COSMETICS ACT

Wholly Amended by Act No. 11014, Aug. 4, 2011 Amended by Act No. 11690, Mar. 23, 2013 Act No. 11985, Jul. 30, 2013 Act No. 12497, Mar. 18, 2014 Act No. 13117, Jan. 28, 2015 Act No. 14027, Feb. 3, 2016 Act No. 14264, May 29, 2016 Act No. 15488, Mar. 13, 2018 Act No. 15947, Dec. 11, 2018 Act No. 16298, Jan. 15, 2019

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to contribute to improving public health and developing the cosmetics industry by prescribing matters concerning the manufacture, importation, sale, exportation, etc. of cosmetics. <*Amended by Act No. 15488, Mar. 13, 2018>*

Article 2 (Definitions)

The terms used in this Act shall be defined as follows: *Amended by Act No. 11690, Mar. 23, 2013; Act No. 14264, May 29, 2016; Act No. 15488, Mar. 13, 2018; Act No. 16298, Jan. 15, 2019>*

1. The term "cosmetic" means any item intended to be used by means of spreading, rubbing, spraying on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or brightening the appearance, or maintaining or improving the health of skin and hair, which have light effects on the human body: Provided, That goods constituting medicines defined in subparagraph 4 of Article 2 of the Pharmaceutical Affairs Act shall be excluded herefrom;

2. The term "functional cosmetic" means any of the following cosmetics prescribed by Ordinance of the Prime Minister:

(a) A product aiding in the whitening of the skin;

(b) A product aiding in improving wrinkles in the skin;

(c) A product aiding in tanning skin gently or protecting skin from ultraviolet rays;

(d) A product aiding in changing or removing the color of hair, or nourishing hair;

(e) A product aiding in preventing or improving dryness, splits, loss, cornification, etc. resulting from weakened functions of skin or hair;

2-2. The term "natural cosmetic" means any cosmetic that contains animals, plants, raw materials, etc. derived therefrom, and complies with the standards prescribed by the Minister of Food and Drug Safety;3. The term "organic cosmetic" means any cosmetic that contains organic materials, plants, animals, materials, etc. derived therefrom, and complies with the standards prescribed by the Minister of Food and Drug Safety;

3-2. The term "custom cosmetic" means any of the following:

(a) A cosmetic made by mixing the contents of a manufactured or imported cosmetic with the contents of any other cosmetic or a raw material prescribed by the Minister of Food and Drug Safety;(b) A cosmetic repackaged by dividing the contents of a manufactured or imported cosmetic into smaller amounts;

4. The term "safe container or packaging" means any container or packaging designed or planned with child-proof lids for children under the age of five;

5. The term "use-by date" means the minimum period from date of manufacture during which consumers can safely use a cosmetic with its unique characteristics preserved in appropriate storage conditions;

6. The term "primary package" means packaging containers which come into direct contact with the contents of cosmetics at the time of manufacturing;

7. The term "secondary package" means one or more packages, protecting materials, and packages for the purpose of labeling (including attached documents, etc.) that encase the primary package;

8. The term "labeling" means letters, numbers, figures, pictures, etc. written on the containers and packages of cosmetics;

9. The term "advertisement" means conduct to display or notify information on cosmetics by means of radio, television, newspapers, magazines, voice, sound, videos, the Internet, printings or billboards, or by other means;

10. The term "cosmetic manufacturing business" means the business of manufacturing (excluding the process of secondary packaging or labeling only) all or part of cosmetics;

11. The term "responsible cosmetic distribution business" means the business of distributing or selling cosmetics, or offering or supplying cosmetics for import agency business while controlling the quality, safety, etc. of such cosmetics;

12. The term "custom cosmetic sales business" means the business of selling custom cosmetics.

Article 2-2 (Types of Business)

(1) The types of business provided in this Act are as follows:

- 1. Cosmetic sales business;
- 2. Responsible cosmetic distribution business;
- 3. Custom cosmetic sales business.

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

CHAPTER II MANUFACTURE AND DISTRIBUTION OF COSMETICS

Article 3 (Registration of Business)

(1) A person who intends to conduct cosmetic manufacturing business or responsible cosmetic distribution business shall register with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. The foregoing shall also apply if any of the important matters prescribed by Ordinance of the Prime Minister with respect to registration information is amended. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018>*

(2) A person who intends to register his/her cosmetic sales business pursuant to paragraph (1) shall meet the facility standards prescribed by Ordinance of the Prime Minister: Provided, That the person need not be equipped with part of the required facilities in cases prescribed by Ordinance of the Prime Minister, such as engaging in only part of cosmetic manufacturing processes. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(3) A person who intends to register his/her responsible cosmetic distribution business pursuant to paragraph (1) shall comply with the standards for quality control and responsible post-sale safety control of cosmetics, which are prescribed by Ordinance of the Prime Minister, and shall employ a manager capable of managing such standards (hereinafter referred to as "responsible distribution manager"). <*Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018*>

(4) Matters necessary for procedures for registration, qualification requirements for and duties of responsible distribution managers, etc. under paragraphs (1) through (3) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

Article 3-2 (Filing Reports on Custom Cosmetic Sales Business)

(1) A person who intends to conduct custom cosmetic sales business shall file a report with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. The foregoing shall also apply if any of the matters prescribed by Ordinance of the Prime Minister with respect to reporting information is amended.

(2) A person who registered his/her custom cosmetic sales business pursuant to paragraph (1) (hereinafter referred to as "custom cosmetic seller") shall employ a person engaged in the mixing and division into smaller amounts of a custom cosmetic (hereinafter referred as "custom cosmetic compounding manager"), as prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15488, Mar. 13, 2018] <<*Enforcement Date: Mar. 14, 2020>>* Article 3-2

Article 3-3 (Grounds for Disqualification)

None of the following persons shall register his/her cosmetic manufacturing business or responsible cosmetic distribution business or file a report on custom cosmetic sales business: Provided, That subparagraphs 1 and 3 shall apply only to cosmetic manufacturing business:

1. A mental patient defined in subparagraph 1 of Article 3 of the Act on the Improvement of Mental Health and the Support for Welfare Services for Mental Patients: Provided, That a person recognized by a specialized medical doctor as appropriate for a cosmetic manufacturer (referring to a person who registered his/her cosmetic manufacturing business pursuant to Article 3 (1); hereinafter the same shall apply) shall be excluded herefrom;

2. A person under adult guardianship or a person declared bankrupt and not yet reinstated;

3. An addict to narcotics defined in subparagraph 1 of Article 2 of the Narcotics Control Act;

4. Aperson for whom his/her imprisonment without labor or heavier punishment declared by a court for a violation of this Act or the Act on Special Measures for the Control of Public Health Crimes was not completely executed or the non-execution of such sentence has not become final;

5. A person for whom one year has not passed from the date his/her registration was revoked or his/her business place was closed under Article 24 (excluding the revocation of registration or the closure of business place because of falling under any of subparagraphs 1 through 3 of this Article).

