MEDICAL DEVICES ACT


식품의약품안전처 (의료기기정책과) 043-230-0415

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CHAPTER I  GENERAL PROVISIONS

Article 1 (Purpose)
The purpose of this Act is to promote the efficient management of medical devices and further contribute to the improvement of national health by providing for matters concerning the manufacturing, importation, distribution, etc. of medical devices.

Article 2 (Definitions) (1) The term "medical device" in this Act means an instrument, machine, device, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals: Provided, That the drugs and quasi-drugs under the Pharmaceutical Affairs Act and the prosthetic limbs and aids among assistive devices for persons with disabilities under Article 65 of the Act on Welfare of Persons with Disabilities shall be excluded herefrom:
1. A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease;
2. A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment;
3. A product used for the purpose of testing, replacing, or transforming a structure or function;
4. A product used for birth control.
(2) The term "technical document" in this Act means a document containing data about functions, safety, and quality of a medical device, including raw materials and the structure of the item, the purposes of use, the method of use, the action mechanism, directions for use, and test specifications.
(3) The term "medical device handler" in this Act means any of the following persons who have obtained a license or have filed a report pursuant to this Act with regard to their businesses of handling medical devices, or a person who opens a medical institution under the Medical Service Act, or a person who opens a veterinary
hospital under the Veterinarians Act:
1. A manufacturer of medical devices;
2. An importer of medical devices;
3. A repairer of medical devices;
4. A distributor of medical devices;
5. A lessor of medical devices.

Article 3 (Classification and Designation of Grades) (1) In order to ensure systematic and reasonable safety control of medical devices in conformity with purposes of use of each medical device and differences in potential risks to human bodies while in use, the Minister of Food and Drug Safety shall classify and designate the grade of each medical device. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Matters necessary for the standards and procedures for the classification and designation of the grade of each medical device under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 4 (Relationship with other Acts)
Notwithstanding the provisions of this Act, the installation and operation of radiation-emitting equipment for diagnosis and special medical treatment equipment shall be governed by Articles 37 and 38 of the Medical Service Act and Articles 17-3 and 17-4 of the Veterinarians Act.

CHAPTER II  MEDICAL DEVICES COMMITTEE

Article 5 (Medical Devices Committee) (1) A Medical Devices Committee shall be established within the Ministry of Food and Drug Safety to investigate and deliberate on the following in response to a request from the Minister of Health and Welfare or the Minister of Food and Drug Safety: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Matters concerning standard specifications of medical devices;
2. Matters concerning the re-examination and re-evaluation of medical devices;
3. Matters concerning medical devices subject to tracking and control;
4. Matters concerning the classification and designation of grades of medical devices;
5. Matters concerning the certification of medical devices and the scope of reporting thereon to be entrusted;
6. Other important matters concerning medical devices.

(2) The organization and operation of the Medical Devices Committee, and necessary matters shall be prescribed by Presidential Decree.

CHAPTER III  MANUFACTURING, ETC. OF MEDICAL DEVICES

SECTION 1 Manufacturing Business

Article 6 (Licenses, etc. to Engage in Manufacturing Business) (1) A person who intends to engage in the business of manufacturing medical devices shall obtain a manufacturing business license from the Minister of Food and Drug Safety: Provided, That none of the following persons is eligible for such manufacturing business license: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. A mentally ill person as defined in subparagraph 1 of Article 3 of the Mental Health Act: Provided, That the foregoing shall not apply to a person deemed by a medical specialized competent to engage in the manufacturing business;
2. A person declared incompetent, quasi- incompetent, or bankrupt and not yet reinstated;
3. A person addicted to narcotics or any other noxious substance;
4. A person for whom a sentence of imprisonment without labor or heavier punishment declared by a court for a violation of this Act has not been fully executed or exempted;
5. A person in whose case one year has not passed since his/her manufacturing business license was revoked for a violation of this Act.

(2) A person who has obtained a manufacturing business license under the main sentence of paragraph (1) (hereinafter referred to as "manufacturer") shall obtain a manufacturing license, certification for manufacturing, or file a manufacturing report as follows with respect to medical devices he/she intends to manufacture: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. For medical devices designated and publicly notified by the Minister of Food and Drug Safety and unlikely to pose any risk to human safety and health even upon
occurrence of a failure or malfunction because of marginal potential risk to human health: A manufacturing license, certification for manufacturing, or a manufacturing report by item category;

2. For any medical device, other than those falling under subparagraph 1: A manufacturing license, certification for manufacturing, or a manufacturing report by type of item.

(3) When a person files an application for a manufacturing license under the main sentence of paragraph (1), he/she shall file an application for a manufacturing license or certification for manufacturing at least one item, or file a manufacturing report of at least one item, under any of the subparagraphs of paragraph (2).<Amended by Act No. 13116, Jan. 28, 2015>

(4) A person who intends to obtain a manufacturing license pursuant to paragraph (1) or person who intends to obtain a manufacturing license or certification for manufacturing, or file a manufacturing report pursuant to paragraph (2) shall be equipped with necessary facilities and manufacturing and quality control systems before filing an application for such license or certification, or filing a report, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases prescribed by Ordinance of the Prime Minister, such as entrusting testing for quality control or manufacturing process to a third person.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) A manufacturer who intends to obtain a manufacturing license or certification for manufacturing, or to file a manufacturing report pursuant to paragraph (2) shall submit necessary data, such as data on manufacturing and quality control systems, technical documents, and clinical test data, to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(6) If permission to engage in the manufacture and sale of items has already been granted or a report on items to be manufactured for sale has already been filed pursuant to Article 31 (2) of the Pharmaceutical Affairs Act for a compounded, or combination of a drug or quasi- drug and a medical device because its main function is equivalent to that of a drug or quasi- drug, a manufacturing license or certification for manufacturing shall be deemed granted or a manufacturing report shall be deemed filed pursuant to paragraph (2).<Amended by Act No. 13116, Jan. 28, 2015>
(7) Any person who intends to obtain a manufacturing business license pursuant to paragraph (1) shall employ a quality manager to conduct affairs provided for in Article 6-2 (1), as prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 12392, Jan. 28, 2014>

(8) Items subject to, procedures, standards, and conditions for, and the management of manufacturing business licenses under the main sentence of paragraph (1) and manufacturing licenses, certification for manufacturing, or manufacturing reports under paragraph (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015>

[Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 6 (4) and (5).

Article 6-2 (Matters to Be Observed, etc. by Quality Managers) (1) A quality manager (hereinafter referred to as "quality manager") under Article 6 (7) shall conduct affairs concerning the direction and supervision of employees engaged in manufacturing of medical devices, manufacturing management, quality control, and safety control (including safety control to deal with possible side effects, etc. after the launch of medical devices; hereinafter in this Article the same shall apply).
(2) A quality manager shall receive regular education on the latest standards and specifications for medical devices, quality control, and safety control at least once a year.
(3) Where necessary to prevent harm to people's health, the Minister of Food and Drug Safety may order a quality manager to undergo further education in addition to education already being provided regularly under paragraph (2) at least once a year.
(4) In addition to matters prescribed by paragraphs (1) through (3), necessary matters concerning the scope of duties, the content, hours, methods and procedures of education, educational expenses, designation of an institution offering education, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 12392, Jan. 28, 2014]

Article 6-3 (Restrictions on Manufacturing Licenses, etc.) (1) None of the following medical devices is eligible for a manufacturing license, certification for manufacturing, nor a manufacturing report:
1. A medical device, the use, operation mechanism, raw materials, etc. of which are the same as any medical device, a license to manufacture which was revoked pursuant to Article 36 (1) and one year has not passed from the date of revocation;
2. A medical device containing or made using raw materials recognized by the Minister of Food and Drug Safety as having safety and efficacy defects, and in direct or indirect contact with the human body;
3. A medical device designated by the Minister of Food and Drug Safety, which uses or contains raw materials that may infect people with diseases that could pose a risk to national health, such as bovine spongiform encephalopathy, and is in direct or indirect contact with the human body;
4. Other medical devices not in compliance with standards for manufacturing licenses, certification for manufacturing of, or manufacturing reports on medical devices established and announced by the Minister of Food and Drug safety.

