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Guidance for Industry

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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U.S. Department of Health and Human Services
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
May 11, 1998

Guidance for Industry¹

Notifications of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

Prior to the Food and Drug Administration Modernization Act of 1997 (FDAMA), companies could not use a health claim or nutrient content claim in food labeling unless the Food and Drug Administration (FDA) published a regulation authorizing such a claim. Two new provisions of FDAMA (specifically sections 303 and 304 which amend, respectively, sections 403(r)(3) and 403(r)(2) (21 U.S.C. 343(r)(3) and (2)) of the Food, Drug, and Cosmetic Act, known as the Act) will now permit distributors and manufacturers to use claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences. These provisions are intended to expedite the process by which the scientific basis for such claims is established.

Since the passage of FDAMA, FDA has been reviewing both the statute and the accompanying legislative history in order to determine the most appropriate approach for implementing these new provisions. Due to the speed with which the FDAMA provisions became effective, the agency has decided to issue this guidance document during the initial phase of implementing these new provisions.

Submission procedures and use of a public docket for claims

Notifications should be submitted in duplicate to Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204. The notification should be clearly marked as "Notification for a Health Claim [or Nutrient Content Claim] Based on an Authoritative Statement." Whether notifications will be placed in a public docket upon receipt will be addressed in notice and comment rulemaking for an implementing regulation.

When a notification is received, FDA intends to review whether the notification includes the information necessary for the claim to be authorized under sections 303 and 304 of FDAMA. This may include, for example, a review for the submission of all the required elements and the identification of an appropriate statement from an appropriate scientific body (as identified below). The agency intends to notify the submitter by letter as soon as possible within the 120 days after submission when the notification does not comply with sections 303 and 304. When a notification does not meet the requirements of sections 303 and 304, the use of the claim is not authorized under FDAMA. The submitter may choose to revise the notification and resubmit it, in which case a food could not be marketed with the claim until at least 120 days after resubmission. As provided by FDAMA, FDA also may act to prohibit or modify a claim by regulation or a United States district court may find that the requirements of section 303 or 304 of FDAMA have not been met.

¹This guidance has been prepared by the Office of Food Labeling in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. This guidance represents the Agency's current thinking on the procedures for a firm to notify FDA of their intent to use a health claim or nutrient content claim based on an authoritative statement of a scientific body. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Scientific body

FDAMA permits claims based on current, published authoritative statements from “a scientific body of the United States with official responsibility for public health protection or research directly related to human nutrition . . . or the National Academy of Sciences (NAS) or any of its subdivisions.” The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) are federal government agencies specifically identified as scientific bodies by FDAMA.

FDA believes that other federal agencies may also qualify as appropriate sources for such authoritative statements. Along with NAS (or any of its subdivisions), the agency currently considers that the following federal scientific bodies may be sources of authoritative statements: the CDC, the NIH, and the Surgeon General within Department of Health and Human Services; and the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service within the Department of Agriculture.

Authoritative statement

FDA also believes it is necessary to clarify what constitutes an authoritative statement under FDAMA. FDAMA itself states that an authoritative statement: (1) is “about the relationship between a nutrient and a disease or health-related condition” for a health claim, or “identifies the nutrient level to which the claim refers” for a nutrient content claim, (2) is “published by the scientific body” (as identified above), (3) is “currently in effect,” and (4) “shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.”

In addition, given the legislative history of sections 303 and 304 of FDAMA, FDA currently believes authoritative statements also should: (5) reflect a consensus within the identified scientific body if published by a subdivision of one of the Federal scientific bodies, and (6) be based on a deliberative review by the scientific body of the scientific evidence.

Not all pronouncements by the designated scientific bodies would meet these criteria. For example, authoritative statements by the Surgeon General would normally be found only in the Surgeon General Reports.

FDA intends to consult, as appropriate, with the scientific body that is the source of a statement cited as the basis for a claim, as well as with the other federal scientific bodies that have public health responsibilities and expertise relative to the claim. The agency has already begun this liaison process.

Scientific standard with respect to health claims

FDAMA upholds the “significant scientific agreement” standard for health claims. This conclusion is based on FDAMA and its legislative history. FDAMA provides that FDA may issue a regulation under section 403(r)(3)(B)(i) of the Act to prohibit or modify a claim. Section 403(r)(3)(B)(i) permits FDA to promulgate regulations authorizing health claims only if FDA “determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”

Consistent with this provision, FDA intends to determine whether the standard of significant

scientific agreement is met by a health claim based on an authoritative statement. And consistent with earlier regulations, FDA does not believe this standard would allow for a claim based on, for example, findings characterized as preliminary results, statements that indicate research is inconclusive, or statements intended to guide future research.

Content of notification and other statutory requirements

FDAMA requires that a person must submit a notification of the claim at least 120 days before the first introduction into interstate commerce of the food with a label containing the claim. FDA notes that, as indicated by FDAMA, the notification is to include: (1) "the exact words used in the claim," (2) "a concise description of the basis upon which such person relied for determining that the requirements" for an authoritative statement "have been satisfied," (3) "a copy of the statement referred to . . . upon which such person relied in making the claim," and (4) for a health claim, "a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers," or, for a nutrient content claim, "a balanced representation of the scientific literature relating to the nutrient level to which the claim refers."

FDA expects that to provide a "balanced representation of the scientific literature," a bibliography of the scientific literature on the topic of the claim would be compiled. A brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement should be submitted.

