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 garlic, decreased serum cholesterol, and the risk in adults of cardiovascular disease 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 garlic, decreased serum cholesterol, and the risk in adults of cardiovascular disease 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 garlic, decreased serum cholesterol, and the risk in adults of cardiovascular disease 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. 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. 98–16460 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–0421]

Food Labeling: Health Claims; Zinc and the Body's Ability to Fight Infection and Heal Wounds 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 claim relating to the relationship between zinc and the body's ability to fight infection and heal wounds in adults. This 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 statements that the petitioner submitted in that notification, and, in conformity with the requirements of FDAMA, the agency is prohibiting the claim because the statements submitted as the basis of the claim are not ''authoritative statements'' of a scientific body, as required by FDAMA; therefore, section 303 of FDAMA does not authorize use of this 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)(2) and (r)(3) of the act by adding new paragraphs (r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D) to section 403 of the act (21 U.S.C. 343(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D), respectively), 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 published elsewhere in this issue of the **Federal Register** (see ''Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk 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.

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 eighth claim in the notification. The notification included two statements that the petitioner identified as authoritative statements on which the following claim is based: ''In adults, zinc may increase the body's ability to fight infection and heal wounds. Sources of zinc include whole grains, fish, seafood, meat, poultry, eggs, legumes, and dietary supplements.''

The first sentence of this claim will be discussed in greater detail in section III of this document. The agency notes that this claim describes the relationship between zinc and two diseases and, thus, in point of fact, reflects two prospective health claims. The second sentence, ''Sources of zinc include whole grains, fish, seafood, meat, poultry, eggs, legumes, 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, zinc may increase the body's ability to fight infection and heal wounds.'' The agency has determined that neither of the two statements submitted as the basis for this claim meets the requirements in section 403(r)(3)(C) of the act to be an ''authoritative statement.'' Because the prospective claim is not based on authoritative statements, it is not appropriate for the claim to appear on food labels and labeling. Consequently, FDA is issuing this interim final rule to prohibit the use of this claim. A discussion of the basis for the agency's action on the notification follows.

First, FDA determined that the components required by section 403(r)(3)(C) of the act were present in the notification submitted to support this claim. Second, FDA determined that, as a threshold matter, the two statements cited in support of the claim may be attributable either to an appropriate Federal scientific body or to an employee or employees of such a body.

The notification in support of the claim that is the subject of this document cites: (1) A report on nutrition monitoring prepared for the Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA), and (2) an electronic version provided on the Internet of a quarterly report from USDA's Agricultural Research Service (ARS). Thus, one statement in the notification is attributable to USDA and DHHS and is intended for use by Federal agencies including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and USDA/ARS. The second statement is attributable to USDA/ARS. NIH and CDC are highlighted in the statute as scientific bodies. FDA believes that USDA/ARS is also a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition for the purposes of section 403(r)(2)(G) and (r)(3)(C) of the act. Accordingly, the statements provided in the notification in support of the claim may be attributable to appropriate Federal scientific bodies or to their employees.

Finally, however, neither of the two statements discussed in sections III.A and III.B of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: ''Zinc is an essential mineral in the diet and is a component of many enzymes. As such, it is involved in many metabolic processes including wound healing, immune function, growth and maintenance of tissues.'' The notification identified Statement 1 as an ''authoritative statement'' for purposes of making the claim that is the subject of this rulemaking. The statement is found in a discussion on minerals that is contained in ''Nutrition Monitoring in the United States—An Update Report on Nutrition Monitoring'' that was prepared for USDA and the Public Health Service of DHHS by the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) (DHHS Publication No. (PHS) 89–1255, September 1989, 71). The notification provided a photocopy of selected pages from the report.

The agency notes that the report was prepared under a DHHS contract by LSRO/FASEB, an organization that is neither a Federal Government agency nor affiliated with the National Academy of Sciences. Contractual activities involved in preparation of the report were overseen by several Federal agencies that participate in the National Nutrition Monitoring System (NNMS). The report provides an independent expert panel's review of the dietary and nutritional status of the U.S. population, as well as the factors that determine status, based on information available through the NNMS; the report is an advisory document for the government agencies. A disclaimer that appears on the inside front cover of the report (which was not included in the

notification) states that, although the report was printed and distributed as part of a series of reports from the NNMS, ''the interpretations contained in this report do not necessarily express the views or policies of the U.S. Government and its constituent agencies'' (Ref. 2). Additionally, as noted in the foreword of the report (page vii), representatives of participating Federal Government agencies ''reviewed final drafts of the report for technical accuracy and satisfaction of the scope of work'' (Ref. 2).

