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Food and Drug Administration

21 CFR Part 101

[Docket Nos. 1994P–0390 and 1995P–0241]

Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the agency) is reopening for 60 days the comment period for the proposed rule entitled "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims" (the 1995 proposal). In that document, FDA proposed to amend its existing nutrient content claims and health claims regulations to provide additional flexibility in the use of these claims on food products. Since the publication of the 1995 proposal, FDA established a task force for the Consumer Health Information for Better Nutrition Initiative, which recommended that FDA seek public comment on several topics related to qualified health claims and unqualified health claims (i.e., health claims that are supported by significant scientific agreement (SSA) and authorized by FDA by regulation). Some of these topics on unqualified health claims were specifically addressed in the 1995 proposal and, therefore, FDA is reopening the comment period on the 1995 proposal to seek comment on the proposed amendments to permit

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unqualified health claims on certain foods that do not contain 10 percent or more of one of certain required nutrients, the proposed amendments to provide criteria that FDA would consider in determining whether to grant an exemption from disqualifying nutrient levels related to unqualified health claims of certain nutrients, and the proposed amendments to retain the word "may" or "might" in unqualified health claims. In addition, FDA is seeking comment on the proposed use of unlisted synonyms and abbreviated health claims. Specifically, for unlisted synonyms (i.e., terms not defined by regulation), FDA repeats its request for data or other information demonstrating that unlisted synonyms that are anchored to defined terms in nutrient content claims are reasonably understood by consumers to be synonyms of the defined terms. For abbreviated health claims, FDA seeks comments and requests data or other information regarding whether abbreviated health claims would mislead consumers.

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

ADDRESSES: You may submit comments, identified by Docket Nos. 1994P–0390 and 1995P–0241, by any of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

E-mail: *fdadockets@oc.fda.gov*. Include Docket Nos. 1994P–0390 and 1995P–0241 in the subject line of your e-mail message.

FAX: 301–827–6870.

Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions):

Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period

In the **Federal Register** of December 21, 1995 (60 FR 66206), 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. In the 1995 proposal, FDA proposed the following: (1) To allow additional synonyms for nutrient content claims without specific preclearance by the agency (i.e., unlisted synonyms), (2) to permit health claims on certain foods that do not currently qualify to bear a claim because they do not contain 10 percent of one or more of certain required nutrients, (3) to permit the use of

shortened versions of authorized health claims (i.e., abbreviated health claims) under certain circumstances, (4) to eliminate and/or make optional some of the specific health claim elements required by regulation, and (5) to provide criteria that FDA would consider in determining whether to grant an exemption from disqualifying nutrient levels to permit some foods to bear an unqualified health claim even though they contain high levels of one or more of certain nutrients. FDA proposed these amendments in response to petitions submitted by the National Food Processors Association (NFPA) (docket number 1994P–0390) and the American Bakers Association (ABA) (docket number 1995P–0241).

FDA requested comments on the 1995 proposal by March 20, 1996. On March 22, 1996 (61 FR 11793), FDA extended the comment period for 120 days, until July 18, 1996. On January 24, 1997 (62 FR 3635), FDA reopened the comment period for the 1995 proposal until March 10, 1997, to provide interested persons an opportunity to obtain and comment on an FDA study, entitled "Consumer Impacts of Health Claims: An Experimental Study" that is relevant to issues in the 1995 proposal. The agency also sought comment on two consumer research studies submitted by The Quaker Oats Co. pertaining to the use of abbreviated health claim statements (62 FR 3635 at 3636). Finally, on March 11, 1997 (62 FR 11129), FDA extended the comment period for the 1995 proposal until April 24, 1997, in response to requests to allow interested persons more time to review the studies and submit comments. Due to competing priorities, including evolving food safety issues, the agency has not yet published a final rule on the 1995 proposal.

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 to help American consumers improve their health and decrease their risk of contracting diseases by making sound dietary decisions. Under this initiative, the agency established a task force on Consumer Health Information for Better Nutrition (the task force). The task force was charged with the following: (1) Reporting on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should apply the "weight of the evidence" standard established under the initiative for qualified health claims in order to achieve these goals; (2) developing a framework of regulations that will give these principles the force and the effect of law; (3) identifying procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of qualified health claim petitions; and (4) developing a consumer studies research agenda designed to identify the most effective ways to best present scientifically based, truthful and nonmisleading information to consumers and to identify the kinds of information known to be misleading to consumers.

