REGISTERING HEALTHCARE PRODUCTS WITH THE FDA

For many years, Thais have understood that consuming dietary supplements such as vitamins, minerals, amino acids and herbs can help them live healthier lives. Based on this, many healthcare companies view Thailand as a strong market with significant growth potential, thus leading to an increase in the number of dietary supplements being registered with the Food and Drug Administration (FDA).

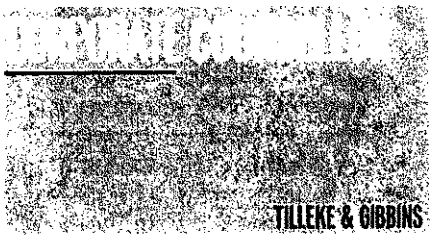
However, these companies may be faced with a challenging experience at first, especially if they are accustomed to dealing with regulatory authorities in the US, the UK or the EU, where the regulatory requirements are frequently less burdensome.

The first difficulty that can be encountered is that unlike the authorities in some other countries, the Thai FDA generally does not distinguish between dietary supplements and regular food or drug products. Frequently, the FDA will classify a dietary supplement as either a food or a drug product, and the company wishing to register the product will be required to follow the complex and comprehensive regulatory procedures required for food or drugs.

In order to determine the classification, the examiner will refer to the list and amount of ingredients in the product. For example, a high percentage of calcium or vitamins in a product could mean that a dietary supplement will be classified as a drug rather than a food supplement.

Determining which category a product will fall in is essential, as it affects the time frame for obtaining smooth registration of the product. For example, if a dietary supplement product is classified as a food product by the FDA, the average time to receive a registration licence is usually three to six months after the application has been filed. If, however, the FDA classifies the dietary supplement as a generic drug product, then the average registration time will be six months to one year after the application has been filed.

In rare instances, a dietary supplement can even be classified as a new drug product, in which case the average registration time could be as long as two years. Some companies may choose to amend the ingredients list and quantity slightly so as to fall into the food category, thus leading to a faster registration process.



The ability to achieve normal registration timelines with a dietary supplement product also depends to a substantial extent upon whether an application includes all of the documentation required by the FDA. Companies accustomed to operating in countries without strict regulations frequently provide files for dietary supplement products that do not measure up to Thai FDA standards. When reviewing these applications, the FDA will often request additional documents. Among the ones commonly requested by this country's FDA are a Good Manufacturing Practice Certificate and a Certificate of Free Sale, which are not available in all countries.

The FDA may also request a certificate of analysis, details of the analytical method and analytical data such as infrared spectrum. The FDA can also require a stability study, dissolution and disintegration profiles and safety data. The request for these documents will further extend the time required to obtain a registration certificate and thus introduction to the market.

When faced with a difficult request from the FDA, it is sometimes possible for applicants to obtain documents that are acceptable to it even if they do not specifically fulfil the initial request. For example, if it is not possible for an applicant to submit a Good Manufacturing Practice Certificate, the FDA may instead accept the ISO 17025 accreditation for food products or ISO 13485 accreditation for drug products.

To avoid losing time in determining the appropriate category for a product and the additional documents that will be required, companies should carefully consult the FDA's regulatory advisers to be certain the category chosen and material they propose to file will satisfy FDA requirements. This will ensure that companies can get their healthcare products into the Thai marketplace in the shortest possible time.

This article was prepared by Paul Russell of the Regulatory Affairs Department at Tilleke & Gibbins. Please send comments to Andrew Stoutley at andrew.s@tillekeandgibbins.com