

and human dietary supplements.¹⁰ In light of the need for improved health messages and science-based competition among food (including dietary supplement) producers to promote better health, and given the broader goals of the Consumer Health Information for Better Nutrition Initiative, FDA believes that it would be prudent to expand the scope of this ANPRM to request comments on the appropriateness and nature of dietary guidance statements on food labels.

II. Health Claims

A. Regulatory Alternatives for Qualified Health Claims

FDA is considering three alternatives (i.e., options) identified in the Task Force report (Ref. 4) for regulating health claims that do not meet the SSA standard of evidence (i.e., qualified health claims) required in 21 U.S.C. 343(r)(3)(B)(i) and § 101.14(c) to evaluate the scientific validity of health claims. The options identified by the Task Force are: Option 1—incorporate the interim procedures and evidence-based ranking system into a regulation under notice-and-comment rulemaking; option 2—reinterpret the SSA standard to apply to the accuracy of the characterization of the evidence supporting the claim, instead of the underlying substance-disease relationship, and subject qualified health claims to notice-and-comment rulemaking; and option 3—treat qualified health claims as wholly outside the NLEA and regulate them solely on a postmarket basis, if they are false or misleading. FDA is seeking comment on each of the options described, including comments about the strengths and weaknesses of each

refer to health claims. That is, FDA considers that the term “health message” includes the various forms of dietary statements (e.g., a health claim, a dietary guidance statement).

¹⁰ Health messages on product labels can be divided into several categories, including health claims, dietary guidance statements, and “structure/function” claims. A structure/function claim describes the effect of a substance or product on the structure or function of the human body (see 21 U.S.C. 321(g)(1)(C) and 343(r)(6)). An example of a structure/function claim is: Calcium helps build strong bones. Structure/function claims do not refer to a disease, and in this way often resemble one type of dietary guidance statement as described in section III.A of this document. Structure/function claims may appear on conventional foods as well as dietary supplements. Such claims are not pre-reviewed by FDA, but must be truthful and not misleading as required under sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n), and 343(a)(1)). Additional requirements apply when a structure/function claim is used in the labeling of a dietary supplement. For example, firms must notify FDA of a structure/function claim within 30 days after first marketing the product with the statement, and a disclaimer must accompany the statement (see 21 U.S.C. 343(r)(6) and 21 CFR 101.93).

option from the perspective of public health, policy, law, and practicality; and which is the best option and why. The agency also is requesting comments that suggest additional options for regulating qualified health claims, together with an analysis of the strengths and weaknesses of each suggested alternative from the perspective of public health, policy, law, and practicality.

1. Option 1

The first option would be to codify the current interim procedures and evidence-based ranking system into a regulation, or codify a variation of these. This approach addresses both procedural and substantive concerns about qualified health claims, and also allows such claims to be made in labeling in a more timely manner than under option 2. With respect to the procedural issues, this approach is consistent with the spirit of the NLEA because it maintains the premarket clearance system that provides for FDA review of qualified health claims and the supporting data, and an opportunity for public participation. This option is similar in approach to the suggestions made in comments on the December 20, 2002, guidance on qualified health claims. Even though the process would not include notice-and-comment rulemaking for the agency's decision on a qualified health claim, the petition with the requested qualified health claim and the supporting data would be made available to the public for comment.

Second, this approach responds to the first amendment concerns identified in *Pearson* by providing for the use of disclaimers to communicate to consumers the level of scientific evidence in support of health claims and to cure potentially misleading health claims. The addition of a clarifying disclaimer to a potentially misleading claim would provide consumers with truthful and nonmisleading information. (See *Pearson*, 164 F.3d at 658–59.)

Finally, this approach allows for faster review and, if necessary, revision of qualified health claims. Under this option, the agency's review of a petition for a qualified health claim would usually be completed within 270 days after receipt of the petition. In addition, the agency's decision on a qualified health claim would remain in the form of an enforcement discretion letter and not, as some comments to the December 20, 2002, guidance requested, in the form of a regulation. Thus, FDA could more readily revise its decision about a qualified health claim if subsequent data were to indicate the need to do so.

The data underlying qualified health claims are, by definition, preliminary and subject to change as more studies are conducted. If the qualified health claim were established in a regulation, FDA could amend it only through notice-and-comment rulemaking. Thus, a claim that becomes inaccurate or misleading because of new scientific developments would remain in labeling until the regulation was revised.

2. Option 2

The second option would be to require each qualified health claim to undergo notice-and-comment rulemaking, which is the statutorily prescribed process for health claims for conventional foods. Requiring rulemaking before a qualified health claim is allowed on food labels is consistent with suggestions made in a comment on the December 20, 2002, guidance.

This approach would require FDA to reinterpret the SSA standard to apply to the claim (including the disclaimer, if any) instead of the underlying substance-disease relationship. Thus, the agency's focus would be on whether the words of the claim accurately reflect the data supporting it (e.g., “limited and preliminary scientific research suggests * * *”), rather than whether there is SSA supporting the substance-disease relationship.

Because the SSA requirement in FDA's health claim regulations (§ 101.14(c)) tracks the language of the statute (21 U.S.C. 343(r)(3)(B)(i)), and both require FDA to evaluate whether there is SSA that the claim is supported by the totality of publicly available scientific evidence, it would not be necessary to amend § 101.14(c) to implement this option. However, FDA would have to revoke its contrary interpretation of the statute and § 101.14(c) in the preambles to the general health claim regulations. In those preambles, FDA stated that SSA was about the substance-disease relationship instead of the words of the claim.

Mandatory rulemaking for each qualified health claim may not provide sufficient flexibility to implement changes in the claims necessitated by rapid developments in science. Moreover, this process could be quite burdensome without any apparent corresponding public health benefit if the claim is based on weak scientific evidence. In addition, the reinterpretation of the SSA standard to apply to the claim rather than the underlying substance-disease relationship could eliminate the value of the standard because claims about