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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N–0496]

RIN 0910–AF09

Food Labeling: Health Claims; Dietary Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also is soliciting comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. Comments on the regulatory alternatives and the additional topics will inform FDA's rulemaking to establish regulations for qualified health claims, as well as any policy initiative(s) that FDA may undertake to provide information to consumers to help them make wise food choices.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

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FOR FURTHER INFORMATION CONTACT: Paulette Gaynor, Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535)[1] directed FDA to issue regulations authorizing health claims (i.e., labeling claims that characterize the relationship of a substance to a disease or health-related condition) only if the agency determines, based upon 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 (SSA), among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (21 U.S.C. 343(r)(3)(B)(i)). Congress delegated to FDA the authority to establish the procedure and standard for health claims for dietary supplements (21 U.S.C. 343(r)(5)(D)). In accordance with the NLEA, FDA issued regulations establishing general requirements for health claims in labeling for conventional foods (58 FR 2478, January 6, 1993). By regulation (59 FR 395, January 4, 1994), and under Congressional authority[2], FDA adopted the same general requirements, including the procedure and standard, for

[1] The NLEA authorized health claims in food labeling by amending the Federal Food, Drug, and Cosmetic Act (the act) to add section 403(r) to the act (21 U.S.C. 343(r)). This section specifies, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) (for conventional foods) or 403(r)(5)(D) (for dietary supplements).

[2] FDA issued regulations establishing general requirements for health claims in dietary supplement labeling (59 FR 395) under the NLEA and the Dietary Supplement Act of 1992 (Public Law 102–571).

health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods. (See 21 U.S.C. 343(r)(3) and (r)(4).)

The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) and 101.70) (21 CFR 101.14(d) and (e), 101.70)). The standard requires a finding of "significant scientific agreement" (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§§ 101.14(c) and 101.70(f)).

Among its provisions regulating claims, the NLEA required FDA to determine whether claims respecting 10 specific substance/disease relationships met the requirements for a health claim (NLEA section 3(b)(1)(A)(vi) and (x), Public Law 101–535). FDA conducted these statutorily required analyses. Not all relationships that Congress required the agency to consider were found to meet the standard of SSA, and, so, not all were authorized by FDA. Some of the substance/disease relationships that were found to lack SSA became the subject of a lawsuit, *Pearson* v. *Shalala* (*Pearson*), brought by dietary supplement marketers and health advocacy organizations.

In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. Although the U.S. District Court for the District of Columbia initially ruled in favor of FDA (14 F. Supp. 2d 10 (D.D.C. 1998)), the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).[3] The appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably concludes that a disclaimer would not eliminate the potential deception.

The Appeals Court further stated that it did not "rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." (164 F. 3d at 659.) Also, the court saw "no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim." Id. at 659 n.10. This language was the genesis of the "weight of the evidence" criterion discussed in this ANPRM.

In the **Federal Register** of October 6, 2000 (65 FR 59855), following the Appeals Court ruling in *Pearson*, FDA published a notice announcing its intention to exercise its enforcement discretion with regard to certain categories of dietary supplement health claims that may not meet the SSA standard currently endorsed in § 101.14(c).[4] The October 6, 2000, notice

[3] The appellate court decided the case on January 15, 1999. On March 1, 1999, the Government filed a petition for rehearing en banc. The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

[4] In the **Federal Register** of December 1, 1999 (64 FR 67289), FDA published a notice to inform the public of the steps FDA planned to follow to carry out the *Pearson* decision.

identified circumstances in which the agency intended to consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling. Included in the agency's consideration was whether the scientific evidence in support of a given health claim outweighed the scientific evidence against it. In the **Federal Register** of December 20, 2002 (67 FR 78002), FDA published a notice of availability announcing that the agency was identifying qualified health claim enforcement discretion factors in the form of guidance and expanding its consideration of enforcement discretion to include health claims in the labeling of conventional foods as well as dietary supplements.[5]

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker* v. *Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) (*Whitaker*). In *Whitaker*, the district court, interpreting *Pearson*, found that "credible evidence," rather than "weight of the evidence," is the appropriate standard for FDA to apply in evaluating qualified health claims. *Whitaker*, 248 F.Supp. 2d at 10. In light of *Whitaker*, FDA believes that the weight of the evidence standard in the October 6, 2000, **Federal Register** notice and the December 20, 2002, guidance must be tempered by the test of credible evidence (68 FR 41387 at 41388–41389).

Also in December 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional foods and dietary supplements

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In the **Federal Register** of December 22, 1999 (64 FR 71794), FDA published a notice of availability of guidance clarifying the SSA standard in light of *Pearson*. The October 2000 notice announced FDA's revisions to the 1999 implementation strategy.

