DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0075]

Food Labeling; Timeframe for Final Rules Authorizing Use of Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide a timeframe in which it will issue, in rulemakings on health claims, final rules announcing whether it will authorize the use of the claim at issue. FDA is also providing for extensions of that timeframe for cause. The agency is issuing this final rule in response to a recent judicial decision.

DATES: This final rule will be effective June 23, 1997.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 17, 1997 (62 FR 12579), FDA proposed to amend its health claim regulations (§ 101.70 (21 CFR 101.70)) to establish a timeframe in which it would issue final rules in proceedings on whether to authorize claims on diet-disease relationships. FDA issued this proposal in response to the decision in *Nutritional Health Alliance* v. *Shalala*, 95 Civ. 4950 (RO) (S.D.N.Y.) (*NHA* v. *Shalala*), which involved a First Amendment challenge to the constitutionality of FDA's health claim regulations. As part of its decision, the court ordered FDA to establish a reasonable timeframe for the issuance of health claim final rules.

FDA proposed to amend § 101.70 to state that within 270 days of the date of publication of a proposal to authorize a health claim, the agency will publish a final rule that either authorizes the use of a health claim or explains why the agency has decided not to authorize one (proposed § 101.70(j)(4)(i)). FDA also proposed to provide that, for cause, the agency may extend the period in which it will publish a final rule. The proposal stated that FDA will publish a notice of any such extension in the **Federal Register**, and that it will explain in that notice the basis for the extension, the length of the extension, and the date by which the final rule will be published (proposed § 101.70 (j)(4)(ii)).

In response to the proposal, FDA received four letters, each containing one or more comments. Some of the comments addressed issues, such as the burdensomeness of the health claim petition process, disqualifying levels, and the legality of the court's decision in *NHA* v. *Shalala*, that are outside the scope of this rulemaking, which focuses only on the establishment of a timeframe for issuance of final rules in health claim proceedings. Therefore, FDA will not address these comments in this document. The relevant comments that FDA received, and the agency's response to them, are set out in the discussion that follows:

II. Response to Comments

A. Timeframe of 270 Days

1. As stated in section I of this document, FDA proposed to establish a timeframe of 270 days from the date that it issues a proposal to the date of publication of the final rule. FDA justified providing a 270-day timeframe by describing the steps it had to take to arrive at a final rule and by reviewing its experiences in three health claim proceedings: Folate and neural tube defects (61 FR 8779, March 5, 1996), sugar alcohols and dental caries (61 FR 8752 at 43433, August 23, 1996), and whole oat products and coronary heart disease (62 FR 3584, January 23, 1997).

Although several of the comments found merit in FDA's proposal to establish a timeframe, all asserted that the 270-day timeframe is too long. One comment asserted that it would be unreasonable to allow this much time to pass between the publication of the proposal and the final rule. Two comments argued that the major issues raised by a health claim petition are resolved in the 190-day period before the agency issues a proposal. One of these comments argued that the 190-day period conforms with other statutory time limits placed on the agency, such as those for food additives, abbreviated new drug applications, and device classification petitions, and, thus, that little additional time should be allowed for publication of a final rule. These comments took issue with FDA's reliance on the folate proceedings for support of the 270-day proposal. One comment argued that the controversy in that rulemaking concerned the development of FDA's fortification policy for folic acid, not the health claim itself; and the other comment asserted that FDA disregarded the recommendations of the Public Health Service on folate and neural tube defects. One of these comments also took issue with FDA's reliance on the whole oat product proceeding, arguing that in the whole oat product proceeding FDA should first have issued authorization for claims on oatmeal and oat bran and then considered the comments that it received that suggested that the evidence before the agency supported a claim for whole oat flour. Finally, one comment asserted that the timeframe should require the agency to put a high priority on completing the proceeding. The comment stated that providing 180 to 210 days would better accomplish this goal, and that if a longer period were justified in a particular proceeding, FDA could grant itself an extension.

