



Taiwan Cosmetic Regulatory 2015

A ChemLinked Team Work Shared
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Cosmetic regulations in Taiwan were not subject to any significant changes in 2015. Taiwan Food and Drug Administration did however announce plans to revise the overarching cosmetic regulation in Taiwan.

AMENDING STATUTE FOR CONTROL OF COSMETIC HYGIENE

In Mar 2015, ChemLinked contacted Lin Yijie, an official from Taiwan Food and Drug Administration to help us understand the upcoming "Statute for Control of Cosmetic Hygiene". Lin stated that the development of the new legislation was still in the incipient stages.

The new Statute for Control of Cosmetic Hygiene may contain several significant changes. The main amendments are:

1. The scope of cosmetics is extended to oral products.
2. For cosmetics containing medical, poisonous or potent drugs, pre-market application is replaced by notification of key product information and preparing evaluation dossiers for inspection.
3. Labeling requirements are revised.
 - i. Name, address and phone number of manufacturer/importer; Name, address and phone number of factory;
 - ii. Product name;
 - iii. License number and lot number;
 - iv. Date of Manufacture and shelf life;
 - v. Name of ingredients, usage, storage method, weight or volume and precautions for use.
4. Experts or pharmacists working in cosmetic manufacturers are required to implement GMP requirements and are subject to administration and supervision.
5. Where a product advertisement violates related requirements, the manufacturer will be ordered to rectify the advertisement and the information will be subsequently filed.

6. Manufacturers are required to keep information about raw material suppliers and other links downstream in the supply chain.

7. Considering that cosmetics may cause hygiene and safety problems, the competent authority has the power to conduct tests and inspection when cosmetics are imported.

8. Any individuals reporting illegal activities will be rewarded and violators will be fined.

Lin spoke to ChemLinked stating that, "the focus of the amendment would be the strengthening of manufacturers/importer self-management and products post-market surveillance." The main shift in focus will see the pre-market approval system replaced with a simplified notification system and a move towards a self-regulating market. At present official guidance documents detailing the new regulatory requirements and new compliance obligations have not been released, so it remains to be seen whether or not the new system will align with the notification systems implemented in the member states of ASEAN.

Statute for Control of Cosmetic Hygiene, the overarching cosmetic regulation in Taiwan has not been amended for many years. Taiwan's current cosmetic regulations are inadequate to deal with actual industry and market requirements. Once the new Statute for Control of Cosmetic Hygiene is published, it will bring about a huge change for the Taiwan cosmetic industry.

STANDARDIZING COSMETICS MANAGEMENT

On 7 Jul 2015, Taiwan FDA released Guideline for Risk Assessment of Cosmetic Nanomaterials. This guideline is divided into two parts: physicochemical property assessment and safety assessment.

It is regulated that the assessment of physicochemical properties shall be conducted prior to safety assessment

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