Article 3-4 (Qualification Test for Custom Cosmetic Compounding Managers)

(1) A person who intends to become a custom cosmetic compounding manager shall pass the qualification test conducted by the Minister of Food and Drug Safety regarding cosmetics and raw materials.

(2) The Minister of Food and Drug Safety shall revoke the qualification of a custom cosmetic compounding manager where such manager passed the test by fraud or other improper means, and a person whose qualification was revoked can not apply for the qualification test for three years from the date of revocation.

(3) The Minister of Food and Drug Safety may designate an agency or organization having professional personnel and facilities required to effectively perform duties related to the qualification test prescribed in paragraph (1), as a testing administration agency to which such duties may be entrusted.

(4) Matters necessary for the qualification examination, such as the schedule, procedure and method for the qualification examination, exam subjects, issuance of a qualification certificate, and designation of

testing administration agencies under paragraphs (1) through (3), shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted by Act No. 15488, Mar. 13, 2018] <<*Enforcement Date: Mar. 14, 2020>>* Article 3-4

Article 4 (Examination of Functional Cosmetics)

(1) A cosmetic manufacturer, responsible cosmetic distributor (referring to a person who registered his/her responsible cosmetic distribution business pursuant to Article 3 (1); hereinafter the same shall apply), or university, research institute, etc. prescribed by Ordinance of the Prime Minister that intends to engage in the sale, etc. of a functional cosmetic recognized shall undergo an examination by the Minister of Food and Drug Safety or shall submit a report to the Minister of Food and Drug Safety for safety and effectiveness of each product. The foregoing shall also apply if any information contained in the report submitted or any matter examined is amended. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018*>

(2) Examinations of effectiveness under paragraph (1) shall be limited to the efficacy and effects provided for in the items of subparagraph 2 of Article 2.

(3) A person who intends to undergo an examination under paragraph (1) shall submit data necessary for such examination to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) Matters necessary for the scope of and procedures, etc. for examinations or submission of reports under paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

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Article 4-2 (Management of Cosmetics Used by Infants or Children)

(1) When a responsible cosmetic distributor intends to label or advertise cosmetics as usable by infants or children, he/she shall prepare and retain the following materials that can prove safety and quality by product (hereinafter referred to as "material on safety by product"):

- 1. Materials explaining about products and manufacturing methods;
- 2. Materials on the evaluation of cosmetics safety;
- 3. Materials evidencing the efficacy and effects of products.

(2) The Minister of Food and Drug Safety shall periodically conduct fact-finding surveys on cosmetics prescribed in paragraph (1) in terms of materials on safety by product, actual status of consumers using cosmetics, cases of experiencing adverse reactions after use, etc., and formulate a plan for the attenuation of hazardous elements.

(3) The Minister of Food and Drug Safety may render education or public relations so as to enable consumers to use cosmetics prescribed in paragraph (1) safely.

(4) Matters necessary for the ages of infants or children, scope of labeling and advertising, scope of preparation and retainment period of materials on safety by product, etc. under paragraph (1), and fact-finding surveys, and the scope of, timing and procedures for formulating plans, etc. under paragraph (2) shall be prescribed by Ordinance of the Prime Minister.

Article 5 (Obligations of Business Operators)

(1) A cosmetic manufacturer shall comply with the requirements prescribed by Ordinance of the Prime Minister with respect to methods for managing records, facilities and equipment related to the manufacture of cosmetics, and methods for and obligation of test, inspection and verification of raw materials, materials, finished products, etc. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>* (2) A responsible cosmetic distributor shall comply with the requirements prescribed by Ordinance of the Prime Minister with respect to the quality control standards of cosmetics, responsible post-sale safety control standards, methods for and obligation of quality tests, the obligation to report information on the safety and efficacy of cosmetics, and the obligation to establish safety measures. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(3) A custom cosmetic seller shall comply with the requirements prescribed by Ordinance of the Prime Minister with respect to methods for managing the facility and apparatus in a custom cosmetic shop, the obligation to comply with the safety control standards for the mixing or division into smaller amounts of custom cosmetics, and the obligation to explain contents and raw materials to be mixed or divided into smaller amounts. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(4) A responsible cosmetic distributor shall file a report on data, such as a track record of manufacturing or importing cosmetics and a list of raw materials used in the process of manufacturing a cosmetic, with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. In such cases, the responsible cosmetic distributor shall file a report on the list of raw materials with Minister of Food and Drug Safety before distributing or selling the relevant cosmetic. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018*>

(5) A responsible distribution manager and a custom cosmetic compounding manager shall undergo training for securing safety and quality management of cosmetics every year. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018>*

(6) Where deemed necessary to prevent risks to public health, the Minister of Food and Drug Safety may order a cosmetic manufacturer, a responsible cosmetic distributor, and a custom cosmetic compounding manager (hereinafter referred to as "business operator") to undergo training concerning cosmetics-related statutes or regulations, and institution (including matters necessary for securing safety and quality management of cosmetics). *Newly Inserted by Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018*> (7) Where a person who should undergo training under paragraph (6) conducts cosmetic manufacturing business, responsible cosmetic distribution business, or custom cosmetic sales business at two or more locations, he/she may designate a person prescribed by Ordinance of the Prime Minister as the person-in-

charge from among his/her employees and require the person to undergo training. <*Newly Inserted by Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018*>

(8) Matters necessary for institutions providing training, details of training, persons required to undergo training, training fees, etc. under paragraphs (5) through (7) shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018>*

Article 5-2 (Recall of Hazardous Cosmetics)

(1) A business operator shall without delay recall or take measures necessary to recall a cosmetic, where he/she becomes aware of the fact that the cosmetic that poses or could pose a risk to the public health in violation of Article 9, 15, or 16 (1) is on the market. *<Amended by Act No. 15947, Dec. 11, 2018>*

(2) A business operator who intends to recall or take measures necessary to recall a cosmetic under paragraph (1) shall report a recall plan to the Minister of Food and Drug Safety in advance. *Amended by Act No. 15488, Mar. 13, 2018>*

(3) The Minister of Food and Drug Safety may reduce or remit the administrative disposition under Article 24 to be imposed on the business operator who has conscientiously conducted the recall or taken necessary measures for recall under paragraph (1), because of the relevant cosmetics, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 15488, Mar. 13, 2018>*

(4) Cosmetics subject to recall under paragraphs (1) and (2), the risk grade necessary to recall a violative cosmetic, the risk classification criteria, the procedures for reporting a recall plan, recall procedures, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 15947, Dec. 11, 2018>*

Article 6 (Reporting on Business Closure)

(1) A business operator shall file a report with the Minister of Food and Drug Safety in any of the following cases, as prescribed by Ordinance of the Prime Minister: Provided, That the foregoing shall not apply where the business operator suspends his/her business for less than one month or resumes his/her business after suspension for less than one month: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018>*

- 1. Where he/she intends to close or suspend business;
- 2. Where he/she intends to resume business after suspension;
- 3. Deleted. <by Act No. 15947, Dec. 11, 2018>

