Guidance for Industry and FDA

Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

GUIDANCE

Comments and suggestions regarding this document may be submitted at any time. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1450.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

July 2003

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Office of Nutritional Products, Labeling, and Dietary Supplements
Division of Nutrition Programs and Labeling HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-1450
www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
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Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to notify the public of interim procedures that the Food and Drug Administration (FDA) is implementing for petitioners who submit qualified health claim petitions to the agency. This guidance describes the procedures that FDA intends to use, on an interim basis, to respond to qualified health claim petitions until the agency can promulgate regulations under notice-and-comment rulemaking; it also provides a linkage between the ranking of scientific evidence and the wording of qualified health claims. In addition, this guidance updates the agency's approach outlined in December 2002 (Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements) and the agency's approach to implementing *Pearson v. Shalala* (164 F.3d 650 (D.C. Cir. 1999)) to include conventional foods. This guidance does not apply to unqualified health claims, which must meet the "Significant Scientific Agreement" (SSA) standard.[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

FDA is issuing this document as final guidance setting out interim procedures that the agency intends to use for qualified health claims in the labeling of conventional human food and dietary supplements until the agency can promulgate regulations under notice and comment rulemaking.

[1] This guidance has been prepared by the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

[2] FDA uses the term, "unqualified health claim," to refer to health claims that are or could be authorized under the Nutritional Labeling and Education Act of 1990 (NLEA) and regulations promulgated under that act, including 21 CFR 101.70.

III. OBJECTIVE

FDA intends to use the following interim procedures to ensure that its premarket review is consistent with the spirit of the Nutrition Labeling and Education Act and the First Amendment. FDA will continue to evaluate unqualified health claims under its current regulatory process and standard for significant scientific agreement (21 CFR 101.14 and 101.70).

A. Criteria for Exercise of Enforcement Discretion

FDA plans to establish criteria for considering exercising enforcement discretion for qualified health claims based on the extent to which the totality of the publicly available evidence supports the claim (see Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data). Different levels of evidence will result in different qualifying language as described in Table 1, which provides standardized language for the B, C, and D categories to be used as part of the qualifying language for qualified health claims until consumer research[3] is complete.

Table 1. Standardized Qualifying Language for Qualified Health Claims.

Scientific Ranking*	**FDA Category**	**Appropriate Qualifying Language****
Second Level	B	… "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests…however, FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests… FDA concludes that there is little scientific evidence supporting this claim."

*From Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data.

**The language reflects wording used in qualified health claims as to which the agency has previously exercised enforcement discretion for certain dietary supplements. During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary depending on the specific circumstances of each case.

[3] Attachment D of the Task Force Report (available at http://www.fda.gov/oc/mcclellan/chbn.html).

B. Procedures

1. Filing Review

FDA plans to begin accepting petitions for qualified health claims on September 1, 2003. Within 45 days of receipt of a qualified health claim petition, FDA intends to determine whether the petition is complete (see Section C below). If the petition is incomplete, the agency plans to inform the petitioner of the deficiencies and what steps the petitioner should take to rectify these deficiencies. If FDA determines that the petition is complete, it intends to file the petition. The agency recognizes that it can evaluate petitions more efficiently and effectively if they are well-organized and contain all the relevant information. FDA encourages potential petitioners to meet with the agency prior to preparing a petition to discuss their plans.

2. Prioritization

FDA has only limited resources for reviewing health claims. Thus, to maximize the public health benefit of its claims review process, FDA intends to prioritize on a case-by-case basis all complete petitions according to several factors, including whether the food or dietary supplement that is the subject of the petition is likely to have a significant impact on a serious or life-threatening illness; the strength of the evidence; whether consumer research has been provided to show the claim is not misleading; whether the substance of the claim has undergone an FDA safety review (i.e., is an authorized food additive, has been GRAS (generally recognized as safe) affirmed, listed, or has received a letter of "no objection" to a GRAS notification); whether the substance that is the subject of the claim has been adequately characterized so that the relevance of available studies can be evaluated; whether the disease is defined and evaluated in accordance with generally accepted criteria established by a recognized body of qualified experts; and whether there is prior review of the evidence or the claim by a recognized body of qualified experts.

3. Opportunity for Public Comment

Upon filing of a petition, FDA intends to post the petition on its website and request public comment for 60 days. FDA plans to post comments submitted by the public on FDA's website or to make comments available for public review at the Division of Dockets Management, HFA-305.