FDAMA imposes several additional conditions on claims based on authoritative statements and the foods for which such claims are made. For example, FDAMA requires that such a claim be "stated in a manner so that the claim is an accurate representation of the authoritative statement referred to" and "so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

FDAMA requires, with respect to health claims, that the food for which such a claim is made not exceed the disqualifying amounts of nutrients that may increase the risk of a disease or health-related condition in the general population. FDAMA also requires, for example, that nutrient content claims use the terms already defined in regulations by the agency, in, e.g., Title 21, Code of Federal Regulations (CFR) sections 101.13 and 101.54. Finally, FDAMA requires that a claim based on an authoritative statement, with the food for which the claim is made, not be false or misleading in any particular.

Under FDAMA, persons submitting notifications must include "the exact words used in the claim." Submitted health claims should use the word "may" to characterize the relationship between the nutrient and the disease or health related condition so as to indicate that the disease or health-related condition is caused by many factors. Likewise, a claim for a health effect attributed to a single brand name product would be misleading. Foods bearing health claims based on authoritative statements should comply with the provisions of 21 CFR 101.14. These include, for example, requirements that the substance that is the subject of a claim is safe and lawful and that its level is sufficiently high and in an appropriate form to justify the claim.

A nutrient content claim based on an authoritative statement that uses terms the agency has defined, such as "good source" or "high," must, under FDAMA, refer to a nutrient level (i.e., a daily value) that is identified by the authoritative statement. In addition, foods bearing such nutrient content claims should comply with 21 CFR 101.13.

To ensure that compliance with all relevant regulations can be assessed, the FDA believes that information on analytical methodology for the nutrient that is the subject of a claim should be submitted as part of the notification, consistent with 21 CFR 101.69 and 21 CFR 101.70.

Dietary Supplements

Finally, FDA believes that there is need for further consideration concerning dietary supplements. FDAMA does not provide for health claims based on authoritative statements for dietary supplements. This is because FDAMA amended the section of the Act that deals with procedures and standards for health claims for conventional foods, but did not amend the section that deals with procedures and standards for health claims for dietary supplements. That is, section 403(r)(3) of the Act specifies the procedure and standard by which health claims may be made for conventional foods. Section 403(r)(5)(D) specifies that health claims with respect to dietary supplements shall not be subject to section 403(r)(3), but rather to a procedure and standard established by regulation by FDA. Section 303 of FDAMA amended section 403(r)(3) of the Act to allow for health claims based on authoritative statements, but did not address section 403(r)(5)(D).

The FDA intends to propose that health claims based on authoritative statements be permitted for dietary supplements.

In contrast, with respect to nutrient content claims, FDAMA amended section 403(r)(2) of the Act, which applies to both conventional foods and dietary supplements. Thus, dietary supplements may make nutrient content claims based upon authoritative statements in accordance with FDAMA and the applicable regulations for nutrient content claims, and the contents of this guidance document would apply.

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foreign air carriers may apply to the Department for a waiver or modification of the requirements contained in part 221 (Tariffs). An application processing fee for such waiver or modification is warranted since the applicant seeks the special benefit of the Department's approval for relief from provisions of the requirements regulating tariffs.

No applications under this schedule item were processed during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of \$12 per Application is retained.

Schedule Item 69. Application for provision of certified copies of tariff material upon request (with DOT seal). Section 389.15 of the regulations provides that certified copies of tariffs filed with the Department will be provided upon request. Certification of these data are required in civil cases in order for parties to formally submit air carrier tariff provisions involving charges and conditions of carriage in international air transportation officially filed with the Department. A fee for providing this service is warranted because of the special benefit to the applicant of having certified copies of officially filed tariff material for use in legal proceedings.

The basis of our proposed fee is as follows:

Direct Labor	\$807.58
Overhead	646.30
Total Cost	1,453.88
Applications processed	6
Cost per application	242.31
Proposed fee, Item 69: per application	240.00

Other Exemptions and Authorizations: Schedule Items 70-76

Schedule Item 70. Application for an exemption for slots at a slot-controlled airport. Under section 41714 of the Statute, an air carrier may apply to the Department for an exemption from 14 CFR Part 93, Subparts K and S (the High Density Rule), in order for the carrier to increase its number of operations (takeoff or landing "slots") at JFK, La Guardia, and/or O'Hare airports (Reagan National also is slot controlled, but is excluded from the exemption). Recognizing that air carriers may be restrained from entering markets as consequence of slot restrictions, the Congress provided the exemption mechanism as a way to increase air carrier access at three of the four slot-controlled airports. A processing fee for a slot exemption application is justified since the applicant is seeking the special benefit of the Department's

authorization enabling access to takeoff and landing rights that otherwise would not be available.

Our proposed fee for this item is based on the following:

Direct Labor	\$11,155.93
Overhead	6,211.62
Total Cost	17,367.55
Applications processed	4
Cost per application	4,341.89
Proposed fee, Item 70: per application	4,340.00

Schedule Item 71. Motion for confidential treatment of documents. Section 302.39 of the Department's Procedural Regulations sets forth the procedures that an applicant or other party must follow in seeking the Department's concurrence to withhold certain information from public disclosure in the context of a Departmental proceeding. A processing fee for this item is justified since the applicant is seeking the special benefit of the Department's approval to withhold sensitive information.

Our proposed fee for this item is determined as follows:

Direct Labor	\$499.57
Overhead	253.37
Total Cost	752.94
Applications processed	2
Cost per application	376.47
Proposed fee, Item 71: per application	380.00

Schedule Item 72. Application for approval of and antitrust immunity for inter-carrier agreements. Under sections 41308 and 41309 of the Statute, air carriers and foreign air carriers may seek approval of antitrust immunity for agreements and activities with common business objectives. Applicants seek the benefit of this immunity in order to protect themselves from lawsuits alleging behavior normally not permitted under the antitrust laws. A processing fee is warranted since the applicant is seeking the special benefit of the Department's approval of immunity from antitrust enforcement.

