

SECTION 5 LITERATURE FOR SCIENTIFIC, MEDICAL INFORMATION RE: THERAPEUTIC VALUE OF ALOE SUPPLEMENTS

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It must be very frustrating for marketers of dietary supplements containing *Aloe vera* that solid science and human clinical trials exist showing that *Aloe vera* has a therapeutic or preventative effect on many diseases, and yet disease claims may not appear on dietary supplement labels. Some medically substantiated results, that are not valid structure/function claims, and that would be considered disease claims for dietary supplements, are:

- a.) Aloe reduces severe joint and muscle pain associated with arthritis, tendonitis, and injuries.
- b.) Aloe prevents adjutant arthritis.
- c.) Aloe prevents gastrointestinal problems, such as ulcers and kidney ailments.
- d.) Aloe helps restore hair loss associated with aging.
- e.) Aloe relieves irritable bowel syndrome.
- f.) Aloe relieves acid reflux.
- g.) Aloe relieves peptic and duodenal ulcers.
- h.) Aloe relieves colitis.
- i.) Aloe has a beneficial effect on the accumulation of blood lipids associated with heart disease.
- j.) Aloe decreases total cholesterol, phospholipid, and nonesterified fatty acid levels.
- k.) Aloe is antimicrobial, and antiviral.
- l.) Aloe reduces fever or heat sores.
- m.) Aloe cures noncystic acne.
- n.) Aloe reduces high blood pressure.

Finally, as we read in the "Aloe Science" article by Ken Jones in the August issue of *ALOE TODAY*, *Aloe vera* gel has shown effectiveness in the treatment of diabetes mellitus in that it reduces not only blood sugar levels, but also triglyceride levels. None of these therapeutic benefits may be claimed on labels, in labeling (e.g., brochures or catalogs), or in advertisements for supplements.

On the other hand, exercising First Amendment rights, one may freely publish a paper or monograph, or sell a book concerning aloe in the treatment of disease. Is there anything in

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between—any way to spread the good therapeutic news without violating Section 6 of the Dietary Supplement Health and Education Act of 1994 (“DSHEA”)? Yes, there is Section 5 literature, sometimes called “Third-Party Literature,” referring to Section 5 of DSHEA. This type of document is meant to educate consumers about the current science on dietary ingredients so that they may make more informed choices in purchasing supplements.

Section 5 literature most often appears in the form of Herb Sheets found in the book or magazine section of health food stores. A piece of Section 5 literature about *Aloe vera* could legally discuss its effectiveness in treating the symptoms of arthritis, whereas the label claims for an *Aloe vera* product would be limited to structure/function claims such as “Supports joint strength and function.” Similarly, Section 5 literature on ginkgo biloba may discuss its therapeutic value for the memory loss symptoms of Alzheimer’s disease, whereas the label of a ginkgo product may only contain claims such as “Maintains good memory as you age” or “Maintains healthy brain function.”

When Congress passed DSHEA, it included Findings in Section 2 of the Act that unmistakably show the educational intent of the legislation, and the relationship between educated consumers, good health, and disease prevention:

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies; . . .

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements; (Emphasis added.)

As a means toward consumer education, and to resolve a conflict between the industry and the FDA about what constitutes “labeling,” Congress included in DSHEA a provision that allows medical and scientific information about dietary supplements to be given to consumers, especially the therapeutic (drug) value of dietary ingredients – provided that certain conditions are met, e.g., that the literature be separated from product for sale.

Section 5 of DSHEA allows manufacturers, distributors, retailers, and other persons involved with the sale of dietary supplement products to distribute scientific literature concerning the therapeutic benefits of supplements and their ingredients. Scientific literature that is used in connection with the sale of a supplement product is not considered “labeling” and is not, therefore, subject to the requirements of Section 6 of DSHEA (which allows only structure/function statements) provided that the literature meets all the requirements set forth in Section 5. Thus, Section 5 creates an exception or “safe harbor” to the general rule that a company cannot expressly or implicitly make therapeutic claims about its dietary supplement products by, among other things, making literature available to consumers which describes the therapeutic benefits of the *Aloe* formula or one of its ingredients.

