U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Labeling
June 11, 1998

Guidance for Industry (1)

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

Prior to the Food and Drug Administration Modernization Act of 1997 (FDAMA), companies could not use a health claim or nutrient content claim in food labeling unless the Food and Drug Administration (FDA) published a regulation authorizing such a claim. Two new provisions of FDAMA (specifically sections 303 and 304 which amend, respectively, sections 403(r)(3) and 403(r)(2) (21 U.S.C. 343(r)(3) and (2)) of the Food, Drug, and Cosmetic Act, known as the Act) will now permit distributors and manufacturers to use claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences. These provisions are intended to expedite the process by which the scientific basis for such claims is established.

Since the passage of FDAMA, FDA has been reviewing both the statute and the accompanying legislative history in order to determine the most appropriate approach for implementing these new provisions. Due to the speed with which the FDAMA provisions became effective, the agency has decided to issue this guidance document during the initial phase of implementing these new provisions.

Submission procedures and use of a public docket for claims

Notifications should be submitted in duplicate to Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204. The notification should be clearly marked as "Notification for a Health Claim (or Nutrient Content Claim) Based on an Authoritative Statement." Whether notifications will be placed in a public docket upon receipt will be addressed in notice and comment rulemaking for an implementing regulation.

When a notification is received, FDA intends to review whether the notification includes the information necessary for the claim to be authorized under sections 303 and 304 of FDAMA. This may include, for example, a review for the submission of all the required elements and the identification of an appropriate statement from an appropriate scientific body (as identified below). The agency intends to notify the submitter by letter as soon as possible within the 120 days after submission when the notification does not comply with sections 303 and 304. When a notification does not meet the requirements of sections 303 and 304, the use of the claim is not authorized under FDAMA. The submitter may choose to revise the notification and resubmit it, in which case a food could not be marketed with the claim until at least 120 days after resubmission. As provided by FDAMA, FDA also may act to prohibit or modify a claim by regulation or a United States district court may find that the requirements of section 303 or 304 of FDAMA have not been met.

Scientific body

FDAMA permits claims based on current, published authoritative statements from "a scientific body of the United States with official responsibility for public health protection or research directly related to human nutrition . . . or the National Academy of Sciences (NAS) or any of its subdivisions." The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) are federal government agencies

specifically identified as scientific bodies by FDAMA.

FDA believes that other federal agencies may also qualify as appropriate sources for such authoritative statements. Along with NAS (or any of its subdivisions), the agency currently considers that the following federal scientific bodies may be sources of authoritative statements: the CDC, the NIH, and the Surgeon General within Department of Health and Human Services; and the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service within the Department of Agriculture.

Authoritative statement

FDA also believes it is necessary to clarify what constitutes an authoritative statement under FDAMA. FDAMA itself states that an authoritative statement: (1) is "about the relationship between a nutrient and a disease or health-related condition" for a health claim, or "identifies the nutrient level to which the claim refers" for a nutrient content claim, (2) is "published by the scientific body" (as identified above), (3) is "currently in effect," and (4) "shall not include a statement of an employee of the scientific body made in the individual capacity of the employee."

In addition, given the legislative history of sections 303 and 304 of FDAMA, FDA currently believes authoritative statements also should: (5) reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies, and (6) be based on a deliberative review by the scientific body of the scientific evidence.

Not all pronouncements by the designated scientific bodies would meet these criteria. For example, authoritative statements by the Surgeon General would normally be found only in the Surgeon General Reports.

FDA intends to consult, as appropriate, with the scientific body that is the source of a statement cited as the basis for a claim, as well as with the other federal scientific bodies that have public health responsibilities and expertise relative to the claim. The agency has already begun this liaison process.

Scientific standard with respect to health claims

FDAMA upholds the "significant scientific agreement" standard for health claims. This conclusion is based on FDAMA and its legislative history. FDAMA provides that FDA may issue a regulation under section 403(r)(3)(B)(i) of the Act to prohibit or modify a claim. Section 403(r)(3)(B)(i) permits FDA to promulgate regulations authorizing health claims only if FDA "determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

Consistent with this provision, FDA intends to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement. And consistent with earlier regulations, FDA does not believe this standard would allow for a claim based on, for example, findings characterized as preliminary results, statements that indicate research is inconclusive, or statements intended to guide future research.