No applications under this schedule item were concluded during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of \$1,080 per Application is retained.

Schedule Item 73. [Reserved.]

Schedule Item 74. [Reserved.]

Schedule Item 75. Petition for a change in mail rates. Section 41901 of the Statute provides that the United States Postal Service or a certificated air carrier may file a petition with the

Department to change the mail rates set by the Department to be paid by the Postal Service to U.S. air carriers for the carriage of U.S. mail between the United States and foreign countries and/or within the State of Alaska. A fee for processing a petition is warranted since the petitioner is seeking the special benefit of the Department's approval to change existing mail rates.

No applications under this schedule item were processed during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of \$420 per Application is retained.

Schedule Item 76. Application for overseas military personnel charter operator authority. Under Part 372 of the Department's regulations, any U.S. citizen desiring to operate as an overseas military personnel charter operator may apply to the Department for operating authority. If granted this authority, the operator is relieved from provisions of section 41102 of the Statute for the purpose of enabling the operator to provide overseas military personnel charters utilizing aircraft chartered from direct air carriers or foreign air carriers. A processing fee is warranted since the applicant is seeking the special benefit of the Department's permission to advertise, organize, provide, sell and/or offer to sell overseas military personnel charters.

No applications under this schedule item were processed during the cost-collection period, nor has the Department had occasion to process any such applications for several years. Absent evidence of a cost change, the current fee of \$665 per Application is retained.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N-0826]

Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to permit the use on dietary supplements

of health claims based on authoritative statements under the notification procedures in the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and dietary supplements. FDAMA also permits health claims based on authoritative statements for conventional foods; however, FDAMA does not provide for the use of health claims based on authoritative statements for dietary supplements. FDA believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA.

DATES: Submit written comments on the proposed rule by April 6, 1999. Submit written comments on the information collection provisions by February 22, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Constance B. Henry, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION:

I. The FDA Modernization Act of 1997

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105-115), which amended the Federal Food, Drug, and Cosmetic Act (the act). Sections 303 and 304 of FDAMA amended section 403(r)(3) and (r)(2) of the act (21 U.S.C. 343(r)(3) and (r)(2)). Specifically, FDAMA added new section 403(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D), which provides for the use in food labeling of nutrient content claims and health claims based on authoritative statements. FDAMA requires that a notification of a prospective nutrient content claim or a prospective health claim be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce.

The notification must include specific information including: (1) The exact wording of the prospective nutrient

content claim or health claim; (2) a concise description of the basis upon which the petitioner relied for determining that the requirements of section 403(r)(2)(G)(i) of the act for nutrient content claims or section 403(r)(3)(C)(i) of the act for health claims have been satisfied; (3) a copy of the authoritative statement upon which the person relied in making the claim; and (4) a balanced representation of the scientific literature relating to the nutrient level for a prospective nutrient content claim or relating to the relationship between the nutrient and the disease or health-related condition for a prospective health claim. For a prospective nutrient content claim, the authoritative statement must identify the nutrient level to which the claim refers. For a prospective health claim, the authoritative statement must be a statement about the relationship between a nutrient and a disease or health-related condition to which the claim refers. For both types of claims, the authoritative statement must be currently in effect and it must have been published either by a scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition (e.g., the National Institutes of Health or the Centers for Disease Control and Prevention) or by the National Academy of Sciences or any of its subdivisions (hereinafter referred to as a "scientific body").

Under new section 403(r)(2)(H) and (r)(3)(D) of the act, such a claim may be made until: (1) FDA has issued an effective regulation that prohibits or modifies the claim; (2) FDA has issued a regulation finding that the requirements under section 403(r)(2)(G) of the act for a prospective nutrient content claim or under section 403(r)(3)(C) of the act for a prospective health claim have not been met; or (3) a District Court of the United States in an enforcement proceeding under chapter III of the act has determined that the requirements under section 403(r)(2)(G) of the act for a prospective nutrient content claim or under section 403(r)(3)(C) of the act for a prospective health claim have not been met. During the 120 days following submission of a notification and before the claim may appear on a food, the agency may notify any person who is making the claim that the notification did not include all of the required information.

Section 304 of FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and dietary supplements because section 304 amended section 403(r)(2) of the act,

which provides for nutrient content claims on both conventional foods and dietary supplements. Section 303 of FDAMA, however, does not provide for health claims for dietary supplements based on authoritative statements. In particular, section 403(r)(5)(D) of the act specifies that health claims for dietary supplements shall not be subject to section 403(r)(3) of the act, but rather to a procedure and standard that FDA establishes by regulation. In section 303 of FDAMA, Congress amended section 403(r)(3) of the act, which provides for procedures and standards for health claims for conventional foods, to allow for health claims based on authoritative statements for conventional foods, but Congress did not amend section 403(r)(5)(D) of the act. Therefore, FDA believes that section 403(r)(3)(C) of the act provides only for use of a health claim based on an authoritative statement on any conventional food that provides an appropriate level of the nutrient that is the subject of the health claim, but that does not exceed the disqualifying nutrient levels identified in § 101.14(a)(5) (21 CFR 101.14(a)(5)), provided that the food and the claim otherwise comply with section 403(r)(3)(C) of the act and all other provisions of the act.