But there is a catch (even if it’s not a Catch-22): First, Section 5 literature applies only to dietary supplements, which are ingested, and not to topical products. Second, such literature may not be promotional—neither of a particular product nor of a company. Section 5 has five requirements:

(1) Section 5 literature must be used in connection with the sale of a dietary supplement product. Usually, it consists of scientific or medical information about a particular ingredient.

(2) Section 5 literature may not be false or misleading. The government (i.e., FDA or FTC) has the burden of proving that the literature is indeed false or misleading.

(3) Section 5 literature may not promote a particular manufacturer or brand of dietary supplement products. An item of literature is considered “promotional” if the net impression to the consumer is that the literature is a piece of advertising rather than a piece of scientific information.

(4) Section 5 literature must be presented or displayed in a manner so as to include a balanced view of the available scientific information on the same subject matter. This can be accomplished by presenting another piece of literature that contains a different or conflicting point of view, or by providing a short bibliography or list of publications which reflect different opinions—e.g., that the clinical trials described in other articles were flawed, or that the results were inconclusive or merely preliminary—under a heading such as “For other views, see the following.”

(5) If Section 5 literature is displayed in “a retail establishment,” it must be displayed in an area that is physically separate from the area in which dietary supplements are sold.

All of the requirements above must be met in order for the distributor of the literature to be exempt from enforcement action pursuant to Section 6 of DSHEA, that is, for disease claims used in labeling. Note that the disclaimer required on labels when structure/function statements are present, “These statements have not been evaluated. . .,” is not required or even proper on Herb Sheets and other Section 5 literature, because these are not considered labels or labeling.

Section 5 is often referred to as the “third-party literature” section of DSHEA, thus giving the incorrect impression that companies selling dietary supplement products cannot prepare their own medical literature. There is no legal reason, however, that a company selling dietary supplement products cannot have an employee or paid consultant prepare a piece of scientific literature to be used in connection with the sale of one or more of its products. Nonetheless, Section 5 literature, whether prepared by the Company or someone independent of the Company, may not summarize a scientific study or test unless the summary is the author’s or editor’s abstract of a peer-reviewed scientific publication.

Finally, Section 5 specifically states that DSHEA is not meant to restrict the right of dietary supplement companies to sell books or other publications as part of their businesses. These are separate from the Aloe Sheets we are discussing. However, such a book may not promote a particular product, either throughout the text or on the cover, e.g., with a sticker proclaiming “Brought to you by the makers of Aloe ArthroCure Supplement.”

Publications that could be used for, or reprinted as, Section 5 literature include:

- an entire short scientific or medical article;
- the author’s abstract of that article [but not a marketer-prepared summary];
- a magazine article on the subject of a clinical trial, or that synthesizes other research on an ingredient or combination of ingredients;

- an in-house report or “tech report” about a clinical trial;
- a portion of a researcher’s published monograph about an clinical trial of an ingredient or a formula;
- a chapter or section of a chapter from a research book on Aloe and disease.

Regardless of the type of publication used, it may not be promotional if it is intended as Section 5 literature. However, some companies include their toll-free number at the bottom of the sheet and offer further information.

Section 5 literature can educate consumers about the most current scientific, medical advances concerning therapeutic aloe ingredients, and thereby can lead to more informed choices in purchasing dietary supplements. Furthermore, as readers of this newsletter and the Aloecorp website know, *Aloe vera* also reduces the risk of certain diseases, and these statements may be the subject of future FDA-authorized “health claims.” But that is a story for another day. Also, it is common knowledge that *Aloe vera* has many therapeutic properties when applied topically, but that is also a topic for another issue.