On July 11, 2003, FDA published a notice in the **Federal Register** (68 FR 41387) announcing the availability of the "Consumer Health Information for Better Nutrition Initiative—Task Force Final Report" (the task force report), which includes nine attachments. Attachment A ("Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements") of the task force report describes options or alternatives for regulating qualified health claims (i.e., claims that do not meet the SSA standard of evidence required by section

403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)) and § 101.14(c) (21 CFR 101.14(c)) to evaluate the scientific validity of health claims). The task force recommended that FDA solicit comment on these regulatory alternatives as well as several additional topics, including topics related to unqualified claims (i.e., claims that meet the SSA standard of evidence and are authorized by FDA by regulation). Accordingly, in an advance notice of proposed rulemaking published in the **Federal Register** of November 25, 2003 (68 FR 66040) (the qualified health claim ANPRM), FDA requested public comment on the regulatory alternatives and all except two of the additional topics identified in attachment A of the task force report. These two topics are as follows: (1) The minimum nutrient contribution requirement[1] and (2) disqualifying nutrient levels. The task force recommended that FDA seek comments on these two topics, in particular, in the interest of increasing flexibility in regulating the use of health claims. The task force believed that such flexibility would further advance the use of reliable diet and health information to consumers via food labels.

Although FDA identified the minimum nutrient contribution requirement and disqualifying nutrient levels in the qualified health claim ANPRM, FDA stated that because these two topics were raised in the 1995 proposal, the agency intends to seek comments on them by reopening the comment period for the 1995 proposal (68 FR 66040 at 66045). Thus, FDA did not request comments on the minimum nutrient contribution requirement and disqualifying nutrient levels for health claims in the qualified health claim

[1] Although the task force report and qualified health claim ANPRM refer to "minimum nutrient *content* requirements," in order to be consistent with the 1995 proposal, we refer to the requirement in this document as the "minimum nutrient *contribution* requirement." The terms refer to the same requirement in § 101.14(e)(6) and may be used interchangeably.

ANPRM, but is doing so today by reopening the comment period for the 1995 proposal.

In addition, one of the topics on which FDA requested comments in the qualified health claim ANPRM, and on which the agency is also reopening the comment period for the 1995 proposal, is the use of the word "may" in unqualified health claims to describe the relationship between a substance and a disease or health-related condition. Information on FDA's Consumer Health Information for Better Nutrition Initiative and a copy of the task force report can be found at *http://www.fda.gov/oc/mcclellan/chbn.html.*

Finally, FDA is also seeking comment on the proposed use of unlisted synonyms and abbreviated health claims. For unlisted synonyms (i.e., terms not defined by regulation), FDA repeats its request for data or other information demonstrating that unlisted synonyms that are anchored to defined terms in nutrient content claims are reasonably understood by consumers to be synonyms of the defined terms. FDA also seeks comments on the current petition process in § 101.69(n) (21 CFR 101.69(n)) for synonyms and examples of synonyms that industry may be seeking to use. For abbreviated health claims, FDA seeks comments and requests data or other information regarding whether abbreviated health claims would mislead consumers.

II. Request for Comments

Because of the length of time that has elapsed since publication of the 1995 proposal, and the recent availability of the task force report, FDA is interested in updating the administrative record for the 1995 proposal by seeking comments on certain topics before issuing a final rule. Comments previously submitted to the Division of Dockets Management (formerly the Dockets Management Branch) do not need to be resubmitted because all

comments submitted to the previously listed docket numbers will be considered in any final rule to the 1995 proposal. As noted in section I of this document, FDA is seeking comments on three topics within the scope of the 1995 proposal and identified in the task force report and qualified health claim ANPRM: (1) The minimum nutrient contribution requirement, (2) disqualifying nutrient levels, and (3) use of the word "may" in unqualified health claims to describe the relationship between a substance and a disease or health-related condition. Further, FDA is also seeking comment on the proposed use of unlisted synonyms (i.e., terms not defined by regulation) and abbreviated health claims.