(2) No medical device that includes any of the following in its name is eligible for a manufacturing license, certification for manufacturing, or a manufacturing report:
1. A name unsuitable for a medical device, or a name that could be mistaken for another product, or an exaggerated name;
2. A name that indicates a disease for which the relevant medical device is efficacious, efficacy or effect of a medical device;
3. Other names not in compliance with standards established and announced by the Minister of Food and Drug Safety, which correspond to subparagraphs 1 and 2.

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 7 (Conditional Licenses, etc.) (1) The Minister of Food and Drug Safety may grant a manufacturing business license, a manufacturing license, or certification for manufacturing, or receive a manufacturing report on condition that an applicant or reporter be equipped with facilities and manufacturing and quality control systems required under Article 6 (4) within a specified period. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) Matters necessary for granting conditional licenses and conditional certification or receiving conditional reports under paragraph (1), and other matters, shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
[Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 7 (1).

Article 8 (Re-Examination of Newly Developed Medical Devices, etc.)  (1) If an item category or item for which a person intends to obtain a manufacturing license pursuant to Article 6 (2) falls under any of the following, the Minister of Food and Drug Safety may grant the manufacturing license upon requiring the person to undergo a re-examination for safety and efficacy of the item category or the item within a specified period after such item category or item is released to the market for sale, and may issue an order to the person to take necessary measures based upon the results of the re-examination: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. A newly-developed medical device essentially different in the operation mechanism, functions, or purposes of use from the item category or item already permitted, certified or reported;
2. A rare medical device designated by the Minister of Food and Drug Safety as a medical device for a disease with a small number of patients in the Republic of Korea and with a particular utility value.

(2) A manufacturer of a medical device subject to re-examination under paragraph (1) shall file an application for re-examination within the period specified by the Minister of Food and Drug Safety, which shall be between four and seven years from the date he/she obtained the manufacturing license of the relevant item category or item. In such cases, such application shall be accompanied by data about the performance of the device while in use, adverse effects, and other data specified by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

(3) The methods and procedures for, and timing of the re-examination under paragraphs (1) and (2), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 9 (Re-Evaluation) (1) If the Minister of Food and Drug Safety deems it necessary to review the safety and efficacy of a medical device for which a manufacturing license or certification for manufacturing has been granted or on which a manufacturing report has been filed pursuant to Article 6 (2), he/she may re-evaluate the medical device, and may issue an order for necessary measures.
based upon the results of the re-evaluation. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) The methods, procedures, and standards for the re-evaluation under paragraph (1), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 10 (Approval of Clinical Test Plans, etc.) (1) A person who intends to conduct a clinical test using a medical device shall prepare a clinical test plan and obtain approval thereof from the Minister of Food and Drug Safety, and the same shall also apply to any revision to the clinical test plan: Provided, That the foregoing shall not apply to clinical tests prescribed by Ordinance of the Prime Minister, such as tests conducted to observe clinical effects of a medical device available in the market according to the terms and conditions of permission. <Amended by Act No. 11690, Mar. 23, 2013>

(2) A person who intends to manufacture or import a medical device for clinical tests approved under paragraph (1) shall manufacture it in manufacturing facilities that meet the standards prescribed by Ordinance of the Prime Minister or import one manufactured in facilities meeting such standards. In such cases, a medical device may be manufactured or imported without obtaining a license or certification, or filing a report, notwithstanding Article 6 (2) or 15 (2).<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(3) The Minister of Food and Drug Safety may designate a medical institution equipped with facilities, human resources, and equipment necessary for conducting clinical tests, as a clinical testing institution, from among the medical institutions established under the Medical Service Act.<Amended by Act No. 11690, Mar. 23, 2013>

(4) Anyone who intends to conduct a clinical test under paragraph (1) shall comply with the following:<Amended by Act No. 11690, Mar. 23, 2013>

1. Conduct a clinical test in a clinical testing institution designated under paragraph (3);

2. Not select any person admitted into a collective facility, such as a social welfare facility, prescribed by Ordinance of the Prime Minister (hereafter referred to as "admitted person" in this subparagraph) as the subject of a clinical test: Provided, That an admitted person may be selected as the subject of a clinical test, if it is
unavoidable, by the nature of a clinical test, to select the admitted person as the subject of the clinical test and the standards prescribed by Ordinance of the Prime Minister are met;

3. Explain to the subject of a clinical test the details of the test, potential harms that could affect the health of the subject during the clinical test, the details of compensation for such harms, the procedures for compensation, and other relevant matters, and obtain consent from the subject.

(5) When a clinical testing institution designated under paragraph (3) has conducted a clinical test, it shall prepare and issue a report on the results of the clinical test, retain the records of the test, and comply with other matters prescribed by the Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

(6) Where the Minister of Food and Drug Safety deems that a clinical test referred to in paragraph (1) poses, or is likely to pose, a serious risk to national health and hygiene, he/she may change or cancel the clinical test or take other necessary measures.<Amended by Act No. 11690, Mar. 23, 2013>

(7) Except as otherwise expressly provided for in paragraphs (1) through (5), matters that shall be included in a clinical test plan, matters requiring consent from a person subject to a clinical test, and the timing and method of obtaining such consent, the standards for the conduct of clinical tests, and the standards and procedures for the designation of clinical testing institutions, and other relevant matters shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 11 (Preliminary Examinations of Manufacturing Licenses, Reporting, etc.) (1) A person who intends to obtain a manufacturing license or certification for manufacturing, or file a manufacturing report pursuant to Article 6 (2) or a person who intends to conduct a clinical test pursuant to Article 10 may request the Minister of Food and Drug Safety to preliminarily examine materials necessary for the license, certification, reporting, approval, etc. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) Upon receipt of a request for examination made under paragraph (1), the Minister of Food and Drug Safety shall conduct the examination and give written notice of the results to the applicant.<Amended by Act No. 11690, Mar. 23, 2013>
(3) The Minister of Food and Drug Safety shall consider the results of the examination under paragraph (2) when granting a license or certification, receiving a report under Article 6 (2), or granting approval, etc. Article 10.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(4) Subject matter and scope of the preliminary examination under paragraph (1), the procedure and method thereof, and other relevant matters shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 12 (Revised Licenses, etc.) (1) Where any change, such as a location, occurs in any fact stated on a license or certification already granted or a report already filed pursuant to the main sentence of Article 6 (1), Article 6 (2) or (5), a manufacturer shall obtain a revised license or certification from, or file a revised report to the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015>

(2) Procedures and standards for applying for revised licenses or revised certification, or filing revised reports under paragraph (1), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

Article 13 (Obligations of Manufacturers) (1) A manufacturer shall maintain facilities and manufacturing and quality control systems under Article 6 (4), and shall comply with other matters prescribed by Ordinance of the Prime Minister regarding production control, including self-testing. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) A manufacturer shall report to the Minister of Health and Welfare and the Minister of Food and Drug Safety on the results of production of medical devices and other relevant matters, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(3) No manufacturer shall provide money, goods, benefits, labor, entertainment, or any other economic benefit (hereinafter referred to as "economic benefits, etc.") to any medical personnel, founder of a medical institution (including the representative or director of a corporation or any other employee), nor to any employee of a medical institution, with intent to induce such person to adopt or use a medical device or otherwise to promote the sale thereof: Provided, That the foregoing shall not
apply to provision of samples and similar activities, sponsoring academic conferences, supporting clinical tests, holding product presentations, offering discounts under the terms and conditions of payment, conducting post-marketing monitoring (hereinafter referred to as "providing samples and similar activities") with economic benefits, etc. within the extent prescribed by Ordinance of the Ministry of Health and Welfare after consulting with the Minister of Food and Drug Safety. 

<Amended by Act No. 11690, Mar. 23, 2013>

(4) No manufacturer shall interfere with affairs of a quality manager; and where the quality manager requests matters necessary to conduct his/her affairs, no manufacturer shall refuse such request without reasonable grounds.<Newly Inserted by Act No. 12392, Jan. 28, 2014>

[Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 13 (1).