FDA has carefully considered these comments, but it does not agree that 270 days is too long or unreasonable. The agency agrees with the comment that stated that the timeframe should be one that puts a high priority on completion of the rulemaking. This will be the effect of a 270-day timeframe.

The agency points out that claims that most of the issues raised by a petition are resolved by the time FDA publishes a proposal simply do not reflect the agency's experience. If a proposal for a health claim were ever received by the public without controversy, FDA would act rapidly to issue a final rule shortly after the comment period closed. However, every health claim proposal that FDA has issued has been controversial. The agency received numerous responses on each of the proposals for folate, sugar alcohols, and whole oats products cited previously in this section. The proposal for folate, sugar alcohols, and whole oats products received approximately 100, 20, and 1,450 comments, respectively. These comments ranged from questioning the basis for the claim, to the scope of the proposed claim, to the very validity of the claim. The obligation to receive comments on the agency's proposed resolution of the issues raised by a petition, and to respond to those comments, is what sets health claims apart from the proceedings cited in one of the comments.

Contrary to the comments, the whole oat product proceeding illustrates the type of rethinking of the proposal that comments engender. As stated in the proposal (62 FR 12579 at 12581), FDA's proposal to authorize a claim for oatmeal and oat bran elicited comments that it should also authorize the claim for whole oat flour. It is true, as one comment stated, that FDA could have

issued a final rule on oatmeal and oat bran and then proceeded to consider the question of whole oat flour separately. However, doing so would have required the creation of two **Federal Register** documents rather than one. FDA's goal is to ensure that a health claim, providing as much truthful, nonmisleading, and scientifically valid information as possible, is authorized as soon as possible. FDA managers concluded, based on their evaluation of agency resources that, on balance, having to prepare one document would result in more information being authorized faster than if the agency had to prepare two documents. Thus, FDA followed the course that it did.

Moreover, contrary to the comments, FDA's reliance on the folic acid proceeding, as illustrative of the intradepartmental input that FDA tries to receive in arriving at a final rule (62 FR 12579 at 12580 and 12581) was appropriate and relevant. The controversy in the folic acid rulemaking was not focused on FDA's fortification policy per se, nor did FDA disregard the recommendations of the Public Health Service. The question that FDA dealt with in that proceeding was whether authorization of claims about the relationship between folate, including folic acid, and neural tube defects would result in the fortification of the food supply at a level that would present a risk to those who suffer from vitamin B_{12} deficiency (see, e.g., 58 FR 2606 at 2614 (January 6, 1993)). In recognizing the relationship between folate and neural tube defects in 1992, the Public Health Service recognized that this safety question was presented (see 58 FR 2606 at 2609), and that it needed to be addressed. As FDA tried to resolve the question of what level of folate in the food supply would be safe, it found that there was some disagreement within the Public Health Service about this question. Although FDA resolved this question, it took time for it to do so, and the fact that it did take time was the reason that FDA referred to the folate rulemaking in the proposal.

Moreover, there is reason to believe that FDA's need for time to resolve issues within the Public Health Service in arriving at a final rule will continue. Elsewhere in this issue of the **Federal Register**, FDA is isssuing a proposal to authorize a health claim on the relationship of soluble fiber from psyllium husk and the risk of coronary heart disease. This proposal reveals that there are reservations within the Public Health Service about whether the available evidence establishes the scientific validity of this substance-disease relationship. While FDA, because of its commitment to authorize as much health claim information as possible as fast as possible, is issuing the proposal based on its tentative conclusion that the scientific standard is met, it is likely that discussions within the Public Health Service will be necessary in arriving at a final rule. This fact supports that 270 days from the publication of the proposal may well be necessary to arrive at a satisfactory resolution of the issues raised by a substance-disease relationship.

Thus, FDA's experience supports that a significant amount of time is necessary after the close of a comment period in a health claim proceeding for FDA to analyze the comments, evaluate the evidence that bears on the issues raised by the comments, and arrive at a final rule. FDA explained in the preamble to the proposal why it may take up to 195 days to do so (270 days minus the 75 day comment period). The comment that asserted that this work could be done in 105 to 135 days (180 to 210 day timeframe) did not present any evidence to support its assertion.