A. Section 101.14(e)(6): The Minimum Nutrient Contribution Requirement

As explained in the 1995 proposal, FDA published a final rule entitled "Food Labeling: General Requirements for Health Claims for Food" (the 1993 health claims final rule) in the **Federal Register** of January 6, 1993 (58 FR 2478). Among other things, this final rule requires that, to be eligible to bear a health claim, a food other than a dietary supplement contain 10 percent or more of the daily value (DV) for vitamin A, vitamin C, iron, calcium, protein, or fiber, per reference amount customarily consumed (RACC) before any nutrient addition (§ 101.14(e)(6)). Following publication of the 1993 health claims final rule, NFPA and ABA submitted petitions to FDA requesting, among other things, that the agency reconsider its decision regarding the 10 percent nutrient contribution requirement.

In the preamble of the 1995 proposal, FDA recognized that the 10 percent nutrient contribution requirement may have had the unintended effect of prohibiting health claims on certain foods that could be beneficial to consumers and help them maintain a balanced and healthful diet (60 FR 66206

at 66212). The agency was concerned, however, that eliminating the requirement will permit misleading health claims on foods with little or no nutritional value, such as candies or soft drinks, or will encourage overfortification of the food supply (e.g., vitamins or minerals added to soft drinks) (id.). FDA stated that the appearance of health claims on such foods would be inconsistent with Congress' intent when it enacted the health claims provisions in the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535) (id.). Accordingly, the agency reiterated its position that a minimum nutrient contribution requirement was a necessary component of the health claims provisions to ensure that such claims appear on foods that make a nutritional contribution to the diet and are consistent with dietary guidelines (id.). FDA further explained that if the agency were to consider revoking the 10 percent nutrient contribution requirement, it would have to establish an alternative mechanism to ensure that health claims are not made on foods with little or no nutritional value (60 FR 66206 at 66212 through 66213). The NFPA petition did not suggest any alternatives to the requirement to preclude misleading health claims on such foods. In addition, the agency tentatively concluded that the alternatives suggested in the ABA petition would not ensure that health claims were made only on foods that are consistent with dietary guidelines (60 FR 66206 at 66213).

In response to the petitioners' request, FDA proposed to maintain the 10 percent nutrient contribution requirement, but amend § 101.14(e)(6) to exempt certain fruit, vegetable, and grain products from the requirement. These products included fruit and vegetable products comprised solely of fruits and vegetables, enriched grain products that conform to a standard of identity, and bread that conforms to the standard of identity for enriched bread except that

it contains whole wheat or other grain products not permitted under that standard (60 FR 66206 at 66214). FDA specifically requested comment on whether the proposed exemption should be extended to include the following items: (1) Fruit and vegetable products with added oils, sodium, sauces, syrups, or other ingredients; and (2) other foods, for example, other types of grain products such as breakfast cereals (id.).

In light of the task force report's recommendation, FDA is requesting comments on the proposed amendments to § 101.14(e)(6) in the 1995 proposal and on whether and how FDA could provide additional flexibility with respect to the 10 percent nutrient contribution requirement for foods bearing a health claim.

In addition, FDA requests comments on a specific alternative approach to the 10 percent nutrient contribution requirement that was suggested by two comments submitted on the 1995 proposal. In response to the 1995 proposal, FDA received several comments on the need for the 10 percent nutrient contribution requirement, the proposed exemptions to this requirement, and alternative approaches. With respect to alternative approaches, two of the comments proposed a nutrient density approach as an alternative to the 10 percent nutrient contribution requirement. Under this approach, if the percent of the reference daily intake (RDI) or daily reference value (DRV) of vitamin A, vitamin C, calcium, iron, protein, or fiber per RACC is the same as, or more than, the percent caloric contribution of the food per RACC (calculated on the basis of a 2,000 calorie diet), then the food would be eligible to bear a health claim. FDA is specifically seeking comments on the use of a nutrient density approach as an alternative to the current 10 percent nutrient contribution requirement. Any comments related to this alternative approach should

include a rationale explaining why it is appropriate or inappropriate, and include data or other information explaining how this approach will or will not ensure that foods with little or no nutritional value do not bear health claims.

