NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH RE: NOTIFICATION, ISSUANCE OF NOTIFICATION RECEIPTS, RENEWAL OF NOTIFICATION RECEIPTS, VARIATION OF PARTICULARS OF NOTIFICATION RECEIPTS AND ISSUANCE OF REPLACEMENTS OF NOTIFICATION RECEIPTS OF COSMETICS, B.E. 2561 (2018)^{*}

By virtue of the provisions of section 5 paragraph one, section 6 (10), section 14 paragraph two, section 15 paragraph three, section 18 paragraph two and section 19 paragraph two of the Cosmetic Products Act, B.E. 2558 (2015), the Minister of Public Health, upon recommendation of the Cosmetics Committee, hereby issues the Notification as follows.

Clause 1. This Notification shall come into force as from the day of its publication in the Government Gazette.

CHAPTER I QUALIFICATIONS OF APPLICANT FOR NOTIFICATION

Clause 2. A person who wishes to manufacture for sale, import for sale or be contracted for manufacturing a cosmetic must possess the qualifications as follows:

(1) In case of a natural person, being of Thai nationality who is not less than twenty years of age;

(2) In case of a juristic person, being registered in Thailand.

CHAPTER II NOTIFICATION

Clause 3. A manufacturer, contract manufacturer or importer of cosmetics shall submit an application for notification prior to the manufacture or importation of cosmetics.

^{*} Published in the Government Gazette, Vol. 135, Special Issue, Part 208d, page 6, dated 29th August B.E. 2561 (2018)

Disclaimer: This translation is provided by the Food and Drug Administration as the competent authority for information purposes only. Whilst the Food and Drug Administration has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

In submitting an application for notification of cosmetic, the details of the cosmetic shall be notified in the application form for cosmetic notification, Form N.C.1, and the documents and evidence as listed in the list annexed to this Notification shall be submitted together with the payment of a fee for the notification application as prescribed by the Ministerial Regulation on the determination of fees related to cosmetics.

In the notification of a cosmetic, a trade name or a cosmetic name which is exaggerative, impolite or misleading shall not be used; a trade name or a cosmetic name which is inappropriate to the virtuous Thai culture or likely to degrade Thai language shall not be used; and the formula of ingredients must contain the substances which conform to the Notification of the Ministry of Public Health relating to the list of cosmetic substances.

In cases of notification for export only in which the qualities, standards, labels or other details are specified by the person making the purchase order, the Notification of the Food and Drug Administration on notification of cosmetics manufactured or imported for export only of which the qualities, standards, labels or other details are specified by the person making the purchase order, shall be complied.

If the notifier has made a notification for domestic sale of a cosmetic the name of which does not conform to clause 3 paragraph three, or the notifier has brought a product that is not a cosmetic to carry out a notification as a cosmetic, the notification receipt shall be deemed unlawful. The Food and Drug Administration has the right to issue an order to revoke such notification receipt in accordance with the law on administrative procedure with a view to protecting consumers and public interest.

Clause 4. An application for notification, an application for renewal, an application for variation of particulars on a notification receipt and an application for a replacement of a notification receipt shall be submitted as documents at the Food and Drug Administration or at a provincial public health office of the province where the place of business is located, or be submitted through the computer network system of the Food and Drug Administration.

Clause 5. An applicant must undertake to prepare the manufacturing facility or import facility to ensure that its characteristics are in compliance with the Notification of the Ministry of Public Health on rules, procedures and conditions on manufacture or importation of cosmetics.

CHAPTER III ACCEPTANCE OF NOTIFICATION

Clause 6. The competent official shall examine the application and documents or evidence submitted by the applicant. If they are complete and correct and the payment of the fee for the notification receipt has been made in accordance with the Ministerial Regulation on the determination of fees related to cosmetics, the notification receipt shall be issued as follows:

(1) In cases of notification for sale or export under Thailand's standards, a notification receipt for manufacture for sale of cosmetics in the Form N.M.1 or a notification receipt for contract manufacture of cosmetics in the Form N.CM.1 or a notification receipt for importation for sale of cosmetics in the Form N.I.1 shall be issued as evidence.

