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]

BILLING CODE 4160–01–F

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

concerning a particular diet/disease relationship (e.g., calcium and osteoporosis) have become effective, no claim concerning that diet/disease relationship based on the statement of an authoritative scientific body could be made unless it is consistent with the FDA regulation'' (S. Rept. 105–43, at 51 (1997)). Therefore, when a claim about the relationship between a nutrient and a disease or health-related condition is authorized by a regulation issued under section 403(r)(3)(B) of the act, section 403(r)(3)(C) does not authorize a claim about that relationship based on an authoritative statement. Accordingly, the authoritative statement notification process for health claims under section 403(r)(3)(C) of the act does not apply when there is an existing regulation issued under section 403(r)(3)(B) of the act that authorizes claims about the relationship between a nutrient and a disease or health-related condition. However, such a health claim can be made without prior notification provided it is consistent with the existing health claim regulation.

Because of the nature of the health claim regulations issued under section 403(r)(3)(B) of the act, a health claim that is ''consistent with'' such a regulation, whether based on an authoritative statement or not, is authorized by the regulation itself and may be used on an appropriate food or dietary supplement without prior notification to FDA. Manufacturers can make health claims that are consistent with an existing health claim regulation, and use of health claims that are inconsistent with an existing health claim regulation would misbrand the product.

FDA's health claim regulations specify: (1) The relationship between the nutrient and the disease (e.g., calcium and osteoporosis); (2) the significance of the nutrient (e.g., calcium) in reducing the risk of the disease (e.g., osteoporosis); (3) the requirements of the health claim (i.e., information that must be included in the health claim and information that must not be included in the health claim); (4) the nature of foods that are permitted to display the health claim on their labels; and (5) optional information that may be included in the health claim. The regulations specify the elements that a health claim must contain, the elements that it may contain, and the elements that it may not contain; however, they do not specify the exact words to be used in a claim. Accordingly, claims with different wording may be consistent with a health claim regulation provided they meet the requirements of the regulation.

For example, to be consistent with the currently existing regulations relating to calcium intake and reduced risk of osteoporosis, a potential health claim must meet all of the requirements in § 101.72. If a potential claim meets all of the requirements in § 101.72 (i.e., it includes all required information, and it does not include prohibited information), then the health claim is permitted on appropriate foods and dietary supplements as specified in § 101.72(c)(2)(ii), and prior notification about the health claim is not required to use it on an appropriate food or dietary supplement. If the requirements of § 101.72 are not met, the claim would not be consistent with FDA's regulations for calcium and osteoporosis health claims, and such a claim would misbrand any food or dietary supplement on which it appears.

Accordingly, section 303 of FDAMA does not provide for modification of an existing health claim regulation through submission under section 403(r)(3)(C) of the act of a notification for a health claim based on an authoritative statement by a scientific body. A party interested in amending an existing regulation may instead submit a citizen's petition in accordance with the provisions in 21 CFR 10.30.

B. The Prospective Health Claim is a Calcium–Osteoporosis Health Claim that is Not Authorized under Section 403(r)(3)(C) of the Act and is Not Consistent with the Existing Calcium–Osteoporosis Health Claim Authorized by § 101.72

The first sentence in the prospective health claim as submitted in the subject notification, ''Calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures,'' is a health claim relating to calcium intake and the bone disease, osteoporosis. The reference to the risk of fractures may relate to a number of bone diseases, but a review of the five statements identified in the notification as ''authoritative statements'' clarifies that the claim refers to the bone disease known as osteoporosis. As specified in § 101.72, the authorized health claim for calcium intake and the risk of osteoporosis is based on the importance of reducing fractures in older persons due to osteoporosis and on the importance of peak bone mass during critical developmental stages, notably adolescence.

Statement 1 in the notification includes three sentences, the first of which reads: ''Although the precise relationship of dietary calcium to osteoporosis has not been elucidated, it appears that higher intakes of dietary calcium could increase peak bone mass during adolescence and delay the onset of bone fractures later in life.'' The other two sentences state: ''Inadequate dietary calcium consumption in the first three to four decades of life may be associated with increased risk of osteoporosis in later life,'' and ''[e]vidence shows that chronically low calcium intake especially during adolescence and early adulthood, may compromise development of peak bone mass.'' These three sentences are excerpted from the Summary and Recommendations section of the 1988 Surgeon General's Report on Nutrition and Health. The Summary and Recommendations section of the report in which these sentences appear makes no mention of any other type of bone disease except osteoporosis. Moreover, FDA notes that it included the recommendations from the report in its own deliberations in authorizing the health claim related to the relationship between calcium and osteoporosis.