[5] FDA decided to apply the enforcement discretion factors to conventional foods to promote consistency in health messages, to enable consumers to learn about important health information even if it may not necessarily meet the current SSA standard, and to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims (68 FR 41387 at 41389).

to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary decisions. Under this initiative, the agency established the Task Force on Consumer Health Information for Better Nutrition (the Task Force). The Task Force was charged with, among other things, reporting on how the agency can improve consumer understanding of the health consequences of dietary choices and increase competition by product developers in support of healthier diets. This charge includes how the agency should evaluate scientific evidence for qualified health claims, as well as developing a framework for regulations that will give these principles the force and effect of law.

FDA announced the availability of the Task Force report (Ref. 1), in a notice published in the **Federal Register** of July 11, 2003 (68 FR 41387). The notice also announced the availability of two guidances entitled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" (Ref. 2) and "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (Ref. 3) that further updated the agency's approach on how it intends to implement the *Pearson* decision. Further, the notice stated that FDA intended to publish an ANPRM to solicit comments on the regulatory approaches and topics addressed in the Task Force report. This ANPRM is that document.

As of September 1, 2003, the agency has implemented the evidence-based ranking system and the procedures for qualified health claims[6] on an interim

[6] FDA is using the term "qualified health claim" to refer to health claims that do not meet the current SSA standard. This is in contrast to FDA's use of the term "unqualified health claim" to refer to health claims that meet the current SSA standard and are or could be authorized under the NLEA and regulations issued under the act, including 21 CFR 101.70.

[7] Since the October 2000 **Federal Register** notice and under the December 2002 guidance, when FDA decides to exercise its enforcement discretion with respect to a qualified health

basis. However, FDA recognizes the need for transparent, long-term procedures that have the force and effect of law.[7] Such procedures would benefit both the industry and the consumer, provided they result in well-reasoned, science-based decisions that facilitate the communication of truthful and non-misleading information to the consumer. To this end, the agency is issuing this ANPRM to solicit comment on various approaches the agency might adopt to regulate qualified health claims in the labeling of conventional foods and dietary supplements.[8]

Although the Task Force focused primarily on the issue of qualified health claims, its discussions were enriched by considerations related to promoting partnerships with sister public health agencies and others, with the goal of increasing the quantity and improving the impact of health messages[9] on

claim, it so notifies the petitioner by letter. This process was developed as a short-term response to the court decisions described above and does not provide for public participation.

[8] In accordance with the recommendation of the Task Force, FDA is also conducting consumer research to determine whether potentially misleading health claims can be cured by disclaimers in at least some cases. The agency does not have such data for conventional foods or dietary supplements. Within the next year, the agency will be completing research in this area. FDA's rulemaking will be informed by the results of this research, as well as the agency's evaluation and consideration of the regulatory alternatives and public comment.

[9] In the **Federal Register** of November 27, 1991 (56 FR 60537 at 60538), FDA stated that for consistency with the NLEA, the agency was using the term "health claim" in place of "health message," which was used in pre-NLEA **Federal Register** documents (i.e., proposed rule of August 4, 1987 (52 FR 28843); ANPRM of August 8, 1989 (54 FR 32610); and re-proposed rule of February 13, 1990 (55 FR 5176)) that discussed disease-related information on food labeling. Thus, the use of the term "health message" in those previous documents was roughly equivalent to the use of the term "health claim" in post-NLEA **Federal Register** documents. In recent documents (e.g., the December 2002 guidance, the Task Force report), including this ANPRM, however, FDA is using the term "health message"in a broader context than solely to 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/

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conventional human foods 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 option from the perspective of public health, policy, law, and practicality; and which is the best option and why. The agency also is

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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).

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 any substance-disease relationship, no matter how weak or preliminary the evidence, would meet SSA as long as the claim accurately described the level of the evidence.

This approach may be vulnerable to a first amendment challenge because it applies the statutorily prescribed process for reviewing unqualified health claims to qualified health claims. The statutory process requires notice-and-comment rulemaking and permits FDA up to 540 days to complete its review of a health claim petition (see 21 U.S.C. 343(r)(4)(A)(i)). Although the United States Court of Appeals for the Second Circuit has held that a period of 540 days is not an unconstitutional prior restraint for unqualified health claims

(see *Nutritional Health Alliance* v. *Shalala*, 144 F.3d 220 (1998), cert. denied, 525 U.S. 1040 (1998)), it is unclear whether it is too long to restrain qualified health claims in which the SSA standard is applied to the claim itself rather than the substance/disease relationship. FDA is concerned that this approach may be found to be unconstitutional because the value of commercial speech often depends upon its timeliness.

3. Option 3

A third option would be to treat qualified health claims as wholly outside the NLEA and regulate them on a postmarket basis under section 403(a)(1) of the act, which provides that food is misbranded if its labeling is false or misleading. Consistent with FDA's past practice, "false or misleading" would be defined to include lacking substantiation.

