FDA Client Advisory

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FDA Seeks Comments on Qualified Health Claims and Other Issues

EXECUTIVE SUMMARY

On November 25, 2003, the Food and Drug Administration ("FDA") issued an Advanced Notice of Proposed Rulemaking ("ANPRM") to request comments on alternatives for regulating qualified health claims in the labeling of foods as well as several other food labeling issues.

By way of brief background, a "health claim" is a claim characterizing the relationship between a substance and its ability to reduce the risk of a disease or health condition. FDA has traditionally applied the "significant scientific agreement" standard to all health claims – i.e., to make the claim, there must be "significant scientific agreement" that the substance in question reduces the risk of the disease or health condition as claimed. Today, FDA allows "qualified health claims" – health claims that do not meet the "significant scientific agreement" standard, but are not misleading because of the use of qualifying language characterizing the level of support for the claim.

In December 2002, FDA established the Task Force on Consumer Health Information for Better Nutrition ("Task Force"). This Task Force was charged with, among other things, reporting on how the FDA can improve consumer understanding of the health consequences of dietary choices. Included in this mandate was how the agency should evaluate scientific evidence for qualified health claims, as well as developing a framework for regulating qualified health claims.

On July 11, 2003, FDA published a notice announcing the availability of the Task Force report and interim procedures for the evaluation of qualified health claims. Under the interim procedures, FDA assigns one of three disclaimers to a claim based on its evaluation of the data that supports the claim. In that same notice, FDA stated its intent to publish an ANPRM to solicit comments on the regulatory approaches suggested by the Task Force report. This is that ANPRM. The report, interim procedures, and other information on qualified health claims can be found at: http://www.cfsan.fda.gov/~dms/lab-qhc.html.

HEALTH CLAIMS

FDA is considering three alternatives for regulating qualified health claims. These three options were identified in the Task Force report published in July.

Option 1. This option would be to codify the current interim procedures, or some variation, into a regulation. FDA identified several strengths of this approach, and it appears to be its "first choice." First, it would allow claims to be made in a timely manner and, although it would not include notice-and-comment rulemaking for the agency's decision on a particular claim, it would make the supporting data available to the public for comment. Second, it would provide for the use of disclaimers to communicate to

consumers the level of support for the claim, thereby providing truthful and non-misleading information. Third, this approach would allow for faster review (and hence faster revisions, if necessary) of qualified health claims compared to rulemaking (option 2). The agency's review period would be completed within 270 days after receipt of the petition, and the agency's decision would take the form of an enforcement discretion letter. This would also provide greater flexibility to FDA in the event it wishes to reverse or alter a decision on a qualified health claim, compared to if it had to amend a rule.

Option 2. This option would require each qualified health claim to undergo notice-and comment rulemaking, analogous to the statutory requirement for unqualified health claims. Presently, the "significant scientific agreement" standard applies to the substance-disease relationship (e.g., calcium may reduce the risk of osteoporosis). This option would require FDA to reinterpret this standard and now focus on whether the words of the claim, including the qualifying language (e.g., "limited and preliminary scientific research suggests…"), accurately reflect the current scientific evidence rather than whether there is significant scientific agreement supporting the substance-disease relationship. One advantage to this is that it would not require a re-working of the health claim regulations (21 C.F.R. § 101.14). Rather, FDA would have to revoke its contrary interpretation of "significant scientific agreement." Unlike Option 1, this option provides little room for maneuvering, because amendments to any qualified health claim could only be made through notice-and-comment rulemaking. In addition, FDA is concerned that interpreting the "significant scientific agreement" standard to apply to the claim rather than the underlying substance-disease relationship could devalue the standard, because any claim would meet the standard so long as it accurately reflects the supporting evidence. Finally, FDA expressed some concern that this option could spawn a first amendment challenge for its application of the statutorily prescribed process for reviewing unqualified health claims to qualified health claims, because the length of time it would take to approve a qualified health claim could be seen as a restraint on speech that is simply too long.

Option 3. This option would treat qualified health claims as outside the scope of the Nutrition Labeling and Education Act of 1999 ("NLEA"). This means that qualified health claims would be regulated on a post-market basis only – FDA could only evaluate (and take action against) a claim once it has already appeared on a product label or in other labeling. Under this option, FDA would be regulating claims only for "false or misleading" statements, and "false or misleading" would be defined to include lacking substantiation. This approach is similar to the Federal Trade Commission approach. However, FDA would have a more difficult time with enforcement because FTC has administrative subpoena power, whereas FDA does not when dealing with health claims. That is, FTC can subpoena a company's substantiation and evaluate it with relative speed; FDA does not have the same power to subpoena substantiation in its investigation of a health claim. As a result, FDA would have to build enforcement cases on its own, consulting literature, talking to experts, and testing how consumers interpret claims. Also, this option does not allow the public to participate in the process. Additionally, FDA is concerned that the option could be too resource-intensive to protect consumers from misleading claims

already in the marketplace.