Statement 2 is from a Department of Health and Human Services's press release from 1997, and states: ''[S]ecretary Shalala noted that there is a 'window of opportunity' during adolescence to increase bone density through calcium intake. Bones grow and incorporate calcium most rapidly during the teen years, and establish approximately 90% of adult mass by age 17.'' The press release describes an educational program developed by a coalition of government, private sector, and medical groups. As stated in the press release, the education program ''is designed to help prevent the next generation from suffering the devastating consequences of osteoporosis by reaching teens with the message of the importance of consuming calcium during the teen years.'' The context of this statement therefore makes it clear that the statement is about reducing the risk for osteoporosis.

Statement 3 is from a 1997 press release from the National Academy of Sciences, and states: ''Calcium recommendations were set at levels associated with maximum retention of body calcium, since bones that are calcium rich are known to be less susceptible to fractures.'' FDA notes that the sentence that follows this statement reads: ''In addition to calcium consumption, other factors that are thought to affect bone retention of calcium and risk of osteoporosis include high rates of growth in children during specific periods, hormonal status, exercise, genetics, and other diet components.'' The context of this

statement therefore makes it clear that the statement is about risk of fractures due to osteoporosis.

Statement 4 is from a 1997 press release from one of the institutes of the National Institutes of Health, and states: ''Supplements of calcium and vitamin D can significantly reduce bone loss and the risk of fractures in older people, according to a new report from scientists at Tufts University.'' This statement is the first sentence of the press release. The second sentence reads: ''The research, the first to show these supplements can help older men fight osteoporosis, also demonstrates that the benefits of these low-cost and easily-available supplements can be maintained over several years.'' The context of this statement, therefore, makes it clear that the statement is about risk of fractures due to osteoporosis.

Statement 5 is from a 1991 FDA Consumer article, and states: ''Both women and men need enough calcium to build peak (maximum) bone mass during their early years of life. Low calcium intake appears to be one important factor in the development of osteoporosis.'' This statement is also clearly about osteoporosis.

Statements 1 and 5 explicitly refer to osteoporosis. Statements 2, 3, and 4 are adjacent to sentences that explicitly refer to osteoporosis, or, given their context, are about osteoporosis. Given that these statements are about osteoporosis, the agency concludes that this claim characterizes the relationship of calcium to osteoporosis.

Claims characterizing the relationship of calcium to osteoporosis are authorized under § 101.72, which was issued under section 403(r)(3)(B) of the act. As discussed in section III.A of this document, the prospective claim may be used only if it is consistent with the provisions of § 101.72, in which case it can be made on the label or labeling of appropriate foods and dietary supplements.

The prospective health claim, as stated, is not consistent with, and is therefore not authorized under, § 101.72. FDA reviewed the prospective health claim that was submitted with this notification—''Calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures''—and determined that at least one key element required by § 101.72 is not included in the claim. The submitted claim mischaracterizes the mechanism by which calcium consumption reduces the risk of osteoporosis. Although calcium consumption increases bone density in adolescents and young adults, in older adults it instead reduces bone loss (see § 101.72(a)). In addition, the term ''risk of fractures'' is synonymous with neither osteoperosis nor fractures related to osteoperosis. Accordingly, the claim is not authorized by § 101.72.

In summary, FDA is issuing this interim final rule to prohibit use under section 403(r)(3)(C) of the act of the claim, ''Calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures,'' because it addresses the same nutrient-disease relationship provided for in an existing health claim regulation (§ 101.72), and so its use cannot be authorized under section 403(r)(3)(C) of the act. The claim may be used if it is consistent with § 101.72, the regulation that authorizes use of a calcium-osteoporosis health claim, yet the agency finds that the claim is not consistent with § 101.72. Use of the prospective claim in the labeling of a product would, accordingly, misbrand the product.

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 prospective health claim that is the subject of this notification is a health claim about the relationship between calcium and osteoporosis. Because health claims about the relationship between calcium and osteoporosis are already authorized by regulation issued under section 403(r)(3)(B) of the act, FDA has determined that the prospective health claim is not subject to the authoritative statement procedure provided by section 403(r)(3)(C). 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 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.

A health claim relating to the association between calcium and osteoporosis is authorized under existing regulations. Accordingly, firms can make a claim about calcium and

osteoporosis provided that the food is eligible for the claim and the claim is consistent with the current regulations. The prospective claim relating to the relationship between calcium and bone disease, specifically, increased bone density and the risk of fractures, is not consistent with the existing claim, and would misbrand any food on which it is used. Because firms can highlight the relationship between calcium and osteoporosis, that this prospective claim would misbrand foods does not create any lost opportunities for firms. Therefore, this interim final rule results in neither costs nor 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 relating to the relationship between calcium and osteoporosis is authorized under existing regulations. 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 the 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. Reference

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. 98–16457 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–0424]

Food Labeling: Health Claims; Chromium and the Risk in Adults of Hyperglycemia and the Effects of Glucose Intolerance

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 chromium and the risk in adults of hyperglycemia and the effects of glucose intolerance. 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 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)), 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 fifth claim in the notification. The notification included three statements