Under this approach, FDA could only evaluate and, where necessary, prohibit a claim after it appears on a product label (or in other product labeling). This is similar to the Federal Trade Commission's (FTC) approach, but with one significant difference: FTC has administrative subpoena power, allowing FTC to obtain a company's substantiating data, evaluate the data, and, where appropriate, take enforcement action with relative speed. In contrast, while FDA holds administrative subpoena power in some circumstances, the agency is not vested with such power for the investigation and enforcement of health claims in the labeling of conventional foods and dietary supplements.

As a result, the agency would have to build enforcement cases by first searching the literature and consulting with experts. Depending on the nature of the matter, FDA might also have to test how consumers would interpret the claim (where, for example, there was a serious question about the existence of an implied claim). There is also a concern that this option would not afford

FDA any role in reviewing or clearing claims before they appeared in labeling and would not provide any opportunity for public participation. Finally, this option could be inefficient and too resource intensive for FDA to be able to protect consumers from misleading claims that would already be in the labeling of products in the marketplace.

B. Issues Raised in the Task Force Report

In its report, the Task Force recommended that FDA seek comment on several additional topics: (1) Data and research on a substance/disease relationship, including incentives for SSA; (2) revised claim language for unqualified health claims; (3) interim final rules for unqualified health claims; (4) use of phrases such as "FDA authorized" in qualified and unqualified health claims; (5) consumer education; (6) evaluations of outside groups; and (7) competent and reliable evidence.

1. Data and Research on a Substance/Disease Relationship, Including Incentives for SSA

Although FDA intends to provide for the use of qualified health claims, the agency remains interested in authorizing unqualified health claims by regulation under the SSA standard. Based on the July 2003 interim evidence-based ranking guidance (Ref. 2), the level of scientific evidence to support the substance/disease relationship for an unqualified health claim would continue to be based on relevant, high quality studies, such as randomized, controlled intervention trials and prospective observational cohort studies, which minimize bias. FDA is requesting comments on how to provide incentives for manufacturers to develop the data needed to obtain SSA for an unqualified health claim. In addition, FDA is requesting comments on how to more

effectively develop public-sponsored research on substance/disease relationships.

2. Revised Claim Language for Unqualified Health Claims

The health claim regulations require unqualified health claims to state that the substance "may" reduce the risk of the specified disease (e.g., "calcium may reduce the risk of osteoporosis") (§ 101.14(d)(2)(ii)). In the final rule on general requirements for health claims for conventional foods (58 FR 2478 at 2505), FDA explained that the agency's use of the term "may" relates to the potential to reduce the risk of disease. The agency intended the use of the word "may" to convey to consumers that there is no guarantee that any one dietary practice will, in fact, reduce an individual's risk of a disease. FDA noted that absolute claims about diseases affected by diet generally are not possible because such diseases are almost always multifactorial, and that diet is only one factor that influences whether a person will get such a disease (58 FR 2478 at 2505). For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Id. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. Id. Thus, FDA intended the word "may" to alert consumers that there is no certainty that risk of disease will be reduced for each individual. However, it seems to the agency that in common practice the word "may" could be, and perhaps often is, interpreted as a reflection of the science supporting the claim rather than the certainty about the ability of a dietary practice to affect any one consumer. Thus, the word "may" leads to uncertainty about the science behind the claim, which was not FDA's intention.

The Task Force suggested that FDA consider removing the requirement for the word "may" from unqualified health claims to eliminate the uncertainty about the science underlying claims that meet SSA. FDA is requesting comments on whether the agency should make this change, whether there are alternatives to this change, and whether such a change would assist consumers in identifying the level of science supporting such health claims.

3. Interim Final Rules for Unqualified Health Claims

The Task Force recommended that FDA solicit comment on whether FDA should authorize unqualified health claims through interim final rules (IFRs) to expedite the availability of the health claim in food labeling. Before *Pearson*, the agency's general practice was to provide for the unqualified health claim through full notice-and-comment rulemaking, i.e., by issuing a proposed rule with a comment period, followed by a final rule authorizing the health claim (see section 403(r)(4)(A)(i) and § 101.70(j)). Although this practice has made for a relatively slow process, the comments received have proved useful to the agency (e.g., to more accurately articulate the science and to better define the substance that is the subject of the claim). However, as a general matter, comments have not persuaded the agency that any particular proposed health claim should not be allowed.

In light of this consideration, after *Pearson*, FDA began using authority given to the agency by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amendments to the act to authorize some unqualified health claims faster (see 65 FR 59855 at 59856). FDA has authorized three health claims, based on a finding of SSA, through the IFR

process under section 403(r)(7) of the act.[11] First, in the **Federal Register** of September 8, 2000 (65 FR 54686), FDA issued an IFR that authorized a health claim for plant sterol/stanol esters and reduced risk of coronary heart disease (CHD) ((§ 101.83) (21 CFR 101.83)). The agency intends to issue a final rule on this claim, that includes consideration of public comment. Second, in the **Federal Register** of October 2, 2002 (67 FR 61773), FDA issued an IFR that amended the health claim regulation in 21 CFR 101.81 authorizing a health claim about the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of CHD to include an additional eligible source of whole oat beta-glucan soluble fiber (the oatrim IFR). After consideration of comments, the agency adopted as a final rule, without change, the provisions of the oatrim IFR (68 FR 44207, July 28, 2003). Third, in the **Federal Register** of December 2, 2002 (67 FR 71461), FDA issued an IFR that amended the health claim regulation in 21 CFR 101.80 authorizing a health claim about the relationship between dietary sugar alcohols and dental carries to include the sugar D-tagatose (the D-tagatose IFR). After consideration of comments, the agency adopted as a final rule, without change, the provisions of the D-tagatose IFR (68 FR 39831, July 3, 2003).