Therefore, FDA has concluded that 270 days from the publication of a proposal represents a reasonable and appropriate timeframe for publication of a final rule in a health claim proceeding.

2. Two comments complained that 270 days represented an unfair burden on industry. One comment asserted that it would mean that a company would have to wait 16 months from the time that it submitted its petition to make a claim that it had documented was supported by significant scientific agreement.

FDA recognizes that these comments raise a significant point. The court in *NHA* v. *Shalala* expressed concern about the fact that speech that FDA has tentatively determined is scientifically valid is prohibited while FDA arrives at a final rule (see slip op. at 10). Nonetheless, FDA points out that there are countervailing interests here that must be balanced against those of a manufacturer in making health claims. As the court recognized in *NHA* v. *Shalala*, the Government has a substantial interest in ''preventing the spread of unsubstantiated health claims on labels so that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels.'' (Slip op. at 8.) Moreover, a system that requires premarket authorization of health claims directly and materially advances these substantial interests (id.).

The question that the comments thus raise is whether requiring that firms wait 9 months from the time that their requested speech has been determined to be presumptively valid (that is, from the date that FDA proposes to authorize the claim they seek to make) imposes more of a burden than is necessary to further the Government's legitimate interests. (See *Board of Trustees of the State University of New York* v. *Fox*, 492 U.S. 469, 478 (1989).) FDA concludes that it does not.

In the March 17, 1997, proposal, FDA carefully delineated why it will require 270 days from the date of issuance of the proposal to decide whether health claims about the substance-disease relationship that it has proposed to authorize will in fact be scientifically valid. While, as stated in section II.A.1 of this document, it may be possible for FDA to issue a final rule in less time, and FDA will endeavor to do so, 270 days represents a reasonable estimate of the amount of time that it will require to ensure that the authorization it issues in the final rule is consistent with the policies embodied in the Federal Food, Drug, and Cosmetic Act and in the implementing regulations.

None of the comments have demonstrated that a 270-day period is substantially excessive. (See *Board of Trustees of the State of New York* v. *Fox*, *supra*, 492 U.S. at 479.) Thus, FDA is making no change in the provision for a 270-day timeframe in response to these comments.

3. One comment argued that persons should be permitted to begin using health claims when they are issued in proposed form by FDA. The comment pointed out that the agency would not have issued the proposal if it did not believe that there was significant scientific support for the validity of the relationship that is the subject of the claim. One comment said that the timeframe that FDA establishes should provide predictability and certainty for the industry.

FDA has considered how to accommodate the concerns expressed by these comments. The agency finds that it cannot authorize claims to be made based on the proposal. The point of the health claim proceeding is to ensure that claims are scientifically valid, truthful, and not misleading. There is always the possibility that even though FDA has tentatively concluded that a substance-disease relationship is scientifically valid, it will receive comments that will challenge that tentative conclusion. For example, FDA tentatively concluded that there is a

relationship between sodium and hypertension, but the agency received comments arguing that the available scientific evidence did not support that sodium had an effect on hypertension (see 58 FR 2820 at 2822 to 2826, January 6, 1993). It would have been inappropriate for FDA to allow claims on sodium and hypertension while it was still deciding whether these claims are valid. To permit claims on the basis of a proposal would be to permit preliminary claims. The health claim provisions of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) were passed to protect consumers against such claims (see 59 FR 395 at 403, January 4, 1994). Therefore, FDA finds that it cannot accommodate this comment.

As for providing predictability and certainty, FDA points out that no predictability or certainty that a claim could ultimately be made can derive from the filing of a petition. On several occasions, firms have filed petitions that they thought demonstrated that there was significant scientific agreement in support of a claim, but FDA has found that it could not agree and denied the petition (e.g., see FDA response to petition on calcium and hypertension (Docket No. 96P–0047).