(2) Where a cosmetic manufacturer or responsible cosmetic distributor filed a closure report with the head of the competent tax office under Article 8 of the Value-Added Tax Act or the head of the competent tax office cancelled his/her business registration, the Minister of Food and Drug Safety may revoke the registration of the cosmetic manufacturer or responsible cosmetic distributor. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(3) If necessary to revoke the registration of a cosmetic manufacturer or responsible cosmetic distributor under paragraph (2), the Minister of Food and Drug Safety may request the head of the competent tax office to provide information about his/her business closure. In such cases, upon receipt of such request, the head of the competent tax office shall provide the Minister of Food and Drug Safety with information about the business closure of the cosmetic manufacturer or responsible cosmetic distributor pursuant to Article 39 of the Electronic Government Act. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(4) The Minister of Food and Drug Safety shall notify the reporter of whether to accept a report on business closure or suspension under Article 1 (1) within seven days from the date of receipt of such report. *<Newly Inserted by Act No. 15947, Dec. 11, 2018>*

(5) Where the Minister of Food and Drug Safety fails to notify the reporter of whether to accept his/her report within the period specified in paragraph (4) or of the extension of the handling period under the statutes or regulations related to handling civil petitions, such report shall be deemed accepted on the day after the end of such period (where the handling period is extended or re-extended under the statutes or regulations related to handling civil petitions, referring to the relevant handling period). *Newly Inserted by Act No. 15947, Dec. 11, 2018*>

Article 7 Deleted. < by Act No. 15488, Mar. 13, 2018>

CHAPTER III HANDLING OF COSMETICS

SECTION 1 STANDARDS

Article 8 (Safety Standards for Cosmetics)

(1) The Minister of Food and Drug Safety shall designate and publicly notify raw materials which cannot be used for the manufacture, etc. of cosmetics. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety shall establish and publicly notify the standards for using raw materials, such as preservatives, colorants and sunblocks, which are subject to special restriction on use, and no preservatives, colorants and sunblocks the standards for the use of which are not established and publicly notified shall be used. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(3) As for raw materials of cosmetics, etc. that could pose a risk to the public health, such as those known to contain harmful materials in Korea or overseas, the Minister of Food and Drug Safety shall promptly assess the risks of such materials and determine whether such materials are hazardous, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) After completing a risk assessment under paragraph (3), the Minister of Food and Drug Safety shall designate the relevant raw materials of cosmetics as unusable in manufacturing cosmetics or shall prescribe the standards for using such materials. *Amended by Act No. 11690, Mar. 23, 2013*>

(5) The Minister of Food and Drug Safety shall review the safety of the standards for using raw materials established and publicly notified under paragraph (2), and may amend such standards for using raw materials based on the findings of review. In such cases, matters relating to the frequency, procedures, etc. for safety review shall be prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(6) A cosmetic manufacturer, responsible cosmetic distributor, or university, research institute, etc. prescribed by Ordinance of the Prime Minister may file an application with the Minister of Food and Drug Safety to establish and publicly notify the standards for using a raw material that has no standards established or publicly notified under paragraph (2), or to amend the standards for using any raw material established and publicly notified under paragraph (2), as prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(7) Upon receipt of an application filed under paragraph (6), the Minister of Food and Drug Safety shall review whether the content of the application is feasible, and may establish and publicly notify or amend the standards for using the relevant raw material if the content of such application is deemed feasible. *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

(8) The Minister of Food and Drug Safety may establish and publicly notify other safety control standards for distributed cosmetics. *Amended by Act No. 11690, Mar. 23, 2013*>

Article 9 (Safe Containers and Packaging)

(1) Every responsible cosmetic distributor and custom cosmetic seller shall use child-proof containers and packages for the sale of cosmetics in order to prevent children from being physically harmed by misuse. *<Amended by Act No. 15488, Mar. 13, 2018>*

(2) Items requiring child-proof containers and packages under paragraph (1), standards for containers and packages, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *Amended by Act No. 11690, Mar. 23, 2013>*

SECTION 2 LABELING, ADVERTISEMENTS AND HANDLING

Article 10 (Matters to be Stated on Packages of Cosmetics)

(1) Each of the following matters shall be stated and labeled on the primary or secondary package of cosmetics, as prescribed by the Ordinance of the Prime Minister: Provided, That in cases of packages prescribed by Ordinance of the Prime Minister including packages of cosmetics with a small quantity of contents, matters other than the name of a cosmetic, the trade name of the responsible cosmetic distributor and custom cosmetic seller, the price, the manufacturing number and the use-by date (where the best-before date after opening is stated, the manufacturing date shall also be stated; hereafter the same shall apply in this Article) shall not be stated and labeled thereon: *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018>*

1. Name of a cosmetic;

2. Trade name and address of the business operator;

3. All ingredients used in manufacturing the relevant cosmetic (excluding ingredients prescribed by

Ordinance of the Prime Minister, such as trace ingredients that are not harmful to the human body);

4. Volume or weight of contents;

5. Manufacturing number;

6. Use-by date or best-before date after opening;

7. Price;

8. For a functional cosmetic, the word "functional cosmetic" or the logo determined by the Minister of Food and Drug Safety indicating that the product is a functional cosmetic;

9. Cautions for use;

10. Other matters prescribed by Ordinance of the Prime Minister.

(2) Notwithstanding the main sentence of paragraph (1), the following matters shall be labeled on the primary package: *Amended by Act No. 15488, Mar. 13, 2018*>

1. Name of the cosmetic;

2. Trade name of the business operator;

3. Manufacturing number;

4. Use-by date and best-before date after opening.

(3) The name of a product and the trade name of the business operator may be also labeled in Braille for visually-impaired persons when labeling the information under paragraph (1) on the containers and packages of cosmetics. *Amended by Act No. 15488, Mar. 13, 2018*>

(4) Standards and methods for labeling 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 11 (Price Indication of Cosmetics)

(1) Prices referred to in Article 10 (1) 7 shall be indicated by a person who directly sells cosmetics to consumers (hereinafter referred to as "seller").

(2) Methods of indication prescribed in paragraph (1) and other necessary matters shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 12 (Cautions for Statements or Labeling)

Matters prescribed in Articles 10 and 11 shall be stated or labeled in a more conspicuous place than a place where other characters or sentences are and shall be accurately stated or labeled in easily readable and comprehensible Korean characters, as prescribed by Ordinance of the Prime Minister, and scripts in Chinese characters and foreign languages may also be placed. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 13 (Prohibition of False Labeling and Advertising)

(1) Neither business operator nor seller shall label or advertise in any of the following manners: *Amended by Act No. 15488, Mar. 13, 2018>*

1. Labeling or advertisements likely to mislead consumers into thinking the cosmetics are medicines;

2. Labeling or advertisements likely to mislead consumers into thinking any cosmetic other than a functional cosmetic is a functional cosmetic, or labeling or advertisements different from the examination results of its safety and efficacy;

3. Labeling or advertisements likely to mislead consumers into thinking any cosmetic other than a natural or organic cosmetic is a natural or organic cosmetic;