FDA recognizes that the general rulemaking process (i.e., non-IFR process) for unqualified health claims may be lengthy; however, this process may help

[11] Section 403(r)(7) of the act (21 U.S.C. 343(r)(7)) authorizes FDA (by delegation from the Secretary of Health and Human Services) to make regulations issued under section 403(r) of the act effective upon publication pending consideration of public comment and publication of a regulation that considers such comment, if the agency determines that such action is necessary for public health reasons. This authority enables FDA to act promptly on petitions that provide information that is necessary to: (1) Enable consumers to develop and maintain healthy dietary practices, (2) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food, or (3) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible. Regulations made effective upon publication under this authority are deemed to be final agency action for purposes of judicial review. The legislative history indicates that such regulations should be issued as interim final rules (H.R. Rep. No. 105–399, at 98 (1997), reprinted in 1997 U.S.C.C.A.N. 2880, 2888).

ensure the validity of the scientific evidence under the SSA standard before such a claim is authorized, and may help prevent the unfair market advantage that could arise if FDA were to inappropriately characterize a substance or misinterpret the publicly available scientific evidence. The agency is interested in comments on the balance between the priorities of timeliness and comprehensiveness in the agency's review of an unqualified health claim. FDA is requesting comments on whether the agency should continue to use the IFR process for some or all unqualified health claims as a means of expediting the agency's processing of these petitions. Are there specific circumstances when IFRs should or should not be considered appropriate for health claims that meet the SSA standard?

4. Use of Phrases Such as "FDA authorized" in Qualified and Unqualified Health Claims

The agency has for decades discouraged or prohibited use of such phrases as "FDA authorized" or "FDA approved" in labeling. The agency's policy on such statements was generally based on one of two reasons: (1) All products of the type were FDA approved, so that a label statement regarding one product implied a difference that did not exist; or (2) "approval" terminology was not appropriate because FDA did not approve any individual (or specific) product. FDA is requesting data or other information on whether a phrase indicating FDA authorization (e.g., "FDA says * * *") would encourage consumers to have more confidence in a claim it accompanied than in a claim without the phrase. FDA is interested in receiving evidence of data concerning any confusion or potential confusion. Should such a phrase be encouraged at all, even if it were to give the consumer confidence in the claim? Would such

a phrase, when used with claims supported by different levels of science, confuse or potentially confuse consumers?

5. Consumer Education

The Task Force report noted growing evidence of a public health gap in knowledge and behavior with respect to substance/disease relationships. Even when the scientific evidence for substance/disease relationship does not meet the standard of SSA, there may be considerable evidence of a relationship between the substance and the disease, and consumers may find this information useful in planning their diets. FDA is requesting comments on how the agency could best educate consumers about the role of qualified health claims on food labeling, and how such claims may be used by consumers to advance their own understanding of diet and health matters.

6. Evaluations of Outside Scientific Groups

FDA has been requested on several occasions to consider accepting the evaluations of outside scientific groups as representing scientific consensus that could justify health claims. Some wanted to be able to convene their own groups of experts. Others wanted FDA to rely on such organizations as the American Heart Association or the American Dietetic Association, which evaluate scientific information and provide advice to their constituents on diet and health. In its report, the Task Force asked FDA to consider the recommendations of such groups as evidence of the strength of the science underlying a health claim. However, to make such a system work fairly to the benefit of all, including consumers, FDA would need to have confidence in the scientific validity of the group's conclusions about the particular claim in question. Some groups would have more expertise than others, and FDA is not aware of a mechanism for evaluating them fairly and accurately. FDA is

requesting comment on whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim. If the agency should give weight to the evaluations of these groups, how should this weight be determined?

FDA's Food Advisory Committee (FAC) is a body of experts chartered to advise the agency on scientific issues upon request; however, FDA does not believe that the FAC is an appropriate body to conduct the initial evaluation of the data supporting a proposed health claim. Because of the limited number of meetings in the FAC's charter and other issues that may be brought before the FAC, FDA does not believe that the FAC could conduct a timely evaluation of such data. On an interim basis, FDA has chosen to use experts identified by another Federal agency (i.e., Agency for Healthcare Research and Quality (AHRQ)) whose mission includes retaining large numbers of such experts under contract. Both FDA and AHRQ are agencies within the Department of Health and Human Services. This process should provide the scientific expertise and additional resources that FDA needs to conduct its scientific reviews within acceptable timeframes.

