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Current Regulations for Labelling and Advertising Of Nutritional Supplements

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Abstract- The present study is on to regulate the nutritional supplements for labelling and advertising. Nutritional are commonly used in entire world. There is a tendency for underreporting their ingestion by patients and the magnitude of their use is under recognised by Physicians. This review will mainly discuss single ingredients and complex mixtures of natural nutrition's marketed under a single label and advertising. These create difficulties in developing and harmonizing nutrition information listings, which have broad international applications. For these reasons, the codex guidelines on nutrition labelling play an important role to provide guidance to member countries when they want to develop or update their national regulations and to encourage harmonization of national standards with international standards. As for all products on the market, advertising for dietary supplements must be truthful and substantiated. The U.S Food and Drug Administration (FDA) and Federal Trade Commission (FTC) work together in regulating dietary supplement advertising. FDA is primarily responsible for claims on product labelling, while FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. These two agencies collaborate to ensure consistency in dietary supplement advertising regulation. The conclusion of current regulations for labelling and advertising of nutritional supplements was marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labelling and advertising claims be truthful, not misleading and substantiated.

Keywords- DSHEA, Federal trade commission, Labelling and advertising, NELA.

INTRODUCTION

A **dietary supplement** is intended to provide nutrients that may otherwise not be consumed in sufficient quantities. Supplements as generally understood include vitamins, minerals, fibre, fatty acids, or amino acids, among other substances. U.S. authorities define dietary supplements as foods, while elsewhere they may be classified as drugs or other products. There are more than 50,000 dietary supplements available. More than half of the U.S. adult population (53% – 55%) consume dietary supplements with most common ones being multivitamins.[1]. These products are not intended to prevent or treat any disease and in some circumstances are dangerous, according to the U.S. National Institutes of Health. For those who fail to consume a balanced diet, the agency says that certain supplements "may have value." [2]Most supplements should be avoided, and usually people should not eat micronutrients except people with clearly shown deficiency.[3] Those people should first consult a doctor.[4] An exception is vitamin D, which is recommended in Nordic countries due to weak sunlight. FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labelling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.
- FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market. **This section provides detailed information about:**

- **Products & Ingredients**
- Information on selected dietary supplement products, ingredients, and other substances.
- **Information for Consumers**
- Tips for dietary supplement users, including older supplement users.
- **Information for Industry**
- Resources and links for applications, forms, guidance, and other items of interest to industry members.
- **Report an Adverse Event**

  Learn how consumers, health care providers, and others can report a complaint, concern, or problem related to dietary supplements. Includes links to guidance for dietary supplement manufacturers, packers, and distributors.
- **New Dietary Ingredients Notification Process**

  Background information for industry, instructions for submitting premarket notifications, and links to relevant guidance and Federal Register documents.

Dietary Supplements: What You Need to Know

The majority of adults in the United States take one or more dietary supplements either every day or occasionally. Today's dietary supplements include vitamins, minerals, herbals and botanicals, amino acids, enzymes, and many other products. Dietary supplements come in a variety of forms: traditional tablets, capsules, and powders, as well as drinks and energy bars. Popular supplements include vitamins D and E; minerals like calcium and iron; herbs such as chinacea and garlic; and specialty products like glucosamine, probiotics, and fish oils.

The Dietary Supplement Label

All products labelled as a dietary supplement carry a Supplement Facts panel that lists the contents, amount of active ingredients per serving, and other added ingredients (like fillers, binders, and flavourings). The manufacturer suggests the serving size, but you or your health care provider might decide that a different amount is more appropriate for you.

Effectiveness

If you don't eat a nutritious variety of foods, some supplements might help you get adequate amounts of essential nutrients. However, supplements can't take the place of the variety of foods that are important to a healthy diet. Good sources of information on eating well include the Dietary Guidelines for Americans and My Plate.

Scientific evidence shows that some dietary supplements are beneficial for overall health and for managing some health conditions. For example, calcium and vitamin D are important for keeping bones strong and reducing bone loss; folic acid decreases the risk of certain birth defects; and omega-3 fatty acids from fish oils might help some people with heart disease. Other supplements need more study to determine their value. The U.S. Food and Drug Administration (FDA) does not determine whether dietary supplements are effective before they are marketed.