**Article 14 (Reporting on Permanent Closure, Temporary Shutdown, etc.)**

When a manufacturer permanently closes or temporarily shuts down his/her factory, resumes the operation of a factory temporarily shut down, or any change occurs in other matters prescribed by Ordinance of the Prime Minister, he/she shall report the fact to the Minister of Food and Drug Safety within 30 days from the date of permanent closure, temporary shutdown, resumption, or change: Provided, That the foregoing shall not apply if the period of temporary shutdown is less than one month. <Amended by Act No. 11690, Mar. 23, 2013>

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**SECTION 2 Importation Business**

**Article 15 (Importation Business License, etc.)**

(1) A person who intends to engage in the business of importing medical devices shall obtain an importation business license from the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

(2) An holder of an importation business license granted under paragraph (1) (hereinafter referred to as "importer") shall obtain an import license or import certification, or file an importation report as follows with regard to medical devices that he/she intends to import:<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan.
28, 2015>

1. For medical devices designated and publicly notified by the Minister of Food and Drug Safety and unlikely to pose any risk to human safety and health even upon occurrence of a failure or malfunction because of marginal potential risk to human health: An import license, import certification, or importation report by item category;

2. For any medical device other than those falling under subparagraph 1: An itemized import license, import certification, or importation report.

(3) When a person files an application for an importation business license pursuant to paragraph (1), he/she shall file an application for the import license or import certification for at least one item, or file an importation report on at least one item under paragraph (2).<Amended by Act No. 13116, Jan. 28, 2015>

(4) A person who intends to obtain an importation business license or import certification pursuant to paragraph (1) or a person who intends to obtain an import license or file an importation report pursuant to paragraph (2) shall be equipped with facilities necessary for conducting quality inspections and manufacturing and quality control systems before applying for such license or certification or file such report, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases prescribed by Ordinance of the Prime Minister, such as entrusting quality control testing to a third person.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) If a license has already been granted or a report has already been filed to import an item pursuant to Article 42 (1) of the Pharmaceutical Affairs Act for a compounded or combination of a drug or quasi- drug and a medical device because its main function is equivalent to that of a drug or a quasi- drug, the relevant import license or import certification shall be deemed already granted or the relevant importation report shall be deemed already filed pursuant to paragraph (2).<Amended by Act No. 13116, Jan. 28, 2015>

(6) The proviso to Article 6 (1), Article 6 (5), (7), and (8), Articles 6- 2, 6- 3, 7 through 9, and 11 through 14 shall apply mutatis mutandis to medical devices imported pursuant to paragraphs (1) through (5) and the importers of such medical devices. In such cases, the term "manufacturing" shall be construed as "import," "manufacturing business license" as "importation business license," "manufacturing
[Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 15 (4).

SECTION 3 Repairing Business

Article 16 (Reporting on Repairing Business) (1) A person who intends to engage in the business of repairing medical devices (hereinafter referred to as "repairer") shall file a report on his/her repairing business with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister: Provided, That it is unnecessary to file a report on repairing business if a person who has obtained a manufacturing license or certification for manufacturing, or has filed a manufacturing report pursuant to Article 6 (2), or who has obtained an import license or import certification, or has filed an importation report pursuant to Article 15 (2) repairs a medical device manufactured or imported by his/her own company. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) A person who intends to file a report on his/her repairing business pursuant to paragraph (1) (including a person who intends to repair medical devices imported by his/her own company under the proviso to the said paragraph) shall be equipped with facilities and a quality control system, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply in cases specified by Ordinance of the Prime Minister, such as entrusting the testing for quality control to a third person. <Amended by Act No. 11690, Mar. 23, 2013>

(3) Items subject to reporting to engage in the repairing business under paragraph (1), standards for, and terms and conditions of accepting reports, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) The proviso to Article 6 (1), and Articles 12 through 14 shall apply mutatis mutandis to reporting under paragraph (1). In such cases, the term "manufacturing" shall be construed as "repairing," "manufacturing business license" as "report on the
repairing business," "production management" as "repairing management," and "manufacturer" as "repairer," respectively.

### SECTION 4 Distribution Business and Leasing Business

**Article 17 (Reporting on Distribution Business)** (1) A person who intends to engage in the business of distributing medical devices (hereinafter referred to as "distributor") or a person who intends to engage in the business of leasing medical devices (hereinafter referred to as "lessor") shall file a report on his/her distribution business or leasing business with the Governor of a Special Self-Governing Province or the head of a Si/Gun/Gu (which shall refer to the head of an autonomous Gu; the same shall apply hereinafter) having jurisdiction over his/her place of business, separately for each place of business, as prescribed by Ordinance of the Prime Minister. 

<Amended by Act No. 11690, Mar. 23, 2013>

(2) In any of the following cases, a person may not be required to file a report under paragraph (1):

<Amended by Act No. 11690, Mar. 23, 2013>

1. Where a manufacturer or importer of medical devices distributes or leases medical devices manufactured or imported by him/her, to a medical device handler;
2. Where a person who has filed the report on his/her distribution business under paragraph (1) engages in a leasing business;
3. Where a person who has established a pharmacy or a drug wholesaler sells or leases medical devices;
4. Where a person sells medical devices for birth control or medical devices used for self-diagnosis in places other than medical institutions, prescribed by the Ordinance of the Prime Minister.

(3) As to the reporting under paragraph (1), Article 6 (1) 2, 4, and 5 and Articles 12 through 14 shall apply mutatis mutandis. In such cases, the term "manufacturing" shall be construed as "distribution or leasing," "manufacturing business license" as "reporting on a distribution business or a leasing business," and "manufacturer" as "distributor or lessor," respectively.

**Article 18 (Obligations of Distributors, etc.)** (1) A person qualified to distribute or lease medical devices pursuant to this Act shall comply with the method of ensuring quality
of medical devices at his/her place of business and other rules for the maintenance of order in distribution, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

(2) No distributor or lessor shall provide any economic benefit, etc. to any medical personnel, person who has established a medical institution (including the representative or director of a corporation and any other employee), nor to any employee of a medical institution, with intent to induce such person to adopt or use a medical device or otherwise to promote the distribution or leasing thereof: Provided, That the foregoing shall not apply to activities such as providing samples with economic benefits, etc., within the extent prescribed by Ordinance of the Ministry of Health and Welfare in consultation with the Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

CHAPTER IV  HANDLING, ETC. OF MEDICAL DEVICES

SECTION 1 Standards

Article 19 (Standard Specifications)

As for a medical device deemed, by the Minister of Food and Drug Safety, requiring standards for the quality of the medical device, the Minister of Food and Drug Safety may establish standard specifications for such medical device, such as the scope of application, the shape or structure, testing specifications, and labeling. <Amended by Act No. 11690, Mar. 23, 2013>

SECTION 2 Labeling and Advertisements

Article 20 (Descriptions on Containers, etc.)

A container or an outer package of a medical device shall bear the following descriptions: Provided, That the foregoing shall not apply to a container or an outer package prescribed by Ordinance of the Prime Minister:<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. The trade name and address of the manufacturer or importer;
2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer);
3. The name of product, the name of model, and the license (certification or report) number;
4. The manufacturing number and the date of manufacturing (the use-by date may be stated in lieu of the date of manufacturing, if the use-by date exists);
5. Weight or packaging unit;
6. A label stating "medical device";
7. A "single-use only" and "do not reuse" label for a single-use medical device.

**Article 21 (Descriptions on Outer Package, etc.)**

If it is impossible to read any description under Article 20, which is written on a container or an outer package of a medical device because it is covered by an outer container or another outer package, the same description shall be also written on the outer container or the other outer package.

**Article 22 (Descriptions of Accompanying Documents)** (1) Documents accompanying a medical device shall describe the following: 

1. The method of, and instructions for, use;
2. Instructions for maintenance and inspections, if maintenance and inspections are required;
3. Matters that the Minister of Food and Drug Safety requires to be described pursuant to Article 19;
4. Other matters prescribed by Ordinance of the Prime Minister.

(2) The accompanying documents under paragraph (1) may be furnished in the form of a diskette, a CD-ROM or other electronic media, or a printed manual.