FDA is seeking comments on each of these three options, including comments about the strengths and weaknesses of each from the perspectives of public health, policy, law, and practicality. The agency is also interested in the public's suggestions as to additional options for regulating qualified health claims.

FDA is also requesting comments on other issues pertaining to health claims, including:

- How to provide incentives for manufacturers to develop the data needed for an unqualified health claim (i.e. significant scientific agreement);
- Whether FDA should remove the word "may" (e.g. "calcium may reduce the risk of osteoporosis") from approved, unqualified health claims;
- Whether FDA should authorize unqualified health claims through interim final rules, which can be promulgated faster than full notice-and-comment rulemaking, but may not allow a thorough review of comments from industry before the claim is permitted;
- Whether it should permit the use of claims such as "FDA authorized" or "FDA approved" with health claims (qualified or unqualified);
- How FDA can best educate consumers about the role of qualified health claims on food labeling;
- Whether the evaluations of non-government groups (e.g. American Heart Association) should be given weight in FDA's evaluation of health claims; and
- The meaning and/or relevance of FTC's "competent and reliable scientific evidence" standard for the purposes of supporting a qualified health claim.

DIETARY GUIDELINES

The Task Force recommended that FDA seek opportunities to promote the development and use of more dietary guidance statements on food. This would serve to assist the public in making better food choices and establishing healthier eating patterns.

Unlike health claims, which target a specific substance and specific disease or health related condition, dietary guidance statements focus instead on general dietary patterns, practices, and recommendations that promote health. These dietary guidance statements may be made on conventional food and dietary supplement labels without FDA review or authorization before use.

FDA is requesting comments on the appropriate definition of "dietary guidance" for labeling purposes, as well as the current approach to distinguish between health claims and dietary guidance. Presently, health claims meet a two part test to be termed as such: a substance and a disease or health-related condition. FDA has been using the term "dietary guidance" to refer to statements that do not contain both basic elements of a health claim. For example, dietary guidance statements may focus on general dietary patterns rather than a specific substance, or they may link a specific substance to a nondisease result, such as a healthy lifestyle or building bones.

FDA is also requesting comments on the appropriate definition of whether a "substance" element is present in a claim, since that serves as the primary distinction between a health claim and a dietary guideline. FDA is requesting comments on the usefulness of statements that expressly include the substance that is the basis for the claim as opposed to the food itself (e.g., "calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis" versus "yogurt may

reduce the risk of osteoporosis").

FDA is requesting comments on whether dietary guidance statements should include recommendations for making food substance "substitutions" or "replacements." For example, should FDA encourage dietary guideline recommendations for food intake, such as mono- and polyunsaturated fat? FDA wants to ensure that, if these statements are made, they are clear and non-misleading in ways that will enhance and benefit public health.

Finally, FDA is requesting comments on dietary guidance statements on food labels generally and on approaches appropriate for FDA to consider under its statutory authorities.

REQUEST FOR OTHER COMMENTS

FDA is also requesting comments, including available data, on the following:

- What effects do health claims have on consumer purchases of foods and dietary supplements? What effects do health claims have on the total diet?
- Is there a difference between consumers' willingness to buy products with qualified health claims and consumers' willingness to buy products with health claims based on significant scientific agreement?
- What effects would the different qualifying phrases described in the interim procedures for qualified health claims guidance and the Task Force report have on the willingness of consumers to buy the products containing the claims? Is there evidence that consumers would find the difference among qualifying phrases to be substantial?
- What types of foods and dietary supplements are most likely to use qualified health claims in their labeling? What types of claims are most likely to be used by those products?
- What types of existing products will manufacturers re-formulate in order to be able to make qualified health claims? What types of claims are most likely to lead to reformulation?
- What new products might be developed in response to qualified health claims?
- Would any of the regulatory options discussed in the ANPRM have a significant effect on small businesses or other small entities?
- What additional research should FDA, other government agencies, or other organizations sponsor to answer these questions?

FDA is encouraging all interested parties to submit information in response to the ANPRM by January 26, 2004. The ANPRM can be found at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-29448.htm or 68 Fed. Reg. 66,040.

FOR MORE INFORMATION

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