

DEPARTMENT OF HEALTH AND HUMAN SERVICES

U. S. FOOD AND DRUG ADMINISTRATION

21 CFR PART 101

[Docket No. 99N-0554]

How to Use Health Claims and Nutrient Content Claims in Food Labeling; Public Meeting

The Association of Food and Drug Officials (AFDO) is a non-profit, professional association consisting of state, federal, and local regulatory officials as members, with industry representatives participating as associate members. From its very inception almost 103 years ago, AFDO has recognized the need for uniform laws and regulations to prevent regulatory chaos for national and international corporations. AFDO's primary purpose has been to promote, as its motto states, "*Uniformity through Cooperation and Communication.*"

The Executive Board of AFDO is pleased to offer the following comments on the specifically listed questions in the Federal Register relative to Sections 303 and 304 of the Food and Drug Administration Modernization Act of 1997 (FDAMA):

1. **Scientific Basis for Claims**

- a. An "authoritative statement" is, in the case of defining this phrase from the standpoint of the amendments to the Federal Food, Drug, and Cosmetic Act, a statement of FACT from an agency or educational institution recognized nationally for its expertise in the field of nutrition and disease-related conditions. Such a statement must be viewed in the full context in which it is made, and for the purpose of substantiating a health or nutrient content claim, must be a positive statement that is not colored by relative words such as "may," "might," or "one study shows...." The statement must be a straightforward conclusion by the "authority" that the "authority" believes it to be true without caveats.
- b. The Food and Drug Administration (FDA) should define "authoritative statement" by regulation.
- c. If FDA defines the term, FDA should determine if a statement forwarded to it for use as a health or nutrient content claim is an "authoritative statement."
- d. Absolutely. Refer to (a) above. The context in which the statement is made is inextricably tied to the statement.
- e. When reviewing an "authoritative statement," FDA must be able to relate the statement to the evidence that was utilized by the authority to come to its conclusion. To simplify FDA's review of requests to utilize an "authoritative statement," FDA should require the requester to supply FDA with such information, and may also contact the authority for further documentation.

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2. Existing Regulatory Requirements

a. and b. Several years and many man-hours of work went into the development of FDA's nutrient content and health claims regulations. All affected parties were given ample opportunity to comment on the regulations during the proposal stages. Therefore, with the exception of those subsections which may require amendment in order to conform to the requirements under FDAMA to permit the use of "authoritative statements" to justify a health or nutrient content claim, FDA must continue to adhere to these requirements. If FDA determines that additional amendments are required in order to permit "anchoring" of claims, the use of synonyms not previously approved, abbreviated health claims, or other revisions, such revisions should be published for notice and comment.

3 Procedural and Definitional Issues

- a. As previously stated in (1)(a) above, any agency FDA may identify must meet the criteria mentioned. AFDO is not in a position to make this determination.
- b. FDA should state by regulation, that prior to approval of the use of an "authoritative statement," FDA will make the final decision as to whether a statement meets the definition of "authoritative statement" before such a statement may be used; and that FDA will apply appropriate regulations as to the wording of any claim related to such statement.
- c. As previously noted, FDA should require (1) substantiation that the product in question meets all FDA regulations that apply to the use of the nutrient content claim or health claim; (2) the full context in which the "authoritative statement" was made; and (3) any scientific evidence the company may have which justifies the statement being made.
- d. Yes. AFDO believes that analytical methodology is the key to determining whether or not a product or substance qualifies for a claim. This is especially true for many dietary supplements. Studies conducted by industry associations and some national and state government bodies indicate that the strength and purity of many of these products, and the amount of so-called "active" ingredients, varies widely among brands.
- e. A "balanced presentation of scientific literature" is one which includes an array of published studies on the subject under discussion, both pro and con. If the literature includes fifty studies on the subject, it would not be appropriate to provide only five studies, of which four promote the use of the claim and one is negative, when the body of literature may have a ratio of three to two, for and against. Further, in order to have a 'balanced presentation,' the sources of the studies must be considered. A study published in a minor journal or in an obscure journal in Eastern Europe, for instance, should not carry as much weight as a study published in a recognized national/international journal.

- f. FDA should not keep a "notification" confidential, with the exception of any proprietary information which may have been submitted as substantiation that the *product* qualifies for the claim. Any information in the public domain that is being used to substantiate the claim should be placed on the public docket. Others wishing to use any "approved" claim would still be required to substantiate the fact that their product meets the requirements in the regulations for use of the claim.

- g. If a notification is not complete or does not support the requested claim, FDA should respond by letter. This would enable the company to supply additional substantiation before the request is placed on the public docket or the claim is totally denied by regulation (which should not occur unless there is enough evidence to ensure that the decision is correct and irrevocable for the near future).

AFDO thanks FDA for the opportunity to comment on this important matter.

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