Notice of the Ministry of Health and Welfare, No. 2006-225

In amending the Enforcement Regulations of the Cosmetics Act, for the purpose of listening to the public opinion in advance, we hereby announce the Amendment reasons and their details in accordance with Article 42 of Administrative Law.

Partial Amendment (Plan) of the Enforcement Regulations of the Cosmetics Act

1. Reason

It is to establish the list of cosmetics which are to use containers and wrappings, and their standards, for preventing incidents involving children, in accordance with the fact that a manufacturer or an importer should use containers and wrappings for the sales of the manufactured or imported cosmetics. In addition, it is to introduce the manufacturers' and importers' duty to keep the test data regarding the stability of cosmetics, and otherwise to reinforce inadequate regulations by preparing, for example, the detailed standards for indication and advertising.

2. Main Contents

A. Revision of Regulations Related to Cosmetic Manufacturing Business Change (Plan, Article 4.1 and 4.2)
(1) Amendment is required to revise the regulations related to the changes to cosmetics manufacturers, which occur by transfer, acquisition by transfer and inheritance, in accordance with other regulations of the Pharmacy Act and Food Sanitation Act wherein the change of property rights by transfer, acquisition by transfer and inheritance is regarded as an alteration, not as a new declaration.
(2) The change of the CEO of a cosmetics company by transfer, acquisition by transfer and inheritance shall be regarded as an alteration in the cosmetics manufacturing business and in the case of notifying this alteration, the corresponding proof documents shall be submitted. In the case of transfer or acquisition by transfer, a certificate of the transferor's seal impression shall be submitted, and in the case of inheritance, a family document and if the inheritor is a corporation, a corporate registration document shall be submitted.
(3) The above-described revision is expected to simplify the related administrative procedures and to reduce administrative inconvenience and complaints.

B. Revision of Cosmetic Quality System Consignment (Plan, Article 5.4)

(1) According to the present regulations, in the case of consigning quality inspection to another company, a cosmetics company should still be equipped with a laboratory, even though it is allowed that it may not be equipped with the necessary facilities and appliances for the inspection. Therefore, it is necessary to revise this inadequate regulation.
(2) A revision shall be made to allow the cosmetics company, in the case of Item 1, not to be necessarily equipped with a laboratory, facilities and appliances.
(3) Reasonably adjusting the facility standards for cosmetic quality system inspection, is expected to encourage business competitiveness.

C. Preparation of Product List and Standards in Accordance with Container Use Duty for Protecting Children's Safety Against Cosmetics (Plan, Article 13.2, Annex 4 II. Separate Standard 14.2)
(1) In accordance with cosmetic manufacturers' and importers' duty to use a container which is designed to be difficult for a child under the age of 5 to open, it is necessary to designate the related details by the Ordinance of the Ministry of Health and Welfare.
(2) More specifically, it is to make the use of safe containers an obligation on the products designated by law, which, for example, excludes disposable products, products for commercial use, pump sprays, trigger sprays and compressed air sprays (including aerosol spray) and include products such as nail enamel remover containing acetone, and to decide the standards and the test methods for the containers and wrappings.
(3) The preparation of detailed regulations in accordance with the obligation of using safe containers, is expected to prevent child-related incidents caused by inhaling or eating cosmetics.

D. Preservation Duty of Cosmetic Stability Test Data (Plan, Annex1.1.I and 1.2.G, newly prepared)
(1) The Ministry of Government Legislation decided to set out by law the details of the duties of cosmetics manufacturers and importers.
(2) Therefore, in the case of a product on the Use Period Indication List, its stability test data shall be preserved for at least more than a year from the use period of the final product and as long as it is necessary.
(3) The above-mentioned regulation is expected, whenever necessary, to re-confirm product stability by the preserved test data.

E. Providing Precautions in the Use of AHA (α-hydroxy acid)-Containing Cosmetics (Plan, Annex 2 II. Separate Notice 8)

(1) It is necessary to prepare a legal base for providing the precautions in use of AHA-containing cosmetics.
(2) In the case of AHA-containing cosmetics, the AHA may increase UV sensitivity of skin and therefore the manufacturers or the importers shall clearly indicate the necessity of using sunblock in combination, and in the case that the AHA exceeds 10 % or the acidity of a product is under 3.5, it may cause a side-effect and therefore the manufacturers or the importers shall clearly indicate the necessity of consulting a dermatologist before use.
(3) The above-mentioned indication system is expected to prevent national health hazards caused by the unsafe use of cosmetics.