II. The Proposal

FDA believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA. This approach is consistent with the agency's final rule that makes dietary supplements subject to the same general requirements that apply to conventional foods with respect to health claims (59 FR 395, January 4, 1994). This approach is also consistent with the guidance of the Commission on Dietary Supplement Labels. Although the commission did not discuss the provisions of FDAMA as enacted, it did state in its 1997 report (Ref. 1) that the process for the approval of health claims should remain the same for dietary supplements and conventional foods.

Therefore, FDA is proposing to add a new section to subpart E of part 101 (21 CFR part 101) to provide for the use of health claims based on authoritative statements on dietary supplements. The agency intends this rule to provide for the same process and standard for the use on dietary supplements of health claims based on authoritative statements as provided by section 403(r)(3)(C) of the act for conventional foods.

This proposed regulation tracks the language of FDAMA section 303 and it

would place dietary supplements on equal footing with conventional foods with respect to health claims. The agency notes that it has issued a document entitled "Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" (Internet "http://www.cfsan.fda.gov/~dms/guidance.html") (Ref. 2), as well as nine interim final rules in response to notifications of health claims based on authoritative statements (63 FR 34084, 34092, 34097, 34101, 34104, 34107, 34110, 34112, and 34115, June 22, 1998). FDA has received comments on the nine interim final rules, several of which take issue with the process and principles outlined in sections I.A and I.B of the "Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts" interim final rule (63 FR 34084 at 34085 through 34087). FDA will respond to those comments in proposing implementing regulations for sections 303 and 304 of FDAMA, and when it completes those nine rulemakings. At this time, however, FDA advises that the process and principles in the guidance and the nine interim final rules reflect the agency's current thinking with respect to implementation of sections 303 and 304 of FDAMA. The agency also advises that, in proposing regulations to implement sections 303 and 304 of FDAMA, it will provide further detail on how the notification procedures will be implemented with respect to the use of health claims based on authoritative statements on all foods. The agency expects that those implementing regulations would maintain the equal treatment intended by this proposal. Therefore, the agency expects to withdraw this regulation, if finalized, when that implementing regulation is issued because this regulation would then no longer be necessary.

III. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all 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). Executive Order 12866 classifies a rule

as 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 a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as "a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any 1 year." FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule is not a major rule for the purpose of congressional review.

In this rule, FDA is proposing to permit the use on dietary supplements of health claims based on authoritative statements under the notification procedures in FDAMA. The proposed rule potentially affects the entire dietary supplement industry.

There are several types of products that may be considered to be dietary supplements. These products include, but are not limited to, vitamin and mineral supplements, herbal products, and products that contain other similar nutritional substances. Estimates of the number of dietary supplements are approximate because no one source collects information on all types of dietary supplements. Some sources include only dietary supplements of vitamins and minerals, others include herbals or botanicals, and still others

include types of products that may or may not be dietary supplements, such as sports nutrition products and "functional foods," a term for which there is no definition. FDA tentatively estimates the number of dietary supplement products to be 29,000. FDA estimates the number of stockkeeping units, a count of the number of labels, to be approximately 75,000.

In its analysis of the proposed rule to establish regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (63 FR 23624 at 23628 and 23629, April 29, 1998), FDA estimated that approximately 850 firms manufacture dietary supplements. For purposes of determining the benefits and costs of this regulation, FDA will use 850 as an estimate of the number of dietary supplement firms.

Because the notification procedure established by FDAMA is voluntary, the only dietary supplement firms likely to take advantage of this procedure will be those firms who anticipate that private benefits will exceed private costs. Consequently, FDA will not attempt to estimate the internal benefits and costs for individual dietary supplement firms. Those firms who anticipate that the benefits will exceed the costs will make health claims based on authoritative statements. The number of health claim notifications submitted can, therefore, measure the effects of the proposed rule. Since the notification procedures for statements on dietary supplements were established in October 1997, FDA has received more than 3,000 notifications of nutritional support statements (structure-function claims). FDA believes that dietary supplement firms will continue to rely mainly on structure-function rather than health claims. FDA expects the number of health claim notifications to be a small fraction of the number of nutritional support statement notifications. Based on FDA's experience with health claims and with other similar notification procedures that fall under its jurisdiction, FDA has estimated that 12 firms per year may submit an average of 5 health claim notifications each, for a total of 60 notifications. The agency specifically invites comments on this estimate.

In addition to the benefits and costs internal to dietary supplement firms, FDA expects this proposed rule to generate benefits and costs to society. Most of the benefits from this proposed rule will come from the increased availability of the information provided by health claims. FDA cannot quantify those benefits. To the extent that the

lack of these claims has caused consumers to seek out the information from other sources, this rule will benefit consumers by reducing the cost of searching for information and by ensuring that the information provided to consumers is appropriate. The proposed rule will also impose additional costs on FDA and on the scientific bodies of the U.S. Government whose authoritative statements form the basis for the claims. FDA is unable to quantify those costs at this time, however.

B. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small businesses.

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification (SIC) codes. Dietary supplements fall into several codes, including Food Preparations Not Elsewhere Classified (SIC 2099), Industrial Inorganic Chemicals Not Elsewhere Classified (SIC 2819), Medicinal Chemicals and Botanical Products (SIC 2833), Pharmaceutical Preparations (SIC 2834), and Industrial Organic Chemicals Not Elsewhere Classified (SIC 2869). According to SBA size standards, dietary supplement firms are small entities if they have fewer than 500 employees in SIC codes 2099 and 2899, fewer than 750 employees in SIC codes 2833 and 2834, and fewer than 1,000 employees in SIC codes 2819 and 2969. Based on these standards, FDA has previously estimated that approximately 95 percent of dietary supplement manufacturers could be considered small under SBA size standards (63 FR 23624 at 23631).