4. Other labeling or advertisements likely to deceive or mislead consumers by misrepresentation.

(2) The scope of labeling and advertising set forth in paragraph (1) and other necessary matters shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 14 (Substantiation of Contents of Labeling and Advertisements)

(1) A business operator or seller shall be able to substantiate the facts about labeling and advertisements which he/she has placed. *<Amended by Act No. 15488, Mar. 13, 2018>*

(2) If the Minister of Food and Drug Safety deems it necessary to substantiate labeling or advertisements placed by a business operator or seller pursuant to paragraph (1) as it or they fall under Article 13 (1) 4, he/she may request the manufacturer, manufacturer-seller or seller to submit relevant data specifying the details thereof. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(3) A business operator or seller in receipt of a request to submit the demonstration data under paragraph (2) shall submit it to the Minister of Food and Drug Safety within 15 days after receipt of such request: Provided, That the period for submission may be extended when the Minister of Food and Drug Safety deems extenuating circumstances exist. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(4) When a business operator or seller continues placing labeling or advertisements without submitting the demonstration data within the period for submission prescribed in paragraph (3) even after having been requested to do so under paragraph (2), the Minister of Food and Drug Safety shall issue an order to suspend the labeling or advertisements until he/she submits such substantiation data. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(5) A business operator or seller may refuse the submission of substantiation data requested by other organizations under other Acts, such as the Act on Fair Labeling and Advertising when he/she has submitted substantiation data requested by the Minister of Food and Drug Safety pursuant to paragraphs (2) and (3). *<Amended by Act No. 11690, Mar. 23, 2013>*

(6) The Minister of Food and Drug Safety shall comply with other organizations' request for the submitted substantiation data, made under other Acts, such as the Act on Fair Labeling and Advertising, except in extenuating circumstances. *<Amended by Act No. 11690, Mar. 23, 2013>*

(7) Necessary matters concerning the subject matters of substantiation, scopes of and requirements for substantiation data, and methods of submission under paragraphs (1) through (4) shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 14-2 (Certification of Natural Cosmetics and Organic Cosmetics)

(1) The Minister of Food and Drug Safety may certify a cosmetic that complies with the standards prescribed by the Minister as a natural cosmetic or organic cosmetic in order to encourage the quality improvement of natural cosmetics and organic cosmetics and to provide consumers with more accurate product information.

(2) A cosmetic manufacturer, responsible cosmetic distributor, or university, research institute, etc. prescribed by Ordinance of the Prime Minister that intends to obtain a certification under paragraph (1) shall apply for certification to the Minister of Food and Drug Safety.

(3) The Minister of Food and Drug Safety shall revoke the certification of a cosmetic certified under paragraph (1) in any of the following cases:

1. Where the cosmetic was certified by fraud or other improper means;

2. Where the cosmetic fails to comply with the standards for certification under paragraph (1).

(4) In order to effectively perform duties related to certification, the Minister of Food and Drug Safety may designate an agency or organization having required professional personnel and facilities as a certifying agency and may entrust such duties to the certifying agency.

(5) Certification procedures and standards for designation of certifying agencies under paragraphs (1) through (4) and other matters necessary to operate the certification system shall be prescribed by Ordinance of the Prime Minister.

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Article 14-3 (Validity Period of Certification)

(1) The validity period of a certification under Article 14-2 (1) shall be three years from the date of certification.

(2) A person who intends to extend the validity period of a certification shall apply for an extension to the Minister of Food and Drug Safety at least 90 days prior to the expiration of such validity period.

Article 14-4 (Labeling of Certification)

(1) A cosmetic certified under Article 14-2 (1) may bear a certification label prescribed by Ordinance of the Prime Minister.

(2) No one shall place the certification label prescribed in paragraph (1) or any similar label on any cosmetic not certified under Article 14-2 (1).

Article 14-5 (Revocation of Designation of Certifying Agencies)

(1) The Minister of Food and Drug Safety may require a relevant public official to inspect whether a certifying agency designated under Article 14-2 (4) (hereinafter referred to as "certifying agency") properly performs business affairs related to certification, if deemed necessary.

(2) Where a certifying agency falls under any of the following subparagraphs, the Minister of Food and Drug Safety may revoke the designation of the certifying agency or issue an order to suspend all or part of its business affairs for a specified period not to exceed one year: Provided, That he/she shall revoke such designation in the case of subparagraph 1:

1. Where the certifying agency was designated by fraud or other improper means:

2. Where the certifying agency fails to comply with the standards for designation prescribed under Article 14-2 (5).

(3) Matters necessary for the revocation of designation and suspension of business affairs under paragraph

(2) shall be prescribed by Ordinance of the Prime Minister.

SECTION 3 PROHIBITION ON MANUFACTURE, IMPORTATION, AND SALE

Article 15 (Prohibition of Business)

No person shall sell (including offering or supplying for import agency business) any of the following cosmetics, or manufacture, import, store or display them for sale: *Amended by Act No. 14264, May 29, 2016; Act No. 15488, Mar. 13, 2018>*

1. Functional cosmetics that fail to undergo an examination or a report on which has not been submitted, as prescribed in Article 4;

2. Fully or partially deteriorated cosmetics;

3. Cosmetics contaminated by pathogens;

4. Cosmetics mixed or mingled with foreign substances;

5. Cosmetics using raw materials that cannot be used for cosmetics as prescribed in Article 8 (1) and

(2), or cosmetics that fail to meet safety control standards for distributed cosmetics under paragraph (8) of the same Article;

6. Cosmetics using the horns of rhinoceros or bones of tigers, or the extracts thereof;

7. Cosmetics manufactured either under unsanitary conditions which are likely to cause harm to health and sanitation, or in facilities which fail to satisfy facility standards under Article 3 (2);

8. Cosmetics which are likely to cause harm to health and sanitation due to poor containers and packages;

9. Cosmetics which have forged or falsified the use-by date or best-before date after opening (including the date of manufacture stated) prescribed in Article 10 (1) 6.

Article 15-2 (Prohibition of Distribution or Sale of Animal-Tested Cosmetics)

(1) No responsible cosmetic distributor shall distribute or sell any cosmetics for which animal testing under subparagraph 1 of Article 2 of the Laboratory Animal Act (hereafter referred to as "animal testing" in this Article) was conducted, or cosmetics manufactured (including manufacturing by consignment) or imported using raw materials for which animal testing was conducted: Provided, That the foregoing shall not apply to any of the following cases: *Amended by Act No. 15488, Mar. 13, 2018*>

1. Where animal testing is needed to determine the standards for using raw materials requiring a specific restriction on usage, such as preservatives, coloring or sunblocks under Article 8 (2), or to assess hazards of cosmetics raw materials, etc. posing risks to public health pursuant to paragraph (3) of the same Article;

2. Where animal testing is needed because no alternative to animal testing (referring to non-animal testing or testing on a limited number of animals or reducing animal pains, and recognized as such by the Minister of Food and Drug Safety; hereafter the same shall apply in this Article) exists;

3. Where animal testing is needed to export cosmetics in accordance with the statutes and regulations of the export partner country;

4. Where animal testing is needed for product development in accordance with the statutes and regulations of the importing country;

5. Where raw materials developed through animal testing conducted under other statutes and regulations are used for the manufacture, etc. of cosmetics;

6. Other cases prescribed by the Minister of Food and Drug Safety, where it is otherwise impractical to conduct alternatives to animal testing.

