DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 93N–0481]

RIN 0910–AA23

Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke a regulation authorizing a health claim on the relationship between folic acid and neural tube defects (NTD's) on the labels and in the labeling of dietary supplements that became final by operation of law. The agency intends to replace this revoked regulation with one that is published elsewhere in this issue of the Federal Register. This action is being taken to ensure that the regulation that authorizes claims on this nutrient disease relationship is fully responsive to the public comments that FDA has received on this matter.

DATES: Written comments by April 4, 1996. The agency is proposing that any final rule that may issue based on this proposal become effective on the date of publication of the final rule in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS–175), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5375.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535) amended the Food, Drug, and Cosmetic Act (the act) to give the Secretary of the Department of Health and Human Services (the Secretary), and by delegation FDA, the authority to issue regulations authorizing health claims on the labels and in the labeling of foods. Section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with procedures and standards established under section 403(r)(3) and (r)(5)(D) of the act.

The 1990 amendments also directed the Secretary to determine through rulemaking whether claims regarding 10 nutrient-disease relationships met the requirements of the act. The relationship of folic acid and NTD's was among those 10 topics (section 3(b)(1)(A)(x) of the 1990 amendments).

A. The 1991 Proposed Rule

In the Federal Register of November 27, 1991 (56 FR 60537), FDA proposed to not authorize a health claim on folic acid and NTD's. The agency tentatively concluded that the available evidence did not establish that the standard that FDA had proposed for health claims for dietary supplements under section 403(r)(5)(D) of the act was met; that is, that there was not significant scientific agreement, based on the totality of publicly available scientific evidence, that the claim is valid.

B. The Public Health Service Recommendations

In September 1992, following the availability of significant new data, the Public Health Service (PHS) issued a recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 milligram (mg) of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTD's. The recommendation was based on data suggesting that folic acid, when given at a high dose (4 mg), can reduce the risk of recurrence of NTD's and on studies that used multivitamins containing folic acid at dose levels from 0 to 1,000 micrograms per day. The PHS recommendation identified approaches and identified outstanding issues, including the recommended intake of folate, the potential role of other nutrients in reduction of risk of NTD's, safety concerns, and the ''folate-preventable'' fraction of NTD's.

C. The Dietary Supplement Act of 1992

In October 1992, the Dietary Supplement Act of 1992 (the DS act) was enacted. This statute imposed a moratorium on FDA's implementation of the 1990 amendments with respect to dietary supplements until December 15, 1993. The DS act directed FDA to issue proposed rules to implement the 1990 amendments with respect to dietary supplements by June 15, 1993, and to issue final rules based on these proposals by December 31, 1993. The DS act also amended the so-called ''hammer'' provision of the 1990 amendments, section 3(b)(2) of the 1990 amendments, to provide that if the agency did not meet the established December 31, 1993, timeframe for issuance of final rules, the proposed regulations would be considered final regulations.

D. The 1993 Final Rules for Health Claims for Food in Conventional Food Form

In the Federal Register of January 6, 1993 (58 FR 2606), FDA published a final rule to not authorize a health claim for folic acid and NTD's. However, the agency reaffirmed its support of the PHS recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other NTD's. The agency noted, however, that unresolved questions about the safe use of folate remained. The agency concluded that it could not authorize a health claim until these questions were resolved. Because of the DS act, FDA took no final action with respect to the use of a health claim on folic acid and NTD's on dietary supplements.

E. The 1993 Proposal to Authorize a Health Claim on Folic Acid and NTD's

In the Federal Register of October 14, 1993 (58 FR 53254), FDA published a proposed rule to authorize the use of a health claim about the relationship of folate and NTD's on the labels of foods in conventional food form and dietary supplements. FDA tentatively concluded, based on its discussions with an advisory committee, that it could ensure the safe use of folate. FDA provided 60 days for comment on this proposed action. The comment period closed on December 13, 1993.

F. The 1994 Final Rule

Section 3(b)(2) of the 1990 amendments, as amended by section 202(a)(2)(B)(ii) of the DS act, provides that if the Secretary does not promulgate final regulations on any of the health claims applicable to dietary supplements in a timely manner, the proposed regulations shall be considered final regulations but not until December 31, 1993. Because FDA was unable to publish a final rule by December 31, 1993, in the proceeding instituted in October of 1993, FDA published a notice in the Federal Register of January 4, 1994 (59 FR 433), announcing that the regulation that it had proposed in the October 1993 folate/NTD proposal was considered to be a final regulation for dietary

supplements by operation of law, effective July 1, 1994.

This document did not conclude the rulemaking begun in October of 1993, however. Rather, the January 4, 1994, document was part of a separate proceeding that is compelled under section 3(b)(2) of the 1990 amendments (see H. Rept. 101–538, 101st Cong., 2d Sess. 18 and 136 Congressional Record 5842 on the effect of this ''hammer'' provision).

In the January 4, 1994 document, FDA stated that the rulemaking that it instituted in October of 1993 was ongoing, and that it intended to issue a final rule that would resolve the issues in that ongoing proceeding. Elsewhere in this issue of the Federal Register, FDA is issuing a final rule to conclude that proceeding. Given that FDA has now issued that final rule, the regulation that resulted must to supersede the regulation that became final by operation of law. The agency is now instituting this rulemaking to bring about this supersession.

II. The Proposal

FDA is proposing to withdraw the regulation that became final by operation of law on January 4, 1994 (the January 4, 1994, regulation). FDA tentatively finds that this action is in the best interests of consumers, manufacturers, and regulatory officials for several reasons.

The January 4, 1994, regulation did not have the benefit of public comment. It reflects FDA's initial views on the folic acid/NTD health claim and what it should say. From the comments received in response to the folic acid/NTD health claim proposal, it is clear that the January 4, 1994, regulation does not adequately address several issues related to this health claim. Because the regulation included in the final rule published elsewhere in this issue of the Federal Register addresses the comments that the agency received and includes changes that the agency has made in response to those comments, FDA tentatively finds that that regulation is better able to implement the act than the January 4, 1994, regulation, and that it provides for a more useable and scientifically valid health claim.

FDA tentatively finds that replacing the January 4, 1994, regulation with the regulation included in the final rule will not result in any hardship to manufacturers who have relied on the January 4, 1994, regulation. The regulation in the final rule in most respects is consistent with the January 4, 1994, regulation. The only differences are those modifications that have been made to shorten the claim and to provide more flexibility to those who decide to use it on their labels or in their labeling. Thus, replacing the January 4, 1994, regulation with the final regulation published elsewhere in this issue of the Federal Register will not present manufacturers with a situation in which they must adjust to a dramatic shift in the standard that they must meet.

FDA is also proposing to limit the comment period to 30 days, and to make any final rule that issues in this proceeding effective on the date of publication. FDA is proposing both of these actions for the same reason. FDA believes that, if the regulation in the final rule is to supersede the January 4, 1994, regulation, this action should proceed as expeditiously as possible. Expeditious action will minimize the possibility for confusion and ambiguity created by this action. FDA tentatively finds that the proposed steps are necessary to facilitate expeditious action, and thus that there is good cause for both of these proposed actions.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA has fully assessed the economic impact of replacing the January 4, 1994, regulation with the regulation contained in the final rule and has determined this proposal will impose no costs, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Comments

Interested persons may, on or before April 4, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 101 be 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).

§ 101.79 [Removed]

2. Section 101.79 *Health claims: folate and neural tube defects* is removed.

Dated: February 26, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–5011 Filed 2–20–96; 12:01pm]

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