B. Disclosure Versus Disqualifying Nutrient Levels for Health Claims

Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that

> * * * does not contain, as determined by the Secretary [of Health and Human Services] by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure [statement] * * *.

This section helps to ensure that consumers who rely on health claims will be consuming foods that assist them in structuring a healthful diet that meets dietary guidelines (60 FR 66206 at 66221).

In § 101.14, FDA established disqualifying nutrient levels for foods, with additional allowances for main dish products and meal products. A food that exceeds its established disqualifying level for any of the four disqualifying nutrients (i.e., fat, saturated fat, cholesterol, and sodium) may not bear a health claim. The general requirements for health claims allow exceptions to the disqualifying nutrient level requirement (§ 101.14(a)(4) and (e)(3)). Specifically, consistent with section 403(r)(3)(A)(ii) of the act, § 101.14(e)(3) provides that FDA may permit a health claim despite the fact that a disqualifying level of one of the four listed nutrients is present in the food, if FDA finds that such

a claim will assist consumers in maintaining healthy dietary practices. If FDA makes such a determination, the health claim must be made in accordance with the regulation that makes such a finding and the label must bear a disclosure statement that complies with § 101.13(h) (21 CFR 101.13(h)) highlighting the nutrient that exceeds the disqualifying level. This disclosure statement identifies the disqualifying nutrient and refers the consumer to more information about the nutrient as follows: "See nutrition information for _____content."

The NFPA petition requested that the disqualification levels in § 101.14(a)(4) be converted to disclosure levels under certain circumstances. The petition suggested that "the presence of one of these nutrients at the prescribed level would require disqualification only if the nutrient was found in another health claim regulation to be directly or adversely related to the disease mentioned in the claim." The petition also stated that "[i]f the nutrient is not so directly related to the disease to which the claim refers, the regulations would require only disclosure by an appropriate referral statement in conjunction with the health claim on the label, as the regulations now require for nutrient content claims."

In the 1995 proposal, FDA explained that a generic change in its regulations would not be consistent with the underlying goals of the NLEA (60 FR 66206 at 66222). The disqualifying nutrient levels assist consumers in constructing total daily diets that meet dietary guidelines (id.). Nevertheless, the agency tentatively found that there may be some instances where disclosure rather than disqualification is appropriate (id.). FDA proposed to continue to decide on a case-by-case basis through the petition process whether to convert disqualifying levels for health claims to disclosure levels in

regulations authorizing specific health claims. However, FDA also proposed criteria that it would use to evaluate petitions requesting an exception to the prohibition in § 101.14(e)(3) against health claims for foods exceeding the disqualifying nutrient levels in § 101.14(a)(4) (id.).

Consistent with the task force report's recommendation, FDA is requesting comment on the proposed amendments to 21 CFR 101.70(f) in the 1995 proposal and on whether and how FDA could provide additional flexibility with respect to exceptions to the disqualifying nutrient levels requirement. FDA continues to believe that the current disqualifying nutrient levels assist consumers in constructing total daily diets that meet dietary guidelines (60 FR 66206 at 66222). FDA seeks comments, including scientific and consumer research that address, among other things, the effectiveness of disclosure through appropriate referral statements in lieu of the current disqualifying levels in assisting consumers to construct healthful diets. FDA is interested in research data or other information that is relevant to this issue that has become available since the publication of the 1995 proposal, as well as any ongoing research in this area.

FDA has also asked for comment on the use of disclosure and disqualifying criteria in the context of cholesterol-raising lipids in the ANPRM published in the **Federal Register** of July 11, 2003 (68 FR 41507), entitled "*Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements" (the *trans* fat ANPRM). In the *trans* fat ANPRM, FDA solicited comment on scientific information and data, including consumer research data, that would support the usefulness and need for a disclosure statement, in conjunction with nutrient content or health claims, concerning the levels of saturated fat, *trans*

fat, or cholesterol in a food or in the diet (68 FR 41507 at 41509). The agency intends to consider comments received in response to the *trans* fat ANPRM that are relevant to the use of disclosure statements in lieu of disqualifying levels in any final rule on the 1995 proposal.