(2) The Minister of Food and Drug Safety shall endeavor to develop alternatives to animal testing and shall take necessary measures to enable responsible cosmetic distributors, etc. to utilize the alternatives to animal testing. *<Amended by Act No. 15488, Mar. 13, 2018>*

Article 16 (Prohibition of Sale)

(1) No person shall sell any of the following cosmetics, or store or display them for sale: Provided, That the foregoing shall only apply to cosmetics to be sold to consumers in the case of subparagraph 3: <*Amended by Act No. 14264, May 29, 2016; Act No. 15488, Mar. 13, 2018>*

1. Cosmetics sold after being manufactured (including manufacturing by consignment) or imported by a person who has not been registered under Article 3 (1);

1-2. Custom cosmetics sold by a person who did not file a report under Article 3-2 (1);

1-3. Custom cosmetics sold without employing a custom cosmetic compounding manager under Article 3-2 (2);

2. Cosmetics violating Articles 10 through 12 or cosmetics with statements or labeling likely to mislead consumers into thinking the cosmetics are medicines;

3. Cosmetics manufactured or imported for consumers to test and use in advance not for the purpose of sale but for publicity and sales promotions;

4. Cosmetics, the package of which or statement or labeling on which has been damaged (excluding damage necessary to sell a custom cosmetic), forged or falsified.

(2) No one (excluding a custom cosmetic seller who sells cosmetics through a custom cosmetic compounding manager) shall sell contents divided from a container of a cosmetic. *<Amended by Act No.* 15488, *Mar. 13, 2018>*

SECTION 4 COSMETICS INDUSTRY ASSOCIATION

Article 17 (Establishment of Association)

Business operators may establish an association to guarantee their independent activities and common interests and to contribute to improving national health. *Amended by Act No. 15488, Mar. 13, 2018*>

CHAPTER IV SUPERVISION

Article 18 (Reporting and Inspection)

(1) The Minister of Food and Drug Safety may order a business operator, seller or any other person who handles cosmetics for their business to file a necessary report, or may require a relevant public official to enter a place for manufacturing cosmetics, place of business, warehouse, store, or any other place handling cosmetics in order to inspect relevant facilities, books, documents or other goods or to ask questions to relevant persons. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

(2) The Minister of Food and Drug Safety may collect the minimum amount of a cosmetic necessary to inspect the propriety of quality or safety standards, or statements or labeling on packages, etc. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) The Minister of Food and Drug Safety may operate a monitoring system on the sale of products, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) In the case of paragraph (1), a relevant public official shall produce an identity card indicating his/her authority to relevant persons.

(5) Qualification of relevant public officials under paragraphs (1) and (2) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 18-2 (Consumer Watchdog for Cosmetics Safety Control)

(1) For the safety control of cosmetics, the Minister of Food and Drug Safety or the Commissioners of the Food and Drug Safety regional offices may appoint a person recommended by the head of the relevant association or consumer organization, from among the executive officers and employees of an association established under Article 17 or a consumer organization registered under Article 29 of the Framework Act on Consumers, or a person knowledgeable about the safety control of cosmetics as a consumer watchdog for cosmetics safety control.

(2) Duties of consumer watchdogs for cosmetics safety control appointed under paragraph (1) (hereinafter referred to as "consumer watchdog for cosmetics safety control") are as follows:

1. Reporting a cosmetic on the market to the competent administrative agency or providing information for such agency, where the cosmetic fails to comply with the labeling standards prescribed under Article 10 (1) and (2) or is labeled or advertised in any manner provided in the subparagraphs of Article 13 (1);

2. Assisting a relevant public official in entry, inspections, inquiries, and collection under Article 18 (1) and (2);

3. Other duties prescribed by Ordinance of the Prime Minister with respect to the safety control of cosmetics.

(3) The Minister of Food and Drug Safety or the Commissioners of the Food and Drug Safety regional offices may provide consumer watchdogs for cosmetics safety control with education necessary to perform their duties.

(4) The Minister of Food and Drug Safety or the Commissioners of the Food and Drug Safety regional offices shall dismiss a consumer watchdog for cosmetics safety control in any of the following cases:

1. Where he/she retires or is discharged from the association or organization that recommended him/her;

2. Where he/she engages in misconduct or abuses power with respect to the duties provided in the subparagraphs of paragraph (2);

3. Where he/she has difficulty in performing duties due to a disease, injury, etc.

(5) Qualifications and education for consumer watchdogs for cosmetics safety control and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 19 (Corrective Orders)

If deemed necessary, the Minister of Food and Drug Safety may issue a corrective order to persons who fail to comply with this Act. <*Amended by Act No. 11690, Mar. 23, 2013*>

Article 20 (Inspection Orders)

The Minister of Food and Drug Safety may order a business operator to undergo an inspection conducted by a cosmetics testing and inspection institution prescribed in Article 6 (2) 5 of the Act on Testing and Inspection in the Food and Drug Industry, on cosmetics handled by the business operator, if deemed necessary. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013; Act No. 15488, Mar. 13, 2018>*

Article 21 Deleted. <by Act No. 11985, Jul. 30, 2013>

Article 22 (Orders to Repair Facilities)

If the Minister of Food and Drug Safety deems that facilities held by a cosmetic manufacturer are likely to compromise the safety and quality of cosmetics because such facilities fail to satisfy the facility standards

referred to in Article 3 (2) or are decrepit or damaged, he/she may order the cosmetic manufacturer to repair the facilities or prohibit the use of all or part of the facilities until finishing repair. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

Article 23 (Orders to Recall or Destroy Goods)

(1) Where a cosmetic sold, stored, displayed, manufactured or imported, or a raw material, ingredient, etc. of such cosmetic (hereinafter referred to as "goods") could pose a risk to the public health in violation of Article 9, 15, or 16 (1), the Minister of Food and Drug Safety shall issue to a relevant business operator or seller, or any other person handling cosmetics for business an order to take measures, such as recalling or destroying the relevant goods. *<Amended by Act No. 15947, Dec. 11, 2018>*

(2) Where it is deemed that goods sold, stored, displayed, manufactured or imported pose or could pose a risk to the public health, the Minister of Food and Drug Safety shall issue to a relevant business operator or seller, or any other person handling cosmetics for business an order to take measures, such as recalling or destroying the goods. *<Newly Inserted by Act No. 15947, Dec. 11, 2018>*

(3) A business operator or seller or any other person handling cosmetics for business who is issued with an order under paragraphs (1) and (2) shall, in advance, report a recall plan to the Minister of Food and Drug Safety. *<Newly Inserted by Act No. 15947, Dec. 11, 2018>*