**Article 23 (Requirements for Descriptions)**

Descriptions specified in Articles 20 through 22 shall be written at a position more noticeable than any other letter, article, picture, or symbol and shall be written accurately in Korean language with easily comprehensible terms, as prescribed by Ordinance of the Prime Minister.

**Article 24 (Prohibition, etc. on Descriptions and Advertisements)** (1) None of the following descriptions shall be indicated or written on a container, an outer package, packing material, or an accompanying document of a medical device:
1. A false or misleading description;
2. Any performance, efficacy, or effect not included in the license or certification granted under Article 6 (2) or the report filed under Article 15 (2);
3. A method or period of use that is likely to cause harm to national health or hygiene.

(2) No one shall include any of the following in advertising a medical device:

<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
1. A false or exaggerated advertisement about the name, method of manufacturing, performance, efficacy, effect, or mechanism of a medical device;
2. An advertisement using an article likely to mislead any person to believe that a medical doctor, a dentist, a doctor of oriental medicine, a veterinarian, or any other person guarantees, endorses, officially recognizes, provides guidance for, or acknowledges the performance, efficacy, or effect of a medical device or that any of such persons are using such a medical device;
3. An advertisement using an article, a photograph, or a symbol that implies the performance, efficacy, or effect of a medical device, or using any other implication;
4. An advertisement with respect to a medical device, using a document or symbol that implies abortion or that is obscene;
5. An advertisement about the name of a medical device or the method of manufacturing, performance, efficacy, or effect of a medical device without a license or certification or inconsistent with matters reported pursuant to Article 6 (2) or 15 (2): Provided, That medical devices falling under the proviso to Article 26 (1) can be advertised in accordance with the procedure, method, and permitted extent determined and publicly notified by the Minister of Food and Drug Safety;
6. An advertisement without the review under Article 25 (1) or with any content inconsistent with the content reviewed.

(3) The scope of labeling, descriptions, and advertisements of medical devices under paragraphs (1) and (2), and other relevant matters shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 25 (Review of Advertisements) (1) A person who intends to advertise a medical device shall undergo a review in advance by the Minister of Food and Drug Safety in accordance with the guidelines, methods, and procedure of review determined by the
Minister of Food and Drug Safety. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The Minister of Food and Drug Safety may entrust an organization specified by Ordinance of the Prime Minister with affairs related to the review under paragraph (1).<Amended by Act No. 11690, Mar. 23, 2013>

SECTION 3 Handling

Article 26 (General Prohibitions) (1) No one shall repair, distribute, lease, provide, or use any unlicensed, uncertified, or unreported medical device as required under Article 6 (2) or 15 (2), nor manufacture, import, repair, store, or display any medical device with intent to distribute, lease, provide, or use such medical device: Provided, That the foregoing shall not apply where a person manufactures, imports, stores, or displays a medical device for the purpose of display in a fair, exhibition, or exposition in accordance with the procedure and method prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(2) No one shall manufacture, import, distribute, or lease any of the following medical devices: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. A medical device inconsistent with the details licensed, certified, or reported under Article 6 (2), 12, or 15 (2) or (6);
2. A medical device entirely or partially unsanitary or a medical device made of any substance contaminated by pathogenic microbes or any spoiled or decomposed substance;
3. An medical device that has caused, or is likely to cause, harm to national health, the destruction, suspension of use, revocation of a license, etc. of which is ordered by the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu pursuant to Articles 34 through 36.

(3) No repairer of any medical device shall alter the performance, structure, rating, external appearance, dimensions, or any other element of a medical device licensed, certified, or reported under Article 6 (2), 12, or 15 (2) or (6) in the course of repairing the medical device. <Amended by Act No. 13116, Jan. 28, 2015>
(4) No person shall alter or remodel a medical device inconsistently with the details stated in the license, certification, or report granted or filed under Article 6 (2), 12, or 15 (2) or (6) in the course of using the medical device: Provided, That the foregoing shall not apply in any of the following cases:<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Where a manufacturer or importer alters or remodels a medical device prescribed by Ordinance of the Prime Minister, he/she has manufactured or imported, as stated in the revised license, certification, or report granted or filed under Article 12 or 15 (6);
2. Where a person alters or remodels a medical device for his/her own convenience, to the extent not affecting the safety and efficacy of the medical device.

(5) No repairer, distributer, or lessor shall repair, distribute, or lease any of the following medical devices, or store or display any such medical device with intent to repair, distribute, or lease:<Amended by Act No. 13116, Jan. 28, 2015>

1. A medical device manufactured, imported, or repaired inconsistently with the details stated in the license, certification, or report granted or filed under Article 6 (2), Article 12, Article 15 (2) or (6), or Article 16 (1);
2. A medical device that violates Article 24 (1).

(6) No founder of a medical institution shall use, for a clinical test, any medical device not approved for the clinical test by the Minister of Food and Drug Safety under Article 10.<Amended by Act No. 11690, Mar. 23, 2013>

(7) No one shall make any indication on an outer package, packing material, or an accompanying document of any appliance other than a medical device, to mislead any person to believe that the appliance has a function, efficacy, or effect similar to that of a medical device, or include any such misleading content in any advertisement, or distribute or lease, or store or display, with intent to distribute or lease, an appliance marked or advertised with such misleading content.

Article 27 (Testing and Inspections) (1) Before the Minister of Food and Drug Safety grants a license or certification or accepts a report pursuant to Article 6 (2), 12, or 15 (2) or (6), or when he/she issues an order to undergo an inspection pursuant to Article 33, he/she may conduct testing or an inspection on the safety, performance, etc. of the relevant medical device. <Amended by Act No. 11690, Mar. 23, 2013; Act No.
(2) The Minister of Food and Drug Safety may require a testing and inspection institution of medical devices designated by the Minister of Food and Drug Safety under Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry to conduct the testing and inspection under paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>

(3) through (5) Deleted.<by Act No. 11985, Jul. 30. 2013>

Article 28 (Designation, etc. of Quality Control Examination Agencies) (1) The Minister of Food and Drug Safety may examine facilities, and manufacturing and quality control systems to verify: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Whether a person who intends to obtain a manufacturing business license under Article 6 (1), and a person who intends to obtain a manufacturing license or certification for manufacturing under Article 6 (2) is equipped with facilities, and manufacturing and quality control systems under the main sentence of Article 6 (4);
2. Whether a manufacturer maintains facilities, and manufacturing and quality control systems as required under Article 13 (1) and fulfills his/her obligations concerning production control;
3. Whether a person who intends to obtain an importation business license under Article 15 (1), and a person who intends to obtain an import license or import certification, or file an importation report under Article 15 (2) is equipped with facilities, and manufacturing and quality control systems required for the factory for imported medical devices under the main sentence of Article 15 (4);
4. Whether an importer maintains facilities, and manufacturing and quality control systems required for the factory for imported medical devices under Article 13 (1) applied mutatis mutandis pursuant to Article 15 (6), and fulfills his/her obligations concerning import management.

(2) The Minister of Food and Drug Safety may designate an agency to conduct examinations of facilities, and manufacturing and quality control systems under paragraph (1) (hereinafter referred to as "quality control examination agency"). <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
(3) An entity who intends to obtain designation as a quality control examination agency pursuant to paragraph (2) shall have experts necessary for conducting examination of facilities, and manufacturing and quality control systems.<Amended by Act No. 13116, Jan. 28, 2015>

(4) In conducting examination of facilities, and manufacturing and quality control systems, a quality control examination agency designated pursuant to paragraph (2) shall observe matters prescribed by Ordinance of the Prime Minister, such as preparing a quality control examination report and submitting it to the Minister of Food and Drug Safety, and keeping the records on quality examinations.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) Except as otherwise expressly provided for in paragraphs (1) through (4), the requirements for designation of quality control examination agencies, procedures and methods for such designation, and other relevant matters, shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013> [Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 28 (1) through (4).

CHAPTER V  CONTROL

Article 29 (Medical Devices subject to Tracking and Control)  (1) If it is necessary to track the location of any of the following medical devices (hereinafter referred to as "medical devices subject to tracking and control") because it is likely to cause a fatal harm due to an adverse effect while in use or a defect, the Minister of Food and Drug Safety may separately designate it as one subject to control: <Amended by Act No. 11690, Mar. 23, 2013>

1. A medical device inserted into the human body for at least one year;
2. A medical device for life support usable in any place other than a medical institution.