As discussed earlier, FDA estimates that about 12 firms per year will submit health claims notifications based on authoritative statements. Because most businesses in the dietary supplement industry would be classified as small under SBA standards, FDA assumes that many businesses potentially affected by this proposed rule will be small. FDA,

therefore, concludes that the proposed rule will affect a substantial number of small entities. The proposed rule would, however, impose no involuntary costs and would benefit small businesses wishing to make health claims based on authoritative statements.

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives that would minimize the impact on small entities. FDA believes that the proposed rule will impose no involuntary burdens on small entities. Other regulatory options were nevertheless considered, including taking no new regulatory action and waiting until the implementing regulation for section 303 of FDAMA to propose that health claims based on authoritative statements be permitted for dietary supplements. FDA rejected the option of taking no new regulatory action because it would make conventional foods and dietary supplements subject to different standards for health claims. As stated previously in this document, the agency expects to withdraw this rule, if finalized, when the implementing regulation for section 303 of FDAMA is issued.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective upon publication in the **Federal Register**. Under section 553(e) of the Administrative Procedure Act (5 U.S.C. 553(e)) and FDA's procedural regulations at 21 CFR 10.40(c)(4)(i), the agency may make a final substantive rule effective immediately upon publication if the rule "grants or recognizes an exemption or relieves a restriction." If it becomes final, this rule would not place an affirmative requirement on anyone but rather would relieve a restriction on the dietary supplement industry. As more fully discussed previously, FDAMA makes the streamlined notification procedures for health claims available only to the conventional food industry. The agency is proposing to relieve this restriction in FDAMA to make health claims based on authoritative statements also available for use by the dietary supplement industry.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Notification Procedures for Dietary Supplement Health Claims Based on Authoritative Statements.

Description: This proposed rule would permit producers of dietary supplements to market a product whose label or labeling bears a health claim based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences, or any of its subdivisions, using the same process and standard established for conventional foods by the provisions of section 403(r)(3)(C) of the act. Under this proposed rule, a dietary supplement producer may use such a health claim in the labeling of an appropriate product 120 days after a complete notification of the claim is submitted to FDA, unless: (1) The agency has issued an effective regulation that prohibits or modifies the claim, (2) the agency has issued a regulation finding that the requirements of proposed § 101.90(a) have not been met, or (3) a Federal District Court in an enforcement proceeding under chapter III of the act (21 U.S.C. 301-310) has determined that the requirements of proposed § 101.90(a) have not been met. This proposed rule would prescribe the type of information that a dietary supplement producer must include in a notification that it would submit to the agency.

As noted previously, FDA recently announced the availability of a guidance on the submission of a notification of a nutrient content claim or health claim based on an authoritative statement of a

scientific body under the provisions of section 403(r)(2)(G) or (r)(3)(C) of the act. In estimating the annual reporting burden under this proposed rule, FDA

has assumed that submitters of notifications will follow that guidance. *Description of Respondents:* Persons and businesses, including small businesses.

TABLE 1.—Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours
101.90	12	5	60	40	2,400

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with health claims and with other similar notification procedures that fall under its jurisdiction. Because the claims are based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences, or any of its subdivisions, FDA believes that the information submitted with a notification will be either provided as part of the authoritative statement or readily available to anyone wishing to submit a notification.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send written comments regarding information collection by February 22, 1999, to the Office of Information and Regulatory Affairs, OMB (address above), Attn: Desk Officer for FDA.

VII. Comments

Interested persons may, on or before April 6, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

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. Commission on Dietary Supplement Labels, "Report of the Commission on Dietary Supplement Labels," p. vii, November 1997.

2. "Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim

Based on an Authoritative Statement of a Scientific Body," FDA, DHHS, June 11, 1998.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.90 is added to subpart F to read as follows:

§ 101.90 Notifications for health claims based on authoritative statements.

(a) A claim of the type described in § 101.14(a)(1) which is not authorized by the Food and Drug Administration (FDA) in a regulation found in this part shall be authorized and may be made with respect to a dietary supplement if:

(1) A scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(2) A person has submitted to FDA, at least 120 days (during which FDA may notify any person who is making a claim as authorized by paragraph (a) of this section that such person has not submitted all the information required by this paragraph) before the first introduction into interstate commerce of the dietary supplement with a label containing the claim:

(i) A notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of paragraph (a)(1) of this section have been satisfied;

(ii) A copy of the statement referred to in paragraph (a)(1) of this section upon which such person relied in making the claim; and

(iii) A balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(3) The claim and the dietary supplement for which the claim is made are in compliance with § 101.14(a)(5) and (e)(3) and are otherwise in compliance with sections 403(a) and 201(n) of the act (21 U.S.C. 343(a) and 21 U.S.C. 321(n)); and

(4) The claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in paragraph (a)(1) of this section and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet. For purposes of this paragraph, a statement shall be regarded as an authoritative statement of a scientific body described in paragraph (a)(1) of this section only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

(1) Such time as FDA issues a regulation under the standard in § 101.14(c);

(i) Prohibiting or modifying the claim and the regulation has become effective; or

(ii) Finding that the requirements of paragraph (a) of this section have not

been met, including finding that the petitioner has not submitted all the information required by such clause; or
 (2) A District Court of the United States in an enforcement proceeding under chapter III of the act (21 U.S.C. 301-310) has determined that the requirements of paragraph (a) of this section have not been met.