(2) In cases of notification for export only or notification when the qualities, standards, labels or other details are specified by the person making the purchase order, a notification receipt for manufacture of cosmetics for sale (for export only) in the Form N.M.E.1 or a notification receipt for contract manufacture of cosmetics (for export only) in the Form N.CM.E.1 or a notification receipt for importation of cosmetics for sale (for export only) in the Form N.CM.E.1 shall be issued as evidence.

CHAPTER IV

RENEWAL OF NOTIFICATION RECEIPTS, VARIATION OF PARTICULARS OF NOTIFICATION RECEIPTS AND ISSUANCE OF REPLACEMENTS OF NOTIFICATION RECEIPTS

Clause 7. A notifier who wishes to renew a notification receipt shall submit an application for renewal of notification receipt in the Form N.C.2 to the notification authority within one hundred and eighty days prior to the date of expiration of the notification receipt, and pay the fee for the application in accordance with the Ministerial Regulation on the determination of fees related to cosmetics.

The competent official shall examine the application and documents or evidence submitted by the applicant. If they are complete and correct and the payment of the fee for the renewal has been made in accordance with the Ministerial Regulation on the determination of fees related to cosmetics, the receipt for the renewal of notification receipt in the Form N.C.3 shall be issued as evidence.

Clause 8. A notifier whose notification receipt expires for not more than one month can submit an application for its renewal and for allowance of leniency by indicating a reason for failure to submit the renewal application within the specified period. However, such person shall be liable to a fine of five hundred baht per day, and shall proceed to submit the renewal application in accordance with clause 7.

Clause 9. A notifier who wishes to vary a particular on the notification receipt shall submit an application for variation of particular on the cosmetic notification receipt together with the documents and evidence specified in the application for variation of particular on the cosmetic notification receipt, Form N.C. 4, to the notification authority, and pay the fee for the application for variation of particular on the notification receipt as specified in the Ministerial Regulation on the determination of fees related to cosmetics.

The competent official shall examine the application and documents or evidence submitted by the applicant. If they are complete and correct, the competent official shall issue a letter acknowledging the application for variation of particular on the cosmetic notification receipt, or make an endorsement on the receipt for variation of particular on the notification receipt in the Form N.C. 5, as evidence.

Clause 10. In the case where a notification receipt is fundamentally damaged, lost or destroyed, the notifier shall submit an application for replacement of the cosmetic notification receipt together with the documents and evidence specified in the application for replacement of the cosmetic notification receipt, Form N.C. 6, within fifteen days from the date of knowledge of such fundamental damage, loss or destruction, and pay the fee for the application as specified in the Ministerial Regulation on the determination of fees related to cosmetics.

The competent official shall examine the application and documents or evidence submitted by the applicant. If they are complete and correct and the payment of the fee for replacement of notification receipt has been made in accordance with the Ministerial Regulation on the determination of fees related to cosmetics, the competent official shall issue a replacement of the notification receipt as evidence. In this regard, in the issuance of a replacement, the notification authority [sic.] shall issue the original notification receipt for the manufacture, contract manufacture or importation, as the case may be, with the word "REPLACEMENT" at the middle top of the notification receipt, and shall also specify the date, month and year of the issuance of the replacement.

CHAPTER V DUTIES OF NOTIFIER

Clause 11. A notifier shall manufacture or import cosmetics in accordance with the notification made.

Clause 12. A notifier shall comply with the rules, procedures and conditions prescribed by the Minister in the following Notifications:

(1) Notification of the Ministry of Public Health on rules, procedures and conditions on the manufacture or importation of cosmetics;

(2) Notification of the Ministry of Public Health on the acceptance of notification and report of adverse effects from the use of cosmetics occurring to consumers;

(3) Notification of the Ministry of Public Health on rules, procedures and conditions on requirements for persons manufacturing for sale, persons importing for sale or contract manufacturers to collect information pertaining to cosmetics for inspection.

TRANSITORY PROVISIONS

Clause 13. A notification receipt issued prior to the date on which this Notification comes into force shall be valid until such notification receipt expires.

