

[FDA Notification for Permissible Structure/Function Claims for Dietary Supplements](#)

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MLM Distributors and MLM companies often ask about the notification requirements for permissible structure/function claims for dietary supplements, under FDA rules of DSHEA (Dietary Supplement Health Education Act). Here is summary, directly from the FDA, which may prove helpful:



PART 101 -- FOOD LABELING
Subpart F--Specific Requirements for Descriptive
Claims That Are Neither Nutrient Content Claims
nor Health Claims

Sec. 101.93 Certain types of statements for dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

- (i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;*
- (ii) The text of the statement that is being made;*
- (iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and*
- (iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.*

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the

statement is truthful and not misleading.

(b)Disclaimer. The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c)Text for disclaimer.

(1) Where there is one statement, the disclaimer shall be placed in accordance with paragraph (d) of this section and shall state:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d)Placement. The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e)Typesize. The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

For additional information on FDA Rules and Regulations, visit the following links:

[What is the Relationship between MLM and the FDA?](#) Video

[The FDA and Health Claims](#) Article

[FDA Health Claims: The Final Rules](#) Article

FDA: New Health Claim Rules:

- [Introduction](#)
- [A Historic Act](#)
- [The President Speaks](#)
- [And Congress Speaks Out](#)
- [The Impact on the Network Marketing Industry](#)
- [Why and How They Work](#)
- [Abuses Lead to Legislation](#)
- [Rules You Don't Want to Break](#)
- [The Disclosure Issue](#)

[Choosing the Right Product for Your Direct Selling Company](#)

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[MLM and the FDA](#)

[MLM's History with the Government](#)

[New Video – Unauthorized Medical Claims and FDA Issues](#)

[FDA to Issue Revised NDI Guidance – Nutraceuticals World Reports](#)

[Nutritional Supplements, Health Claims and MLM](#)

[MLM Attorney – How a MLM Lawyer Can Help Your Direct Selling Business](#)

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This article is also available online at: <http://mlmlegal.com/MLMblog/?p=408>

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Jeffrey Babener
On Assignment

On any given day you can catch [Jeffrey Babener](#) lecturing on Network Marketing at the University of Texas or the University of Illinois, addressing thousands of distributors in Los Angeles, Bangkok, Tokyo and Russia, or writing a new book on Network Marketing, an article for Entrepreneur Magazine or a chapter for a University textbook. Over two decades he has served as marketing and legal advisor to some of the world's largest direct selling companies, the likes of Avon, Nikken, Melaleuca, Discovery Toys, NuSkin, and he has provided counsel to the most successful telecom network marketing companies...Excel, ACN, World Connect, ITI, AOL Select and Network 2000. An active spokesperson for the industry, he has assisted in new legislation and served on the Lawyer's Council, Government Relations Committee and Internet Task Force of the Direct Selling Association (DSA) as well as serving as General Counsel for the Multilevel Marketing International Association. He is an MLM attorney supplier member of the DSA and has served as legal counsel and MLM consultant on MLM law issues for many DSA companies.

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