Dated: October 7, 1998.
William B. Schultz,
Deputy Commissioner for Policy.
 [FR Doc. 99-1365 Filed 1-20-99; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 98N-0970]

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its menstrual tampon labeling regulation to provide an absorbency term for tampons that absorb 15 to 18 grams (g) of fluid. The purpose of this proposed rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. FDA is issuing this proposed rule under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments on the proposed rule should be submitted by April 21, 1999. See section II of this document for the proposed effective date of a final rule based on this document. Written comments on the information collection requirements should be submitted by February 22, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION

CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of October 26, 1989 (54 FR 43766), FDA published a final rule which, among other things, amended its menstrual tampon labeling regulation to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: Less than 6, 6 to 9, 9 to 12, and 12 to 15 g of fluid. The final rule did not include corresponding terms of absorbency for 15 to 18 g nor the range above 18 g of fluid. Tampon manufacturers have asserted that many women with heavy menstrual flow need higher absorbency tampons to manage their heavy menstrual flow (see 54 FR 43766 at 43769).

FDA has consulted with the Center for Disease Control on this proposed rule. Tampons with absorbency up to 18 g have been marketed in other countries with very low Toxic Shock Syndrome (TSS) rates. FDA believes that the proposed rule will not materially increase the risk of TSS for women using tampons in accordance with the labeling.

Tampons are currently classified into class II (special controls) (see 21 CFR 884.5460 and 884.5470). Any person who is required to register under section 510 of the act (21 U.S.C. 360) and part 807 (21 CFR part 807) and who intends to begin the introduction or delivery for introduction into interstate commerce of a tampon for commercial distribution is required to submit a premarket notification to FDA at least 90 days before making such introduction or delivery in accordance with section 510(k) of the act and subpart E of part 807. Under § 807.87(e), a premarket notification for a device is to contain, among other things, labeling for the device. Because there is no uniform labeling term for tampons that absorb 15 to 18 g of fluid, the agency is now proposing that tampons that absorb 15 to 18 g of fluid be labeled as "ultra absorbency". The agency is specifically seeking comment on the term "ultra" for this absorbency range, and it invites suggestions of any alternative terms. At this time, FDA is not proposing a term describing tampons with absorbency above 18 g of fluid, and does not anticipate that tampons in the above 18 g absorbency range will be considered

for premarket clearance based on this proposed rule.

II. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule in the *Federal Register*.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (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.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all 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). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because manufacturers already are required to identify the absorbency ranges of their tampons, establishing a standardized term for tampons that absorb 15 to 18 g of fluid will impose no significant economic impact on any small entities. The agency therefore certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

3

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Ref 3

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 17 1998

MEMORANDUM TO: David Satcher, M.D., Ph.D., Surgeon General
Harold Varmus, M.D., Director, NIH
Claire V. Broome, M.D., Acting Director, CDC

Subject: Request for Designee to Assist FDA in Implementing the Authoritative Statements Provision of the FDA Modernization Act -- ACTION

I am writing to request that you designate a senior-level representative with expertise in human nutrition to assist the Food and Drug Administration (FDA) in implementing the authoritative statements provisions, related to health and nutrient content claims for foods, of the recently enacted Food and Drug Administration Modernization Act of 1997 (FDAMA).

Under current regulations, companies cannot use a health or nutrient content claim in food labeling unless FDA has published a regulation authorizing such a claim. FDA may authorize a health claim only when it determines, based on the totality of publicly available scientific evidence, that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Two new provisions of FDAMA will now permit manufacturers to use claims based on current published authoritative statements from federal scientific bodies without prior authorization from FDA. These statements can be used as a basis to make such claims 120 days after a firm submits a notice of the claim to FDA. Manufacturers may continue to make such claims in food labeling until FDA, by regulation, prohibits or modifies the claim or finds that the manufacturer has not complied with certain "authoritative statement" requirements of FDAMA, or until a United States district court makes such a finding. These provisions are intended to expedite the process by which the scientific basis for such claims is established.

An authoritative statement is described in the statute as a statement which is currently in effect about the relationship between a food substance/nutrient and a disease or health-related condition or identifies the nutrient level to which the claim refers. Such a statement must be published by an appropriate government scientific body (having official responsibility for public health protection or research relating directly to human nutrition) or by the National Academy of Sciences or its subdivisions. The statute identifies certain of these federal scientific bodies, including NIH and CDC within the Department. After reviewing the statute and legislative history, we have also preliminarily identified other government scientific bodies that fit this criteria, namely the Office of the Surgeon General and certain agencies within the Department of Agriculture (USDA); in particular, the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service. The final designation of what constitutes an appropriate scientific body in this context, as well as other issues, will be the subject of later rulemaking.

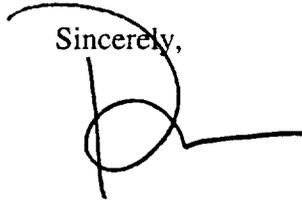
While the new FDAMA provisions may expedite the use of important public health information in food labeling, they also present the potential for inappropriate or unreliable information appearing on food labeling. Therefore, we believe it is important for FDA to establish mechanisms to enable prompt evaluation of claim notices submitted to the agency and to promote the development and use by federal scientific bodies of appropriate and consistent messages that may serve as authoritative statements.

