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Advertising in the Face of Food and Drug Administration Restrictions

In making a product stand out in a highly competitive market, business owners may be tempted to neglect legal restrictions on what they can claim about their product. Such marketing-driven companies should take heed; the number of enforcement actions by the Thai Food and Drug Administration (FDA) over misleading claims or false statements has been increasing. A claim should be understood as a key expression on an advertisement or label stating that the product has a certain effect. A statement, on the other hand, has a broader meaning and refers to any acts promoting the product. In looking for false statements, the FDA is not only monitoring national media—its usual targets of control and supervision—but also local media, such as community radio stations and newspapers. Now, more than ever, companies must diligently examine their product claims.

The Law and Its Consequences

In Thailand, as a general rule, language used in advertising material must not lead to a misunderstanding and should not be false, deceitful, or contrary to Thai culture. It is not permissible to use words that exaggerate product quality, such as "excellent," "magnificent," "exceptional," "perfect," "effective," "magic," or "best." Furthermore, certain industries are required to comply with specific rules and regulations. The tobacco, alcohol, pharmaceutical, food, medical devices, and cosmetics industries are examples of sectors that must exercise caution before issuing communications to the public. Advertising material for certain products must receive approval from the FDA prior to being used in the marketplace and must be distributed to the public in an approved manner.

The FDA may impose fines on companies that violate advertising rules and regulations. In certain cases, the Office of the Consumer Protection Board can order the offender to issue an announcement clarifying the content of the material or to make a restatement, which involves submitting a new statement as an advertisement. Completely removing the material from circulation is often seen as an appropriate course of action to remedy an infraction. Needless to say, this results in significant expenses that could have been avoided through proper confirmation of regulatory compliance.

Zapping an Energy Drink Company

In early October 2010, a major energy drink company was held liable for making a claim about the quality of a product without the approval of the FDA. As the content of the advertisement was misleading to consumers, not only was the company prohibited from presenting such unproven statement for publication, but the media was also forbidden by FDA regulations from publishing it. Both the owner and the media face fines, and the FDA may order the manufacturing of the product to be suspended.

Dangerous Supplementing of Supplement Claims

The FDA brought an action against a company that manufactures food supplements and distributes same through a multi-level marketing system. The scheme encourages members to recruit other members and imposes no restrictions on membership. The manufacturer of the product applied for and received FDA approval of its marketing material. The approved material was then distributed to members for their use in promoting the food supplement product. Rather than simply redistributing the approved material, the members began to promote their products on their own and added certain new claims. The information became misleading and noncompliant with the content approved by the FDA. The company attempted to defend itself on the ground that the members themselves had revised the statements. The FDA, however, disregarded this defense and imposed sanctions on the manufacturer because the manufacturer could not provide evidence of measures taken to prevent such distribution of misleading information. Because of this initial case, the FDA decided to conduct an audit on all advertising prepared by the company.

While pursuing a creative marketing and advertising strategy, it is essential to gain and maintain a foothold in the market. To avoid undesirable consequences, however, marketing initiatives must be complemented with a thorough understanding of FDA regulations. For more information, business owners are encouraged to consult the FDA newsletter, which includes FDA decisions on product advertising and product safety. The FDA newsletter is publicly available in the Thai language at: www.fda.moph.go.th.

FDA Compliance Audit

Are your business practices and materials susceptible to regulatory scrutiny? How do you know whether your advertisements are setting your company up for a regulatory complaint?

A confidential FDA compliance audit is an easy way to help ensure that your company is following the rules. In a compliance audit, a team from Tilleke & Gibbins, including a lawyer and a paralegal, will visit your offices in order to review, collect, and assess those areas of your business that are susceptible to regulatory review. The team will examine, as applicable, your:

1. Advertising and promotional materials (past, current, and planned);
2. Product labels, product inserts, and product packages (past, current, and planned);
3. Thai FDA product registration certificates;
4. Customer complaint procedures;
5. Contracts with your distributors, vendors, and affiliates in order to determine the allocation of liability in regard to advertising;
6. Organizational structure; and
7. Other problematic areas as observed during the course of the compliance audit.

The results of our investigation and review will be presented to your company in the form of a confidential compliance audit report, which aims to help you comply with the evolving legislation and regulations in Thailand. Our compliance audit reports set out practical advice and suggested strategies on how current processes, policies, procedures, legal agreements, and practice could be supplemented to minimize and manage regulatory risks. By knowing the risks and implementing effective procedures and policies to mitigate them, your company's vulnerability will be decreased significantly.

If you would like more information on our compliance audit service, please contact Alan Adcock, Deputy Director, Intellectual Property, at alan.a@tillekeandgibbins.com.