component combination ratio>

☐ Instruction of manufacturing method

Medicine	Health Functional Food	Examination

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

☐ Check the facilities etc. for prevention of cross-contamination

Classification	Contents of evaluation	Result of evaluation
Prevention standard of cross-contamination	○ Cleaning and sterilization standard of machinery and instrument - property of cleaning method - property of sterilization, washing agent use - property of disinfection agent ○ Standard of Cleaning Validation - property of facilities subject - standard cleaning method · property of cleaning method of manufacture tank · property of cleaning method of plugger · property of condition of CIP establishment · property of cleaning method of another manufacture facilities, etc. - property of sampling for identity test of cross-contamination - property of test item - property of test contents and standard of judgement - Index for identity of cross-contamination · identity of particular component · property of selection of washing agent etc. and index	
Property of inter-operating facilities	○ Work place - preparation room · weighing room - manufacture room · extraction and concentration room · purification and sterilization room · mixture room · grinding room · granule room · forming room · extrusion room - dressing room - others work place · pitting room · others	

Classification	Contents of evaluation	Result of evaluation
Property of inter-operating facilities	○ property of warehouse etc. and storage facilities - ingredient, material warehouse and product storage etc. ※ ingredient, material warehouse, half-finished, finished, returned warehouse shall be separated (by wall, floor, room etc.) or divided (by partition, curtain etc.) or classified (by line etc.). ○ other matters - production power of manufacture facilities - production result for a recent one year by items - property of regulation related with other health functional food Act etc.	

☐ Final opinion

200 . .

Investigator: (seal)

Investigator: (seal)

To the Commissioner of the Regional Food and Drug Administration, head of the National Quarantine Service