Safety and Risk

Many supplements contain active ingredients that can have strong effects in the body. Always be alert to the possibility of unexpected side effects, especially when taking a new product. Supplements are most likely to cause side effects or harm when people take them instead of prescribed medicines or when people take many supplements in combination. Some supplements can increase the risk of bleeding or, if a person takes them before or after surgery, they can affect the person's response to anesthesia. Dietary supplements can also interact with certain prescription drugs in ways that might cause problems.

Discussion

General Labelling Requirements

The following basic information is required to be declared in English on the labels of pre-packed foods:

(a) Name or description of food

A common name or a description which is sufficient to indicate the true nature of the food product. Refer to "Part IV Standards

and Particular Labelling Requirements for Food" of the Food Regulations to ensure that the terms used for the common name or the descriptions comply with the requirement.

(b) Statement of ingredients

A complete list of ingredients and additives used in the food listed in descending order of the proportions by weight in which they are present. For instance, the ingredients listed at the top of the list should be the one that weighed the most compared to the rest of the ingredients.

The exact identity or the permitted generic terms [1] of the ingredients and additives should be declared. International Numbering System (INS) number or E number can be used for declaration of food additives. It is not mandatory to state that a food contains water.

For compound ingredients which comprise more than one constituent, the constituents should be declared in descending order. For example, "soy sauce (water, soybean, black bean, salt, sugar)".

(c) Declaration of foods and ingredients known to cause hypersensitivity

Regulation 5(4)(ea) requires declaration of foods and ingredients known to cause hypersensitivity. The following foods and ingredients are required to be declared when present as an ingredient/additive or as a component of a compound ingredient:

(i)	Cereals containing Gluten	This group includes wheat, rye, barley, oats, spelt or their hybridised strains and their products.
(ii)	Crustacean and Crustacean Products	This group includes crayfish, prawns, shrimps, lobsters, crabs and their products.
(iii)	Eggs and egg Products	This group includes eggs from laying hens as well as eggs from duck, turkey, quail, goose, gull, guinea fowl and their products.
(iv)	Fish and fish Products	This group also includes molluscs such as oysters, clams, scallops and their products.
(v)	Peanuts, soybeans and their products	Peanuts may be declared using similar terms such as "groundnuts". Terms such as "soya" or "soy" can be used for soybeans.
(vi)	Milk and milk products (including lactose)	This group includes milk from cows, buffaloes, or goats and their products.

Option 1: Declaration using statement of ingredients

All food ingredients and additives used in food products, including those listed as food ingredients and additives causing hypersensitivity should be declared clearly in the statements of ingredients in descending order by weight. For compound ingredients comprising two or more food ingredients, the compositions in descending order by weight, should be declared in parenthesis next to the compound ingredients. For example, "Batter (water, cornstarch, wheat flour, salt, sodium bicarbonate)"

Option 2: Declaration using "Contains" statement

When a "Contains" statement is used, it should appear immediately after the statement of ingredients. However, information provided in the "Contains" statement should not contradict that declared in the statement of ingredients. All food ingredients and additives used in foods should be declared clearly in the statement of ingredients. The "Contains" statement should not be used to declare additional food ingredients/additives which are not declared in the statement of ingredients. Allergenic ingredients which are unintentionally introduced into foods such as through contamination or carried-over from such ingredients during manufacturing, transportation, storage or any other means must not be declared in the "Contains" statement.

Special considerations

* To be in line with international practice, when cereals, whey and nuts are used as distillates for alcoholic beverages, or fish gelatin or isinglass* as fining/clarifying agents in beer and wine, these ingredients are not required to be declared on the label. Food traders have to bear full responsibility for ensuring that the information they choose not to declare does not, in actual fact, cause harm to consumers.
* The use of disclaimer statements such as "may contain" to declare the presence of ingredients known to cause hypersensitivity, when manufacturers cannot discount the possibility of cross contamination in their food products, is not encouraged. This may unnecessarily restrict consumer choice and undermine valid warnings. Nonetheless, food traders whose products carry the "may contain" statement, may be required to provide justification if consumers raise any concerns on the presence of potential food allergens.
* *Isinglass* is semi-transparent whitish gelatin prepared from the swim bladders of sturgeon and certain other fishes and is used as a clarifying agent in beer and wine.

