

DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY

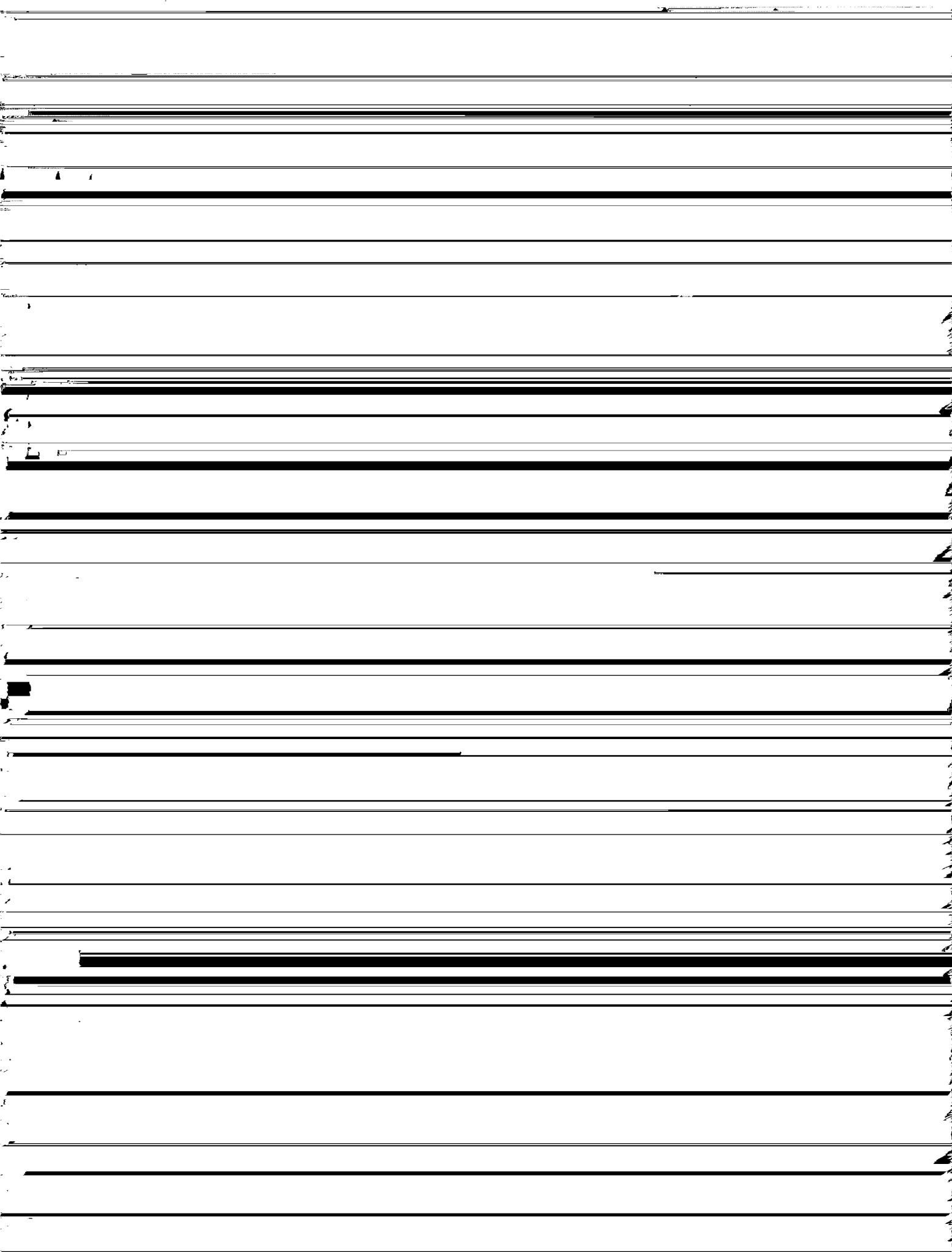


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INTRODUCTION

The dietary supplement industry is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly. The number of products — and the variety of uses for which they are promoted — have increased significantly in the last few years. The role of the Federal Trade Commission, which enforces laws outlawing “unfair or deceptive acts or practices,” is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.¹

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) work together under a long-standing liaison agreement governing the division of responsibilities

responsibility for claims on product labeling, including packaging, inserts, and other

be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling.

support and careful presentation for such claims.⁵

Supplemental information also is available at <http://www.ftc.gov>.

APPLICATION OF FTC LAW TO DIETARY SUPPLEMENT ADVERTISING

The FTC's work in advertising law can be boiled down to two common sense propositions:

[REDACTED]

by applicable in many cases, however, the implications of the ed are clear enough to determine

that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

Example 4

that the product maintains joint health and mobility.