Given this disclaimer and the statement from the foreword, the component of the submitter's notification that provided ''a concise description of the basis upon which [the submitter] relied for determining that the requirements of [403(r)(3)(C)(i)] have been satisfied'' (as required by 403(r)(3)(C)(ii)(I) of the act) needed to address why this statement was in fact an authoritative statement. It did not. The disclaimer indicates that Federal Government agencies cannot be considered to have ''published'' the report in the sense that it represents official policy of the agencies, as discussed in section I.A.2 in ''Health Claims; Vitamins C and E,'' which is published elsewhere in this issue of the **Federal Register**. The foreword of the report indicates that it may involve a deliberative review of the scientific evidence about the dietary and nutritional status of the U.S. population, but that it does not involve a deliberative review of the scientific evidence about diet/disease relationships. Further, the foreword indicates that the Federal agencies did not themselves conduct a deliberative review of the scientific evidence necessary for the statements in the report to be ''authoritative statements,'' as described in section I.A.3 in ''Health Claims; Vitamins C and E,'' which is published elsewhere in this issue of the **Federal Register**, but rather only a review for technical accuracy of a final draft of the report itself.

FDA concludes that the statement is not an ''authoritative statement'' because it does not reflect the official policy of an appropriate scientific body, nor has an appropriate scientific body conducted a deliberative review of the scientific evidence.

B. Statement 2

Statement 2 reads: ''Dietary zinc shortages—a bigger problem in developing countries than in the United States—may be linked to depressed growth in children, slower wound-healing and difficult births.'' The notification identified Statement 2 as an ''authoritative statement'' for purposes of making the claim that is the subject of this rulemaking. The statement is found in *Human Nutrition* (quarterly reports of selected research projects, 1st quarter 1995) issued by the USDA's ARS and provided on the Internet (''http://www.ars.usda.gov/is/qtr/q195/hn195.htm'' accessed on 12/24/97). *Human Nutrition* is a periodic compilation of brief (one paragraph) descriptions of ongoing research being conducted within the various ARS facilities. The subject statement (submitted to the agency as a hardcopy reprint from the Internet) appears in a description of research entitled ''Boosting a key amino acid in plants could help people get more zinc in their diets.'' The paragraph describes the nature and outcome of one ARS study using rats and is attributed to William House and Ross Welch of the United States Plant, Soil and Nutrition Laboratory, Ithaca, NY.

FDA asked USDA whether the statement is an ''authoritative statement'' under FDAMA. USDA responded to FDA that the statement is not an authoritative statement of USDA because it was not based upon a deliberative review of the scientific evidence regarding a relationship between the nutrient and the disease in question. USDA explained that the ARS quarterly reports describe progress on individual projects without a deliberative review of all relevant scientific evidence (Ref. 3). Therefore, FDA has concluded that the statement is not an ''authoritative statement'' under section 403(r)(3)(C) of the act because it is not based on a deliberative review of the scientific evidence.

In summary, FDA has concluded that the notification does not include any authoritative statement published by a scientific body as required by section 403(r)(3)(C) of the act. Accordingly, the subject claim relating to the relationship between zinc and, in adults, the body's ability to fight infection and heal wounds is not authorized under section 403(r)(3)(C) of the act and is, therefore, prohibited. The agency notes that, at any future time, a notification may be submitted to the agency that bases such a claim or claims on a statement that meets the requirements of section 403(r)(3)(C) of the act. If there is no authoritative statement that may serve as a basis for such claims, an interested person may petition the agency under section 403(r)(4) of the act and 21 CFR 101.70 to authorize a health claim or claims by regulation under section 403(r)(3)(B) of the act.

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

For the reasons described in this section of the document, 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 statements submitted in support of the prospective health claim do not meet the requirements for authoritative statements in 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)(3)(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.

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]

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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.