(d) Declaration of net content in package

The net quantity of the food present in the package is required to be declared on the label. The net quantity is derived using the Minimum Quantity System or the Average Quantity System, and must be expressed in terms of volumetric measure for liquid foods (for example, milliliters, liters), net weight for solid foods (for example, grams, kilograms) or either weight or volumetric measure for semi-solid or viscous foods such as tomato paste, yoghurt. In the case of weight measure, suitable words such as "net" shall be used to describe the manner of measure. Food packed in a liquid medium[2] will be required to have both "net weight" and "drained weight" declared.

Examples of products that require drained weight declaration:

(i) Products with liquid packing medium which is drained away prior to consumption of the product. The products include canned seafood in brine e.g. abalone, pacific clams, tuna, crabmeat and canned vegetables in brine such as button mushrooms, whole corn kernels, chickpeas, gingko nuts in water.

(ii) Preserved/pickled products in liquid medium with salt, vinegar or sugar. The liquid medium is neither drained away nor consumed. The products include pickled green chili, cucumbers, onions, capers, mustard greens, and preserved ginger, salted plums.

(iii) Canned fruit and vegetable packed in juices or sugar syrups. For this instance, juice content is not a decisive factor to purchase. The products include canned rambutans in pineapple juice, peaches, pears, lychees, longans in light syrup, fruit cocktail in syrup.

Examples of products that do not require drained weight declaration:

(i) Products for drinking which contain solid bits. For such products, the liquid portion forms the most part of the product. These products include grass jelly drink, fruit juice with aloe vera bits, juice drink with nata de coco, birds' nest flavored drink with jelly, bottled hashima dessert.

(ii) Products containing solid food in gravy, paste or sauce
Which are meant to be consumed as a dish. The products include shark's fin soup, peanut soup, curry chicken, sardines and baked beans in tomato sauce, fried gluten in soy sauce, braised peanuts and vegetarian mock meat in soy sauce, kimchi and sauerkraut.

(iii) Products containing solid food in oil predominantly. The products include canned seafood such as tuna, anchovies in vegetable oil, sundried tomato in oil and fermented bean curd.

(iv) Products containing solid food with small amount of water due to syneresis. The products include bean curd and jelly.

(e) Name and address of the local manufacturer or importer

The name and address of the local manufacturer, packer or vendor should be printed on the labels of foods of local origin. In the case of an imported food, the label should indicate the name and address of the local importer, distributor or agent. Telegraphic, facsimile and post office addresses alone are not acceptable.

(f) Country of origin of food

The name of the country of origin of the food should be indicated on the labels for imported foods. The name of a city, town or province alone is not acceptable.

Exemptions

Labelling requirements do not apply under these conditions:

(i) Food weighed, counted or measured in the presence of the purchaser.

(ii) Food that is loosely packed at the retailer's premises.

(iii) intoxicating liquors are not required to carry a statement of ingredients on their labels

Points to note

Pre-packed foods that are intended for human consumption and offered as a price, reward or sample for the purpose of advertising are required to comply with the labelling requirements stated under "General Labelling Requirements".

Recipes or suggestions or pictorial illustrations on how to serve pre-packed foods may be included on food labels only if they are closely accompanied by the words "Recipe" or "Serving Suggestion", in printed letters of a minimum of 1.5 mm in height.

Additional Labelling Requirements

Date-marking of expiry date

The pre-packed foods listed in Table 2 are required to be labelled with their expiry dates. Expiry date refers to the date after

which the food may not retain its normal nature and quality. The expiry date should be qualified by words like "USE BY", "SELL BY", "EXPIRY DATE", "BEST BEFORE" or other words of similar meaning. Where the validity of the date mark is dependent on its storage, the storage direction of that food must be stated on the label or package. For example: "BEST BEFORE: 31 Dec 2010. Store in a cool, dry place. "The date-marking must be permanently marked or embossed on the package, and printed in letters not less than 3mm in height.