4. Scientific Review

After the comment period closes, FDA may pursue any one of several options for scientific review of data submitted in a petition in support of the substance/disease relationship. For example, FDA may conduct the review internally, it may

convene an advisory subcommittee, or it may use appropriate third-party reviewers under contract to FDA, e.g., the Agency for Healthcare Quality and Research (AHRQ). In the case of a petition forwarded to AHRQ, AHRQ plans to send the petition to an Evidence-Based Practice Center (EPC) with which it has a contract to review the scientific evidence in the petition and to rank the degree of scientific certainty of the validity of the substance/disease relationship. AHRQ also plans to ask the EPC to review those science-related public comments received by FDA that discuss or provide evidence. Within 120 days after the commencement of the third party review, FDA would expect to receive a report that includes a description of the evidence reviewed, an analysis of that evidence, a summary of and response to public comments that pertain to the evidence, and its assessment as to the degree of scientific certainty in support of the substance/disease relationship.

5. Consolidation of Like Petitions

If FDA receives more than one petition for a qualified health claim that describes the same relationship between a substance and a disease or health-related condition during its review, the agency plans to consolidate all of the related petitions received, if appropriate.

6. Consultation with Other Federal Agencies

To fully inform FDA's review, FDA intends, as appropriate, on a case-by-case-basis, to consult with other scientific Federal agencies with official responsibility for public health protection or research related to human nutrition and dietary supplements.

7. Regulatory Decision

As mentioned above, FDA plans to either conduct its own review or use an appropriate third party to conduct a scientific review. In the case of third party review, after FDA receives, for example the EPC report, FDA intends, based on the totality of the publicly available evidence, public comment, and other relevant regulatory considerations, to determine whether to consider exercising enforcement discretion with respect to the proposed claim. If FDA decides to consider exercising enforcement discretion, the agency plans to determine what qualifying statement(s) and other information should accompany the claim to ensure that it is truthful and not misleading. In reaching its determination, FDA intends to review and evaluate the third party report, the totality of the publicly available evidence, and all of the public comments submitted within the comment period, as well as consider how the proposed qualified claim will affect consumers' dietary choices. FDA also intends to consider whether to exercise enforcement discretion with respect to other requirements in 21 CFR 101.14, and what other factors, in addition to qualifying language, are relevant to considering the exercise of enforcement discretion.

8. Notification to Petitioner

On or before day 270 after receipt of the filed petition, FDA plans to notify the petitioner in a letter of: a) the agency's determination; b) the basis for its determination; and c) if the agency decides to consider exercising enforcement discretion, the qualified claim for which the agency intends to consider exercising such discretion and the provisions of 21 CFR 101.14 for which the agency intends to consider exercising such discretion. FDA also plans to notify the petitioner of any other factors the agency intends to consider in deciding whether to exercise enforcement discretion when the claim appears in labeling of conventional human food or dietary supplements. FDA plans to post the letter and any third party report on the agency's website.

9. Extensions

If the agency determines that it is appropriate, upon good cause, FDA may, decide to extend by 30-60 days the time period to notify the petitioner.

10. Reconsideration

If a petitioner or other party disagrees with an FDA determination, that party may request reconsideration. FDA intends to reconsider its determination if the party presents significant new relevant evidence or provides a persuasive analysis that the agency's interpretation of the original evidence was incorrect. FDA intends to use the same process described above for reconsideration of the agency's determination. FDA may, on its own initiative, decide to reconsider a determination.

C. Content of Petitions

1. Requirements

Except as described in C.2. (below), the agency believes that the requirements of 21 CFR 101.70 continue to apply, including the requirement to demonstrate that the substance that is the subject of the claim is safe and lawful under 21 CFR 101.14(b)(3)(ii).

2. Summary of Scientific Information

FDA intends to exercise enforcement discretion with respect to the requirement in 21 CFR 101.70 that the summary establish that the proposed claim is supported by significant scientific agreement. Instead, the summary should explain how credible evidence supports the claim as worded in the petition and why the petitioner believes that the specific wording of the claim, including any explanatory information, disclaimer or other qualification, is accurate and not

misleading. As required by 21 CFR 101.70, the summary should include an analysis of the potential effect of the claim on total intakes of the substance (i.e., current intakes plus increases due to the claim), including any adverse or beneficial changes in dietary practices. The agency encourages petitioners to include consumer research to document consumer understanding. FDA recommends that the consumer research address the research questions set out in Attachment D of the Task Force Report.[3]