



INDUSTRY ADVISORY:
MAKING DIETARY SUPPLEMENT CLAIMS IN
THE UNITED STATES

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It is important for GOED members and the omega-3 dietary supplement industry as a whole to understand the regulations associated with making structure-function claims on dietary supplement products in the United States. The U.S. Food and Drug Administration (FDA) is very clear on what constitutes a structure-function claim, which is permissible on supplement labels. See [21CFR101.93](#) and [the Guidance for Industry](#).

GOED is issuing this Industry Advisory to remind members and the dietary supplement industry that it is NOT permissible to promote dietary supplement products by citing journal articles reporting on studies in diseased populations as this connection may cause your product to be considered a drug. Specifically, when scientific references are used commercially by the seller of a product to promote a product to consumers, such references may become evidence of the product's intended use. Such practice is in violation of [21 CFR 101.93\(g\)\(2\)\(iv\)\(C\)](#):

“Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;”

and may draw the attention of the FDA.

While there are likely plenty of examples, in 2013, the FDA sent [a warning letter](#) to Synticare Corporation advising that the FDA determined a number of its products were being promoted for conditions that caused the products to be drugs under the Federal Food, Drug, and Cosmetic Act. One of the issues cited was the use of scientific references to promote products. The following is text copied from that warning letter:

In addition, when scientific references are used commercially by the seller of a product to promote the product to consumers, such references may become evidence of the product's intended use. For example, under 21 CFR 101.93(g)(2)(iv)(C), a citation of a publication or reference in the labeling of a dietary supplement is considered to be a claim about disease treatment or prevention if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease. The home page of your website provides links to online summaries of two studies that pertain to prevention and treatment of macular degeneration:

[*Age-Related Eye Disease Study \(AREDS\), National Eye Institute, National Institutes of Health*](#)

[*Age-Related Eye Disease Study 2, The Lutein/Zeaxanthin and Omega-3 Supplementation Trial*](#)

Your website promotes your products AREDS 1, AREDS 1 Smokers, and AREDS 2 for prevention and treatment of macular degeneration by claiming that they contain the same ingredients used in these studies.