List of pre-packed foods that is required to be date marked with their expiry dates

1. Cream,reduced cream, light cream, the tare of whipped cream and sour cream excluding mark Is optional for sterilized canned cream.
2. Cultured milk and cultured milk drink.
3. Pasteurised milk and pasteurised drink.
4. Yoghurt, low-fat yoghurt fat reduced yoghurt and nonfat yoghurt and yoghurt products.
5. Pasteurised fruit juice and pasteurised fruit drink.
6. Pasteurised vegetable juice and pasteurised vegetable drink.

Format of date marking;

Example: The expiry date of pasteurised milk can be declared as **" 31 May 12** or **31"**

Nutrition labelling

Nutrition labelling is required when nutrition claims, or permitted health claims are made. More information about these claims can be found in the following topics of this material. The Food Regulations require nutrient declaration in an acceptable nutrition information panel, for pre-packed foods for which nutrition claims are made. The information to be declared in the panel includes the energy, protein, fat and carbohydrate contents of the food. Declaration of other nutrients is mandatory when such nutrients are the subject of a nutrition claim. An acceptable nutrition information panel, which can also be found in the Twelfth Schedule of the Food Regulations, is shown in following

Additional requirements for foods claimed to be source of energy or protein

Foods claimed to be a source of energy are required to state on their labels the quantity of that food to be consumed in one day, which should yield at least 300 kcal. The labels should also include an acceptable nutrition information panel. Foods claimed to be a source or an excellent source of protein should include on the label the quantity of that food to be consumed in one day, and an acceptable nutrition information panel. To claim as a source of protein, at least 12% of the total calorie yield of the food should be derived from protein. To claim as an excellent source of protein, at least 20% of the total calorie yield of the food should be derived from protein. In addition, the amount of food stated on the label as the quantity to be consumed in one day should also contain at least 10g of protein. Recommendation statement are Recommended daily intake: 3 servings"; "Add 20g powder in 200ml water. Drink 2 times daily."

Specific labelling requirements for certain food categories

Specific labelling requirements are stipulated for certain food categories under their individual specification standards. Please refer to Table 6 for examples of food categories with specific labelling requirements.

Food type	Food Regulations
Irradiated food	Regulation 38
Wholegrain	Regulation 40A
Bakery products	Regulation 53
Edible fats and oils	Regulation 79
Milk	Regulation 109
Coffee (coffee and chicory, coffee mixture, instant or soluble coffee and chicory)	Regulation 158, 159, 161
Fruit juice	Regulation 171
Natural mineral water	Regulation 183A
Fruit wine	Regulation 195
Compounded liquor	Regulation 210
Infant formula	Regulation 254
Rice	Regulation 260

Advertising Dietary Supplements

As for all products on the market, advertising for dietary supplements must be truthful and substantiated. The U.S. Food and

Drug Administration (FDA) and the Federal Trade Commission (FTC) work together in regulating dietary supplement advertising. FDA is primarily responsible for claims on product labelling, while FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. These two agencies collaborate to ensure consistency in dietary supplement advertising regulation.

Claims describing the role of a dietary supplement in supporting wellness are allowed on dietary supplement labels provided the manufacturer has evidence substantiating these claims and notifies FDA of the claim within 30 days of marketing the product. In some instances, the dietary supplement must contain the following disclaimer on the label: "This statement has not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. "There are three types of permissible claims for dietary supplements: health claims, structure/function claims, and nutrient content claims. Health claims describe a relationship between a food, food component, or dietary supplement ingredient and reduction in the risk of a disease or health-related condition. An example of a health claim is "a healthful diet with adequate foliate may reduce a woman's risk of having a child with a brain or spinal cord defect. A structure function claim describes the role of a nutrient or dietary ingredient in affecting the normal structure or function of the human body. Examples of structure function claims include "helps promote urinary tract health", "helps maintain cardiovascular function", and "promotes relaxation" .Lastly, nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as "free", "high", and "low". The majority of nutrient content claims apply to ingredients with an established daily value (e.g., Vitamin C, calcium). An example of this would be that a supplement with at least 12 mg of Vitamin C per serving could state on its label that the product is an "Excellent source of Vitamin C".

