



Council for Responsible Nutrition

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 2004D-0466
Substantiation for Dietary Supplement Claims
(Statements of Nutritional Support, Structure/Function Claims)**

These comments are submitted by the Council for Responsible Nutrition, a leading trade association representing the dietary supplement industry.

The Food and Drug Administration (FDA) has issued a draft guidance regarding substantiation requirements for certain dietary supplement claims, namely those regarding statements of nutritional support, commonly known as structure/function claims, permitted under Section 403(r)(6) of the FD&C Act. In these comments, we will refer to these claims as “structure/function claims.” The Act requires that the manufacturer of a dietary supplement making a structure/function claim have substantiation that the claim is truthful and not misleading. The draft guidance intends to describe the amount, type, and quality of evidence needed to support such claims.

FTC Standard is the Appropriate Standard

FDA indicates that it intends to apply a substantiation standard consistent with the FTC standard of “competent and reliable scientific evidence.” CRN agrees that this is the appropriate standard. FDA further indicates that its guidance document is modeled on and is intended to complement the FTC guidance document issued in 2001. CRN believes this is exactly the right approach, but has some concerns that the FDA document does not incorporate some of the key features of the FTC guidance.

Under the FDA guidance document, as under the FTC document, there will be no certain formula to determine what information is needed to substantiate a claim. Rather, the evidence required will depend on the claim. Thus, the examples provided in the guidance provide critical insight into the nature of FDA’s current thinking about the manner in which the guidance may be applied.

Role of Qualifying Statements in Limiting Scope of Claim to be Substantiated

The FTC guidance makes it clear that the scope of a claim can be limited by the language of the claim itself. For example, if a company claims that “10 out of 15 studies” show a certain effect, then the company needs to be able to show that this is the case. The FDA guidance is not as clear about whether a company can limit the scope of its claim by such language. In example 3, FDA says the statement “recommended by scientists” implies general scientific agreement or consensus regarding the claim, and says the opinion of a small group of scientists would not support this claim. The agency does not say how this statement might be qualified to avoid the implication of consensus. For example, would the statement “recommended by antioxidant researchers at three universities” be sufficiently specific to avoid the implication of general scientific agreement?

In example 13, FDA indicates that an animal study of an effect on brain health is unlikely to support a claim that the supplement may promote brain health in healthy people. However, FDA does not indicate how the claim might be qualified in this situation so that it is truthful and not misleading. For example, could a company say that “animal tests suggest the possibility that supplement X may promote brain health”?

In example 14, FDA indicates that a statement that a particular grain “has been used effectively for centuries to promote gastrointestinal health” may not be adequate, even if substantiated by historical evidence, because there is no objective scientific evidence to confirm its effectiveness. This would appear to disallow all or most claims based on traditional uses, which we believe would be inappropriate action on FDA’s part.

In example 19, the agency suggests that one study supporting an effect on nocturnal leg cramps would not be sufficient to support such a claim, if there are conflicting trials of equal quality. FDA indicates that if there is no plausible explanation for the disparate results, then the evidence from the positive study would probably not be adequate to support the claim. However, FDA does not indicate how the claim might be qualified so that the available evidence is correctly described. The company sponsoring the positive study might say, for example, “The most recent study found an effect on nocturnal leg cramps, despite disappointing results in 2 previous studies.”

Example 20 is similar, involving a sleep aid that is found in one small randomized, placebo-controlled study to be effective, but not in several other larger studies. FDA says the claim may not be substantiated, on its face, but does not address whether a qualified claim that adequately describes the state of the evidence would be appropriate. For example, a company might say that “despite negative findings in 3 large studies on other products, a small but carefully-controlled study on this new product suggests that it may help people fall asleep.” Again, the principle is whether adequately qualified language in the claim itself can correctly convey the level of substantiation for the claim.

CRN appreciates the opportunity to comment on FDA's draft guidance document on the substantiation of structure/function claims. We look forward to continuing to work with the agency to clarify this and other issues affecting the full implementation and enforcement of the Dietary Supplement Health and Education Act (DSHEA).

Sincerely,

A handwritten signature in black ink that reads "Annette Dickinson". The signature is written in a cursive style. To the right of the signature, there is a vertical red line that extends from the top of the signature down to the printed name below.

Annette Dickinson, Ph.D.
President