F. Specification of Penalty Criteria for Infringement of Cosmetics Denotation and Advertisement Rules (Plan, Annex 4. Separate Standard 15.)
(1) The penalty criteria in the case of infringing the rules of denotation and advertisement, which was designated by Article 12 of Cosmetics Act, is not sufficient and therefore, it is necessary to prepare a more detailed criteria thereof.
(2) In accordance with the above detailed criteria, infringing acts regarding denotation and advertisement shall be specified and the corresponding penalty criteria shall be divided into two categories, which are the interruption of sales business (in the case of infringing denotation rules) and the interruption of advertisement business (in the case of infringing advertisement rules).
(3) The above-described specification of penalty criteria is expected to increase the corresponding legal effectiveness.

3. Notice

A. Related Law: Omitted
B. Budget Plan: Not Required
C. Negotiation: None
D. Others: (1) Old and New Legal Texts Comparison, Attachment
(2) Enactment Notice:
(3) Regulation Examination:

Ordinance of the Ministry of Health and Welfare, No.

Partial Amendment (Plan) of Enforcement Regulations of the Cosmetics Act

The enforcement regulations of the Cosmetics Act shall be partially amended as follows:

In Article 3.1, the Condition shall be deleted.

Article 4.1.1 shall become "change of a manufacturer including the change of a representative or a CEO of a corporate by transfer, acquisition by transfer or inheritance (hereinafter referred as "Change of Manufacturer")" and Article 4.1.2 shall become "Alteration of Manufacturer's Brand". Article 4.1.3 shall be newly added as "3. Manufacturing Location Change" and Article 4.2.1 shall become as follows:

1. Change of Manufacturer
A. A medical certificate proving that the corresponding manufacturer does not come under Article 3.2.1 and 3.2.3
B. A proof document of the corresponding change, a certificate of the transferor's seal impression in the case of transfer or acquisition by transfer, and a family document in the case of inheritance
C. A corporate registration document (only in the case of a corporation)

In Article 5.4, "facilities and appliances" shall be replaced by "a laboratory, facilities and appliances".

Article 6.1.2 shall become "standard and test data (including test samples)".

In Article 10.1, "until January 31 of the following year" shall be replaced by " in compliance with the authorization of the Commissioner of the Korea Food and Drug Administration" and in Article 10.2, "Trade Act regarding the Promotion of Automated Trade System" shall be replaced by "Trade Act regarding the Promotion of Electronic Trade".

Article 13.2 shall be added as follows:

Article 13.2 (product list and standards for safety containers and wrappings)
(1) In accordance with Article 9.2.2, any product that corresponds to one of the following items shall use a safety container or wrapping. However, a disposable product, a product neither maintained nor used at home, a pump or trigger spray, which is difficult to open by turning the top, and compressed air sprays (including aerosol spray) shall not come under this regulation.
1. Nail enamel remover or nail polish remover containing acetone

2. Non-emulsion type liquid product (e.g. Baby Oil) that contains more than 10 % of hydrocarbon per unit and its kinematical viscosity is under 21cSt (40°C).

3. Liquid product containing more than 5% of methyl salicylate per unit

(2) In accordance with Item 1, when a manufacturer or an importer of cosmetics sells the manufactured or the imported cosmetic products, he or she shall use a container or wrapping that is designed to be difficult for a child under the age of 5 to open within a certain period of time.

(3) The standards and test methods of safety containers and wrappings shall conform to the "Safety Standard of Resealing Container of Industrial Products Targeted for Safety Wrapping for Children" announced by the Korean Agency for Technology and Standards.

The following Annex 1.1 I shall be added and in Annex 1.2. F, "Trade Act regarding the Promotion of Automated Trade System" shall be replaced by "Trade Act regarding the Promotion of Electronic Trade". Furthermore, Annex 1.2. G shall be prepared as follows.

