New Definition of Controlled Cosmetics Will Change the Beauty Industry

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It is generally known to practitioners in the cosmetics industry that the Thai Cosmetic Act requires registration of *specially controlled cosmetics* prior to an act of manufacture, sale, or import. Similarly, any business operator who wishes to manufacture or import *controlled cosmetics* must notify the Thai Food and Drug Administration (FDA) of the required information according to the law. *General cosmetics*, meaning those which neither contain controlled or specially controlled substances nor qualify as *specially controlled cosmetics* or *controlled cosmetics* by way of Ministry Announcement, have traditionally been subject to lenient requirements such as label control prior to marketing activity.

The foregoing practice changed when the Ministry of Public Health (MoPH) issued an Announcement regarding the Definition of Controlled Cosmetics on July 8, 2008. Published on September 25, 2008 in the *Royal Gazette*, the law became effective on the day after publication, i.e. September 26, 2008. This recently issued MoPH Announcement, on one hand, will no longer provide leniency to *general cosmetics* manufacturers and importers. On the other hand, this Announcement will relieve the burdens that had previously been placed upon the manufacturers and importers of *specially controlled cosmetics*.

According to the Announcement, all cosmetics are now categorized as *controlled cosmetics.* Manufacturers and importers of *general cosmetics* and *specially controlled cosmetics* are now subject to the same regulatory compliance as manufacturers and importers of *controlled cosmetics*. This means that submission of notification to the FDA prior to the initiation of marketing or manufacturing activity is required.

The obligation for the importers and manufacturers of *specially controlled cosmetics* to register their products prior to marketing activities will no longer exist. To meet the FDA's compliance requirement, *specially controlled cosmetics* (which are now treated as *controlled cosmetics*) are merely required to file a notification to the FDA before manufacturing or selling.

To provide notification regarding *controlled cosmetics* with the Thai FDA, the following information is required:

1. Registered business name and address of office and storage place of manufacturer or importer;
2. Name, category, or kind of cosmetics to be manufactured or imported;
3. Details of all ingredients; and
4. Product label.

The FDA allows approximately two years of adjustment period for the industry. Manufacturers and importers of *general cosmetics* (which are now categorized as *controlled cosmetics*) must comply with these requirements and notify the FDA of their products by December 31, 2010. Within the same time frame, the manufacturers and importers of both *specially controlled* and *controlled cosmetics* must adjust their labels to comply with the *controlled cosmetics* standard.

The changes in the product registration procedure being implemented by the FDA are the result of ASEAN Harmonized Cosmetic Regulatory Scheme whereby the requirements or procedures shall be reduced to the simplest form, lessening the FDA's role in pre-marketing control. Under the ASEAN Harmonized Cosmetic Regulatory Scheme, the FDA will focus on a post-marketing surveillance system. ◆