(2) Matters necessary for the criteria for the designation and control of medical devices subject to tracking and control under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>
Article 30 (Preparation, Preservation, etc. of Records) (1) Each manufacturer, importer, distributor, lessor, or repairer of medical devices subject to tracking and control (hereafter referred to as "handler" in this Article) shall prepare and retain records containing details of manufacturing, distribution (including purchase), leasing, or repairing of medical devices subject to tracking and control, and each person who has established a medical institution, and each medical doctor, oriental medicine doctor, dentist, or similar person who works for a medical institution, handling medical devices subject to tracking and control (hereafter in this Article referred to as "user"), shall prepare and retain records to make it possible to track patients who use a medical device subject to tracking and control.

(2) No handler or user shall, without justifiable grounds, refuse compliance with an order by the Minister of Food and Drug Safety such as a request for submission of data.<Amended by Act No. 11690, Mar. 23, 2013>

(3) Matters necessary for the preparation and retention of records under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

Article 31 (Control of Adverse Effects) (1) If a medical device handler discovers any case or risk of death or occurrence of a serious adverse effect on human health while in use, he/she shall immediately report such discovery to the Minister of Food and Drug Safety and shall retain the records thereof. <Amended by Act No. 11690, Mar. 23, 2013>

(2) When a manufacturer, an importer, a repairer, a distributor, or a lessor of a medical device (hereinafter referred to as "manufacturer, etc.") becomes aware that the medical device has caused, or is likely to cause, harm to human health due to its poor quality or other relevant factors, he/she shall recall such medical device or take measures necessary for recall without delay. In such cases, a manufacturer or an importer shall establish a recall plan, considering adverse effects on human health and other relevant factors, and report the plan to the Minister of Food and Drug Safety in advance, as prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013>

(3) Upon receipt of a plan for recall of a medical device submitted under the latter part of paragraph (2), the Minister of Food and Drug Safety may order the relevant
manufacturer or importer to announce such plan to the public.<Amended by Act No. 11690, Mar. 23, 2013>

(4) The Minister of Food and Drug Safety shall notify a founder of a medical institution who has used a medical device which has caused or risks the death of people or a serious adverse effect on human health as a result a report he/she has received pursuant to paragraph (1) or the latter part of paragraph (2), of the adverse effect, recall plan, etc. of such medical device.<Newly Inserted by Act No. 13116, Jan. 28, 2015>

(5) A founder of a medical institution in receipt of notification pursuant to paragraph (4) shall notify patients who have received medical treatment using the relevant medical device, of the adverse effect of, recall plan for, etc. the medical device, by a making a visit, mail, telephone, e-mail, or fax. In such cases, a founder of a medical institution shall submit a material evidencing that he/she has notified patients, to the Minister of Food and Drug Safety. <Newly Inserted by Act No. 13116, Jan. 28, 2015>

(6) The Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may fully or partially exempt manufacturers, etc. who have conscientiously recalled the relevant medical device or taken measures necessary therefor under paragraph (2), from administrative dispositions under Article 36, as prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(7) Procedures for, and details of, reporting adverse effects under paragraph (1), guidelines and procedures for, methods of recalls, and matters to be included in recall plans under paragraph (2), and methods of making public announcements under paragraph (3), guidelines and procedures for, and methods of giving notifications under paragraph (4), and details of, procedures for, and methods of notification, and procedures for and methods of submitting evidentiary materials under paragraph (5), and other necessary matters, shall be prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
CHAPTER VI SUPERVISION

Article 32 (Reporting, Inspection, etc.) (1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may, if deemed necessary, require a handler of medical devices to file a necessary report or assign relevant public officials to perform the following acts: <Amended by Act No. 11690, Mar. 23, 2013>

1. Entering a medical institution handling medical devices, a factory, warehouse, store, office, or any other place in which medical devices are handled in the course of business to inspect facilities therein, relevant books, documents, or other objects or asking questions to relevant persons;

2. Collecting medical devices that are suspected to fall under any subparagraph of Article 34 (1) or a minimum quantity of medical devices, as necessary for testing or quality inspection.

(2) A public official who intends to enter a place, conduct an inspection, make an inquiry, or collect a medical device pursuant to paragraph (1), shall carry with him/her an identification document verifying his/her authority and present it to interested persons.

(3) Matters necessary for the extent of the authority and duties of the relevant public officials and their identification documents under paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister after consultation with the Minister of Health and Welfare. <Amended by Act No. 11690, Mar. 23, 2013>

Article 33 (Inspection Orders)

If the Minister of Food and Drug Safety deems that a medical device is likely to cause harm to national health, he/she may order a handler of the medical device to undergo an inspection by a medical device testing and inspection institution designated by the Minister of Food and Drug Safety in accordance with Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>

Article 34 (Orders for Recall, Destruction, Public Announcement, etc.) (1) The Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may order a manufacturer, etc. to recall any of the following
medical devices, to destroy such medical devices or take any other measure in a manner that can prevent any harm to public hygiene, or to announce such fact to the public, depending upon the degree of the harm: <Amended by Act No. 11690, Mar. 23, 2013>

1. A medical device distributed, stored, displayed, manufactured, or imported in violation of Article 26;
2. A medical device deemed likely to cause serious damage to national health or have a fatal effect on national health when used.

(2) If a person to whom an order under paragraph (1) was issued fails to comply with the order or if an urgent measure is required for national health, the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may require relevant public officials to destroy, envelop, or seal the goods at issue or take other necessary measures. In such cases, Article 32 (2) shall apply mutatis mutandis.<Amended by Act No. 11690, Mar. 23, 2013>

(3) Matters necessary for the guidelines and methods for recall, destruction, etc. and the method of public announcement based upon the degree of harm posed by medical devices under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

Article 35 (Orders for Suspension of Use, etc.)
If the findings of an inspection under Article 33 reveals that a medical device used by a person who has established a medical institution or a veterinary hospital is inappropriate or is likely to fall under any subparagraph of Article 34 (1), the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may order the person to suspend the use of, or repair, the medical device, or take other necessary measures.<Amended by Act No. 11690, Mar. 23, 2013>

Article 36 (Revocation of Licenses, etc. and Suspension of Business Activities, etc.)
(1) If any of the following events occurs to a manufacturer, etc., the relevant license or certification may be revoked, the place of business may be closed, the manufacturing, importation, and distribution of the relevant item category or item may be prohibited, or an order to suspend business activities completely or partially for up to a year may be issued, by the Minister of Food and Drug Safety if the person
is a manufacturer, importer, or repairer of the medical device, and by the Governor of a Special Self-Governing Province or the head of a Si/Gun/Gu, if the person is a distributor or a lessor of the medical device: Provided, That the relevant license or certification shall be revoked or the place of business shall be closed, in cases falling under subparagraph 1, 22, or 23: 

-Amended by Act No. 11690, Mar. 23, 2013; Act No. 12107, Aug. 13, 2013; Act No. 13116, Jan. 28, 2015-