(4) The Minister of Food and Drug Safety may require a relevant public official to destroy the relevant goods or take other necessary measures in any of the following cases: *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15947, Dec. 11, 2018>*

1. Where a person issued with an order under paragraph (1) or (2) fails to comply with the order;

2. Other urgent measures are necessary for public health.

(5) Risk grades necessary to recall goods under paragraphs (1) through (3), the risk classification criteria, procedures and plans for recall or destruction, follow-up measures, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 13117, Jan. 28, 2015; Act No. 15947, Dec. 11, 2018>*

Article 23-2 (Publication of Hazardous Cosmetics)

(1) The Minister of Food and Drug Safety may order the relevant business operator to publish the relevant facts in any of the following cases: *Amended by Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018*>

1. When the Minister receives a report on a recall plan under Article 5-2 (2);

2. When the Minister receives a report on a recall plan under Article 23 (3).

(2) Matters necessary for methods and procedures for publication under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 24 (Revocation of Registration)

(1) Where a business operator falls under any of the following cases, the Minister of Food and Drug Safety may revoke his/her registration or issue an order to close his/her place of business (only applicable to business reported under Article 3-2 (1); hereafter in this Article the same shall apply), to prohibit the manufacture, importation, or sale (including offer or supply for import agency business) of an item, or to suspend all or part of his/her business affairs for a specified period not exceeding one year: Provided, That the Minister of Food and Drug Safety shall revoke such registration or close his/her place of business in cases falling under subparagraph 3 or 14 (excluding an order to suspend advertising activities only): <*Amended by Act No. 11690, Mar. 23, 2013; Act No. 13117, Jan. 28, 2015; Act No. 14264, May 29, 2016; Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018; Act No. 16298, Jan. 15, 2019*>

1. Where the business operator fails to register any change in cosmetic manufacturing business or responsible cosmetic distribution business under the latter part of Article 3 (1);

2. Where the business operator fails to have the facilities under Article 3 (2);

2-2. Where the business operator fails to file a report on changes in custom cosmetic sales business under the latter part of Article 3-2 (1);

3. Where the business operator falls under any subparagraph of Article 3-3;

4. Where the business operator manufactures or imports a cosmetic that poses or could pose a risk to the public health;

5. Where the business operator sells functional cosmetics on which he/she fails to undergo an examination or submit a report, in violation of Article 4 (1);

5-2. Where the business operator fails to prepare or retain materials on safety by product under Article 4-2 (1);

6. When the business operator fails to comply with matters to be observed, in violation of Article 5;

6-2. When the business operator fails to recall or to take measures necessary to recall a cosmetic subject to recall, in violation of Article 5-2 (1);

6-3. When the business operator fails to report or falsely reports a recall plan, in violation of Article 5-2(2);

7. Deleted; <by Act No. 15488, Mar. 13, 2018>

8. When the business operator violates the standards for safety containers and packages of cosmetics under Article 9;

9. When the business operator places statements or labeling on the containers or packages of cosmetics and attached documents, in violation of Articles 10 through 12;

10. When the business operator labels or advertises cosmetics, in violation of Article 13 or in violation of an order for suspension under Article 14 (4);

11. When the business operator sells cosmetics, or manufactures, imports, stores, or displays cosmetics for the purpose of sale, in violation of Article 15;

12. When the business operator refuses or interferes with an inspection, questioning, collection, etc. under Article 18 (1) and (2);

13. When the business operator fails to comply with an order for correction, inspection, repair, recall, destruction, or publication under Article 19, 20, 22, 23 (1) or (2), or 23-2;

13-2. When the business operator fails to report or falsely reports a recall plan under Article 23 (3);

14. When the business operator performs his/her business affairs during a period of business suspension.

(2) Standards for administrative dispositions under paragraph (1) shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

Article 25 Deleted. <by Act No. 11985, Jul. 30, 2013>

Article 26 (Succession to Status of Business Operators)

When a business operator dies or transfers his/her business, or a merger between corporate business operators takes place, the heir, transferee, corporation surviving the merger or formed in the course of such merger shall succeed to the status of the business operator. *<Amended by Act No. 15488, Mar. 13, 2018>*

Article 26-2 (Succession to Effects of Administrative Sanctions)

Where a person succeeds to the status of a business operator pursuant to Article 26, he/she shall succeed to any administrative sanction imposed on the business operator under Article 24 for one year from the date the sanction period ends; and where the procedure for imposing an administrative sanction is ongoing, it may continue with respect to such person: Provided, That the foregoing shall not apply where the person who succeeded to the status of the business operator proves that he/she did not know such administrative sanction or violation at the time of succession to the status.

Article 27 (Hearings)

The Minister of Food and Drug Safety shall hold a hearing, where he/she intends to revoke the certification of a cosmetic under Article 14-2 (3), to revoke the designation of a certifying agency or to order the suspension of all or part of its business affairs under Article 14-5 (2), or to revoke the registration of a business operator or to order the closure of his/her place of business, the prohibition of the manufacture, import or sale (including offer or supply for import agency business) of an item, or the suspension of all or part of his/her business affairs under Article 24. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 14264, May 29, 2016; Act No. 15488, Mar. 13, 2018*>

Article 28 (Penalty Surcharges)

(1) The Minister of Food and Drug Safety may impose a penalty surcharge of not more than one billion won on a business operator who should be subject to business suspension under Article 24 in lieu such business suspension. *Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018>*

(2) Amounts of penalty surcharges, based on the types, degrees, etc. of violations subject to penalty surcharges under paragraph (1), and other necessary matters shall be prescribed by Presidential Decree.
(3) If necessary to impose a penalty surcharge on a business operator, the Minister of Food and Drug Safety may request, in writing, tax information about the business operator from the head of the competent tax office, specifying the following: *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

- 1. Personal information of the taxpayer;
- 2. The purpose of using the tax information;
- 3. Sales amount based on which the penalty surcharge is imposed.

(4) When a person liable to pay a penalty surcharge under paragraph (1) fails to pay it by the due date, the Minister of Food and Drug Safety may revoke the penalty surcharge imposed under paragraph (1), as prescribed by Presidential Decree, and order the person to suspend business under Article 24 (1) or collect such penalty surcharge in the same manner as delinquent national taxes are collected: Provided, That when the Minister of Food and Drug Safety cannot order the person to suspend business under Article 24 (1) due to business closure, etc. under Article 6, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) The Minister of Food and Drug Safety may request the following data or information from the person described in each subparagraph in order to collect an unpaid penalty surcharge under paragraph (4). In such cases, a person who receives such request shall comply therewith unless there is good cause: *<Newly Inserted by Act No. 15488, Mar. 13, 2018>*

1. A certified copy of building register under Article 38 of the Building Act: The Minister of Land, Infrastructure and Transport;

2. A certified copy of land cadastre under the Act on the Establishment and Management of Spatial Data: The Minister of Land, Infrastructure and Transport;

3. A certified copy of motor vehicle register under the Motor Vehicle Management Act: The Special Metropolitan City Mayor, Metropolitan City Mayors, Special Self-Governing City Mayors, Do Governors, or Special Self-Governing Province Governor.