7. Competent and Reliable Scientific Evidence

FDA's July 2003 interim evidence-based ranking guidance (Ref. 2) describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a health claim petition. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease relationship can be assigned to one of four ranked levels.

The interim evidence-based ranking system presupposes that FTC's requirement of "competent and reliable scientific evidence" to substantiate a

claim related to health or safety has been met. For purposes of FDA's evaluation of qualified health claims based upon credible evidence under *Pearson*, the Task Force recommended that FDA consider scientific evidence only if it is competent and reliable. FTC defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence" based upon the expertise of professionals in the relevant area, that has been "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted" in the profession to "yield accurate and reliable results." *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988).

FDA is requesting comments on the meaning and/or relevance of "competent and reliable scientific evidence" for the purposes of supporting a qualified health claim. FDA seeks these comments within the specific context of qualified health claims only. Any agency interpretation of "credible evidence" in the context of qualified health claims would not apply to the meaning of that term in other regulatory contexts within FDA's purview.

C. Issues for Future Consideration

Although the regulatory alternatives discussed previously focus primarily on assessing scientific data as a basis for qualified health claims, the Task Force recognized that there may be merit in developing greater flexibility in other areas of health claim regulation. The Task Force believed that more flexibility in regulating the use of health claims would further advance the use of reliable diet and health information to consumers via food labels. With respect to increased flexibility, the Task Force recommended that FDA solicit comments on two issues, in particular: (1) Disqualifying nutrient levels, and

(2) minimum nutrient content requirements (referred to in the Task Force report as "minimal nutrient limits").

Disqualifying nutrient levels—Under existing regulations in § 101.14(a)(4), a health claim generally is not allowed on a food label or in food labeling when the food contains more than a specified level of total fat, saturated fat, cholesterol, or sodium.[12] However, when there is a public health benefit, FDA has made exceptions to these disqualifying nutrient levels. For example, FDA authorized a health claim in § 101.83 for plant sterol/stanol esters and reduced risk of CHD in labeling for dressings for salad and spreads even though these products exceed the disqualifying level for total fat because they contain more than 13 grams of fat per reference amount customarily consumed (RACC) (see § 101.83(c)(1)).

Minimum nutrient content requirement—Under § 101.14(e)(6) of FDA's general health claim regulations, a food may not bear a health claim unless the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per RACC prior to any nutrient addition. FDA has provided for some flexibility in this requirement in that nutrients that traditionally have been added through fortification in accordance with FDA's fortification policy may be considered to meet the 10-percent requirement (see, e.g., 58 FR 44036 at 44037; August 18, 1993). In addition, FDA has excepted some unqualified health claims from this general requirement (see, e.g., § 101.83(c)(1) (health claim about plant sterol/stanol esters and reduced risk of CHD on dressings for salad)). Here

[12] The disqualifying nutrient levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed (RACC), per label serving size, and, only for foods with an RACC of 30 g or less or 2 tablespoons or less, per 50 g (§101.14(a)(4)).

again, additional flexibility may be appropriate for considering health claims for foods that may not meet the minimum nutrient content requirement.

As the Task Force report noted, FDA received a petition from the National Food Processors Association (NFPA) on these two issues, among others. In response to the NFPA petition and a separate petition from the American Bakers Association, in the **Federal Register** of December 21, 1995 (60 FR 66206 (the 1995 proposed rule)), FDA proposed to amend its regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products. The 1995 proposed rule proposed refinements to the agency's current regulations to allow additional synonyms for nutrient content claims without specific preclearance by the agency, to permit health claims on certain foods that do not currently qualify because they do not meet the minimum nutrient content requirement, to permit the use of shortened versions of authorized health claims under certain circumstances, to eliminate some of the required elements for health claims, and to specify the criteria that FDA will consider in evaluating petitions seeking exemption from the disqualifying nutrient levels.

FDA is identifying these two issues (i.e., disqualifying nutrient levels and minimum nutrient content requirement) in this ANPRM to acknowledge the Task Force report's recommendation that FDA solicit comment on them. However, because these issues were raised in the 1995 proposed rule, FDA intends, in the near future, to re-open the comment period on the 1995 proposed rule to solicit additional comments on these issues. Thus, to avoid duplication and confusion, FDA is not requesting comments on disqualifying nutrient levels and minimum nutrient content requirements for health claims in this ANPRM.

III. Dietary Guidance

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to consumers about healthy eating patterns and wise food choices. Such advice originated with the "Basic Four" and has progressed through today's "Dietary Guidelines for Americans" (developed jointly by U.S. Department of Health and Human Services and U.S. Department of Agriculture (USDA)) and USDA's "Food Guide Pyramid." The agency believes that encouraging the use of dietary guidance statements on food labels is an important component of the Consumer Health Information for Better Nutrition Initiative.