C. Use of "May" in Health Claims

In the 1995 proposal, the agency explained that a common requirement in authorized health claims is a statement that development of the particular disease that is the subject of the claim depends on many factors (60 FR 66206 at 66219). FDA then tentatively concluded that this statement reminding consumers about the multifactorial nature of the disease was not necessary and could be made optional (id.). The agency based its decision upon the following considerations: (1) Information showing that consumers are generally aware that the development of major chronic diseases is dependent upon a number of different factors and (2) consideration of the requirement that authorized health claims use the term "may" or "might" (e.g., "calcium may reduce the risk of osteoporosis"). As explained in the 1995 proposal,

> * * * the requirement that authorized health claims use "may" or "might" to relate the ability of the substance that is the subject of the claim to reduce the risk of the corresponding disease or health-related condition is an indication to consumers of the multifactorial nature of the disease or health-related condition. * * *

(id.). Therefore, in the 1995 proposal, FDA made optional the statement in unqualified health claims that development of a particular disease depends on many factors, but retained the word "may" or "might" to describe the ability of a substance to reduce the risk of a disease or health-related condition and to reflect the multifactorial nature of the disease or health-related condition.

In the qualified health claim ANPRM, FDA again explained that it considered the use of the word "may" to reflect that diseases are almost always multifactorial, and that diet is only one factor that influences a person's risk for disease (68 FR 66040 at 66043). However, the agency acknowledged that, although the word "may" is intended to alert consumers that there is no certainty that any one dietary practice will, in fact, reduce an individual's risk of disease, the word "may" could instead be interpreted as a reflection of the science supporting the claim (id.). Accordingly, in the qualified health claim ANPRM, FDA requested comment on whether the agency should remove the requirement for the word "may" from unqualified health claims to eliminate the uncertainty about the science underlying claims that meet SSA (id.). The agency questioned 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 (id.).

Any comments received in response to this topic in the qualified health claim ANPRM will also be considered as comments to the 1995 proposal. If the agency determines that the word "may" or "might" should be removed from unqualified health claims to eliminate the uncertainty about the science underlying a claim that meets SSA, would a separate statement be necessary (and not be made optional as proposed in the 1995 proposal) to convey to consumers the multifactorial nature of the disease in a health claim? Would consumers be misled by a health claim stating that a substance "will" reduce the risk of a disease or health-related condition? Would consumers think that the product bearing such a health claim will benefit them without understanding that other nondietary factors may contribute equally, if not greater, to the disease risk?

In the 1995 proposal, the agency stated that it reviewed the "required elements" in each of the eight unqualified health claims that were authorized at the time of publication of the 1995 proposal to determine whether any of the required elements are unnecessary or could be made optional (60 FR 66206 at 66216). Since the publication of the 1995 proposal, the agency has authorized four additional unqualified health claims: (1) Dietary noncariogenic carbohydrate sweeteners and dental caries (§ 101.80 (21 CFR 101.80)), (2) soluble fiber from certain foods and risk of coronary heart disease (§ 101.81 (21 CFR 101.81)), (3) soy protein and risk of coronary heart disease (§ 101.82 (21 CFR 101.82)), and (4) plant sterol/stanol esters and risk of coronary heart disease (§ 101.83 (21 CFR 101.83)). Notably, none of these more recent health claims requires a statement, commonly required in the other health claims, that development of a disease or health-related condition depends on many factors. Instead, the following health claims include a requirement identical to the one proposed in the 1995 proposal that the claim does not imply that consumption of the particular substance is the only recognized means of achieving a reduced risk of the disease (see §§ 101.80(c)(2)(i)(F), 101.81(c)(2)(i)(F), 101.82(c)(2)(i)(F), and 101.83(c)(2)(i)(F)), and that the claim includes the use of "may" or "might" to describe the ability of the substance to reduce the risk of the disease or health-related condition and to reflect the multifactorial nature of the disease or health-related condition (see §§ 101.80(c)(2)(i)(B), 101.81(c)(2)(i)(A), 101.82(c)(2)(i)(A), and 101.83(c)(2)(i)(B)).[2] The agency now solicits comments on whether these four

[2] In addition, in the final rules for the soy protein and coronary heart disease (CHD) health claim and the oats and CHD health claim, FDA expressly deferred its decision regarding the use of abbreviated claims for these health claims, pending consideration of the issue in the 1995 proposal (64 FR 57700 at 57720, October 26, 1999 (soy protein and CHD), 62 FR 3584 at 3594, January 23, 1997 (oats and CHD)).

health claims contain any of the "elements" that are unnecessary or could be made optional.