1. Where a manufacturer, etc. falls under any subparagraph of Article 6 (1) (limited to where the person falls under Article 6 (1) 2, 4, or 5, if the person is a distributor or a lessor): Provided, That the foregoing shall not apply where an heir has transferred his/her status as a manufacturer, etc. to a third person within six months from the commencement date of inheritance pursuant to Article 47 (2);
2. Where a manufacturer, etc. manufactures or imports a medical device without obtaining a license or certification, or filing a report in violation of Article 6 (2) or 15 (2);
3. Where a manufacturer, etc. fails to be equipped with facilities and manufacturing and quality control systems under the main sentences of Article 6 (4), and Article 15 (4), or facilities and manufacturing and quality control systems under the main sentence of Article 16 (2);
4. Where a manufacturer, etc. fails to fulfill any of the conditions imposed under Article 7 (1);
5. Where a manufacturer, etc. fails to undergo a re-examination or take measures required based on the results of a re-examination in violation of Article 8, or is found, as a result of a re-examination, to have failed to secure safety or efficacy;
6. Where a manufacturer, etc. fails to undergo a re-evaluation or take measures required based on the results of a re-evaluation in violation of Article 9, or is found, as a result of a re-evaluation, to have failed to secure safety or efficacy;
7. Where a manufacturer, etc. manufactures medical devices in a manufacturing facility not in compliance with standards or imports medical devices manufactured in such a facility in violation of Article 10 (2);
8. Where a manufacturer, etc. fails to obtain a revised license or revised certification or file a revised report in violation of Article 12 (1) (including cases to which Article 12 (1) shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));
9. Where a manufacturer, etc. fails to perform any of his/her obligations in relation to manufacturing, quality control, production management, importation management, or repairing management, in violation of Article 13 (1) (including cases to which Article 13 (1) shall apply mutatis mutandis pursuant to Article 15 (6) or 16 (4));
10. Where a manufacturer, etc. provides any economic benefit, etc. in violation of Article 13 (3) (including cases to which Article 13 (3) shall apply mutatis mutandis pursuant to Article 15 (6)) or Article 18 (2);
11. Where a manufacturer, etc. fails to comply with the matters concerning the maintenance of order in distribution, in violation of Article 18 (1);
12. Where a manufacturer, etc. commits a violation in describing any matters under Articles 20 through 23;
13. Where a manufacturer, etc. violates Article 24 (1) or (3) in making an indication or placing a description in a container, an outer package, packing material, or an accompanying document of a medical device;
14. Where a manufacturer, etc. makes an advertisement of a medical device in violation of Article 24 (2) or (3);
15. Where a manufacturer, etc. fails to prepare or retain records or refuses compliance with any order, such as a request for submission of data, in violation of Article 30;
16. Where a manufacturer, etc. fails to report an occurrence of an adverse effect or fails to retain the records of an occurrence of an adverse effect, in violation of Article 31 (1);
17. Where a manufacturer, etc. fails to recall medical devices, fails to take measures necessary for recall or fails to report a recall plan in violation of Article 31 (2), or fails to comply with an order to publicly announce such a recall plan in violation of paragraph (3) of said Article;
18. Where a manufacturer, etc. refuses, interferes with, or evades the entry, inspection, inquiry, or collection by a relevant public official under Article 32 (1);
19. Where a medical device handled by a manufacturer, etc. is found, as a result of an inspection conducted under Article 32 or 33, to have caused, or to be likely to cause, harm to national health;
20. Where a manufacturer, etc. fails to comply with any order issued under Article 33, 34, or 35;
21. Where a manufacturer, etc. manufactures, imports, repairs, sells, or leases a medical device that has caused, or is likely to cause, harm to national health, or a medical device deemed not having the claimed performance capability, efficacy, or effect;
22. Where a manufacturer, etc. has no facility or place of business at the location permitted or reported in accordance with this Act;
23. Where a manufacturer, etc. continues his/her business during a period for which his/her business activities are suspended.

(2) Notwithstanding paragraph (1), if the relevant manufacturer or importer is not culpable for the cause in question in the cases falling under paragraph (1) 5 or 6 and it is deemed that the purpose of the relevant license, certification, or report can be achieved by changing the material or structure, etc. of the medical device, an order for such change only may be issued.<Amended by Act No. 13116, Jan. 28, 2015>

(3) If a person fails to comply with an order for change under paragraph (2), the Minister of Food and Drug Safety may also issue any of the administrative dispositions under paragraph (1).<Amended by Act No. 11690, Mar. 23, 2013>

(4) In cases falling under paragraph (1) 18, the Minister of Health and Welfare may request the Minister of Food and Drug Safety to issue an order revoking the relevant license or certification, closing the place of business, prohibiting the manufacture, importation, or distribution of the item category or the item, or suspending the business activities.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

(5) The criteria for the administrative dispositions under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister.<Newly Inserted by Act No. 11690, Mar. 23, 2013>

[Enforcement Date: Jan. 29, 2016] Matters concerning manufacturing and a quality control system among the amended provisions of Article 36 (1).

**Article 37 (Revocation of Designation, etc.)**

(1) If a clinical testing institution or quality control inspector designated pursuant to Article 10 (3) or 28 (2) falls under any of the following, the Minister of Food and Drug Safety may revoke its designation or issue an order to suspend business activities for a specified period not exceeding six months: Provided, That the designation shall be revoked in cases falling under subparagraph 1, 2, or 5: <Amended by Act No. 11690, Mar. 23, 2013; Act No.11985, Jul. 30,
1. If an institution has obtained designation by fraud or other improper means;
2. If an institution prepares and issues a false report on results of a clinical test or prepares and submits a false report on a quality control review intentionally or by gross negligence;
3. If an institution fails to meet the requirements for designation under Article 10 (3) or 28 (3);
4. If an institution fails to comply with the rules under Article 10 (5) or 28 (4);
5. If an institution continues its business during a period of suspension of business activities.

(2) No institution whose designation has been revoked pursuant to paragraph (1) shall be qualified for another designation within three years from the date of the revocation.

(3) The criteria for the administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

**Article 38 (Imposition of Penalty Surcharges)**

(1) In cases of requiring an order to suspend business activities pursuant to Article 36 (1) or (3), if the disposition to suspend business activities is likely to cause severe inconvenience to users of medical devices or to jeopardize public interest, the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 50 million won in lieu of the suspension of business activities, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Matters necessary for the types of violations punishable by the imposition of a penalty surcharge under paragraph (1), the amount of a penalty surcharge based upon the severity, etc. of the relevant violation, the method of collection and other relevant matters shall be prescribed by Presidential Decree.

(3) If necessary for the collection of a penalty surcharge, the Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may request the head of a competent tax office in writing stating the following details, to furnish him/her with tax information: <Amended by Act No.
11690, Mar. 23, 2013

1. The relevant taxpayer's personal information;
2. Purposes of use;
3. Data about the amount of sales that serves as the basis for the imposition of the penalty surcharge.

(4) If a person obligated to pay a penalty surcharge under paragraph (1) fails to pay it by the deadline for payment, the Minister of Food and Drug Safety, the Governor of the competent Special Self-Governing Province, or the head of the competent Si/Gun/Gu may revoke the imposition of the penalty surcharge under paragraph (1) and then issue a disposition to suspend business activities pursuant to Article 36 (1) or (3) or collect the penalty surcharge in the same manner as delinquent national taxes are collected or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue, as prescribed by Presidential Decree: Provided, That if it is impossible to issue the disposition to suspend business activities pursuant to Article 36 (1) or (3) because of the permanent closure of business, etc. under Article 14, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected, or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue. <Amended by Act No. 11690, Mar. 23, 2013; Act No.11998, Aug. 6, 2013>

(5) Penalty surcharges collected pursuant to paragraphs (1) and (4) shall devolve on the State or local governments to which the competent collecting agency belongs.

Article 39 (Hearings)
The Minister of Food and Drug Safety, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu shall hold a hearing, if he/she intends to issue any of the following administrative dispositions:<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Revoke a license or certification, close a place of business, prohibit manufacturing, importation, or distribution of an item category or an item, or completely or partially suspend business activities under Article 36;
2. Revoke designation under Article 37.