Article 28-2 (Publication of Violations)

(1) The Minister of Food and Drug Safety may release to the public matters related to dispositions and prescribed by Presidential Decree concerning the person against whom an administrative disposition has been determined pursuant to Article 22, 23, 23-2, 24 or 28, such as the reason for and details of the disposition, the name, address and name of representative of the person subject to the disposition and the name of the relevant items.

(2) Matters necessary for the publication such as the methods of the publication set forth under paragraph

(1) shall be prescribed by Presidential Decree.

Article 29 (Support for Voluntary Management)

The Minister of Food and Drug Safety may provide administrative or financial support to business operators in order to settle and spread a voluntary management system under which they voluntarily endeavor to comply with criteria for labeling, advertisements, quality control, and domestic and foreign certification. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

Article 30 (Exception to Products for Exportation)

Products for exportation only that are not sold domestically may be in compliance with provisions of an importing country, notwithstanding Articles 4, 8 through 12, and 14, subparagraphs 1 and 5 of Article 15, Article 16 (1) 2 and 3, and Article 16 (2). *Amended by Act No. 14264, May 29, 2016*>

CHAPTER V SUPPLEMENTARY PROVISIONS

Article 31 (Re-Issuance of Registration Certificate)

When a business operator loses his/her certificate of registration, certificate of completion of report, or a notice on the examination results of functional cosmetics, or such certificate or notice becomes unusable, he/she may be re-issued such certificate, as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

Article 32 (Fees)

A person who intends to file a registration, file a report, undergo an examination, obtain a certification, or apply for the qualification test or the issuance of a qualification certificate under this Act shall pay a fee, as prescribed by Ordinance of the Prime Minister. The same shall apply where he/she intends to change any matters registered, reported, examined, or certified. *<Amended by Act No. 15488, Mar. 13, 2018>*

Article 33 (Support for Cosmetics Industry)

The Minister of Health and Welfare and the Minister of Food and Drug Safety shall establish the foundation for promoting the cosmetic industry and formulate and implement policies necessary for enhancing competitiveness, and shall secure finances thereof and grant support necessary for developing technology, conducting survey and research projects, providing overseas information, and building an international cooperation system. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

Article 33-2 (International Cooperation)

The Minister of Food and Drug shall strive for international cooperation through such activities as entering into an agreement with an importing or exporting country, in order to promote the export of cosmetics and to ensure the safety and quality control of cosmetics.

Article 34 (Entrustment or Delegation of Authority)

(1) Part of the authority of the Minister of Food and Drug Safety vested under this Act may be delegated to the Commissioners of the Food and Drug Safety regional offices, the Special Metropolitan City Mayor, a Metropolitan City Mayor, or a Do Governor, as prescribed by Presidential Decree. *<Amended by Act No. 11690, Mar. 23, 2013>*

(2) The Minister of Food and Drug Safety may entrust some of his/her duties related to cosmetics vested under this Act to an association established pursuant to Article 17 or an agency, corporation or association related to cosmetics, as prescribed by Presidential Decree. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 15488, Mar. 13, 2018>*

CHAPTER VI GENERAL PROVISIONS

Article 35 Deleted. <by Act No. 15488, Mar. 13, 2018>

Article 36 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than 3 years or by a fine not exceeding 30 million won: *<Amended by Act No. 12497, Mar. 18, 2014; Act No. 15488, Mar. 13, 2018>*

1. A person who violates the former part of Article 3 (1);

1-2. A person who violates the former part of Article 3-2 (1);

1-3. A person who violates Article 3-2 (2);

2. A person who violates the former part of Article 4 (1);

2-2. A person who obtains a certification by fraud or other improper means as prescribed in Article 14-2 (3) 1;

2-3. A person who uses the certification label in violation of Article 14-4 (2);

3. A person who violates Article 15;

4. A person who violates Article 16 (1) 1 or 4.

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

Article 37 (Penalty Provisions)

(1) Any person who violates Article 4-2 (1), 9, 13, 16 (1) 2 or 3, or 16 (2), or who fails to comply with a suspension order issued under Article 14 (4) shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 10 million won. *Amended by Act No. 11985, Jul. 30, 2013; Act No. 12497, Mar. 18, 2014; Act No. 16298, Jan. 15, 2019>*

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

Article 38 (Penalty Provisions)

Any of the following persons shall be punished by a fine not exceeding two million won: *Amended by Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018*>

- 1. A person who violates any of the matters to be observed under Article 5 (1) through (3);
- 1-2. A person who violates Article 5-2 (1);
- 1-3. A person who violates Article 5-2 (2);
- 2. A person who violates Article 10 (1) (excluding Article 10 (1) 7) and (2);

2-2. A person who uses the certification label prescribed in Article 14-4 (1) on a cosmetic the validity period of certification for which under Article 14-3 has expired;

3. A person who violates any order issued under Article 18, 19, 20, 22 or 23, or refuses, interferes with or evades an inspection, collection or disposition by a relevant public official.

Article 39 (Joint Penalty Provisions)

If the representative of a corporation or an agent or employee of, or any other person employed by, a corporation or an individual commits any violation under Articles 36 through 38 in connection with the business affairs of the corporation or individual, not only shall the violator be punished, but also the corporation or individual shall be punished by a fine under the relevant provisions: Provided, That the same shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business affairs to prevent such violation. *Amended by Act No. 15488, Mar. 13, 2018*>

Article 40 (Administrative Fines)

(1) Any of the following persons shall be subject to an administrative fine not exceeding one million won: <*Amended by Act No. 14027, Feb. 3, 2016; Act No. 15488, Mar. 13, 2018; Act No. 15947, Dec. 11, 2018>*

1. Deleted; <by Act No. 15488, Mar. 13, 2018>

2. A person who fails to undergo an examination of revised matters, in violation of the latter part of Article 4 (1);

3. A person who fails to report the track record of producing or importing cosmetics or a list of materials of cosmetics, in violation of Article 5 (4);

- 4. A person who violates any order issued under Article 5 (5);
- 5. A person who fails to report business closure, in violation of Article 6;
- 5-2. A person who fails to indicate the price of a cosmetic, in violation of Article 10 (1) 7 or Article 11;

6. A person who fails to file a report, in violation of Article 18;

7. A person who distributes or sells animal-tested cosmetics or cosmetics manufactured (including manufacturing by consignment) or imported cosmetics using animal-tested raw materials in violation of Article 15-2 (1).

(2) Administrative fines under paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, as prescribed by Presidential Decree. *<Amended by Act No. 11690, Mar. 23, 2013>*

ADDENDA

Article 1 (Enforcement Date)

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Articles 21, 25 and 37 (limited to the provisions concerning inspection reports under Article 21 (2)) shall enter into force one year after the date of its promulgation.

Article 2 (General Transitional Measures)

Dispositions, procedures and other acts taken or done pursuant to the previous Cosmetics Act before this Act enters into force shall be deemed taken or done pursuant to the provisions of this Act corresponding thereto.