D. Synonyms in Nutrient Content Claims

Section 403(r)(1)(A) and (r)(2)(A)(i) of the act provide that a claim that either expressly or by implication characterizes the level of a nutrient (nutrient content claim) may be made in the label or labeling of a food only if the characterization of the level made in the claim uses terms that are defined in regulations of the Secretary (and by delegation, FDA). Based on these provisions, the agency defined expressed claims as any direct statement about the level (or range) of a nutrient in the food (§ 101.13(b)(1)). In addition, it defined implied claims as nutrient content claims that describe the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran" suggests that the food is high in fiber) or that suggest that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an expressed claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat") (§ 101.13(b)(2)(i) through (b)(2)(ii)).

The agency has specifically defined a number of expressed nutrient content claims (e.g., "free," "low," "reduced," "light," "good source," "high," and "more") and provided for their synonyms (e.g., "no," "little," "contains," and "rich in"). (See e.g., 21 CFR 101.54 and 101.56.) These synonyms may be used in place of the defined term but their use must comply with all of the requirements applicable to the relevant defined term. The agency also provided for certain implied nutrient content claims in § 101.65(c) and (d).

Section 403(r)(4)(A)(ii) of the act provides that any person may petition the agency for permission to use terms in a nutrient content claim that are

consistent with the terms defined by the agency by regulation. Within 90 days of the submission of such a petition, FDA shall issue a final decision denying the petition or granting such permission. In addition, § 101.69(n) sets forth the specific procedures and requirements for a petition for a synonymous term.

In its petition, NFPA requested that FDA reconsider allowing synonyms and implied nutrient content claims to be used without FDA preclearance under certain circumstances. NFPA argued that, because the regulations sharply limit the terminology that can be used to describe the level of a nutrient in a food and require "premarket clearance" of such terms, the regulations ban a host of truthful and nonmisleading labeling statements. The petition requested that FDA propose an amendment that would permit nonmisleading terms or statements that are reasonably understood by consumers to be synonyms of terms defined in subpart D of part 101 (21 CFR part 101, subpart D) to be used in product labeling when the corresponding defined term is also used in the labeling. Requesting similar amendments for implied claims, NFPA stated that such amendments would ensure that claims characterizing the level of a nutrient in a food are truthful and nonmisleading, while giving manufacturers greater freedom to construct such labeling messages creatively.

In the 1995 proposal, the agency recognized that there might be some merit to the argument that more latitude in the use of truthful, nonmisleading nutrient content claims may assist consumers in maintaining healthy dietary practices because greater flexibility in the use of these terms would provide the food industry with an increased incentive to develop more healthful products (60 FR 66206 at 66209). The agency noted that, while a plethora of uncontrolled terms would confuse consumers by diminishing the usefulness

of clearly defined and limited terms, NFPA's "anchoring" concept, if properly implemented, could offer the possibility of increasing the available terms without confusing consumers (id.). The agency stated that it was granting NFPA's petition to initiate rulemaking on the use of additional synonyms anchored to authorized terms. It noted, however, that before the agency could finalize the 1995 proposal for the use of such synonyms, it would need data demonstrating that consumers will understand synonyms that are used in this manner[3] (60 FR 66206 at 66210).