The FDAMA provisions became effective at the end of February and FDA has already begun receiving notifications relative to nutrient content or health claims. In order to facilitate the process of reviewing food label claims that may be based on such authoritative statements, I believe it is critical to establish channels of communication between the FDA and the federal scientific agencies responsible for these statements. Toward this end, I ask that you designate a representative with expertise in human nutrition to provide information relevant to FDA's determination of: 1) whether the published statement referenced in the claim notification is an authoritative statement, and 2) whether, for a health claim, the statement represents significant scientific agreement. The designee will serve to speak for his or her agency relative to these issues.

The importance of this liaison effort cannot be over emphasized. I am, therefore, certain you will understand the value of a close collaboration with the FDA in this area and anticipate your full and timely support of these liaison activities.

Please provide the name and contact information for your designee directly to the FDA (contact Dr. Christine Lewis, phone 202-205-4434 or fax 202-205-5560). Please provide this information no later than a week from the date of this memorandum.

Sincerely,

A handwritten signature in black ink, appearing to be 'D. Shalala', with a long horizontal line extending to the right.

Donna E. Shalala

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Ref 4

MAR 17 1998

The Honorable Dan Glickman
Secretary of Agriculture
Washington, D.C. 20250

Dear Dan:

I am writing to request that you designate senior-level representatives with expertise in human nutrition to assist the Food and Drug Administration (FDA) in its implementing the authoritative statements provisions, related to health and nutrient content claims for foods, of the recently enacted Food and Drug Administration Modernization Act of 1997 (FDAMA).

Under current regulations, companies cannot use a health or nutrient content claim in food labeling unless FDA has published a regulation authorizing such a claim. FDA may authorize a health claim only when it determines, based on the totality of publicly available scientific evidence, that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Two new provisions of FDAMA will now permit manufacturers to use claims based on current published authoritative statements from federal scientific bodies without prior authorization from FDA. These statements can be used as a basis to make such claims 120 days after a firm submits a notice of the claim to FDA. Manufacturers may continue to make such claims in food labeling until FDA, by regulation, prohibits or modifies the claim or finds that the manufacturer has not complied with certain "authoritative statement" requirements of FDAMA, or until a United States district court makes such a finding. These provisions are intended to expedite the process by which the scientific basis for such claims is established.

An authoritative statement is described in the statute as a statement which is currently in effect about the relationship between a food substance/nutrient and a disease or health-related condition or identifies the nutrient level to which the claim refers. Such a statement must be published by an appropriate government scientific body (having official responsibility for public health protection or research relating directly to human nutrition) or by the National Academy of Sciences or its subdivisions. The statute identifies certain of these federal scientific bodies, including NIH and CDC within the Department. After reviewing the statute and legislative history, we have also preliminarily identified other government scientific bodies that fit this criteria, including certain agencies within the Department of Agriculture (USDA); in particular, the Food and Nutrition Service (FNS), the Food Safety and Inspection Service (FSIS), and the Agricultural Research Service (ARS). The final designation of what constitutes an appropriate scientific body in this context, as well as other issues, will be the subject of later rulemaking.

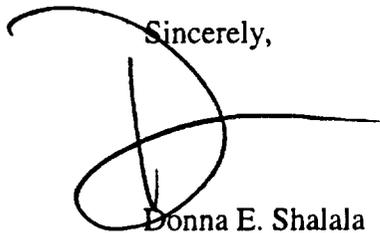
While the new FDAMA provisions may expedite the use of important public health information in food labeling, they also present the potential for inappropriate or unreliable information appearing on food labeling. Therefore, we believe it is important for FDA to establish mechanisms to enable prompt evaluation of claim notices submitted to the agency and to promote the development and use by federal scientific bodies of appropriate and consistent messages that may serve as authoritative statements.

The FDAMA provisions became effective at the end of February and FDA has already begun receiving notifications relative to nutrient content or health claims. In order to facilitate the process of reviewing food label claims that may be based on such authoritative statements, it is critical to establish channels of communication between the FDA and the federal scientific agencies responsible for these statements. Toward this end, I ask that you designate a representative from FNS, FSIS, and ARS with expertise in human nutrition to provide information relevant to FDA's determination of: 1) whether the published statement referenced in the claim notification is an authoritative statement, and 2) whether, for a health claim, the statement represents significant scientific agreement. The designees will serve to speak for their agencies relative to these issues.

I would like to ask that the name and contact information for your designees be provided directly to the FDA (contact Dr. Christine Lewis, phone 202-205-4434 or fax 202-205-5560) as soon as possible.

I look forward to a productive relationship between USDA and FDA in addressing these FDAMA provisions.

Sincerely,

A handwritten signature in black ink, appearing to be 'D. Shalala', with a long horizontal line extending to the right.

Donna E. Shalala

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EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W.

SUITE 600

WASHINGTON, D.C. 20036

PHONE: (202) 466-6937

FAX: (202) 466-6938

E-MAIL: WWW.EMORD.COM

Ref 5-

RECEIVED

98 FEB 23 AM 10:43

U.S. DEPARTMENT OF THE SECRETARY
COMMUNICATIONS
CONTROL CENTER

February 23, 1998

VIA UPS NEXT DAY AIR

Donna E. Shalala

Secretary

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Washington, D.C. 20201

Re: Submission in Compliance with 21 U.S.C. § 343(r)(3)(C)

Dear Secretary Shalala,

Weider Nutrition International, Inc.¹ by counsel and in accordance with 21 U.S.C. § 343(r)(3)(C), hereby submits an original and two copies of its notification at least one hundred and twenty days before the first introduction of its products into interstate commerce with the statements presented below. Weider Nutrition International, Inc. submits 1) the exact words of the claims it intends to use and concise descriptions of the basis upon which the requirements of § 343(r)(3)(C)(i) have been satisfied; 2) a copy of the statements referred to in § 343(r)(3)(C)(i) on which it relies and 3) a balanced representation of the scientific literature relating to the relationship between the nutrient and disease or health-related condition to which the claim refers.