I. In the case of a product on the Use Period Indication List, in accordance with Article 10.1.5, its stability test data shall be preserved for at least more than a year from the use period of the final product and as long as it is necessary.

G. In the case of a product on the Use Period Indication List, in accordance with Article 10.1.5, its stability test data shall be preserved for at least more than a year from the use period of the final product and as long as it is necessary.

In Annex 2 II., Separate Notice 8 shall be prepared as follows:

8. Product Containing AHA

A. Use sunblock in combination (it may increase UV sensitivity of skin)
B. Confirm if there is any side-effect by applying it to a small area of the skin, in the case of the first use of the above product or changing to this product
C. Consult a dermatologist before the use because the above product contains a high amount of AHA and it may cause a side-effect (only in the case of a product wherein AHA exceeds 10 % or the acidity of a product is under 3.5)

In Separate Standard 8.B of Annex 4 II., among Infringement Details, "D and H" shall be replaced by "D and I". In the same Standard 9.A, among Infringement Details, "A and E" shall be replaced by "A, E and G".

Separate Standard 14.2 of Annex 4 II. shall be prepared as follows.

14.2. In the case that a manufacturer or an importer infringes the rules for safety containers and wrappings, and sells the manufactured or imported cosmetic products	Article 9.2.1	Interruption of the manufacturing business of the corresponding product for 3 months	Interruption of the manufacturing business of the corresponding product for 6 months	Interruption of the manufacturing business of the corresponding product for 12 months

In Separate Standard 15 of Annex 4 II., among Infringement Details, “advertisement” shall be replaced by “denotation and advertisement” and the administrative penalty criteria of A and B of the same Standard shall be as follows.

Interruption of sales business for 3 months (infringement of denotation rule) or Interruption of advertising business of the corresponding product for 3 months (infringement of advertisement rule)	Interruption of sales business for 6 months (infringement of denotation rule) or Interruption of advertising business of the corresponding product for 6 months (infringement of advertisement rule)	Interruption of sales business for 12 months (infringement of denotation rule) or Interruption of advertising business of the corresponding product for 12 months (infringement of advertisement rule)

Interruption of sales business for 2 months (infringement of denotation rule) or Interruption of advertising business of the corresponding	Interruption of sales business for 4 months (infringement of denotation rule) or Interruption of advertising business of the corresponding	Interruption of sales business for 6 months (infringement of denotation rule) or Interruption of advertising business of the corresponding	Interruption of sales business for 312months (infringement of denotation rule) or Interruption of advertising business of the corresponding product for

product for 2 months (infringement of advertisement rule)	product for 4 months (infringement of advertisement rule)	product for 6 months (infringement of advertisement rule)	12 months (infringement of advertisement rule)

Subsidiary Act

(1) (enforcement date) This Act shall be enforced as of the date of the public announcement.

However, the Product List and Standard for Safety Containers and Wrappings, and Annex 4 II. Separate Standard, in accordance with the amended rules of Article 13.2.1, and Specified Administrative Rules, in accordance with the amended rules of Article 14.2, shall be enforced as of January 13, 2007.

(2) (application) Administrative Rules in accordance with the amended rules of Separate Standards 8 and 9 of Annex 4 II. shall start to be applied to cosmetics manufactured after the enforcement date of this Amendment.

Old and New Legal Texts Comparison

Current Act	Amendment (Plan)
Article 3 (declaration of manufacturing business) (1) In accordance with Article 3.1, those who have a cosmetics manufacturing business (hereinafter referred as "Manufacturer") shall attach the following documents (including electronic documents) to the Cosmetics Manufacturing Business Declaration (including a form prepared by an electronic mail), using the form introduced in the Attachment No.1, and submit them to the Commissioner of the Korea Food and Drug Administration. However, in the case of the continuation of a manufacturing business by using the same facility as a result of transfer, acquisition by transfer,	Article 3 (declaration of manufacturing business) (1)---------- ---------- ---------- ---------- ---------- --. <deleted>

