

On Jan 1, 2008, Asean member countries implemented the Asean Harmonisation Cosmetics Regulation Scheme in order to harmonise a previously chaotic process. A multitude of confusing laws and procedures has now been transformed into a streamlined system with just a single category for cosmetic products and an efficient registration process.

The Thai Food and Drug Administration (FDA) implemented a new online cosmetic product registration system on Nov 1, 2010. Registration is now less time-consuming and more environmentally friendly than under the previous paper-based system.

The FDA has also created a single product category, which forces some cosmetic companies to re-register their products. This is an important change from past practice, when there were three categories.

According to the Society of Cosmetic Chemists of Thailand, the local industry has been growing by 10-20% per year over the last 10 years and is expected to see 30% growth this year, reflecting similar rapid growth in cosmetic imports.

Thailand is becoming an extremely attractive place for cosmetic product distributors to do business. But

BEATING COSMETIC PRODUCT REGISTRATION HURDLES

distributors new to the market should be aware of possible hurdles that typically arise during the FDA product registration process. By preparing effectively, applicants can save costs and bring their products to market quickly.

Product Name: Cosmetic products rely mainly on their names to attract consumers. Therefore, distributors need to take the utmost care when naming their products, prior to applying for registration in Thailand. To avoid rejection by the FDA, each word in the product name must correctly reflect the objective of the product, and the words used must not mislead consumers.

One difficulty for companies is using product names that differ from the ingredients or purpose of the product. For example, if the product name is "Tradename Tanning Body Lotion" but the product formula contains no ingredients that act as a tanning agent, the FDA will not register it.

The manufacturer or importer must also be careful to avoid using a product name that could be deemed to imply an

exaggerated claim or contain homophonous words.

For example, a product used to combat wrinkles is called "Tradename Eraser Wrinkle Serum". The word "eraser" will not be permitted because, in reality, the product cannot erase wrinkles. FDA officials would deem the name to be an overclaim.

Use of a homophonous word for a prohibited or improper word is also not allowed. An example is "Btox", which is derived from the prohibited word "Botox". "Btox" would be denied registration because it is confusingly similar to the registered trademark Botox and is deemed an infringement.

Finally, scientific words such as

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"nano" are not recommended, as the FDA would request additional scientific or reliable documents to support the claimed correlation.

Formula: The use of a prohibited ingredient in a formula will definitely lead to rejection, and the manufacturer will be required to alter the product formula to secure FDA approval. Examples of prohibited ingredients commonly found in cosmetics are dimethylamine and diethylene glycol.

Some ingredients are authorised but restricted, and required to comply with special FDA rules. For example, a formula for curling or straightening hair must not include tetraborates in an amount exceeding 8%, whereas in a bath product formula they must not exceed 18% (both are calculated in boric acid form).

A formula containing some specially controlled ingredients, especially natural extracts, must have a product safety document. For example, Citrus Reticulata Peel oil has no restrictions on the amount used in a formula. However, the total concentration of furocoumarin (found

in this extract) in a finished cosmetic product must not exceed one part per million. Therefore, the company must certify the safety assessment and provide an analysis of the amount of furocoumarin in the finished product.

FDA cosmetic category codes: In the registration process, an applicant must choose a cosmetic category code for each product from an FDA database known as the "Cosmetic Data Dictionary".

For example, if the product is a facial makeup set consisting of compact face powder with foundation, sunscreen, and lip gloss, the category code is 12796. If this code is not clearly specified, the characteristics or product type may result in selection of the wrong code, which would lead to rejection.

As the examples above illustrate, it is important that companies pay keen attention to preparation for registering their products and to advertising, as this will ensure a smooth and unhindered product launch.

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