ISSN: 2279 - 0594

Available Online at www.jbpr.in

Journal of Biomedical and Pharmaceutical Research 2 (5) 2013, 19-24

REVIEW ARTICLE

HEALTH CLAIM REGULATIONS FOR DIETARY SUPPLEMENTS IN US

Vibhu Yadav, Shilpi Arora, Ashish Kumar, *Deepak Kaushik, Devendra Pratap Singh, Ankit Saini

*Department of Pharmaceutical Sciences, Maharshi Dayanand University, Rohtak, Haryana

Received 20 August 2013; Revised 30 August 2013; Accepted 4 September 2013

ABSTRACT

Dietary supplements in the recent years have witnessed a tremendous increase in the interest among the consumers due to their potential of providing health benefits. These foods are being marketed globally especially in the Developed countries as in US, the consumers are taking an increasingly proactive approach to health, and realizes that certain dietary behavior can reduce the risk of chronic disease. Dietary supplements are widely used across all the ages and user groups and constitute a considerable business sector in most developed countries. The sale of supplements in U.S is estimated to be $8 billion. Investigator/manufacturers of dietary supplements need to know the relevant regulatory requirement and how to comply with them. The brief review of this article describes how the health claims of dietary supplements are regulated by FDA and also includes the health claim petition filing procedure and FDA review process for the petition.

Key Words: Dietary Supplements, Health Claim, DSHEA, New dietary ingredient, Supplement fact, CSFAN.

INTRODUCTION:

The use of dietary supplements is one of the most striking events that occurred in the US in recent years. Estimate of the prevalence of the vitamin and mineral supplement intake range from 50% in recent surveys and 60% in specialized populations. The most commonly used supplements are vitamins, minerals, and herbal preparations. Supplements users are reported a pocket expenditure of US $ 3.3 billion. Due the increasing use of these dietary supplements safety is the major concern[1].To prevents the use of misbranded, adulterated, and fraudulent health claim FDA had published certain guidelines. For the regulation of dietary supplements, in 1994, DSHEA act was passed. Before this act there were not so tight regulations for marketing of these types of dietary supplements with health claim label[2].

Dietary supplements:

Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled as dietary supplement[3].

REGULATORY BODIES FOR DIETARY SUPPLEMENT:

- Various regulatory bodies exist for regulation of dietary supplements in us. Like CFSAN- Centre for Food Safety and Applied Nutrition.[4]
- DSHEA- Dietary Supplement Health and Education Act.
- FTC- Food Corporation and Treaty.[5] The Federal Trade Commission's (FTC), 1998 Advertising Guide for industry explains how the agency applies its truth in-advertising mandate to statements about the health benefits of dietary supplements.
- NLEA- Nutrition labeling and Education Act and
- FDAMA- Food Drug and Modernization Act.[6,7]

The U.S. Food and Drug Administration's regulatory authority over health claims was clarified in 1990 legislation known as the Nutrition Labeling and Education Act (NLEA). This law established mandatory nutrition labeling for most foods and placed restrictions on the use of food label claims characterizing the levels or health benefits of nutrients in foods. NLEA set a high threshold for the scientific standard under which the U.S. Food and Drug Administration (FDA) may authorize health claims, this standard is known as the significant scientific agreement (SSA) standard. Subsequent legislation known

*Corresponding author: Deepak Kaushik | Email: deepakaushik@rediffmail.com

as the Food and Drug Administration Modernization Act (FDAMA) provided an alternative to FDA review of the health claim where an U.S. government scientific body other than FDA concluded that there is SSA for a substance/disease relationship.

In October 1994, the Dietary Supplement Health and Education Act (DSHEA) were signed into law by President Clinton. Before this time, dietary supplements were subject to the same regulatory requirements as were other foods. This new law, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products. DSHEA requires that a manufacture or distributor notify FDA, before 75 days, that it intends to market a dietary supplement in U.S is New Dietary Ingredient (NDI).[7,8]

Bioterrorism Act for Dietary Supplements:

To protect the public from a threatened or actual terrorist attack on the U.S. food supply. FDA enacted a **Bioterrorism Act**, for Registration of Food Facilities, which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States. This new regulation pertains only to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S. Examples of "food" include[9]:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods

Registration procedure for dietary supplements under Bioterrorism Act:[10]

Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system is also available. Requests for assistance also may be emailed to furls@fda.gov. There is no fee for registration or for updates of any registration. Registrants must use Form 3537 to register or update a registration.

