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 antioxidant vitamin A and beta-carotene and the risk in adults of atherosclerosis, coronary heart disease, and certain cancers 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 antioxidant vitamin A and beta-carotene and the risk in adults of atherosclerosis, coronary heart disease, and certain cancers 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 related to the relationship between antioxidant vitamin A and beta-carotene and the risk in adults of atherosclerosis, coronary heart disease, and certain cancers 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 interim final rule will not result in a significant increase in costs to any small entity. Therefore, this interim final 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 to vii, September, 1989.

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

4. Letter to Christine Lewis, CFSAN, FDA, from William R. Harlan, NIH, April 30, 1998.

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–16455 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–0427]

Food Labeling: Health Claims; B-Complex Vitamins, Lowered Homocysteine Levels, and the Risk in Adults of Cardiovascular Disease

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 B-complex vitamins (folic acid, vitamin B_6, vitamin B_{12}), lowering elevated serum homocysteine levels, and the risk in adults of cardiovascular disease. 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 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 (21 U.S.C. 343(r)(2) and (r)(3)) 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 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 third claim in the notification. The notification included four statements that the submitter identified as authoritative statements on which the following claim is based: ''B-complex vitamins-Folic Acid, Vitamin B_6, Vitamin B_{12}—may reduce the risk in adults of cardiovascular disease by lowering elevated serum homocysteine levels, one of the many factors implicated in that disease. Sources of B-complex vitamins include whole and enriched grains, green leafy vegetables, fish, dry beans, red meat, and dietary supplements.''

The first sentence of this claim will be discussed in greater detail section III of this document. The second sentence, ''Sources of B-complex vitamins include whole and enriched grains, green leafy vegetables, fish, dry beans, red meat, 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) (21 U.S.C. 321(n)) of the act. 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: ''B-complex vitamins—Folic Acid, Vitamin B_6, Vitamin B_{12}—may reduce the risk in adults of cardiovascular disease by lowering elevated serum homocysteine levels, one of the many factors implicated in that disease.'' The agency has determined that none of the four 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 an authoritative statement, 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, each of the four 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 four statements from quarterly reports from the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS) from electronic versions provided on the Internet. Thus, the statements in the notification are all attributable to USDA's ARS. FDA believes that USDA/ARS is 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 an appropriate Federal scientific body or to its employees.

Finally, however, none of the four statements discussed in sections III.A through III.D of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: ''A research team's new evidence confirms earlier data that elevated levels of the amino acid homocysteine increase the odds for significant narrowing of the arteries * * * The Analysis also Showed that Insufficient Levels of Folate and, to a Lesser Extent, Vitamin B_6 contribute to increased risk of artery narrowing. Like a see-saw, homocysteine levels go up as the vitamins go down, and vice versa.'' 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 *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 12/4/97). *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: ''Eating green vegetables, citric and other foods rich in folate (folic acid) may help keep the arteries open, reducing heart disease and stroke risks.'' The paragraph describes the nature and outcome of one ARS study and is attributed to Jacob Selhub and Paul Jaques of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts.

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 (Ref. 2). USDA explained that the ARS Quarterly Reports describe progress on individual projects without a deliberative review of all relevant scientific evidence. 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, 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**.

B. Statement 2

Statement 2 reads: ''When people don't have enough of these [vitamin B_{12} and folate] vitamins to metabolize homocysteine it accumulates in the blood and damages the vessels.'' 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, 4th Quarter 1996) (see discussion of statement 1 in section III.A of this document), which is issued by the USDA's ARS and provided on the Internet (''http://www.ars.usda.gov/is/qtr/q496/hn496.htm accessed'' on 12/3/97) in a description of research entitled: ''One or two alcoholic drinks a day can interfere with people's B vitamin levels, according to a study of 41 men and women.'' The paragraph describes the nature and outcome of one ARS study and is attributed to Judith Hallfrisch of the USDA Beltsville Human Nutrition Research Center on Aging.

The agency 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 (Ref. 2). 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.