Clause 14. The declaration of specifications on the manufacture for sale or importation for sale of regulated cosmetics in the Form N.C. under the Cosmetics Act, B.E. 2535 (1992) which is submitted prior to the date on which this Notification comes into force and remains under the consideration, shall be deemed an application for notification of cosmetic under this Notification *mutatis mutandis*.

In the case where the declaration of specifications on the manufacture for sale or importation for sale of regulated cosmetics in the Form N.C. differs from the application for notification of cosmetic under this Notification, the notification authority has the power to issue an order directing the applicant to submit additional documents to the notification authority or to amend the application for notification of cosmetic to comply with this Notification.

Announced on the 22nd day of August B.E. 2561 (2018) Piyasakol Sakolsatayadorn Minister of Public Health

List Annexed to the Notification of the Ministry of Public Health Re: Notification, Issuance of Notification Receipts, Renewal of Notification Receipts, Variation of Particulars of Notification Receipts and Issuance of Replacements of Notification Receipts of Cosmetics,

B.E. 2561 (2018)

Documents Accompanying the Application for Notification of Cosmetic

1. Documents in relation to the applicant for notification in case of new application or modification

- (1) In the case of a natural person:
 - (a) National ID card of the applicant;
 - (b) Power of attorney (in the case of entrusting another to act on one's behalf);
 - (c) Copy of house registration of the office, manufacturing facility, import facility as well as storage facility of cosmetics, as the case may be (if such place is owned by a person other than the applicant, a document showing permission to use or a rental contract of such place and a copy of National ID card of the person granting the permission to use or of the landlord shall also be submitted);
 - (d) Copy of business registration certificate identifying the business as a manufacturer of cosmetics for sale or an importer of cosmetics for sale;
 - (e) Copy of license to operate a business detrimental to health in case of a cosmetic manufacturing facility which is not a factory (if any) (under the Notification of the Ministry of Public Health on businesses detrimental to health, or a copy of the factory license in case of being a factory);
 - (f) Result of inspection of the place carried out in line with the Notification of the Ministry of Public Health on rules, procedures and conditions on the manufacture or importation of cosmetics;
- (2) In the case of a juristic person:
 - (a) National ID card of the applicant;
 - (b) Copy of certificate of juristic person registration issued no more than 6 months prior;
 - (c) Power of attorney (in the case of entrusting another to act on one's behalf);
 - (d) Copy of house registration of the office, manufacturing facility, import facility as well as storage facility of cosmetics, as the case may be (if such place is owned by a person other than the applicant, a document showing permission to use or a rental

contract of such place and a copy of National ID card of the person granting the permission to use or of the landlord shall also be submitted);

- (e) Copy of license to operate a business detrimental to health in case of a cosmetic manufacturing place which is not a factory (if any) (under the Notification of the Ministry of Public Health on businesses detrimental to health, or copy of the factory license in case of being a factory);
- (f) Result of inspection of the place carried out in line with the Notification of the Ministry of Public Health on rules, procedures and conditions on the manufacture or importation of cosmetics.
- (3) In the case where the applicant is a contract manufacturer, the documents under (1) or (2) and a contract for contract manufacturing shall be submitted.
- (4) In the case where the applicant is a manufacturer or a contract manufacturer for repackaging of single products, the documents under (1) or (2) and a letter indicating consent to repackaging issued by the manufacturer or importer of the cosmetic shall be submitted.
- (5) In the case where the applicant is a manufacturer or a contract manufacturer for bulk packaging, the documents under (1) or (2) and a letter indicating consent to bulk packaging issued by the manufacturer or importer of the cosmetic shall be submitted.

2. Documents in relation to cosmetic products

- (a) In the case where the cosmetic is contained in a container which is similar to that of a drug, e.g. ampoule or vial, or uses the word "ampoule" or "vial" as a part of the name of the cosmetic, the pictures of all sides of the label of the product or a document verifying that the product is a cosmetic shall be submitted to support the consideration.
- (b) Document supporting a statement used as part of the trade name, name of the cosmetic or assertion of its properties (if any);
- (c) In the case of an imported cosmetic, a letter of authorization from product owner or manufacturer, or trademark license agreement shall be submitted.