Article 40 (Monitors of Medical Devices) (1) The Ministry of Health and Welfare, the Ministry of Food and Drug Safety, the Special Metropolitan City, each Metropolitan
City, Do, Special Self-Governing Province, and each Si/Gun/Gu (Gu shall mean an autonomous Gu; the same shall apply hereinafter) shall appoint monitors of medical devices for performance of the competent public officials' duties under Articles 32 (1) and 34 (2). <Amended by Act No. 11690, Mar. 23, 2013>

(2) Monitors of medical devices under paragraph (1) shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Special Metropolitan City Mayor, the Metropolitan City Mayor, Do Governor, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu from among public officials under the jurisdiction of the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, the Special Metropolitan City, or a Metropolitan City, Do, Special Self-Governing Province, or Si/Gun/Gu.<Amended by Act No. 11690, Mar. 23, 2013>

(3) Matters necessary for the qualification for monitors of medical devices under paragraphs (1) and (2), the appointment, and the scope of duties of such monitors shall be prescribed by Ordinance of the Prime Minister after consultation with the Minister of Health and Welfare. <Amended by Act No. 11690, Mar. 23, 2013>

CHAPTER VII SUPPLEMENTARY PROVISIONS

Article 41 (Research and Development for Growth of Medical Device Industry)
The Minister of Health and Welfare or the Minister of Food and Drug Safety may entrust the Korea Health Industry Development Institute established under the Korea Health Industry Development Institute Act with research and development projects for the establishment of infrastructure for evaluation of the quality of medical devices, the support for projects for standardization of specifications of medical devices, and other projects for the growth of the medical device industry and may subsidize it for expenses necessary for such activities.<Amended by Act No. 11690, Mar. 23, 2013>

Article 42 (Establishment of Medical Device Information and Technology Assistance Center) (1) The Medical Device Information and Technology Assistance Center (hereinafter referred to the "Center") shall be established to provide comprehensive information and technological assistance regarding trends in newly-developed
medical devices in Korea and overseas and clinical information, and to conduct business affairs related to certification of medical devices. <Amended by Act No. 13116, Jan. 28, 2015>

(2) The Center shall be a corporation.

(3) Except as otherwise expressly provided for in this Act, the provisions of Civil Act governing incorporated foundations shall apply mutatis mutandis to the Center.

(4) The operation of the Center and other relevant matters shall be prescribed by Presidential Decree.

Article 43 (Business Activities of Center) (1) The Center shall conduct the following business activities: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

1. Provide information and technical support regarding medical devices, including research on international specifications for improving technology for medical devices, and gathering, analysis, and management of information from domestic and overseas sources;
2. Support clinical tests to commercialize newly developed medical devices;
3. Education, public relations, and support in regard to information related to the quality control system, such as risk management, and licenses, certification, and reporting;
4. Support the international certification of standard specifications for advanced management of medical devices;
5. Affairs entrusted by the Minister of Food and Drug Safety pursuant to Article 44 (2);
6. Other business activities deemed necessary by the Minister of Food and Drug Safety in relation to provision of information on, and technical support for medical devices.

(2) The Minister of Food and Drug Safety may subsidize the business activities conducted by the Center pursuant to paragraph (1). <Amended by Act No. 11690, Mar. 23, 2013>

Article 43-2 (Revocation of Certification or Reports) (1) Where a medical device certified or reported pursuant to Article 6 (2) or 15 (2) falls under any of the following, the Minister of Food and Drug Safety may revoke the certification or acceptance of a report: Provided, That he/she shall revoke the certification or
acceptance of a report where such medical device falls under subparagraph 1:
1. Where the medical device has been certified or reported by fraudulent or other illegal means;
2. Where a serious defect is discovered in the quality control or performance of the medical device manufactured after it was certified or reported;
3. Where the medical device has caused or is likely to cause harm to national health or is found ineffective.

(2) Procedures and methods for revocation of certification and reports under paragraph (1), and other relevant matters, shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 43-3 (Guidance, Supervision, etc. of Center) (1) Where necessary to supervise the Center, the Minister of Food and Drug Safety may require the Center to file a report or submit data concerning its affairs, or issue other necessary orders, and require subordinate public officials to inspect the books of accounting, documents, etc. of the Center upon accessing to its offices.

(2) Any public official who inspects the books of accounting, documents, etc. upon gaining access pursuant to paragraph (1) shall carry identification indicating his/her authority and present it to interested persons.

(3) The Minister of Food and Drug Safety shall formulate and implement a guidance and supervision plan each year to verify whether the affairs entrusted pursuant to Article 44 (2) are conducted properly, and other relevant matters.

(4) Other matters necessary for the guidance and supervision of the Center shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 44 (Delegation and Entrustment of Authority) (1) The Minister of Food and Drug Safety may delegate part of his/her authority bestowed by this Act to the head of a Regional Ministry of Food and Drug Safety, the Special Metropolitan City Mayor, a Metropolitan City Mayor, a Do Governor, a Special Self-Governing Province Governor, the head of a Si/Gun/Gu, or the head of a public health clinic, as prescribed by Presidential Decree.

<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
(2) The Minister of Food and Drug Safety may entrust affairs concerning the
certification or reporting of medical devices under this Act to the Center, as
prescribed by Ordinance of the Prime Minister. In such cases, he/she shall establish
and announce guidelines for medical devices, the certification or reporting of which
can be entrusted to the Center and the scope of such medical devices among medical
devices which cause marginal potential harm to human health while in use, following
deliberation thereon by the Medical Devices Committee. <Newly Inserted by Act No.
13116, Jan. 28, 2015>

Article 44-2 (Deemed Public Officials for Purposes of Penalty Provisions)
Executives and employees of the Center that perform the affairs entrusted by the
Minister of Food and Drug Safety pursuant to Article 44 (2) shall be deemed public
officials for the purposes of Articles 127 and 129 through 132 of the Criminal Act.
[This Article Newly Inserted by Act No. 13116, Jan. 28, 2015]

Article 45 (Protection of Submitted Data) (1) Where a person who submits data in
accordance with Articles 6 through 10, 11, 12, or 15 makes a written request for
protection of the data, the Minister of Food and Drug Safety shall not disclose the
submitted data: Provided, That such data may be disclosed if the disclosure is
deemed necessary on public interest grounds. <Amended by Act No. 11690, Mar. 23, 2013>
(2) A person who inspects or reviews the submitted data under the protection
requested in accordance with paragraph (1) shall not disclose the content thereof to
the public.

Article 46 (Special Exceptions for Medical Devices for Animals)
Among affairs within the jurisdiction of the Minister of Health and Welfare and the
Minister of Food and Drug Safety under this Act, affairs related to medical devices
exclusively for animals shall fall under the jurisdiction of the Minister of Agriculture,
Food and Rural Affairs, and the term "Minister of Health and Welfare" or "Minister of
Food and Drug Safety" in the relevant provisions of this Act shall be construed as the
"Minister of Agriculture, Food and Rural Affairs" and the term "Ordinance of the Prime Minister" or "Ordinance of the Ministry of Health and Welfare" as "Ordinance of the Ministry of Agriculture, Food and Rural Affairs" respectively. In such cases,
when the Minister of Agriculture, Food and Rural Affairs intends to formulate
Ordinance of the Ministry of Agriculture, Food and Rural Affairs, he/she shall consult with the Minister of Health and Welfare or the Minister of Food and Drug Safety in advance.

[This Article Wholly Amended by Act No. 11690, Mar. 23, 2013]

Article 47 (Succession to Status of Manufacturers, etc.) (1) If a manufacturer, etc. dies or transfers his/her business or a corporate manufacturer, etc. merges with another corporation, the transferee of the business, or the corporation surviving the merger or newly established as a consequence of the merger shall succeed to the status of the manufacturer, etc.: Provided, That the foregoing shall not apply, if the transferee of the business or the corporation surviving the merger or newly established as a consequence of the merger falls under any of the following:
1. If a manufacturer, importer, or repairer falls under any subparagraph of Article 6 (1);
2. If a distributor or lessor falls under Article 6 (1) 2, 4, or 5.
(2) If an heir who succeeds to the status of a manufacturer, etc. pursuant to paragraph (1) falls under any subparagraph of paragraph (1), he/she shall transfer the business to any third person within six months from the commencement date of inheritance.
(3) If a manufacturer or an importer transfers his/her business related to medical devices licensed, certified, or reported pursuant to Article 6 (2) or (6) or Article 15 (2) or (5), the manufacturer or importer who acquires the business shall succeed to the status of the manufacturer or importer with respect to the license or certification for, or reporting on, the relevant item category or item. <Amended by Act No. 13116, Jan. 28, 2015>

Article 48 (Transfer of Effects of Administrative Sanctions)
If a person succeeds to the status of a manufacturer, etc. in accordance with Article 47, the effects of an administrative dispositions made against the former manufacturer, etc. shall be transferred to the transferee or the corporation surviving a merger or newly established as a consequence of a merger and shall remain effective for one year from the day on which the disposition was made, while if proceedings of an administrative disposition are pending, the proceedings of the administrative sanction may continue against the transferee, the corporation
surviving the merger, or the corporation newly established as a consequence of the merger: Provided, That the foregoing shall not apply if a new manufacturer, etc. is not aware of such a disposition or a violation when he/she succeeds to the business (excluding the succession to the status by inheritance).