C. Statement 3

Statement 3 reads: '' [T]he body needs [folate] to convert homocysteine into a nontoxic amino acid and thus prevent damage to blood vessels * * * Supplement users had the lowest homocysteine levels but not much lower than frequent consumers of fruits, vegetables and cereal.'' The notification identified Statement 3 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, 4th Quarter 1996) (see discussion of statement 1 in section III.A of this document), which is issued by the USDA's ARS and provided on the Internet (''http://www.ars.usda.gov/is/qtr/q496/hn496.htm'' accessed on 12/3/97) in a description of research entitled: ''Eating more fruits, vegetables, and cold cereal fortified with folic acid—a form of folate—should significantly reduce the risk of heart disease and stroke that comes from having high blood levels of homocysteine, a new study shows.'' The paragraph describes the nature and outcome of one ARS study and is attributed to Katherine L. Tucker of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts, Boston, MA.

The agency 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 (Ref. 2). 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.

D. Statement 4

Statement 4 reads: ''Research has linked high homocysteine levels to increased risk of heart disease and stroke.'' The notification identified Statement 4 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, 3d Quarter 1995) (see discussion of Statement 1 in section III.A of this document), which is issued by the USDA's ARS and provided on the Internet (''http://www.ars.usda.gov/is/qtr/q395/hn395.htm'' accessed on 12/3/97) in a description of research entitled ''Measuring blood levels of the amino acid homocysteine only after an overnight fast could miss nearly half of the people with elevated levels.'' The paragraph describes the nature and outcome of one ARS study and is attributed to Andrew G. Bostom and Jacob Selhub of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts, Boston, MA.

The agency 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 (Ref. 2). 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 of the U.S. Government as required by section 403(r)(3)(C) of the act. Accordingly, the subject claim relating to the relationship between B-complex vitamins (folic acid, vitamin B_6, vitamin B_{12}), lowering elevated serum homocysteine levels, and the risk in adults of cardiovascular disease 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 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 a claim, 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 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, 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) of the act.

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 B-complex vitamins (folic acid, vitamin B_6, vitamin B_{12}), lowering elevated serum homocysteine levels, 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 B-complex vitamins (folic acid, vitamin B_6, vitamin B_{12}), lowering elevated serum homocysteine levels, 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 B-complex vitamins (folic acid, vitamin B_6, vitamin B_{12}), lowering elevated serum homocysteine levels, 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. 98–16456 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–0423]

Food Labeling: Health Claims; Calcium Consumption by Adolescents and Adults, Bone Density and The Risk of Fractures

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this interim final rule to prohibit the use on foods of a claim relating to the relationship between calcium, bone density, and the risk of fractures. 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 is prohibiting the claim because section 303 of FDAMA does not apply when FDA has an existing regulation authorizing a health claim about the relationship between the nutrient and the disease or health-related condition at issue. A health claim concerning the relationship between calcium and osteoporosis is already authorized. 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. Submit written 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 fourth claim in the notification. The notification included five statements that the petitioner identified as authoritative statements on which the following claim is based: ''Calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures. Sources of calcium include dairy products, broccoli, spinach, and dietary supplements.''

As discussed in greater detail in section III of this document, FDA has determined that the claim in the first sentence addresses the same relationship as provided for by an existing authorized health claim, specifically § 101.72 (21 CFR 101.72), ''Health claims: calcium and osteoporosis.'' The second sentence, ''Sources of calcium include dairy products, broccoli, spinach, 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) (21 U.S.C. 321(n) of the act. 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

A. Section 303 of FDAMA as it Relates to Existing Authorized Health Claims

The claim at issue in this rulemaking raises the question of the relationship of the notification process established in section 403(r)(3)(C) of the act to the health claims authorization process provided by section 403(r)(4) and (r)(3)(B). In particular, when FDA has issued a regulation under section 403(r)(3)(B) of the act that authorizes claims that characterize the relationship of a nutrient to a disease or health-related condition, may the notification process of section 403(r)(3)(C) be used to make a health claim about the same relationship, thereby effectively modifying the claims already authorized by regulation?

Section 403(r)(3)(C) of the act, as added by section 303 of FDAMA, provides that a health claim ''which is not authorized by the Secretary in a regulation promulgated in accordance with [section 403(r)(3)(B)], shall be authorized and may be made'' if the requirements of section 403(r)(3)(C) of the act are met. When discussing the effect of section 303 of FDAMA, the Senate Report states: ''Once FDA regulations governing health claims