The Task Force recommended that FDA not only seek opportunities to exercise flexibility in its evaluation of health claims in the areas discussed previously, but also to seek opportunities to promote the development and use of more dietary guidance statements on foods. The purpose of such dietary guidance statements is to assist and encourage individuals in making better food choices and establishing healthier eating patterns. If FDA's mission is properly understood to include a role in assisting the public in making wise dietary choices that benefit long-term health, a number of possible strategies become evident. Those strategies include, for example, challenging industry to channel competitive energies into disseminating health information in food labeling and promoting food products on the basis of nutritional value, as well as taste, price, amount, and convenience. Importantly, as mentioned previously, there is also the possibility to pursue a range of consumer information options in collaboration with other Federal agencies, health researchers, and stakeholders as more information about diet/health relationships becomes available.

A. Regulatory Distinctions Between Dietary Guidance and Health Claims

As previously stated, section 403(r) of the act contains statutory provisions for the regulation of health claims, among other types of label statements. Under §§ 101.14 and 101.70, a "health claim" has a specific definition and is regulated differently from other types of statements on labels of conventional foods and dietary supplements. Health claims are specifically about the relationship between a substance and a disease; they are required to be reviewed and authorized by FDA prior to use. Health claims are limited to claims about disease risk reduction, and cannot be claims about the cure, mitigation, or treatment of disease. The latter claims are currently regarded as constituting drug claims under section 201(g) of the act (21 U.S.C. 321(g)) (see *Whitaker* v. *Thompson*, 239 F.Supp. 2d 43, 52–53 (D.D.C. 2003)). The following is an example of a health claim about the relationship between calcium (a substance) and osteoporosis (a disease): "Calcium may reduce the risk of osteoporosis." In comparison, the following is an example of a drug claim: "Consumption of 320 mg daily of Saw Palmetto extract may cure cancer."

Unlike health claims, which target a specific substance and a specific disease or health-related condition, dietary guidance statements focus instead on general dietary patterns, practices, and recommendations that promote health. In addition, such statements can be made on conventional food and dietary supplement labels without FDA review or authorization before use. Like all statements in food labeling, dietary guidance statements must be truthful and nonmisleading as required under sections 201(n) and 403(a)(1) of the act. An example of a dietary guidance statement is: "Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic

diseases." As part of a cooperative effort with the National Cancer Institute (NCI), FDA recently encouraged the produce industry and food manufacturers to use this statement in the labeling of fruits, vegetables, and foods that meet the criteria for NCI's 5 A Day for Better Health Program (Ref. 5).

FDA addressed the issue of dietary guidance during the development of health claim regulations (58 FR 2478, January 6, 1993 (for conventional foods); 59 FR 395; (for dietary supplements)). In the preambles to the final rules, the agency stated that a health claim contains two basic elements: A substance and a disease or health-related condition. To clarify the difference between dietary guidance statements and health claims, FDA stated that it would use the term "dietary guidance" to refer to statements that do not contain both basic elements of a health claim[13] (58 FR 2478 at 2487 and 59 FR 395 at 418). Thus, dietary guidance statements may make reference to a disease or substance, but not both. For example, dietary guidance statements might focus on general dietary patterns or practices and broad categories of foods, rather than a specific substance. Alternatively, they may link a specific substance to a nondisease endpoint such as building bones, a healthy lifestyle, or promoting health. In this case, the substance element is present in the statement but not the disease element.

A health claim expressly or by implication characterizes the relationship of certain substances to a disease or health-related condition (21 U.S.C. 343(r)(1)(B)). Hence, the elements (i.e., the substance element, and the disease or health-related condition element) of a health claim may be either express or implied.

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[13] In this ANPRM, FDA is using the term "statement(s)" in place of the term "claim(s)" to emphasize the distinction between a health claim and dietary guidance when the discussion relates specifically to dietary guidance.

The term "substance" means a specific food or component of food, regardless of whether the food is in conventional food or dietary supplement form (§ 101.14(a)(2)). In discussing the definition of "substance" in the preamble to the final rule on general requirements for health claims for conventional foods (58 FR 2478 at 2479–2480), FDA noted that it agreed with comments that its proposed definition for substance interpreted the NLEA too narrowly with respect to the regulation of health claims about foods, and that Congress intended that foods (in addition to food components) could be the subject of health claims regulated under section 403(r) of the act. (As proposed, § 101.14(a)(2) stated: "Substance means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances" (56 FR 60537 at 60563, November 27, 1991)). However, based upon the legislative history of the NLEA,[14] the agency noted that to be a health claim, a claim about a food must be, at least by implication, a claim about a substance in the food (58 FR 2478 at 2480). FDA further explained that when a consumer could reasonably interpret a claim about the relationship of a food to a disease or health-related condition to be an implied claim about a substance in that food, that claim would satisfy the first element of a health claim (i.e., the substance element). Id.