**Article 49 (Renewal of Licenses, Reports, etc.)**

A manufacturer, etc. shall obtain renewal of his/her license, certificate, or written acceptance of a report, as prescribed by Ordinance of the Prime Minister.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>

**Article 50 (Fees)**

Any of the following persons shall pay fees, as prescribed by Ordinance of the Prime Minister: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 13116, Jan. 28, 2015>
1. A person who intends to obtain a license or certification, or file a report pursuant to this Act;
2. A person who intends to revise matters licensed, certified or reported pursuant to this Act.
3. A person who intends to undergo an examination of technical documents or safety and efficacy or a re-examination of a newly developed medical device, etc. pursuant to this Act;
4. A person who intends to undergo a preliminary examination pursuant to Article 11;
5. A person who intends to undergo a review on an advertisement of a medical device pursuant to Article 25.

**CHAPTER VIII PENALTY PROVISIONS**

**Article 51 (Penalty Provisions)** (1) A person who violates Article 26 (1) shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 20 million won.
(2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.
Article 52 (Penalty Provisions) (1) A person falling under either of the following shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding ten million won:

1. A person who violates Article 10 (1), the former part of Article 10 (2), Article 10 (4), Article 12 (1) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6) or 16 (4)), Article 13 (1), the main sentence of Article 16 (1), Article 17 (1), Article 24 (1) and (2), Article 26 (2) through (7), and Article 45 (2);

2. A person who refuses, interferes with, or evade activities conducted by a competent public official to destroy, envelop, or seal a medical device or take any other measures pursuant to Article 34 (2).

(2) Imprisonment with labor and a fine under paragraph (1) may be imposed concurrently.

Article 53 (Penalty Provisions)

A person who violates Article 13 (3) (including cases to which the said paragraph of the said Article shall apply mutatis mutandis pursuant to Article 15 (6)) or Article 18 (2) shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 30 million won.

Article 54 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding five million won: <Amended by Act No. 13116, Jan. 28, 2015>

1. A person who violates Article 18 (1), Articles 20 through 23, Article 30 (1) and (2), or Article 31 (1) or (5);

2. A person who refuses, interferes with, or evades a competent public official's entry, collection, closure, or other dispositions under Article 32 (1) or 36 (1) or (2);

3. A person who violates an order to undergo an inspection, recall, destruction, public announcement, suspension of use, or suspension of business activities under Article 33, 34 (1), 35, or 36 (1) or (2);

4. A person who commits a violation under Article 37 (1) 1, 2, or 5.
Article 54-2 (Penalty Provisions)
A person who violates Article 6 (7) (including where it is applied mutatis mutandis pursuant to Article 15 (6)), 6-2 (1) (including where it is applied mutatis mutandis pursuant to Article 15 (6)) or 13 (4) (including where it is applied mutatis mutandis pursuant to Article 15 (6)) shall be subject to a fine not exceeding three million won.

Article 55 (Joint Penalty Provisions)
If the representative of a corporation or an agent or employee of, or other person employed by a corporation or an individual commits any violations under Articles 51 through 54 in conducting the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violator accordingly, be subject to a fine under the relevant provisions: Provided, That this shall not apply where such corporation or individual has not been negligent in exercising due attention and supervision concerning the relevant duties to prevent such violations.

Article 56 (Administrative Fines) (1) Any of the following persons shall be subject to an administrative fine not exceeding one million won: <Amended by Act No. 12392, Jan. 28, 2014; Act No. 13116, Jan. 28, 2015>

1. A person who fails to undergo education, in violation of Article 6-2 (2) (including cases to which Article 6-2 (2) shall apply mutatis mutandis pursuant to Article 15 (6)) or (3) (including cases to which Article 6-2 (3) shall apply mutatis mutandis pursuant to Article 15 (6));
1-2. A person who fails to report the results of production or importation, etc. of medical devices, in violation of Article 13 (2) (including cases to which Article 13 (2) shall apply mutatis mutandis pursuant to Article 15 (6));
2. A person who fails to file a report on permanent closure or temporary shutdown of business, in violation of Article 14 (including cases to which Article 14 shall apply mutatis mutandis pursuant to Article 15 (6), 16 (4), or 17 (3));
3. A person who fails to renew his/her license or certificate, or written acceptance of a report, in violation of Article 49.

(2) Administrative fines prescribed under paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, the Governor of a competent Special Self-Governing Province, or the head of a Si/Gun/Gu, as prescribed by
ADDENDA <No. 11690, 23. Mar, 2013>

Article 1 (Enforcement Date)

(1) This Act shall enter into force on the date of its promulgation.
(2) Among the Acts to be amended in accordance with Article 6 of the Addenda, amendments to Acts promulgated before this Act enters into force but the enforcement date of which has yet to arrive, shall enter into force on the date on which the respective Acts enter into force, and the amended provisions of Article 47 (1) of the Pharmaceutical Affairs Act under Article 6 (477) of the Addenda and of Article 18 (1) of the Medical Appliances Act under Article 6 (481) of the Addenda shall enter into force on the dates prescribed by Presidential Decree concerning the relevant Acts within the scope of one year after this Act enters into force.

Articles 2 through 7 Omitted.

ADDENDA <No. 11998, 06. Aug, 2013>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 and 3 Omitted.


Article 1 (Enforcement Date)

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

Article 2 (Applicability to Suspension of Business Activities)

The amended provisions of Article 36 (1) shall also apply to an administrative disposition against violations committed before this Act enters into force.

ADDENDA <No. 12392, 28. Jan, 2014>

Article 1 (Enforcement Date)
This Act shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Designation of Medical Device Quality Manager)
The amended provisions of Articles 6 (7), 13 (4), and 15 (6) shall apply, beginning with the first person who applies for permission to conduct manufacturing or import business after this Act enters into force.

Article 3 (Transitional Measures concerning Designation of Quality Manager)
A manufacturer or an importer who has obtained permission before this Act enters into force or who has obtained permission pursuant to the former provisions without being governed by the amended provisions of Articles 6 (7), 13 (4), and 15 (6) after this Act enters into force shall be in compliance with the aforesaid amended provisions within two years from the date on which this Act enters into force.

ADDENDA <No. 13116, 28. Jan, 2015>

Article 1 (Enforcement Date)
This Act shall enter into force six months after the date of its promulgation: Provided, That matters related to manufacturing and quality control systems in the amended provisions of Articles 6 (4) and (5), 7 (1), 13 (1), 15 (4), 28 (1) through (4), and 36 (1) shall enter into force one year after the date of their promulgation.

Article 2 (Applicability to Introduction of Certification System)
The amended provisions of Articles 6, 7, 11, 12 and 15 regarding applications for certification and reporting and processing of such applications and report shall apply beginning with the first person who applies for manufacturing certification, import certification, or revised certification, or files a manufacturing report, importation report, or revised report after such amended provisions enter into force.

Article 3 (Applicability to Labeling of Single-Use Medical Devices)
The amended provision of subparagraph 7 of Article 20 shall apply beginning with the first single-use medical device taken out from the factory or bonded area after this Act enters into force.

Article 4 (Transitional Measures concerning Processing of Applications for Certification and Reporting)
Where a person who has obtained a license or revised license of a medical device subject to certification and reporting under the amended provisions of Articles 6, 12,
and 15, or has filed a report or revised report thereon from/to the Minister of Food and Drug Safety pursuant to the former provisions before the aforesaid amended provisions enter into force, the person shall be deemed to have obtained certification or revised certification, or have filed a report or revised report pursuant to this Act.

**Article 5 (Transitional Measures concerning Applications for Licenses, etc.)**

The former provisions shall apply to persons who have applied for a manufacturing business license, a manufacturing license, or an importation business license, or an importation license, or have filed a manufacturing report or an importation report pursuant to the former provisions as at the time this Act enters into force.