VI. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of this interim final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the 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). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this interim final rule is not a major rule for the purpose of congressional review.

If in the future FDA authorizes health claims relating to the relationship between zinc and, in adults, the body's ability to fight infection and heal wounds after finding that there is significant scientific agreement about these relationships, the cost to consumers of prohibiting this claim at this time would be the cost of having kept, in the interim, information from appearing in food labeling that would ultimately be shown to be scientifically valid, truthful, and not misleading. At this time, the benefit to consumers of prohibiting this claim is that a claim that has not been shown to be scientifically valid will not appear in food labeling. Accordingly, consumers will be able generally to have confidence when they read food labeling that any diet/disease relationship information in that labeling has been shown to be scientifically valid.

A health claim relating to the relationship between zinc and, in adults, the body's ability to fight infection and heal wounds has not been authorized under existing regulations. The prohibition of this claim in this interim final rule results in no regulatory changes for firms, and therefore no costs to firms are attributable to this interim final rule.

B. Small Entity Analysis

FDA has examined the impacts of this interim final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the Regulatory Flexibility Act, FDA finds that this interim final rule will not have a significant impact on a substantial number of small entities.

A health claim relating to the relationship between zinc and, in adults, the body's ability to fight infection and heal wounds has not been authorized under existing regulations. The prohibition of this claim in this interim final rule results in no regulatory changes for firms, and therefore this rule will not result in a significant increase in costs to any small entity. Therefore, this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 601–612), the agency certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this interim final rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This interim final rule does not trigger the requirement for a written statement under section 202(a) of UMRA because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector, in any 1 year.

VII. The Paperwork Reduction Act of 1995

This interim final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Notification to Donna E. Shalala, DHHS, from Jonathan W. Emord et al., Emord & Associates, P.C., Counsel for Weider Nutrition International, Inc., February 23, 1998.

2. LSRO, FASEB, ''Nutrition Monitoring in the United States—An Update Report on Nutrition Monitoring,'' prepared for USDA and DHHS, DHHS Pub. No. (PHS) 89–1255, PHS, DHHS, U.S. Government Printing Office, Washington, DC, inside front cover and pp. iii–vii, September, 1989.

3. Letter to Christine Lewis, CFSAN, FDA, from Eileen Kennedy, USDA, May 7, 1998.

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–16461 Filed 6–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0420]

Food Labeling: Health Claims; Vitamin K and Promotion of Proper Blood Clotting and Improvement in Bone Health in Adults

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to prohibit the use on foods of a health claim relating to relationships between vitamin K and the promotion of proper blood clotting and improvement in bone health in adults. This interim final rule is in response to a notification of a health claim submitted under section 303 of the FDA Modernization Act of 1997 (FDAMA). FDA has reviewed the notification, and, in conformity with the requirements of FDAMA, the agency is prohibiting the claim as a health claim because the claim does not characterize the relationship of the nutrient vitamin K to a disease or health-related condition, as required by section 303 of FDAMA; therefore, section 303 of FDAMA does not authorize use of this claim as a health claim. Although the claim is not a health claim, it may be the type of claim permissible as a structure/function claim. As provided for in section 301 of FDAMA, this rule is effective immediately upon publication.

DATES: The interim final rule is effective June 22, 1998; comments by September 8, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION:

I. The FDA Modernization Act of 1997

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105–115), which amended the Federal Food, Drug, and Cosmetic Act (the act). Sections 303 and 304 of FDAMA amended section 403(r)(3) and (r)(2) of the act by adding new paragraphs (r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D) of the act (21 U.S.C. 343(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D), which provide for the use in food labeling of nutrient content claims and health claims, respectively, based on authoritative statements. FDAMA requires that a notification of the prospective nutrient content claim or the prospective health claim be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce. FDAMA and its requirements are discussed in more detail in a companion document in this issue of the **Federal Register** (see ''Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risks in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts;'' hereinafter referred to as ''Health Claims; Vitamins C and E''). In particular, aspects of the requirements for an ''authoritative statement'' that are relevant to this rulemaking and FDA's review process for notifications are discussed in sections I.A and I.B, respectively, of that document.

Provided certain conditions are met, section 403(r)(3)(C) of the act authorizes the use of claims ''of the type described in subparagraph (1)(B).'' Section 403(r)(1)(B) of the act describes claims that ''characterize[ ] the relationship of a[ ] nutrient * * * to a disease or health-related condition.'' Accordingly, for a claim to be authorized as a health claim under section 403(r)(3)(C) of the act, it must characterize the relationship of a nutrient to a disease or health-related condition.

II. The Notification

Section 403(r)(2)(G) and (r)(3)(C) of the act became effective on February 19, 1998. On February 23, 1998, the agency received a notification from Weider Nutrition International, Inc., containing nine prospective claims that were identified in the text of the notification as health claims (Ref. 1). The notification included statements that the submitter described as authoritative statements and a scientific literature review for each claim. FDA has created nine separate dockets, one for each of the nine claims and is issuing a separate interim final rule responding to each claim.

This interim final rule addresses the ninth claim in the notification. The notification included one statement that the petitioner identified as an authoritative statement on which the following claim is based: ''In adults, vitamin K promotes proper blood clotting and may improve bone health. Sources of Vitamin K include spinach, cabbage, turnip greens, broccoli, tomatoes, and dietary supplements.''

