

Client Alert

January 2011

New Draft Circular from The Ministry of Health Regarding Cosmetic Regulations

This Draft Circular (“Draft Circular”) regulates the management of cosmetic products that are manufactured in the country and cosmetics that are imported for circulation in Vietnam. This Draft Circular refers to and is intended to conform with the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme, signed on 2 September 2003, of which Vietnam is a signatory member.

Applying to all organizations and individuals engaged in exporting, importing, manufacturing, and trading cosmetics in Vietnam, this Draft Circular is designed to replace Decision 48/2007/QĐ-BYT (“Decision No.48”) dated 31 December 2007 regulating the management of cosmetic products.

The main amendments and supplements in this Draft Circular as compared to Decision No. 48 are as below.

I. Notification of Cosmetic Products

1.1 Dossier of Notification of Cosmetic Products (“Dossier”)

This Draft Circular requires that a company submit a Dossier to regulatory authorities, which must include, *inter alia*, the following:

- (i) an authorization letter from the manufacturer or product owner; and
- (ii) a Business Registration Certificate or Investment Certificate.

In addition, for the importing of cosmetic products, a company must submit a Certificate of Free Sale (“CFS”) of such products.

1.2 The Authorization of Receipt and Process of a Dossier

- (i) For locally manufactured cosmetics, the Dossier must be submitted to the Health Service where a company has a factory. In the case that a company is not the manufacturer and is responsible for launching cosmetic products in the market, the Dossier shall be submitted to the Health Service where the company is headquartered;
- (ii) For imported cosmetic products, the Dossier must be submitted to the Drug Administration;
- (iii) For trading cosmetics in the Industrial Trade Zone of Moc Bai Border Gate Economic Zone, Tay Ninh province, the Dossier must be submitted to the Management Board of Moc Bai Border Gate Economic Zone; and
- (iv) For trading cosmetics in the Lao Bao Special Trade – Economic Zone, Quang Tri province, the Dossier must be submitted to the Management Board of Economic Zone, Quang Tri province.

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II. Export and Import of Cosmetics

Locally manufactured cosmetics for export purposes which are granted a Receipt of Cosmetic Product Notification or a Certificate of Quality Standard Notification may be granted a Certificate of Free Sale at the request of the exporter. Each Certificate of Free Sale is granted for one or many products and is effective for two years from the date of issuance.

With regard to imported cosmetics, *inter alia*, this Draft Circular specifies the regulation of importing cosmetics as gifts and importing cosmetics for exhibition. Importing cosmetics for these purposes does not require notification.

III. Sampling for Quality Control

This Draft Circular regulates sampling principles, the rights and obligations of a person taking samples and the transportation and delivery of samples. This Draft Circular also regulates the priorities in post-examination and the financial source for cosmetic quality control.

IV. Withdrawal of a Cosmetic Product Notification Receipt

During the effective time period of a Cosmetic Product Notification Receipt ("Receipt"), the regulatory authorities shall review and may decide to withdraw a Receipt in certain cases, including, but not limited to, the following:

- Circulating cosmetics with two manufactured lots failing to satisfy quality standards as concluded by a state management agency in charge of cosmetic quality;
- The formula of circulated cosmetics are different from the one provided in the Dossier;
- The cosmetics are not safe for users;
- The cosmetics are concluded by a regulatory agency to infringe on intellectual property rights; or
- The cosmetics are forbidden to circulate in the country of origin, etc.

V. Suspension of Receiving a Dossier of Notification of Cosmetic Products, Dossier of Advertising Registration and Dossier of Workshop/Event Registration for Presenting Cosmetics

Regulatory authorities may suspend the receiving of a Dossier of Notification of Cosmetic Products for 6 to 12 months in certain cases, including, but not limited to, the following:

- The trading of illegal import cosmetics, counterfeiting products, trading cosmetics without a source;
- Trading expired cosmetics;
- Failure to recall cosmetics as requested by the authorities; or
- Importing and trading cosmetics or raw materials which are forbidden to circulate in the original country, etc.

Regulatory authorities may also suspend the receiving of a Dossier of Advertising Registration or a Dossier of Workshop/Event Registration for Presenting Cosmetics for 6 to 12 months in the following cases:

- (i) Advertising or organizing workshops or events for presenting cosmetics when a Receipt of Advertising or Organizing a Workshop/Event has not been granted by regulatory authorities; or
- (ii) Advertising or organizing workshops or events for cosmetics which have not been granted a Cosmetic Product Notification Receipt.