Advisory statements

Products containing the ingredients listed below would need to be labelled with the relevant advisory statements or any other statements to the same effect.

Prohibited Claims on Food Labels and Advertisements

Under regulation 9 of the Food Regulations, false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, stability, quantity, strength, purity, composition, weight, origin, age, effects, or proportion of the food or any ingredients are not allowed to be used on food labels and advertisements, unless otherwise specified.

The use of claims for therapeutic or prophylactic action; claims which could be interpreted as advice of a medical nature from any person; claims that a food will prevent, alleviate or cure any disease or condition affecting the human body; and claims that health or an improved physical condition may be achieved by consuming any food, is also prohibited.

Dietary Supplement Advertising Regulation

As with any consumer product, advertising plays an important role for dietary supplements. Not only do retail outlets engage in advertising for dietary supplements, but so too do dietary supplement manufactures through the use of medical journals, television, radio, magazines, retail trade publications, and public relations campaigns. The Federal Trade Commission ("FTC") is responsible for regulating advertising claims for all foods, including dietary supplements. Specifically, the FTC may prohibit the dissemination of false or misleading dietary supplement advertising. The FTC requires that dietary supplement advertising be truthful and not misleading and have adequate substantiation for all claims. The FTC tries to harmonize its enforcement of advertising claims with the FDA's enforcement of claims in food and dietary supplement labels. However, there are situations where these enforcement approaches do not meet up.

Several bills were introduced in Congress in the late 1990s to remedy different standards of enforcement between the FDA and FTC. In 1998 the Dietary Supplement Fairness in Advertising Act was introduced in the U.S. House of Representatives. The bill would have ensured that dietary supplement advertising that met the provisions of the FDCA and DSHEA and made certain disclosures about studies used in making advertisement claims would not constitute unfair competition or deceptive trade practices under the FTC statutory provisions. In 1999, the Dietary Supplement Fairness in Labelling and Advertising Act was introduced in Congress to exempt all dietary supplement publications considered labelling under the DSHEA (specifically 21 U. S. C. § 342-2) from regulation as advertising by the FTC. Neither of these bills became law and no bills on this topic are currently pending in Congress.

RECOMMENDATIONS REGARDING FUTURE REGULATION OF DIETARY SUPPLEMENTS

This section discusses some recommendations for both the FDA and Congress concerning dietary supplement regulation. It could not be expected that the massive changes the DSHEA enacted for dietary supplement could be swiftly and seamlessly detailed and implemented by the FDA. Ten years later, the FDA has made a serious effort to implement most all of the provisions of the DSHEA with varying amount of success and failure. However, the FDA still has plenty of work to do regarding dietary supplements.

One area that needs further improvement is general dietary supplement safety. By excluding most dietary supplements from drug regulations and excluding all dietary supplements from regulation as food additives, the DSHEA greatly freed up manufacturers of dietary supplements. Dietary supplements are not subject to premarket approval like drugs, nor must they be shown to be GRAS or otherwise comply with the Food Additives Amendment of 1958 like all conventional food. However, this places an enormous safety burden on the FDA, a burden which all too often the FDA has failed to carry. The FDA's action regarding Ephedrine Alkaloids demonstrated the costs of having to meet such heavy burdens. There are several ways to remedy this. First, the FDA's creation of CARES, a unified adrese event reporting system, is a step in the right direction. Second, adverse event reporting should be made mandatory. All dietary supplement manufacturers should be required to submit adverse event reports to the FDA as they become available to such manufacturers. Third, all manufacturers of dietary supplements should be required to register with the FDA. This would greatly strengthen the FDA's ability to detect signals relating to dietary supplement safety. Fourth, the FDA should also adopt the detailed framework for dietary supplement safety recently submitted to the FDA by the IOM, which would create a detailed FDA

post-market surveillance system for dietary supplements. Finally, while the FDA has implemented notification procedures for new dietary ingredients, it has not implemented guidance on the amount and type of evidence needed in this notification to demonstrate the safety of new dietary ingredients. Such guidance is greatly needed in order to provide the dietary supplement industry with standards by which to test and produce new dietary supplements.