The first sentence of this claim will be discussed in greater detail in section III of this document. The second sentence, ''Sources of Vitamin K include spinach, cabbage, turnip greens, broccoli, tomatoes, and dietary supplements,'' is not a health claim. Given that the notification indicated that it was intended to be a notification for health claims, this statement was not reviewed by FDA. The submitter did not separately identify this statement as any particular type of claim.

Nonetheless, as a point of information, the agency wishes to highlight that statements that appropriately constitute nutrient content claims are allowed on labels and in the labeling of foods and dietary supplements. Moreover, statements that constitute dietary guidance are also allowed provided the information is truthful and not misleading as required by sections 403(a) and 201(n) of the act (21 U.S.C. 321(n)). These aspects of nutrient content claims and dietary guidance are discussed in more detail in ''Health Claims; Vitamins C and E,'' which is published elsewhere in this issue of the **Federal Register**.

III. Basis for the Action

FDA has reviewed the notification submitted in support of the prospective claim. In adults, vitamin K promotes proper blood clotting and may improve bone health. In considering this claim, FDA notes that blood clotting does not constitute a disease or health-related condition. Proper blood clotting is a normal, physiological function and vitamin K has a well-established role in this function. Bone health, likewise, does not itself identify a disease or health-related condition. The formation of healthy bones is a normal developmental process to which a number of nutrients contribute. As such, the claim characterizes a relationship of the nutrient to normal body process and not a relationship of the nutrient to a disease or health-related condition, as required by section 403(r)(3)(C) of the act. Accordingly, the subject claim about a relationship between vitamin K and the promotion of proper blood clotting and improvement in bone health is not authorized as a health claim under section 403(r)(3)(C) of the act and is, therefore, prohibited as a health claim.

However, the claim submitted, if truthful and not misleading and depending upon the context, may be of the type known as a structure/function claim and thus eligible to appear on the label or in labeling of products under the exception for such claims for foods in section 201(g)(1)(C) of the act or on dietary supplements under section 403(r)(6) of the act. The agency notes that the phrase ''may improve bone health,'' if used in a labeling context that suggests disease or abnormality of the bone, would constitute an implied health claim and it would cease to be a permissible structure/function claim in that context.

IV. Issuance of an Interim Final Rule, Immediate Effective Date, and Opportunity for Public Comment

For the reasons described in this section, FDA is issuing this rule as an interim final rule, effective immediately, with an opportunity for public comment. New section 403(r)(7)(B) of the act, added by section 301 of FDAMA, provides that FDA ''may make proposed regulations issued under [section 403(r)] effective upon publication pending consideration of public comment and publication of a final regulation'' if the agency ''determines that such action is necessary * * * to enable [FDA] to act promptly to ban or modify a claim'' under section 403(r) of the act. For purposes of judicial review, ''[s]uch proposed regulations shall be deemed final agency action.'' The legislative history indicates that the agency should issue rules under this authority as interim final rules (H. Conf. Rept. 105–399, at 98 (1997)).

As described in section III of this document, FDA has determined that the claim is not a health claim and therefore is not authorized by section 403(r)(3)(C) of the act. FDA has determined that it is necessary to act promptly to prohibit the claim's use under section 403(r)(3)(C) of the act, and accordingly, is issuing this interim final rule to ban its use under section 403(r)(C).

FDA invites public comment on this interim final rule. The agency will consider modifications to this interim final rule based on comments made during the comment period. Interested persons may, on or before September 8, 1998, submit to the Dockets Management Branch (address above) written comments regarding this interim final rule. Comments must be received

by that date. 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.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(k) 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 impact statement is required.

VI. Analysis of Economic Impacts

A. Benefit–Cost Analysis

FDA has examined the impacts of this interim final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the 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). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this interim final rule is not a major rule for the purpose of congressional review.

Prohibiting a health claim about the association between vitamin K and blood clotting and bone health will not result in any regulatory changes for firms and thus, will not result in any costs to firms. Because the proposed claim may be permissible as a structure/function claim as discussed in section III of this document, firms may still be able to communicate the same or similar information to consumers. This prohibition will not result in either costs or benefits.

B. Small Entity Analysis

FDA has examined the impacts of this interim final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the Regulatory Flexibility Act, FDA finds that this interim final rule will not have a significant impact on a substantial number of small entities.

A health claim related to the association between vitamin K and the promotion of proper blood clotting and improvement in bone health has not been authorized under existing regulations. The prohibition of this claim as a health claim in this interim final rule results in no regulatory changes for firms, and therefore this rule will not result in a significant increase in costs to any small entity. Therefore, this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 601–612), the agency certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this interim final rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This interim final rule does not trigger the requirement for a written statement under section 202(a) of UMRA because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector, in any 1 year.

VII. The Paperwork Reduction Act of 1995

This interim final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. References

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Notification to Donna E. Shalala, DHHS, from Jonathan W. Emord et al., Emord & Associates, P.C., Counsel for Weider Nutrition International, Inc., February 23, 1998.

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–16462 Filed 6–19–98; 8:45 am]

BILLING CODE 4160–01–F