In the 1995 proposal, the agency proposed to add § 101.13(r) to permit the use of synonyms in labeling when they are used in accordance with one of two proposed provisions. First, proposed § 101.13(r)(1) reflects the fact that a term may be used as a synonym when the agency has specifically listed it as a synonym for a defined term by regulation ("listed synonym" or "defined term") (60 FR 66206 at 66209). Second, FDA proposed in § 101.13(r)(2) to authorize the use of synonyms that are not specifically listed by regulation ("unlisted synonyms" or "anchored synonyms"), provided that they are anchored to defined terms, not misleading in the context of the entire label, reasonably understood by consumers to be a synonym of the defined term, and the defined term appears prominently and conspicuously on the label (60 FR 66206 at 66209 through 66210). However, the agency reiterated its concerns about consumers' ability to understand synonyms used in this manner and said that it would not be able to finalize this proposed change unless it received

[3] The NFPA petition also requested that FDA permit the use of synonyms with implied claims such as terms, statements, or symbols. In the 1995 proposal, FDA tentatively found that this concept may have some merit. However, FDA pointed out that implied claims that are consistent with a defined term may currently be used in labeling. Therefore, the agency did not propose amendments for the use of synonyms with implied nutrient content claims (60 FR 66206 at 66211).

evidence demonstrating that consumers would be able to understand the synonyms (60 FR 66206 at 66210).

In response to the 1995 proposal, FDA received several comments that specifically addressed the use of anchored synonyms. These comments encompassed a wide variety of views regarding FDA's authority to provide for anchored synonyms and the propriety of those synonyms. None of these comments, however, provided any data, as requested by the agency, to demonstrate that consumers would understand that unlisted terms that are anchored to defined terms are synonyms of those terms. Therefore, FDA is repeating its request for data or information establishing whether consumers would be able to understand and not be misled by unlisted synonyms that are tied to defined terms.

FDA is considering whether, as an alternative to the proposed use of unlisted synonyms, to modify the existing requirements in § 101.69(n) to facilitate the agency's review of a petition for a synonymous term, if the current petition process is too burdensome. The agency requests comments on whether the current petition process in § 101.69(n) for synonyms is too burdensome, and if so, why. In addition, the agency seeks comments on how it can streamline the information currently required under § 101.69(n) to better enable the agency to determine that the use of a synonymous term is consistent with the defined term and would not be misleading. Can FDA provide more flexibility regarding the nature and amount of information or data that is currently required in a petition for approval of synonyms? Further, FDA is interested in any examples of unlisted synonyms that industry believes are limited by the current regulations, truthful and nonmisleading, and for which no premarket clearance should be required.

E. Abbreviated Health Claims

Current § 101.14(d)(2)(iv) requires that all information required to be in a health claim appear together in one place without other intervening material. This regulation also permits a reference statement: "See _____ for information about the relationship between _____ and _____," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the complete health claim appearing at the location referenced in the statement.

In its petition, NFPA requested that FDA amend § 101.14(d)(2)(iv) to permit abbreviated health claims that are accompanied by a referral statement directing the consumer to the label panel where the complete health claim appears. In the preamble to the 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). FDA explained that an abbreviated health claim still constitutes a health claim because it clearly characterizes the relationship between a substance and a disease or health-related condition (id.). Further, such claims are misleading because they do not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet (id.). Moreover, FDA stated that the referral statement in § 101.14(d)(2)(iv) does not constitute a health claim because it does not characterize the relationship between a substance and disease or health-related condition (id.). Such a referral statement simply refers the consumer to a location where the complete

health claim appears (id.). In its petition, NFPA requested that the agency reconsider this position.

In the 1995 proposal, the agency explained that a complete health claim must comply with section 403(a) and (r)(3)(B)(iii) of the act (60 FR 66206 at 66214). Section 403(a) of the act requires that all claims on a food label and in food labeling be truthful and not misleading. Section 403(r)(3)(B)(iii) of the act requires, in part, that a health claim be stated in a manner that enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet. FDA stated that, although it has long required that all information that is necessary to make a claim truthful and not misleading appear in one place, there is nothing in the act that would require that information that is required under section 403(r)(3)(B)(iii) of the act appear as part of the claim each time that it is presented on the label (60 FR 66206 at 66214 through 66215). Thus, FDA tentatively concluded that an abbreviated health claim that is a scientifically valid representation of the relationship between a substance and a disease or health-related condition may be permissible under section 403(a) of the act if it is not false or misleading (60 FR 66206 at 66215). The agency also tentatively concluded that if such an abbreviated claim included a prominent and immediately adjacent reference statement to the complete claim located elsewhere on the label, the requirements of section 403(a) and (r)(3)(B)(iii) of the act would be fulfilled (id.).