Content of notification and other statutory requirements

FDAMA requires that a person must submit a notification of the claim at least 120 days before the first introduction into interstate commerce of the food with a label containing the claim. FDA notes that, as indicated by FDAMA, the notification is to include: (1) "the exact words used in the claim," (2) "a concise description of the basis upon which such person relied for determining that the requirements" for an authoritative statement "have been satisfied," (3) "a copy of the statement referred to . . . upon which such person relied in making the

claim," and (4) for a health claim, "a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers," or, for a nutrient content claim, "a balanced representation of the scientific literature relating to the nutrient level to which the claim refers."

FDA expects that to provide a "balanced representation of the scientific literature," a bibliography of the scientific literature on the topic of the claim would be compiled. A brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement should be submitted.

FDAMA imposes several additional conditions on claims based on authoritative statements and the foods for which such claims are made. For example, FDAMA requires that such a claim be "stated in a manner so that the claim is an accurate representation of the authoritative statement referred to" and "so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

FDAMA requires, with respect to health claims, that the food for which such a claim is made not exceed the disqualifying amounts of nutrients that may increase the risk of a disease or health-related condition in the general population. FDAMA also requires, for example, that nutrient content claims use the terms already defined in regulations by the agency, in, e.g., Title 21, Code of Federal Regulations (CFR) sections 101.13 and 101.54. Finally, FDAMA requires that a claim based on an authoritative statement, with the food for which the claim is made, not be false or misleading in any particular.

Under FDAMA, persons submitting notifications must include "the exact words used in the claim." Submitted health claims should use the word "may" to characterize the relationship between the nutrient and the disease or health related condition so as to indicate that the disease or health-related condition is caused by many factors. Likewise, a claim for a health effect attributed to a single brand name product would be misleading. Foods bearing health claims based on authoritative statements should comply with the provisions of 21 CFR 101.14. These include, for example, requirements that the substance that is the subject of a claim is safe and lawful and that its level is sufficiently high and in an appropriate form to justify the claim.

A nutrient content claim based on an authoritative statement that uses terms the agency has defined, such as "good source" or "high," must, under FDAMA, refer to a nutrient level (i.e., a daily value) that is identified by the authoritative statement. In addition, foods bearing such nutrient content claims should comply with 21 CFR 101.13.

To ensure that compliance with all relevant regulations can be assessed, the FDA believes that information on analytical methodology for the nutrient that is the subject of a claim should be submitted as part of the notification, consistent with 21 CFR 101.69 and 21 CFR 101.70.

Dietary Supplements

Finally, FDA believes that there is need for further consideration concerning dietary supplements. FDAMA does not provide for health claims based on authoritative statements for dietary supplements. This is because FDAMA amended the section of the Act that deals with procedures and standards for health claims for conventional foods, but did not amend the section that deals with procedures and standards for health claims for dietary supplements. That is, section 403(r)(3) of the Act specifies the procedure and standard by which health claims may be made for conventional foods. Section 403(r)(5)(D) specifies that health claims with respect to dietary supplements shall not be subject to section 403(r)(3), but rather to a procedure and standard established by regulation by FDA. Section 303 of FDAMA amended section 403(r)(3) of the Act to allow for health claims based on authoritative statements, but did not address section 403(r)(5)(D).

The FDA intends to propose that health claims based on authoritative statements be permitted for dietary supplements.

In contrast, with respect to nutrient content claims, FDAMA amended section 403(r)(2) of the Act, which applies to both conventional foods and dietary supplements. Thus, dietary supplements may make nutrient content claims based upon authoritative statements in accordance with FDAMA and the applicable regulations for nutrient content claims, and the contents of this guidance document would apply.

(1) This guidance has been prepared by the Office of Food Labeling in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. This guidance represents the Agency's current thinking on the procedures for a firm to notify FDA of their intent to use a health claim or nutrient content claim based on an authoritative statement of a scientific body. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Additional copies are available from:

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(Tel) 202-205-5099
(Internet) http://www.cfsan.fda.gov/~dms/guidance.html

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