As for predictability and certainty from the date of publication of a proposal, FDA advises that, as explained previously, certainty is not possible because new evidence may be submitted in comments that establish that the substance-disease relationship is not scientifically valid. Such a result is not likely, but the agency cannot rule it out.

Predictability also cannot be ensured. While FDA is committing itself to issuing a final rule 270 days from the date of publication of a proposal, it is FDA's firm desire to issue final rules in as little time as possible. Moreover, occasionally, the agency may be compelled to grant itself an extension.

Thus, FDA cannot provide predictability and certainty. However, a firm that submits a well-supported petition can do so with some confidence that, within 16 months from the date of submission, it will likely be able to make claims about the substance-disease relationship that is the subject of its petition.

B. Extensions

4. Several comments asserted that it was likely that FDA would not complete rulemakings within the 270-day period. These comments argued that, therefore, it was important that FDA not be able to grant itself unlimited extensions. One comment stated that extensions should be justified by a publicly available record, that they should be granted for periods of 90 days, and that the total maximum extension should not be for more than 270 days.

FDA does not agree that it is likely that it will not complete health claim rulemakings in a timely manner. As stated previously, FDA considers these proceedings to be a high priority, and it does not anticipate failing to meet the timeframes. However, the agency recognizes that, on occasion, cause may exist for extending the period in which it arrives at a final rule. FDA agrees with the comment that stated that any extensions should be justified with a publicly available record. In fact, FDA stated in the proposal that it would proceed in this manner (62 FR 12579 at 12581).

FDA also finds merit in the argument advanced by the comments that the agency should not be able to grant itself unlimited extensions. If the agency were to adopt a regulation that left it free to do so, FDA would not have adequately addressed the concern expressed by the court in *NHA* v. *Shalala* that the agency not prohibit presumptively valid, nonmisleading health claims for an indefinite period (slip op. at 10).

FDA agrees with the comment that stated that extensions be granted for 90 days. Consequently, the agency has modified proposed § 101.70(j)(4)(ii) to provide that FDA may extend the comment period for a period of no more than 90 days.

FDA also agrees with the comment that suggested that the agency limit the number of extensions that it grant itself. FDA has decided that it should be able to grant itself two extensions rather than three. After one extension, the agency will have had a year to finalize the health claim proposal. The agency's experience has been that it has been able to resolve all issues that have arisen in health claim proceedings in that amount of time. If the agency is unable to resolve any issue within a year, it will likely be because significant scientific agreement with respect to that issue simply does not exist. In such circumstances, the appropriate course of action may be to deny authorization for claims about the substance-disease relationship, or about some aspect of the substance-disease relationship, in question. FDA has modified proposed § 101.70(j)(4)(ii) to reflect the agency's determination to limit itself to two 90-day extensions.

III. Analysis of Impacts

A. Economic Impact

In the proposal, FDA stated that it had examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act. The agency found that the proposed rule was not a significant regulatory action under the Executive Order, and that it would not have a significant economic impact on a substantial number of small entities. FDA received no comments on these conclusions, and, therefore, finds no basis or reason to modify them.

B. Environmental Impact

FDA determined under 21 CFR 25.24(a)(8) that the proposed rule was of a type that did not individually or cumulatively have an effect on the human environment. FDA received no comments on this determination and, therefore, the agency is confirming this conclusion in this final rule.

IV. Paperwork Reduction Act

In the proposal, FDA tentatively concluded that the proposed rule contained no reporting, recordkeeping, labeling, or other third party disclosure requirements, and that there were no ''information collection'' requirements necessitating clearance by the Office of Management and Budget. FDA received no comments on this tentative conclusion. Therefore, FDA concludes that this rule imposes no paperwork burden.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.70 is amended by adding new paragraph (j)(4) to read as follows:

§ 101.70 Petitions for health claims.

* * * * *

(j) * * *

(4)(i) Within 270 days of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or

explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the **Federal Register**. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published.

Dated: May 15, 1997.

William B. Schultz,

Associate Commissioner for Policy Coordination.

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