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Marketing of Diet Supplement Products: Can Product Claims Be Trusted?

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Introduction

Currently in the United States diet supplement companies are being monitored for truthful advertising regarding claims of usefulness for the products they manufacture and distribute. The United States Government Agency which is spearheading this monitor process is the Food and Drug Administration (FDA). This process is in support of FDA's position to ensure this category of products (OTC's in the US) is safe and supports the overall wellness of any consumer. For manufacturers and distributors of these products the FDA has, through several approved Acts by the US Congress, set guidelines on how allowable claims for diet supplement products are defined and can pass FDA scrutiny. Diet supplement productclaims are categorized by the FDA to be either a Health Claim, a Nutrition Content Claim or a Structure/Function Claim. Interestingly, these guidelines would appear to be more stringent than those in place in several European and South American countries. A reading of the advertising claims for similar type products in Europe, Central and South America clearly supports this observation.

Background

Following many unsubstantiated Health Claims for foods and supplements that had occurred during 1985-1987, the US Congress passed the Nutrition Labeling and Education Act (NLEA) of 1990 which allowed only certain claims regarding health improvement for foods and dietary supplements that had FDA approval. Subsequently a second Act known as the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted wherein dietary supplements were defined as vitamins, minerals, herbs, botanical, amino acids or dietary substances for use by man to supplement the diet by increasing the total dietary intake. Concentrates, metabolites, constituent, extracts or combinations of the above are also considered dietary supplements.

Health Claims

Health Claims as defined by the US FDA describe a relation between a food, food component or dietary supplement ingredient and the reduction of risk associated with a disease or health-related condition. There were just eight (8) health claims approved with this Act in 1990. During the period of 1997 to 2006 seven (7) health claims were approved for product marketing following a complex scheme to demonstrate validity. Six (6) of the seven (7) health claims approved by the FDA were associated with products containing particular ingredients useful in reducing the risk of congestive heart disease. The other involved approval of statements regarding the relation of sugar alcohol and dental caries. Health claims are the most difficult to defend for an organization and to have approved by meetinga standard of significant scientific agreement involving multiple well designed clinical intervention trials, clinical reviews by experts and significant publicly available evidence to support the diet-disease relation. For this reason very few products are marketed in the United States today using the health claim approach.

Nutrient Content Claims

Nutrient Content Claims describe the percentage of a nutrient in a product relative to the recommended daily value (DV). The DV indicates the amount of a nutrient that is provided by single serving of a food or diet supplement item. To state, for example, that a product is "good source" of calcium, this nutrient must provide at least ten (10) percent of the DV. A claim that the product is an "excellent source" requires the nutrient to be 20% or more of the DV. Even though many labeled diet supplement products do not teach whether they are good or excellent sources of particular ingredients, information on the label may delineate the percent (%) of DV for the key ingredients

and calories, total fat, total carbohydrates, cholesterol, sodium and potassium and protein provided in a single serving. Some products in the diet supplement category contain as much as 54% of the DV for select ingredients in just one serving.

Structure/Function Claims

In 2000, the FDA issued a final rule entitled "Regulations on Statements made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body". The focus of this act was to clarify the extent to which word claims could be used for various products and support the normal structure of function of the human body. These claims are further classified as claims of general well-being and claims related to a nutrient deficiency disease. Examples of this type of claim are "calcium builds strong bones" or "fiber maintains bowel regularity". Yet another might be "helps improve satiety and mood" but the claim cannot say "reduces depression". "Maintains cholesterol in a healthy range" is allowable but "lowers cholesterol" is not.

The Petition Process

For manufacturers or distributors of diet supplement products, there is a process by which structure/function claims can be approved for product label and marketing use if they are unsure of the claim wording and its acceptability. Petitions can be filed with the FDA by the product manufacturer or distributor to gain approval for unrestricted use in marketing of the product. There is an evaluation approach that the FDA follows which includes requests for comments from the public and experts in addition to an extensive review by the FDA of all available information that might support the proposed structure/function claim. This typically is a 120 day process typically announced through the Federal Register for final decision regarding the acceptability of the claim. Since the passage of the Act in 2000, there have been nearly 29,000 Petitions filed with the FDA to gain allowable claims for foods and dietary supplement.

Summary of Utility

The purpose of this commentary is to provide a perspective about how truth in advertising is being monitored in the United States and explain the process by which claims are presented and allowed for an OTC category of product that can be trusted by the average consumer. It is also an opportunity for international readers to compare the United States approach to claims substantiation with the guidelines available in other countries worldwide.

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