Accordingly, in the 1995 proposal, the agency proposed to amend § 101.14(d)(2)(iv) to provide for the use of an abbreviated health claim when authorized in a specific health claim regulation in subpart E of part 101 (21

CFR part 101, subpart E). Of the health claims considered in the 1995 proposal, the agency proposed to authorize an abbreviated claim for one (21 CFR 101.72), on the relationship between calcium and osteoporosis (60 FR 66206 at 66220 through 66221). Based on its review of the specific requirements of the remaining health claims, however, FDA tentatively concluded that there was no basis upon which it could propose to permit the splitting of the required elements on the food label (60 FR 66206 at 66220). The agency noted that, in the same rulemaking, it was proposing to provide the basis for shorter health claims by making optional some of the elements that are required by regulation to be included in claims (60 FR 66206 at 66214). FDA explained that if those changes are finalized, many of the complete claims will be brief enough to render consideration of abbreviated claims moot (id.).

Following the 1995 proposal, FDA conducted a consumer research study, entitled "Consumer Impacts of Health Claims: An Experimental Study," relevant to issues in the 1995 proposal, including abbreviated health claims. In addition, the Quaker Oats Co. submitted reports of two studies, "Quaker Oatmeal On-Pack Health Claim Survey" and "Consumer Perception Study of a Statement Related to Heart Disease on the Label of Quaker Oats," pertaining to the use of abbreviated health claims. To allow interested persons an opportunity to obtain and comment on these studies, FDA reopened the comment period on the 1995 proposal (62 FR 3635, January 24, 1997).

The agency is interested in additional comments on these studies and the use of abbreviated health claims. FDA is particularly interested in receiving consumer research data or other information that is relevant to the issue of abbreviated health claims that has become available since the 1995 proposal, as well as any ongoing research on consumer understanding of abbreviated

health claims. In addition, FDA seeks comments on whether abbreviated health claims would mislead consumers. The agency is also interested in comments on whether abbreviated claims are needed given the agency's proposal to make optional some of the "specific elements" that are currently required to be included in health claims, thereby leading to shorter claims.

Finally, the agency seeks comments on whether and how the discontinued use of the word "may" in health claims (see section II.C of this document) would affect the use of or need for abbreviated claims. As previously discussed, in the past, the agency has considered the use of the word "may" or "might" in health claims to communicate to consumers the multifactorial nature of the disease or health-related condition (60 FR 66206 at 66219). That is, these words are considered to indicate the ability of a substance to reduce the risk of a disease or health-related condition (id.). In section II.C of this document, FDA seeks comments on whether "may" should be removed from health claims because it could be interpreted as a reflection of the science supporting the claim instead of the multifactorial nature of the disease. Significantly, however, the agency relied, in part, upon the use of "may" to justify making optional the requirement that a health claim state that development of a particular disease depends on many factors, and thereby provide for a shorter health claim (60 FR 66206 at 66219). If the agency were to make optional or discontinue the use of the word "may" or "might" in unqualified health claims, would health claims be misleading to consumers? Would FDA need to retain the requirement that a health claim state that development of a particular disease depends on many factors in order for the claim not to be misleading? If so, would such information need to appear as

part of the claim each time the claim is presented on the label in order for the claim not to be misleading?

III. 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 numbers found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments.

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/26/04

April 26, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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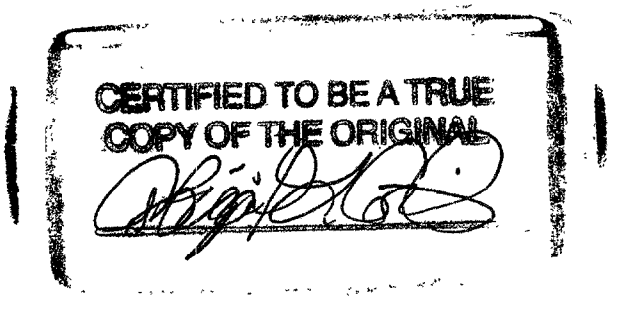
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