



It's All Local: What You Need to Know About the Law Relating to the Marketing of Dietary Supplements in the United States, the European Union and China

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Consumers around the world are increasing their use of dietary supplements. In the United States alone, consumers spend almost \$27 billion per year on dietary supplements.¹ The United States Centers for Disease Control and Prevention's April 2011 report regarding dietary supplement usage found that more than half of adults in the United States take dietary supplements, a percentage that has increased dramatically over the last 20 years.² Between 1994 and 2006, the percentage of Americans using at least one dietary supplement increased from 42 percent to 53 percent of adults—

approximately the same percentage of adult Americans who claim to be dieting at any given time.³ Sales of herbal dietary supplements alone increased by 5 percent in 2009 to just over \$5 billion annually, impressive growth given the economic hardship blanketing the country.⁴

Interestingly, Americans are not alone. Consumers in the European Union (EU) and in China, a rapidly developing and promising market for dietary supplements, are increasing their dietary supplement use as well. In the EU, the vitamins and dietary supplements category grew 2 percent to nearly €7 billion



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in 2009.⁵ Growth came from strong performances in Romania (13 percent), the Netherlands (6 percent), Italy (5 percent) and Greece (4 percent) as consumers increased their purchases of dietary supplements to prevent falling ill.⁶ China's growing economy has created expendable income for Chinese consumers with an interest in natural health products, particularly those "Made in the USA."⁷

With growing demand, dietary supplement companies have diversified their product portfolios and expanded their manufacturing and sales distribution to existing and emerging markets. In so doing, these same companies are confronted with myriad regulations that apply to the registration, sale and advertising of their products, each of which must be evaluated on a country by country or regional basis, as in the case of the EU. This article explores the differences between the U.S. system of regulating sale and advertising of dietary supplements with those of the EU and China, which are established and emerging markets with regulations that limit products and claims to defined categories in the name of consumer protection.

The United States

As many readers of this publication know, the federal Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) share jurisdiction over sale and marketing of dietary supplements in the United States. Outside of those involved in the industry, however, the public appears to be generally uninformed about how dietary supplements are brought to market. According to Consumer Reports, "Common motivations [for using dietary supplements] are to lose weight, stay healthy and avoid the use of prescription drugs. Slightly more than half of older adults (ages 57 to 85) take supplements right along with their

prescription medications. And more than half of respondents to a national Harris poll in 2002 said they believed—incorrectly—that supplements must be approved by a government agency before they can be sold to the public; that the government requires warning labels on supplements' potential side effects or dangers and that manufacturers can't make safety claims without solid scientific support."⁸ In reality, the system is much more self-regulating.

It begins with FDA, which has jurisdiction over labeling and enforcement of laws and regulations relating to quality and manufacturing, such as the current Good Manufacturing Practices. In fact, FDA describes regulation of dietary supplements as follows:

- FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements. [Domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States are required to register their facility with FDA.] Manufacturers must make sure that product label information is truthful and not misleading.
- FDA's post-marketing responsibilities include monitoring safety, e.g. volun-

tary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts and accompanying literature.

FTC regulates advertising of dietary supplement products, but it similarly does not approve products or claims prior to market introduction.⁹ Both agencies rely on companies to comply with the applicable laws and regulations and, where compliance is in question, the agencies use enforcement to weed out adulterated or misbranded products or unsubstantiated or misleading claims.

Recently, increased collaboration between FDA and FTC is creating a notable shift in regulatory enforcement that blurs the jurisdictional lines between the agencies. For example, on February 1, 2011, FDA issued a warning letter to dietary supplement maker Tennessee Scientific, Inc.,¹⁰ alleging that certain claims on the company's website constituted unauthorized disease claims, which also caused the dietary supplement products to be unapproved drugs. What is unusual about this particular warning letter is that FDA cited FTC advertising standards as a further basis for challenging the company's conduct. More specifically, after citing alleged violations of the Food, Drug and Cosmetic Act (FDCA) the letter states: "it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating the claims are true at the time they are made." While FTC is not a signatory of the letter, the letter makes the highly unusual request that Tennessee Scientific respond to FTC regarding the potential violations of the

FTC Act. The Tennessee Scientific action follows other high profile enforcement matters brought by FTC involving POM Wonderful, Nestlé, Iovate and Dannon, in addition to FDA enforcement actions relating to front of pack labeling and claims.

To be sure, enforcement actions are intended not only to stop the marketer's non-compliant behavior but also to send a signal to industry as to how these agencies interpret the laws and regulations that they are charged with enforcing. In many ways, this process is favorable toward dietary supplement marketers because, while manufacturers are charged with operating in compliance with the law or risking enforcement action (not to mention the risks of private litigation), products can be brought to market relatively quickly and without lengthy preapproval or registration processes.