Example 6

An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as

demonstrating that the product resulted in an average ~~weight loss of fifteen pounds over an eight-week period.~~

significantly greater than for the control subjects. However, both the control and test subjects engaged in ~~regular exercise and followed a restricted-calorie diet as~~

part of the study regimen. The advertisement should make clear that users of the supplement must follow the

disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate. To ensure that disclosures are effective, marketers should use clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

Example 9

A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS"

the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required"

Example 10

Accompanying results from two studies suggesting that

the medicine used in its development helps to maintain

healthy cholesterol levels. There are, however,

Substantiation for the Claim. These factors are often weighed together to ensure

Example 12

An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S.

phrases likely convey to consumers an implied claim that there exists a substantial body of competently

compound than the product being marketed. In addition, human research is feasible and relatively inexpensive to conduct in light of the potential sales of the product and is the type of research generally accepted in this particular field of study. The substantiation is likely to be inadequate in this case, both because there are significant methodological

research is both feasible and the accepted approach in

the field.

3. The Quality of the Evidence

In addition to the amount and type of evidence, the FTC will also examine the internal validity of each piece of evidence. Where the claim is one that would require scientific support, the research should be conducted in a competent and reliable manner.

The design, implementation, and results of each piece of research are important to assessing

the adequacy of the substantiation.

There is no set protocol for how to conduct research that will be acceptable under the FTC

no way for an advertiser to ascertain whether the research substantiates the product claims. (For example, did the research use a comparable formulation of the ingredient? Was the study adequately controlled? Did the study yield results that are statistically significant?) The advertiser should carefully review the under-

science, with the assistance of an expert if necessary, before drafting advertising claims.

Example 17

An advertiser makes an unqualified claim about the anti-clotting effect of a supplement that contains a compound extracted from fruit. There are three studies supporting the effect and no contrary evidence. One study consists of subjects tested

effect. Although approval of the supplement under the

German monograph suggests that the supplement is effective, advertisers should still examine the underlying research to confirm that it is relevant to the advertiser's product (for example, that the dosage and formulation are comparable) and to evaluate whether the studies are scientifically sound. Advertisers should also examine any other research that exists, either supporting or contradicting the monograph, especially if it is not

necessary to identify and review the research on which

control groups. Assuming other aspects of methodology

are similar, the studies taken together suggest that, if the product has any effect on body fat, it would be very small. Given the totality of the evidence on the subject

5. The Relevance of the Evidence to the Specific Claim

A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad. Advertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study

are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to use the study.

Example 23

A number of well-controlled clinical studies

improve mental alertness and memory in subjects with

is effective for supporting the immune system. The studied extract is a complex combination of many constituents and the active constituents that may produce the benefit are still unknown. An advertiser wishes to cite this research in its advertisement.

conspicuous disclaimer is necessary. The advertiser should either state what the generally

attested results. Vague disclaimers like "results may vary" are likely to be insufficient.

Example 26

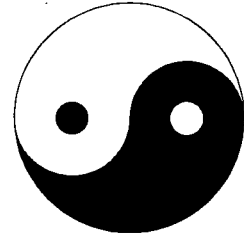
An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the

any review of the scientific literature on the active

in the infomercial, she is given a paid position as an officer the company. The ad is likely to be deceptive for several reasons. First, her qualifications as an expert have been overstated and she has not conducted sufficient examination of the product to support the endorsement. In addition, her connection to the company is one that consumers might not expect and may affect the weight and credibility of her endorsement. Even if she is adequately qualified and has conducted an adequate review of the product, her

position as an officer of the company should be clearly

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.



There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the evidence.

determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not

Example 30

A supplement manufacturer wants to market an herbal product that has been used in the same formulation in China as a tonic for improving mental functions. The manufacturer prepares the product in a manner

claims, "Traditional Chinese Medicine — Used for

Memory." The ad also contains language that clearly

3. Use of the DSHEA Disclaimer in Advertising

Under DSHEA, all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to “diagnose, treat, cure or prevent any disease.” Although DSHEA does not apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being

Example 34

An advertisement for an herbal supplement includes strong, unqualified claims that the product will

effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes

the DSHEA disclaimer prominently in the ad. In face of the strong contradictory message in the ad, the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated.

Example 35

A dietary supplement advertisement makes a number of

materials will be subject to FTC jurisdiction turns largely on whether the materials have been

its product. As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, are also likely to comply with FTC advertising law.

Example 36

An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure."

The book does not endorse or otherwise mention any

Endnotes

¹ The FTC's authority derives from Section 5 of the FTC Act. In addition, supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those

statements "which are in a material respect" See 15 U.S.C. § 12(a) and 15 U.S.C. § 15(a).

² Under NSHEA, a supplement is defined as "any product which is used in conjunction with a drug and which is not a drug." 15 U.S.C. § 1122(a)(1).

