

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

that the petitioner identified as authoritative statements on which the following claim is based: "In adults, chromium may reduce the risk of hyperglycemia and the effects of glucose intolerance. Sources of chromium include whole grains, brewer's yeast, cheese, 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 chromium and two diseases or health-related conditions, and thus reflects two prospective health claims. The second sentence, "Sources of chromium include whole grains, brewer's yeast, cheese, 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 section 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: "In adults, chromium may reduce the risk of hyperglycemia and the effects of glucose intolerance." The agency has determined that none of the three 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 three 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) Two statements from quarterly reports from the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS) from electronic versions provided on the Internet; and (2) one statement from a report issued by the U.S. Surgeon General. Thus, the statements in the notification are attributable to USDA's ARS or to the Surgeon General. FDA believes that USDA/ARS and the Surgeon General, who is housed within the U.S. Department of Health and Human Services (DHHS), are scientific bodies 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, none of the three statements discussed in sections III.A through C of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: "Chromium supplements—in two different formulations—lowered blood pressure in rats bred to spontaneously develop hypertension * * * the supplements, chromium picolinate and chromium nicotinate, also reduced the formation of damaging free radicals in the animals' tissues, indicating that chromium can act as an antioxidant * * * chromium is essential for insulin to operate efficiently and has been shown to reduce diabetic symptoms and restore glucose tolerance in studies of humans and animals." 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, 3d quarter 1997) issued by USDA's ARS and provided on the Internet ("http://www.ars.usda.gov/is/qtr/q397/hn397.htm" accessed on 11/26/97). *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:

"Chromium supplements—in two different formulations—lowered blood pressure in rats bred to spontaneously develop hypertension." The paragraph, which describes the nature and outcome of one ARS study and which refers to previous studies, is attributed to Richard A. Anderson of the Beltsville Human Nutrition Research Center, Beltsville, MD.

The agency notes that the statement focuses first on hypertension in rats, then on the formation of free radicals in rats. The third component of the statement suggests that chromium has an effect in reducing diabetic symptoms and restoration of glucose tolerance in humans as well as animals.

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). 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 of "Health Claims; Vitamins C and E," which is published elsewhere in this issue of the **Federal Register**.

B. Statement 2

Statement 2 reads: "In a 20-week ARS study, rats that daily consumed more than 2,000 times the estimated safe limit of chromium for people showed no sign of toxicity * * * [the findings] bring into question the relevance of a study done 2 years ago * * * that reported DNA damage."

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, 3d quarter 1997) (see discussion of statement 1 in section III.A of this document), which is issued by USDA's ARS and provided on the Internet ("http://www.ars.usda.gov/is/qtr/q397/hn397.htm" accessed on 11/26/97) in a description of research entitled: "There's good news for people concerned about the safety of taking chromium supplements." The paragraph describes the nature and outcome of one ARS study on rats and

is attributed to Richard A. Anderson of the Beltsville Human Nutrition Research Center.

FDA concludes that the statement focuses on levels of intake considered safe in rats and does not identify a relationship between a nutrient and a disease or health-related condition in humans, as described in section I.A.1 of "Health Claims; Vitamins C and E," which is published elsewhere in this issue of the **Federal Register**. Thus, this statement is not an "authoritative statement" under section 403(r)(3)(C) of the act because it is not about the relationship between a nutrient and a disease or health-related condition.

C. Statement 3

Statement 3 reads: "Scientists must often draw inferences about the relationships between dietary factors and disease from animal studies or human metabolic and population studies that approach issues indirectly." 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 a discussion on the nature of scientific evidence contained in "The Surgeon General's Report on Nutrition and Health—Summary and Recommendations" that was published by the Public Health Service (PHS) of DHHS (1988).

FDA concludes that the statement focuses on a general principle of scientific inference and is not about the relationship between a nutrient and a disease or health-related condition. Thus, this statement is not an "authoritative statement" under section 403(r)(3)(C) of the act.

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 chromium and the risk in adults of hyperglycemia and the effects of glucose intolerance 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 10.70 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, 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 chromium and the risk in adults of hyperglycemia and the effects of glucose intolerance 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 related to the association between chromium and the risk in adults of hyperglycemia and the effects of glucose intolerance 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 chromium and the risk in adults of hyperglycemia and the effects of glucose intolerance 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 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. 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. 98-16458 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-0419]

Food Labeling: Health Claims; Omega-3 Fatty Acids 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 omega-3 fatty acids 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 interim final 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 "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", which is published elsewhere in this issue of the **Federal Register**. 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 sixth 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, Omega-3 Fatty Acids may reduce the risk of cardiovascular disease. Sources of Omega-3 Fatty Acids include fish, seafood, flaxseed, soybeans, 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 Omega-3 Fatty Acids include fish, seafood, flaxseed, soybeans, and dietary supplements," is not a health claim. Given that the notification indicated that it was