inheritance, separation or merger, and submitting the proof documents, the submission of the documents mentioned in (3) may be omitted.	
1. ~ 3. (omitted)	1. ~ 3. (same as the current Act)
(2) (omitted)	(2) (same as the current Act)
Article 4 (declaration of manufacturing business change) (1) The following alteration of the declaration details shall be introduced, which is important for a Manufacturer who wishes to notify the change in his or her manufacturing business, in accordance with the regulations of the last part of Article 3.1.	Article 4 (declaration of manufacturing business change) (1)----------.
1.The change of a Manufacturer caused by the other reasons but the regulations of the Condition of Article 3.1	1. Change of a manufacturer including the change of a representative or a CEO of a corporate by transfer, acquisition by transfer or inheritance (hereinafter referred as "Change of Manufacturer")"
2. The change of a Manufacturer's brand or its business location change	2. Alteration of Manufacturer's brand 3. Manufacturing location change
(2) (omitted)	(2) (same as the current Act)
1. In the case of the change of a Manufacturer caused by the other reasons but the regulations of the Condition of Article 3.1	1. Change of Manufacturer, etc.
A. (omitted)	A. (same as the current Act)
<Newly Prepared>	B. A proof document of the corresponding change, a certificate of the transferor's seal impression in the case of transfer or acquisition by transfer, and a family document in the case of inheritance
B. (omitted)	C. (same as the current Act)
2. - 3. (omitted)	2. - 3. (same as the current Act)
(3) (omitted)	(3) (same as the current Act)

Article 5 (facility standard) (1) – (3) (omitted)	Article 5 (facility standard) (1) – (3) (same as the current Act)
(4) In spite of the regulations of Item 1 and 2, in the case that a manufacturer or an importer consigns quality inspection of manufactured or imported cosmetics to an institute, which corresponds to one of the following categories, his or her business site may not be equipped with the facilities and appliances necessary for the inspection.	(4)---------- a laboratory, facilities and appliances ----------.
1. - 4. (omitted)	1. - 4. (same as the current Act)
(5) (omitted)	(5) (same as the current Act)
Article 6 (inspection on functional cosmetics) (1) (omitted)	Article 6 (inspection on functional cosmetics) (1) (same as the current Act)
1. (omitted)	1. (same as the current Act)
2. standard and test data (including the materials regarding the use period and test samples)	2. standards and test data (including test samples)
(2) – (6) (omitted)	(2) – (6) (same as the current Act)
Article 10 (report of production and import of cosmetics) (1) In accordance with Article 5.3, a manufacturer or an importer of cosmetics shall report the production or import results of the corresponding year to the Commissioner of the Korea Food and Drug Administration by January 31 of the following year.	Article 10 (report of production and import of cosmetics) (1) ---------- in compliance with the authorization of the Commissioner of the Korea Food and Drug Administration ----------.
(2) In spite of the above-described rule, an importer who reported the scheduled customs inspection by electronic mail exchange system, in accordance with the Trade Act regarding the Promotion of Automated Trade System, then imported	(2) ---------- "Trade Act regarding the Promotion of Electronic Trade"----------.
	Article 13.2 (product list and standards for safety containers and wrappings) (1) In

the products, may not report the import results. <Newly Prepared>	accordance with Article 9.2.2, any product that corresponds to one of the following items shall use a safety container or wrapping. However, a disposable product, a product neither maintained nor used at home, a pump or trigger spray, which is difficult to open by turning the top, and compressed air sprays (including aerosol spray) shall not come under this regulation 1. Nail enamel remover or nail polish remover containing acetone 2. Non-emulsion type liquid product (e.g. Baby Oil) that contains more than 10 % of hydrocarbon per unit and its kinematical viscosity is under 21cSt (40℃) 3. Liquid product containing more than 5% of methyl salicylate per unit (2) In accordance with Item 1, when a manufacturer or an importer of cosmetics sells the manufactured or imported cosmetic products, he or she shall use a container or wrapping that is designed to be difficult for a child under the age of 5 to open within a certain period of time. (3) The standards and test methods of safety containers and wrappings shall conform to the “Safety Standard of Resealing Container of Industrial Products Targeted for Safety Wrapping for Children” announced by the Korean Agency for Technology and Standards.

〈 Department in Charge of the Provision 〉

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