The EU and China

The regulations governing sale and marketing of a dietary supplement in the EU and China stand in stark contrast to that of the United States. In both instances, claims preapproval is required and can often be a lengthy process. The EU Food Supplements Directive specifies those supplements that may be sold in the EU and specifies those vitamins and minerals that may be sold as supplements or used in the manufacture of supplements.¹¹ The Directive also mandates labeling standards.¹² Similar to U.S. standards, dietary supplements in the EU cannot bear disease reduction claims; however, the EU allows products to feature health claims, both functional claims and those that describe the relationship between a food and reduced risk of a disease or condition, only as approved by the European Commission (EC).¹³ The EC's claims approval process has been the target of significant

criticism and objection from industry because of the time required for review of claims petitions by the European Food Safety Agency (EFSA) and the opinion of some petitioners that EFSA has taken highly conservative positions with regard to claims.¹⁴

Introduction of a dietary supplement product in China is even more complex. Three regulatory agencies govern the sale, manufacture and advertising of dietary supplements. These include the State Food and Drug Administration (SFDA), the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the Ministry of Health (MOH). Before a product even approaches sale, it must go through the registration and approval process. Prior to sale, manufacturers must register dietary supplements with SFDA. According to the Natural Products Association, "a typical registration can take up to two years to complete and cost in the range of \$20,000 to \$50,000."¹⁵ If the product is new to the market, however, the process lengthens and the price increases. It can take as long as five years and up to \$500,000 for registration.¹⁶ After market entry, registration is valid for five years and then must be renewed.

Once a manufacturer successfully registers its product, Chinese law allows limited health benefit claims. SFDA regulates health claims and dietary supplement advertising. Presently, there are 27 health benefit claims that may be made on dietary supplements. SFDA can bring enforcement actions against companies that make unapproved claims and levy fines. In order to obtain approval for use of one of the 27 approved claims, manufacturers must demonstrate that the ingredient or product is safe based upon testing rather than established science or a history of safe use.¹⁷

Protection of public health from unsafe products is the intended effect of this highly matrixed system. The burden and costs of this system may not lead all manufacturers down the path of compliance, however. The Natural Products Association estimates that a large percentage of dietary supplements presently being sold in China have not been approved by SFDA and, thus, are not in compliance with SFDA regulations.¹⁸

Lessons for Manufacturers

As dietary supplement manufacturers expand to serve growing demand, the importance of having a proactive understanding of the local market laws and regulations for product introduction and marketing cannot be overstated. As discussed above, these provisions greatly affect speed to market and a marketer's ability to make desired health benefit claims, the viability of which should be evaluated per local standards prior to a product launch.

In addition, manufacturers should analyze enforcement trends in new and existing markets to determine if their practices – whether relating to manufacturing, sale or advertising – comply with local regulations or could be a source of risk to the company. Intellectual property protection should also be considered, particularly if a new product is being introduced. Although the growth of dietary supplements is worldwide, as demonstrated by the different regulatory systems discussed above, dietary supplements and politics have something in common: It's all local. As manufacturers expand, they must develop an understanding and working relationship with local legal standards in each market in order to succeed. ▲

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2. Report of the U.S. Centers for Disease Control and Prevention “Dietary Supplement Use Among U.S. Adults Has Increased Since NHANES III (1988-1994)” (April 13, 2011), available at: <http://www.cdc.gov/nchs/data/databriefs/db61.htm>
3. MedlinePlus “Use of Dietary Supplements Keeps Climbing: CDC” (April 13, 2011), available at: http://www.nlm.nih.gov/medlineplus/news/full-story_110944.html
4. Report of the American Botanical Council “Herbal Supplement Sales Increase in the U.S. in 2009” (May 7, 2010), available at: http://cms.herbalgram.org/press/2009_Market_Report.html
5. Bnet.com “Europe: an interesting market for dietary supplements and functional/fortified foods” (November 2010), available at: http://findarticles.com/p/articles/mi_hb223/is_9_13/ai_n56369718/?tag=mantle_skin;content
6. *Id.*
7. See U.S. China Health Products Association “Why U.S.-China HPA?” (October 26, 2010), available at: <http://uschinahpa.org/why-u-s-china-health-products-association-is-needed/>
8. *Supra* note 1.
9. See FTC.com “Dietary Supplements: An Advertising Guide for Industry” available at: <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>
10. FDA Warning Letter to Tennessee Scientific, Inc. (Feb. 1, 2011) available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm241970.htm>.
11. See Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0046:EN:HTML>
12. *Id.*
13. See Article 13 Health Claims approval process, available at: http://ec.europa.eu/food/food/labeling/nutrition/claims/health_claims_en.htm
14. See e.g., nutraingredients.com “EFSA rejects MEP’s health claims criticism” (April 27, 2011), available at: <http://www.nutraingredients.com/Regulation/EFSA-rejects-MEPs-health-claims-criticisms;EFSA-refutes-Danone-health-claims-criticism> (July 6, 2010); available at <http://www.nutraingredients.com/Regulation/EFSA-refutes-Danone-health-claims-criticism>
15. Natural Products Association testimony to Joint Commission on Commerce and Trade 2011 (March 15, 2011), available at: <http://www.npainfo.org/clientuploads/regulatory/Legislative/031511%20Comments%202011%20JCCCT%20China.pdf>
16. *See Id.*
17. *See Id.*
18. *See Id.*



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