And additional area that needs improvement is the making of claims of nutritional support on dietary supplement labels. Claims of nutritional support, and particularly structure/function claims and health claims (both qualified and unqualified) are currently subject to varied and numerous regulations. However, there is still consumer confusion and inability to distinguish between such claims. One possible solution might be to create an agency independent of the FDA to handle and review statements of nutritional support for dietary supplements in a consistent manner while clearly defining the differences in each type of claim. Harmonizing FDA and FTC regulations in this area would also be helpful and would lessen consumer confusion. Finally, the FDA should work to better distinguish dietary supplements from conventional foods. As nutrition has become more important to society, the line between dietary supplements and functional yet conventional foods has blurred. And while the DSHEA does require a dietary supplement to be labelled as such, its allowance for dietary supplements to be marketed in conventional food form in certain circumstances only adds to the confusion. The FDA should seek to explain these boundaries both for manufacturers and for consumers through new regulations and public relations campaigns. Because of the similarity between functional foods and dietary supplements, perhaps a new category of regulation should be created combining these two product types. This new category could take these more "drug like" products for which structure/function and various health claims are made and subject them to uniform claim procedures separate from conventional foods.

Dietary Supplement Safety

While the DSHEA did enact new safety standards for dietary supplements, the FDA has not passed general regulations concerning such safety standards. Generally, the FDA must gather data on its own or through voluntary adverse event reporting from industry and then issue warning letters to manufactures. The FDA has issued many such letters as well as taken other actions since passage of the DSHEA. When the FDA feels it has gathered enough evidence to deem a dietary supplement unsafe, it can remove the substance from the market as it did with Ephedrine Alkaloids. The FDA's handling of Ephedrine Alkaloids seems to indicate that it is content to rely on the statutory language of the DESHA for guidance and passive post-marketing surveillance systems. However, in 1997 the FDA did issue one regulation concerning dietary supplement safety. This regulation preserved the definition of "imminent hazard," which is one method by which a dietary supplement can be deemed adulterated under the DSHEA. More recently, the FDA reaffirmed its commitment to dietary supplement safety.

Good Manufacturing Practices

The DSHEA did not enact good manufacturing practices ("GMPs") for dietary supplement but rather subjected dietary supplements to GMPs for conventional food with the proviso that the Secretary could issue GMPs regulations specifically for dietary supplements. The FDA issued an ANPRM in 1997 inviting comments regarding the need for rulemaking for minimum GMPs for dietary supplements and dietary ingredients. Prior to the ANPRM, the FDA had received a draft proposal on dietary supplement GMPs from the dietary supplement industry. In 2003, after a six year delay, the FDA finally issued proposed rules for dietary supplement GMPs. The purpose of the proposed rules are "to the ensure that manufacturing practices will not result in an adulterated dietary supplement and that supplements are properly labelled."The proposed rules focus on the personnel, equipment, production and process controls, holding and distributing, consumer GMPs complaints, and recordkeeping. After an extension, the comment period for the proposed rules ended August 11, 2003.As of April 2204, the FDA has yet to take any further action.