Article 3 (Transitional Measures concerning Registration of Manufacturer-Sellers)

A person who intends to obtain registration as a manufacturer-seller pursuant to amended provisions of Article 3 (1) among manufacturers of cosmetics who filed a report pursuant to previous Article 3 (1) shall file registration, after fulfilling the requirements therefor, within one year after this Act enters into force.

Article 4 (Transitional Measures concerning Registration of Manufacturers)

Manufacturers who have filed a report under previous Article 3 (1) as at the time this Act enters into force shall renew the report as registration within one year after this Act enters into force.

Article 5 (Transitional Measures concerning Statements on Packages of Cosmetics)

Packages (including labeling) on which statements referred to in Article 10 are indicated as at the time this Act enters into force may be used for manufacturing relevant cosmetic items by the date on which two years pass after this Act enters into force.

Article 6 (Transitional Measures concerning Designation of Inspection Institutions)

Any inspection institutions designated by the Commissioner of the Korea Food and Drug Administration pursuant to the previous provisions as at the time this Act enters into force shall be deemed an inspection institution designated pursuant to the amended provisions of Article 21.

Article 7 (Transitional Measures concerning Penalty Provisions)

The application of penalty provisions and administrative fines to any act committed before this Act enters into force shall be governed by the previous provisions.

Article 8 Omitted.

ADDENDA <*Act No. 11690, Mar. 23, 2013*> Article 1 (Enforcement Date) (1) This Act shall enter into force on the date of its promulgation.

(2) Omitted.

Articles 2 through 7 Omitted.

ADDENDA < Act No. 11985, Jul. 30, 2013>

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

ADDENDA <Act No. 12497, Mar. 18, 2014>

Article 1 (Enforcement Date)

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

Article 2 (Transitional Measures concerning Incompetent Persons)

Incompetent persons under the adult guardianship referred to in the amended provisions of Article 3 (2) 2 shall be deemed to include persons for whom a declaration of incompetency remains in effect under Article 2 of the Addenda to the Civil Act (Act No. 10429).

Article 3 (Transitional Measures concerning Quasi-Incompetent Persons)

Notwithstanding the amended provisions of Article 3 (2) 2, the previous provisions shall apply to persons for whom a declaration of quasi-incompetency remains in effect under Article 2 of the Addenda to the Civil Act (Act No. 10429).

ADDENDUM <Act No. 13117, Jan. 28, 2015>

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Article 28-2 shall enter into force on the date of its promulgation.

ADDENDA <Act No. 14027, Feb. 3, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Article 3 shall enter into force on the date of its promulgation.

Article 2 (Applicability to Animal-Tested Cosmetics)

The amended provisions of Article 15-2 shall apply starting with cosmetics for which animal testing was conducted, or manufactured (including manufacturing by consignment) or imported (based on the date of customs clearance) using raw materials for which animal testing was conducted, after this Act

enters into force.

ADDENDA < Act No. 14264, May 29, 2016>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of subparagraph 2 of Article 2, Article 16, the main sentence of Article 24 (1), and Article 27 shall enter into force one year after the date of its promulgation.

Article 2 (Applicability to Revocation of Registration)

The amended provisions of Article 24 (1) 14 shall also apply where any person under a period of business suspension as at the time this Act enters into force performs business after this Act enters into force.

Article 3 (Transitional Measures concerning Products for Export)

Notwithstanding the amended provisions of Article 30, the previous provisions shall apply to cosmetics manufactured before this Act enters into force and intended for export only: Provided, That the amended provisions of Article 30 (limited to the portion concerning Article 4) shall apply to functional cosmetics for which examinations of safety or effectiveness under Article 4 are underway.

ADDENDA <Act No. 15488, Mar. 13, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Articles 3-2 and 3-4 and the amended provisions of Articles 2, 2-2, 3-3, 5, 5-2, 6, 9, 10, 13, 14, 15, 16, 17, 18, 18-2, 20, 23, 23-2, 24, 26, 27, 28, 29, 31, 32, 34, 36, 38, 39, and 40 (only limited to custom cosmetics, custom cosmetic sellers, and custom cosmetic compounding managers) shall enter into force two years after the date of its promulgation.

Article 2 (Transitional Measures concerning Business Registration)

(1) A person who applied for the registration of his/her cosmetic manufacturing business or cosmetic manufacturing-selling business under previous Article 3-1 before this Act enters into force shall be deemed to have applied for the registration of his/her cosmetic manufacturing business or responsible cosmetic distribution business under the amended provisions of Article 3 (1).

(2) Aperson who registered his or her cosmetic manufacturing business or cosmetic manufacturingselling business under previous Article 3-1 before this Act enters into force shall be deemed to have registered his or her cosmetic manufacturing business or responsible cosmetic distribution business under the amended provisions of Article 3 (1).

Article 3 (Transitional Measures concerning Change in Title of Manufacture-Sales Managers)

A manufacture-sales manager provided in previous Article 3 (4) as at the time this Act enters into force shall be deemed a responsible distribution manager provided in amended Article 3 (3).

Article 4 (Transitional Measures concerning Matters to be Stated of Cosmetics)

Any container or package on which the matters provided in previous Article 10 (1) and (2) are stated or labeled as at the time this Act enters into force may be used for manufacturing a cosmetic of the relevant item for one year from the date this Act enters into force.

Article 5 (Transitional Measures concerning Revocation of Registration)

The previous provisions shall apply to the revocation, etc. of registration for any violation committed before this Act enters into force.

Article 6 (Transitional Measures concerning Penalty Provisions and Administrative Fines)

The previous provisions shall apply to the imposition of penalties or administrative fines for any violation committed before this Act enters into force.

ADDENDA <Act No. 15947, Dec. 11, 2018>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Article 6 of the Cosmetics Act (Act No. 15488) shall enter into force on March 14, 2019; the amended provisions of Article 26-2 shall enter into force six months after the date of its promulgation; and the amended provisions of Article 33-2 shall enter into force on the date of its promulgation.

Article 2 (Applicability to Reporting on Business Closure or Suspension)

The amended provisions of Article 6 of the Cosmetics Act (Act No. 15488) shall apply beginning with a business operator who files a report on business closure or suspension after such amended provisions enter into force.

Article 3 (Applicability to Succession to Effects of Administrative Sanctions)

The amended provisions of Article 26-2 shall apply beginning with a person who succeeds to the status of a business operator for the first time after such amended provisions enter into force.

Article 4 (Transitional Measures concerning Breach of Obligation to Indicate Price of Cosmetics)

The previous provisions shall apply to any act committed in violation of Article 10 (1) 7 or Article 11 before this Act enters into force, notwithstanding the amended provisions of subparagraph 2 of Article 38 and Article 40 (1) 5-2.

Article 5 (Transitional Measures concerning Penalty Surcharges)

The previous provisions shall apply to the imposition of penalty surcharges for any violation committed before this Act enters into force.

ADDENDUM <*Act No. 16298, Jan. 15, 2019*> This Act shall enter into force one year after the date of its promulgation.

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KLRI KOREA LEGISLATION