In addition, FDA concluded that a claim about the benefits of a broad class of foods (e.g., fruits or vegetables) that does not make an express or implied connection to a substance found in that class of foods would not constitute an implied claim, and that such a claim is not a health claim. Rather, such a statement would be dietary guidance because it is not expressly or impliedly about a substance. If a substance in a broad class of foods cannot be expressly

[14] See H.R. Rep. No. 101–538, at 20 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3350.

identified, it may be possible to find that it is implied. For example, in the preamble to the final rule concerning a specific health claim about an association between antioxidant vitamins and cancer (58 FR 2622, January 6, 1993), FDA introduced the concept of a marker for the substance element of an implied health claim. In that final rule, FDA decided not to authorize a health claim about a relationship between antioxidant vitamins and cancer, and instead authorized a health claim relating substances in diets low in fat and high in fruits and vegetables to a reduced risk of cancer. In short, the agency authorized a health claim in which the subject was fruits and vegetables that were low in fat and were good sources of certain substances (e.g., fiber, vitamin A, or vitamin C). It was not clear whether the marker substances were actually the active substances or merely served as markers for other unidentified substances. The purpose of identifying the marker substances was to distinguish certain fruits and vegetables that were characterized by compositions known to help reduce cancer risk from other fruits and vegetables that might not provide the same benefit.

B. Issues Relating to Dietary Guidance

FDA recognizes the importance of dietary guidance in assisting and encouraging the U.S. population to make better food choices and establish healthier eating patterns. Although these types of statements are not health claims, consistent and scientifically sound dietary guidance statements can be useful to consumers when they are truthful and nonmisleading. As previously mentioned, FDA has no regulatory authority to review or authorize dietary guidance statements before use. When used in labeling for foods, however, such statements must be truthful and not misleading under sections 201(n) and 403(a)(1) of the act. The agency generally has viewed most dietary guidance

for the general U.S. population as originating from Federal agencies with public health missions related to diet and disease. For example, major Federal documents such as the Dietary Guidelines for Americans issued by USDA and U.S. Department of Health and Human Services exemplify government consensus about dietary recommendations. Given the important role that information on food labels can play in affecting consumers' health and dietary decisions, FDA sees a need to foster enhanced federal cooperative efforts to identify and agree upon dietary guidance that is appropriate for food labels and how such guidance may be used.

1. Definitions

Dietary guidance—FDA requests comments on an appropriate definition of "dietary guidance" for labeling purposes, as well as the current approach, outlined previously, to distinguish between health claims and dietary guidance statements.

Substance—Since the distinction between dietary guidance statements and health claims often focuses on whether the "substance" element is present in the claim (whether express or implied), FDA requests comments on ways in which the definition of "substance" in § 101.14(a)(2) can or should be clarified. Additionally, in regard to the appropriate definition of "substance" for purposes of a health claim, FDA is interested in comments on whether a specific authorized health claim about whole grain foods (described later) properly refers to a substance as compared to a broad category of food. This health claim is authorized based on a statement from an authoritative body under section 403(r)(3)(C) of the act.[15]

[15] Under the provisions of the FDAMA, a manufacturer may submit to FDA a notification of a health claim based on an authoritative statement published by an appropriate authoritative body (i.e., a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition

On March 10, 1999, General Mills, Inc., submitted to the agency a notification containing a prospective claim about the relationship of whole grain foods and heart disease and certain cancers. The notification cited the following statement from the Executive Summary of the National Academy of Sciences report, "Diet and Health: Implications for Reducing Chronic Disease Risk" (page 8), as an authoritative statement: "Diets high in plant foods--i.e., fruits, vegetables, legumes, and whole-grain cereals--are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach." For purposes of eligibility to bear the prospective claim, the notification defined "whole grain foods" as foods that contain 51 percent or more whole grain ingredient(s) by weight per RACC. It suggested that compliance with this definition could be assessed by measuring the dietary fiber level of whole wheat, the predominant grain in the U.S. diet. The level of fiber was intended for compliance purposes only and was not defined as the substance that was the subject of the health claim or as a marker for that substance.

FDA's decision not to prohibit or modify the claim means that, as of July 8, 1999, manufacturers may use the following claim on the label and in labeling of any product that meets the eligibility criteria described in the notification: "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers." FDA seeks comments on whether this claim properly refers to a substance as compared to a broad category of food. The notification and additional materials regarding the claim are publicly available

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(such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions) (21 U.S.C. 343(r)(3)(C)). If FDA does not act to prohibit or modify such a claim within 120 days of receipt of the notification, the claim may be used.

from the Division of Dockets Management (Docket No. 99P–2209) (see **ADDRESSES**).

