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Food registration with the FDA: Overcoming Pitfalls

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With its diverse range of consumers seeking both traditional wares and more modern Western-influenced products, Thailand, like Vietnam and many other Asean countries, has become a hugely attractive and a lucrative market for foreign and local food manufacturers alike.

But for foreign companies that want to import products into Thailand, their first interaction with the Thai Food and Drug Administration (FDA) too often ends with a firm rebuttal, as their products are rejected for registration or they face significant delays. This is especially true if the food and drug regulators in the countries they are used to dealing with lack a strong pre-marketing review system but instead rely only on a post-marketing process to protect consumers in the event of product liability lawsuits, such as the US.

Although these FDA obstacles can be frustrating, companies can achieve success by familiarising themselves with Thai FDA practices and preparing for potential pitfalls.

New food ingredients: Prior to starting the registration process for a food product, a company must first determine whether all its ingredients have already been approved by the Thai FDA. An ingredient that is commonly registered in another country may not necessarily have been registered with the FDA.

For new ingredients, the FDA will request additional supporting documents. For example, a product used in food consumption must be able to show a history of use for more than 15 years in a foreign country and/or safety data.

Companies need to make strategic decisions about whether to retain the new food ingredient in a formula. On the one hand, the new ingredient can be helpful in differentiating the product from competitors, but on the other hand companies face an extended registration process when new ingredients are included.

Misclassification of food: Companies often have a misconception that if their products are classified and registered in a certain category in a country such as Singapore, then they would fall into the same category in Thailand. This is not necessarily the case. Prior to FDA submission, an applicant must be fully aware of: (1) the ingredient list for its products; (2) the source of the ingredients; (3) the manufacturing process; (4) the objectives of use; and (5) the targeted consumer group. These factors will allow the company to:

Fpreliminarily classify the product; and

Fassist in answering registration questions from the Thai FDA.

Misclassifying the product will delay the registration process, because companies are not permitted to transfer a dossier from one category to another. If a category change needs to be made, then the company must restart the application.

Requirements differ from one category to another. For example, if you misclassify a dietary supplement in the food supplement category, which does not require any analysis, when it is in fact a beverage in a sealed container, then this would mean additional documents and a detailed analysis are required. This causes further delays.

These delays can be avoided by carefully preparing and reviewing product ingredients and information before considering the classification.

Preparing your dossier carefully: Asean lacks a system for harmonisation of food products, and thus the product dossier requirements differ between member countries. In addition, some other countries including the US do not necessarily issue the same types of documents required by the Thai FDA.

The Thai FDA conducts a careful substantive examination of the documents provided, and any discrepancies will further delay the registration process. Companies should ensure that all documents, as requested by the FDA, are complete and consistent. If some documents are unavailable, then be prepared to provide a suitable response to the FDA.

Health claims on labels: The Thai FDA takes a stricter approach to claims on labels than in other countries including the US. For example, the Thai FDA permits nutrition claims if appropriate analysis is conducted. However, health claims _ that is, claims relating to benefits, efficacies and functions of the product _ are forbidden.

Foreign companies perceive the Thai FDA interpretation as very strict, as it requires a complete amendment of their labels when they are designed abroad. In some cases, however, it is worth negotiating with the FDA, as its officials are willing to learn from industry specialists. It is important for industries to work closely with the FDA in providing assistance on how to differentiate between health claims, slogans and other advertising statements.

Regional market: Food manufacturers and importers should no longer view Thailand as a stand-alone market when targeting it for their products but rather part of the overall Asean Economic Community that is due to take effect in 2015. Using this approach, companies can maximise efficiency by planning to register their products across several Asean countries.

Understanding the mechanisms adopted by local Asean FDAs may appear cumbersome, but with assistance from technical experts any company can enjoy a smooth product launch and reap the considerable benefits offered by the increased integration of Asean markets.

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