Claims for dietary supplement: [11, 12]

There are three types of claims:

- Health claim
- Nutrition claim
- Structural claim

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product. A structure/function claim is a statement describing how a product may affect the organs or systems of the body and it cannot mention any specific disease. Structure/function claims do not require FDA approval but the manufacturer must provide FDA with the text of the claim within 30 days of putting the product on the market[13].

Health claims:[14]

Health claim means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

1. Nutrient function claim: A nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.
2. Other function claim: These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body.
3. Reduction of disease risk claims: Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition.

Types of health claim: [15, 16]

- Qualified health claims
- Unqualified health claims
- Qualified Health Claims

Health claims that do not meet the significant scientific agreement standard should be permitted, as long as the statements were truthful and not misleading when appropriately qualified to indicate the level of scientific support for the claim. These types of claims are now referred to as "qualified health claims. FDA's 2003 Consumer Health Information for Better Nutrition Initiative provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A listing of petitions open for public comment is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: Qualified Health Claims Subject to Enforcement Discretion. For example, the qualified health claim of an association between omega-3 fatty acids and a reduced risk of coronary heart disease is currently widely used in the marketing of omega-3 products[17].

- **Unqualified health claims/ Authorized health claims:**

Claims that satisfy the significant scientific agreement standard of the Nutrition Labeling and Education Act are referred to as "unqualified health claims. Unqualified health claims must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship.

Both types of health claims characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition, and are supported by scientific evidence. All health claims must undergo review by FDA through a petition process. In comparison, qualified health claims are supported by scientific evidence, but do not meet the significant scientific agreement standard. As a result, to ensure that they are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. Both unqualified and qualified health claims may be used on conventional foods and on dietary supplements[18].

There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement.[19]

- **Claims based on significant scientific agreement:**

The Nutrition Labeling and Education Act (NLEA, 1990) and the Dietary Supplement Health and Education Act (DSHEA) of 1994 allow health claims on food or supplement labels describing the role of a substance in disease risk reduction. The FDA authorizes these claims based on the totality of publicly available scientific evidence and using scientific agreement criteria to determine the validity of the substance/disease relationship.

- **Claims based on authoritative statement:**

The FDA Modernization Act (FDAMA) of 1997 also allows health claims based on an authoritative statement issued by a scientific body of the US Government bearing a public health protection responsibility, such as The National Institute of Health (NIH), The Center for Disease Control (CDC) or The National Academy of Science (NAS). However, FDAMA claims are not available for dietary supplements.

- **Qualified health claims:**

Consumer Health Information for Better Nutrition Initiative of FDA (2003) provides the use of health claims (qualified health claims) for foods or dietary supplements where the scientific evidence to support a substance/disease relationship is still emerging and has not developed enough to meet the SSA standard. These claims have to include qualifying language as part of the claim indicating that the evidence supporting the claim is limited. In July 2003, the FDA provided interim guidelines outlining the petition process and the evidence based ranking system to evaluate the scientific data concerning the claim. Since July 2003, the FDA has authorized several Qualified Health Claims for foods and dietary supplements. Table 5 shows all the approved qualified health claims to date. Health claims in general relate to disease risk reduction, but do not quantify the degree of risk reduction. Health claims language always uses "may or "might" to express the substance and disease relationship. All FDA approved Health claims are generic and not for the exclusive use of the petitioner.

Health claim regulations: [20, 21]

A firm submit a health claim petition based on an authoritative statement by a U.S. government scientific body under section 403(r) (3) (c) of the FD&C Act. The regulations for health claim are given in21 CFR 101.9(k)(1), 101.14(c)-(d) & 21 CFR 101.70.

INFORMATION TO BE INCLUDED IN PETITION: [22, 23]

The requirements of 21 CFR 101.70 apply a general summary of these requirements as follows.

1. a) Preliminary Requirements (21 CFR 101.70 (f) (A)) Explanation of how substance conforms to the requirements of 21 CFR 101.14(b).

b) Relationship between substance and disease or health-related condition;

c) Substance contributes taste, aroma, nutritive value, or a technical effect listed in 21 CFR 170.3(o);

d) Substance is a food, food ingredient, or component that has been shown to be safe and lawful at levels necessary to justify a claim (21 CFR 101.14(b) (3)(ii)).

2. Summary of Scientific data (21 CFR 101.70(f)(B)).
3. Analytical data to show amount of substance that is present in representative foods (21 CFR 101.70(f)(C)).
4. Proposed model health claim(s) (21 CFR 101.70(f)(D)).
5. Attachments (see 21 CFR 101.70(f)(E))

a) Scientific data supporting a claim:

b) Copies of computer literature searches;

c) Copy of all research articles relied upon for support of petition- English only.