Specific Dietary Supplements

Since the DSHEA, the FDA has issued several regulations concerning specific groups of dietary supplements. In 1997, the FDA issued a final rule requiring label warnings on certain iron containing dietary supplements. The FDA issued this final rule to prevent accidental overdose of iron-containing dietary supplements leading to poising and death in children under six years of age. The FDA recently issued a final rule deeming dietary supplements containing Ephedrine Alkaloids (popularly know as Ephedra) to be adulterated "because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labelling, or . . . under ordinary conditions of use."This final rule utilized the DSHEA provisions for dietary supplement safety. The FDA had moved as early as 1997 to ban Ephedrine Alkaloids under dietary supplement safety provisions by issuing proposed rules, but the FDA faced several difficulties, not the least of which was that under the DSHEA, the FDA had the burden of proof in banning Ephedrine Alkaloids. Finally, the FDA has recently taken action regarding weight loss dietary supplements. On April 1, 2004, the FDA announced that it had recently sent warning letters to sixteen weight loss dietary supplement manufacturers. Such warning letters stated that insufficient substantiation under the FDA notification and substantiation regulations for dietary supplement structure/function claims.

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Health Claims

While the DSHEA did expand the types of statements of nutritional support that could be made on dietary supplement labels without prior approval by the FDA, it did not include any provisions for health-related condition or disease claims ("health claims") for dietary supplements. This was left to other statutes and regulations. Health claims are claims that "describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition."

(i) The NLEA

One way that a health claim may appear on a dietary supplement is by following provisions under the NLEA allowing for health claims upon approval by the FDA after careful review of scientific evidence. The DSHEA did not alter the NLEA framework regarding health claims for dietary supplements. In 1994, before passage of the DSHEA, the FDA had issued final rules on health claims for dietary supplements. These regulations stated that dietary supplements would be held to the same health claim standards as conventional foods. Rather than enact new health claim provisions for dietary supplements, the DSHEA appointed the CDSL to issue recommendations on such health claims. The FDA was then to timely complete final rulemaking on the CDSL recommendations or else the 1994 FDA final regulations on dietary supplement health claims would be rescinded. The CDSL issued its final report in 1999, specifically recommending that "[t]he process for approval of health claims as defined by the NLEA should remain the same for dietary supplements and conventional food."This effectively preserved the FDA's 1994 final regulations on health claims and dietary supplements. Thus a dietary supplement may make a health claim by complying with the NLEA provisions regarding health claims for conventional foods. Under the NLEA, a health claim may be made if the FDA has issued a regulation permitting such a health claim. Such regulation shall issue only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The key phrase in this statutory language is "significant scientific agreement." To help manufacturers of dietary supplements (as well as conventional foods) determine what the FDA considers to be "significant scientific agreement," in 1999 the FDA issued a guidance document. The guidance documents states that the "FDA's determination on significant scientific agreement represents the agency's best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim." This is as strict yet objective standard designed to make "the key determination of whether a change in the dietary intake of the substance will result in a change in a disease endpoint." Under the NLEA and accompanying regulations, several health claims have been approved for use on dietary supplement (as well as conventional food) labels. These range from calcium-osteoporosis claims to folate-neural tube defects claims to plant stanols-coronary heart disease claims.

LITERATURE SURVEY

This section includes the work done on related topics by various researchers. Following is the brief description of some of them:

1. Lavonna blair lewis et al. We examined availability and food options at restaurants in less affluent (target area) and more affluent (comparison area) areas of Los Angeles County to compare residents' access to healthy meals prepared and purchased away from home. We also considered environmental prompts that encourage the purchase of various foods.
http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2004.050260
2. Gloria Y et al. To conduct a systematic review of the published literature on the efficacy and safety of herbal therapies and vitamin/mineral supplements for glucose control in patients with diabetes.
http://care.diabetesjournals.org/content/26/4/1277.full
3.stephen bent et al. Herbal medicines are widely used in the United States, with approximately one quarter of adults reporting use of an herb to treat a medical illness within the past year. Herbs contain complicated mixtures of organic chemicals, the levels of which may vary substantially depending upon many factors related to the growth, production, and processing of the herbal product.

CONCLUSION

The Conclusion of Current regulations for labelling and advertising of nutritional supplements was marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labelling and advertising claims be truthful, not misleading and substantiated. The FTC approach generally requires that claims be backed by sound, scientific evidence, but also provides flexibility in the precise amount and type of support necessary. This flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims. To ensure compliance with FTC law, supplement advertisers should follow two important steps: 1)†careful drafting of advertising claims with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and 2) careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and claim advertised.

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