2. The Substance as the Subject of a Health Claim

FDA's experience demonstrates that most substances that are the subject of an authorized health claim are substances that can be found in a number of foods (e.g., calcium) or spread throughout the food supply (e.g., saturated fat). FDA has provided for health claims that include reference to the common substance to assist consumers in their understanding of the nature of the diet/health relationship, and more importantly so that consumers recognize that they can construct healthy diets by using a variety of foods and nutrient sources rather than just one. For instance, in the example of the calcium/osteoporosis claim, FDA requires that the substance that is the basis of the claim (i.e., calcium) be included in the wording of the claim (21 CFR 101.72). FDA requests comments on the usefulness of statements that expressly include the substance that is the basis for the claim (e.g., "Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis") versus "food-specific" claims such as: "Yogurt may reduce the risk of osteoporosis."

3. The Use of Food Category "Substitutions" or "Replacements" as a Form of Dietary Guidance

FDA views food substitution/replacement recommendations as potentially helpful to consumers, but also potentially problematic because they might be misleading or confusing to consumers. For example, the message to substitute mono- and polyunsaturated fats for saturated fats to promote heart health is intended to help consumers reduce their intake of saturated fat and cholesterol within the dietary context of moderate fat intakes. A message to choose fish, shellfish, lean poultry and other lean meats, beans, or nuts daily while limiting

intakes of high-fat processed meats has a similar intention. However, the likelihood that these messages will positively affect the ability of consumers to choose healthful diets depends on an understanding of the total dietary context of the message, which may prove confusing or difficult to effectively communicate to consumers. FDA is requesting comments on whether dietary guidance statements should include recommendations for making food or substance "substitutions" or "replacements." If these types of dietary guidance statements are encouraged, how can FDA ensure that they are made in clear and nonmisleading ways that will enhance and benefit public health?

FDA notes that the agency has used certain criteria such as disqualifying or disclosure levels and minimum "qualifying" criteria to ensure that foods that bear a health claim fit within the context of a healthy diet and contain adequate amounts of the substance of interest. Given the absence of these types of criteria for dietary guidance statements, how can FDA ensure that recommendations for making food or substance "substitutions" or "replacements" are not misleading? FDA requests comments on how such statements can be provided for in a way that is based on sound science and is helpful and nonmisleading to consumers. Moreover, FDA requests comments on whether and how recommendations to make dietary substitutions or replacements can, or should, be differentiated from claims about the effects of biologically active substances for the purposes of food labeling and appropriate consumer communication.

4. Dietary Guidance on Food Labels

FDA is seeking comment on dietary guidance statements on food labels generally and on approaches appropriate for FDA to consider under its statutory authorities. As part of this consideration, FDA is requesting

comments on whether providing a list of dietary guidance statements that FDA recommends for inclusion on food labels would be desirable or useful to manufacturers. In addition, FDA is requesting comments on these topics: (1) Whether and how the agency should partner with other Federal agencies to identify and agree upon recommended dietary guidance statements for food labeling, (2) the appropriate criteria for evaluating the scientific validity of dietary guidance statements that appear on products in the marketplace, and (3) whether and how the agency should address dietary guidance statements from non-federal sources (e.g., States, trade associations, professional associations, etc.).

IV. Future Analysis of Benefits and Costs

For the agency's future analysis of benefits and costs of the regulatory options for qualified health claims, FDA requests comments, including available data, on the following questions:

• 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 SSA?

• What effects would the different qualifying phrases described in the interim procedures for qualified health claims guidance[16] (Ref. 3) and the Task Force report (Ref. 4) have on the willingness of consumers to buy the products

[16] The guidance identifies three different qualifying phrases (or standardized qualifying language) for qualified health claims. These phrases are used according to a scientific ranking assigned to the claim (which is discussed in the interim evidence-based ranking system guidance (Ref. 2)). FDA has categorized these phrases as B, C, and D, as follows: *Category B*: "Although there is scientific evidence supporting the claim, the evidence is not conclusive."; *Category C*: "Some scientific evidence suggests * * * however, FDA has determined that this evidence is limited and not conclusive."; *Category D*: "Very limited and preliminary scientific research suggests * * * FDA concludes that there is little scientific evidence supporting this claim." The Task Force report lists the same three qualifying phrases in its overview of the interim procedures for qualified health claims guidance.

containing the claims? Is there evidence that consumers would find the differences 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 re-formulation?

• What new products might be developed in response to qualified health claims?

• Would any of the regulatory options discussed in this 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?

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal Government holidays. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. Task Force Final Report, "Consumer Health Information for Better Nutrition Initiative" (July 10, 2003) (Internet addresses: *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

2. "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" (Internet addresses: *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

3. "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (Internet addresses: *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

4. Task Force Final Report, Attachment A: "Possible Regulatory Frameworks for Qualified Health Claims" (Internet addresses: *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

5. CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements, "Dietary Guidance Message About Fruits and Vegetables" (July 29, 2003; revised August 28, 2003) (Internet address: *http://www.cfsan.fda.gov/~dms/lab-dg.html*).

VI. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are

to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/7/03

November 7, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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