6. A claim for categorical exclusion or an environmental assessment (21 CFR 101.70(f)(F)).

FDA encourages petitioners to specify whether they are requesting that their petition be reviewed as a QHC, and that they waive review under the SSA standard. The petitioner may indicate within the petition's cover letter that he/she is waiving the right to a review under the SSA standard and request that the petition be reviewed under the interim procedures for a QHC. This request will result in FDA proceeding directly to the QHC procedures and its 270-day timeline. In the absence of such a request, FDA contacts the petitioner to determine if they are petitioning for a SSA or QHC.

Mail the original and one copy of the petition (or a computer readable disk containing the petition) to the following address:

Food and Drug Administration
Office of Nutrition, Labeling and Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, MD 20740

Petition which are incomplete and does not provide the required information that is summarized above are rejected.

PROCEDURE USED BY FDA TO REVIEW QUALIFIED HEALTH CLAIMS:

There are two procedures:

1. Interim Evidence-based Ranking System for "Scientific Data".

2. Interim Procedures for Qualified Health Claims.

These guidance documents describe a process and procedure for systematically evaluating and ranking the scientific evidence relevant to a substance/disease relationship that is the subject of a qualified health claim. Different levels of scientific evidence result in different qualifying language for a claim. The qualifying language provided by the agency's guidance serves as an example for petitioned qualified health claims and may vary depending on the specific circumstances of each substance/disease relationship.FDA intends to use the following interim procedures to ensure that its premarket review is consistent with the spirit of the Nutrition Labeling and Education Act and the First Amendment [24, 25, 26].

FDA will continue to evaluate unqualified health claims under its current regulatory process and standard for significant scientific agreement gas been withdrawn by FDA in 2009.[27] A standardized qualifying language for qualified health claims is given in **Table 1**.[27] The FDA review procedure for health claim petitions is illustrated in **Figure 1**.[28]

Table 1: Standardized Qualifying Language for Qualified Health Claims [26]

Scientific Ranking	FDA Category	Appropriate Qualifying Language
Second Level	B	"although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests however FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests. FDA concludes that there is little scientific evidence supporting this claim."

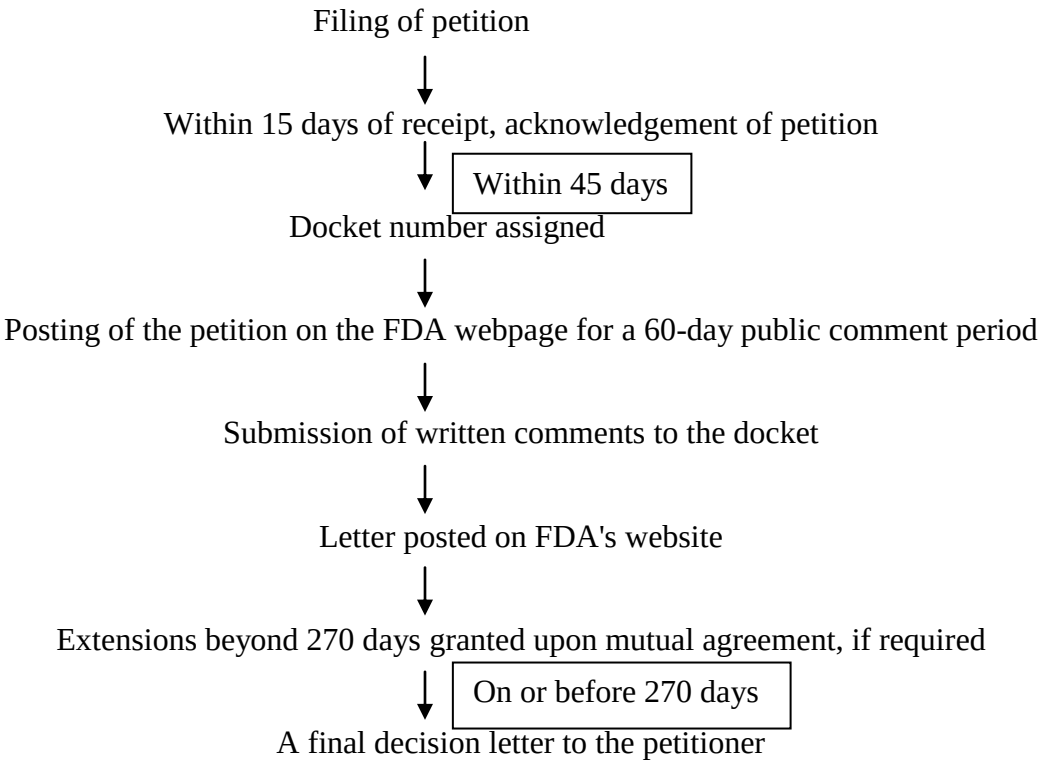

Figure 1: FDA Review procedure for health claim petitions

CONCLUSION:

The recent US Regulation provides the basis for allowance of health claims on Dietary Supplements. Before marketing of dietary supplements with health claim it is necessary to take health claim approval. FDA have various regulatory bodies which review the applications for health claim that helps in the prevention and use of any fraudulent and misleading claims on the dietary supplements. In 1994, FDA enacted DSHEA Act which regulates dietary supplements for their safety and quality. Under this act Dietary supplements are defined and also new regulation is given for new dietary ingredients. 75 days prior approval is required for marketing new dietary ingredients in US. For preparing petition for health claim are given in the 21 CFR 101.70(f)(E).

REFERENCES:

1. Miller CK, Teri R. Knowledge of dietary supplement label information among female supplement users. Journal of Patient Education and Counseling. 2004; 52:291–96.
2. Dickinson A. History and overview of DSHEA. Journal of filaterapia. 2011; 82: 5-10.
3. Glisson JK, Walker LA. How Physicians Should Evaluate Dietary Supplements. The American journal of medicine. 2010; 123(7):577-82.
4. http://www.fda.gov.Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm07308.htm. (Accessed on 17 July, 2013)
5. http://www.ftc.gov/bcp/guides/ad3subst.htm. (Accessed on 18 July 2013).
6. Charles RM. The Regulatory Status of Medical Foods and Dietary Supplements in the United States. The journal of medical nutrition in dietetics. 2000; 7(2):399-400.
7. http://www.cfsan.fda.gov/dms/labfdama.html (Accessed on 23, July 2013).
8. Alison BK. Dietary Supplements. The journal of *Nutrition.* 1998; 14 (9):42-53.
9. http://www.fda.gov/food/guidancecomplianceregulatoryinformation/registrationoffoodfacilities/default.htm (Accessed on 7 July, 2013).
10. http://www.aibmr.com/resources/pdfs/Mandate.pdf (Accessed on7 July 2013).
11. Craig RJ, Hoadley JE. FDA perspectives on health claims for food labels. The journal of Toxicology. 2006; 221:35–43.
12. http://jn.ntrition.org/content/138/6/1216S.full.pdf (Accessed on 8 July 2013).

13. http://ceb.ucop.edu/newsletter/Business1.htm. (Accessed on 10 July, 2013).

14. Rajendra K. Songara, Devendra Pratap Singh, Vipul K. Gupta, Aparna Kulkarni. Nutraceutical Products labeling: Global Issue and regulatory control. International Journal of Drug Formulation & Research Nov.-Dec. 2010, Vol. 1 (iii) 167-200.

15. http://www.fda.gov/SiteIndex/ucm108351.htm. (Accessed on 8 June, 2013).

16. http://www.cfsan.fda.gov/~dms/sclmguid.html. (Accessed on 19 July, 2013)

17. Agarwal S, Hordvik S, Morar S. Nutritional claims for functional foods and supplements. The journal of Toxicology. 2006; 221:44–49.

18. http://www.cfsan.fda.gov/dms/dsclmgui.html (Accessed on 18 June 2013).

19. http://cfr.vlex/vid/101-70-petitions-for-health-claims-19705671. (Accessed on 13 July 2013).

20. http://www.access.gpo.gov/nara/cfr/waisidx 04/21cfr101 04.html. (Accessed on19, 2013)

21. http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/QualifiedHealthClaimsPetitions/ucm096054.htm (Accessed on 23 July, 2013).

22. http://www.cfsan.fda.gov/~dms/hclmqui3.html. (Accessed on 1 July. 2013).

23. http://www.cfsan.fda.gov/~dms/nuttf-b.html. (Accessed on 23 July, 2013).

24. http://vm.cfsan.fda.gov/~dms/ssaguide.html (Accessed on 27 July, 2013).

25. http://www.fda.gov/Food/DietarySupplements/default.htm. (Accessed on 23 July, 2013).

26. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm. (Accessed on 13 July, 2013).

27. Radimer K *et al*. Dietary supplement use by US adults: data from the National Health and Nutrition Examination Survey. *Am J Epidemiol. 2000;*160: 339–349.

28. http://www.fda.gov/oc/initiatives/ephedra/february 2004/ (Accessed on 29 June, 2013).