HEALTH CLAIM

Antioxidant Vitamins C and E may reduce the risk in adults of atherosclerosis, coronary heart disease, certain cancers and cataracts. Sources of Vitamins C and E include fruits, vegetables, and dietary supplements.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that

¹ The address for Weider Nutrition International, Inc. is 2002 South 5070 West, Salt Lake City, UT 84104-6532.

describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

“Antioxidant micronutrients, especially carotenes, vitamin C, and vitamin E, appear to play many important roles in protecting the body against cancer. They block the formation of chemical carcinogens in the stomach, protect DNA and lipid membranes from oxidative damage, and enhance immune function.” Byers, Tim and Perry, Geraldine, Centers for Disease Control, Epidemiology Branch, Division of Nutrition, National Center for Chronic Disease Prevention and Health Promotion in “Dietary Carotenes, Vitamin C, and Vitamin E as Protective Antioxidants in Human Cancers,” *Annual Review of Nutrition*, 1992, Vol 12: 139-59 (Exhibit 1).

“[Antioxidants] may help prevent disease. Antioxidants fight harmful molecules called oxygen free radicals, which are created by the body as cells go about their normal business of producing energy . . . [S]ome studies show that antioxidants may help prevent heart disease, some cancers, cataracts, and other health problems that are more common as people get older.” *National Institute on Aging Age Page: Life Extension: Science or Science Fiction?* <http://www.aoa.dhhs.gov/lifextsn.html>. Administration on Aging, 1994 (Exhibit 2).

“The antioxidant nutrients found in plant foods (e.g. vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer and certain other chronic diseases.” *Nutrition and Your Health: Dietary Guidelines for Americans*, USDA and DHHS, Fourth Edition, 1995 (Exhibit 3).

“A diet high in fiber, high in antioxidants, and low in fat may play an important role in preventing the development of atherosclerosis, coronary heart disease, and some cancers.” *Health in Later Years*, Center for Disease Control, Office of Women’s Health. 1996. <http://www.cdc.gov/od/owh/whily.htm>² (Exhibit 4).

“[I]t is likely that certain antioxidants such as Vitamins C and E, may destroy the oxygen radicals, retard molecular damage, and perhaps slow the rate of aging.” *Ageing- Causes and Defenses*, National Institutes of Aging, Press Release. <http://www.nih.gov/nia/new/press/agingcau.htm>. See also, *The Annual Review of Medicine*, 1993, 44; 419-429, by George R. Martin Ph.D., David B. Danner, M.D., Ph.D., and Nikki J. Holbrook, Ph.D. (Exhibit 5).

² Vitamin E functions as an antioxidant in the body. 66.4% of vitamin E is obtained from fats and oils. An additional 11.5% comes from meats, poultry, fish, eggs, dairy products, sugars, sweeteners and miscellaneous foods. A total of 77.9% of the food sources for vitamin E are within the categories of foods that the Surgeon General has determined should be dramatically reduced by Americans. USDA and DHHS (PHS) *Nutrition Monitoring in the United States: An Update Report on Nutrition Monitoring, Sept 1989*. (Exhibit 7)

“Antioxidants are thought to help prevent heart attack, stroke and cancer.” Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 6).

SCIENTIFIC LITERATURE REVIEW

Vitamins C and E are antioxidants and protect the body at the cellular level. There is a vast body of evidence supporting the antioxidative properties of Vitamins C and E. The controversy among nutrition and public health figures surrounds the degree to which the nutrients are beneficial and how individuals should modify their intake of them. The evidence clearly supports the health claim that Vitamins C and E may reduce the risk of atherosclerosis, coronary heart disease, some cancers and cataracts in adults.

Riemersma, R.A., et. al., “Risk of angina pectoris and plasma concentrations of Vitamin A, C, and E and carotene,” *Lancet*. Jan. 1991, Vol. 337, No. 8732, 1-5. A case controlled study of 110 angina sufferers compared to 394 control middle aged men. Plasma concentrations of vitamins C and E and carotene were inversely related to the risk of angina. The ratio of risk indicates that populations with a high incidence of coronary heart disease may benefit from eating diets rich in natural antioxidants, particularly vitamin E. Due to the effect of processing and food preparation, supplementation may be needed to provide the level of nutrients required (Exhibit A).

Stephens, Nigel G., et. al. “ Randomized controlled trial of vitamin E in patients with coronary disease: Cambridge Heart Antioxidant Study (CHAOS),” *Lancet*. March 1996, Vol. 347, 781-786. Study of the effect of Vitamin E on patients with angiographically proven coronary atherosclerosis (n= 2002) to determine if there was an effect on the risk of subsequent heart attack. Vitamin E treatment significantly reduced the risk of non-fatal myocardial infarction (MI). Risk of deaths from a major cardiovascular event may also be reduced by Vitamin E; treatment, further study required (Double blind placebo study) (Exhibit B).

Meydani, Simin Nikbin, et. al., “Vitamin E supplementation enhances cell-mediated immunity in healthy elderly subjects,” *Am J Clin Nutr*, 1990, Vol. 52, 557-63. Study of healthy older adults (n=32) to determine the effect of supplemental Vitamin E on the immune response. The study demonstrated a beneficial effect of short term (30-Day) supplemental Vitamin E by improving immune response on several indices including increased T-cells. The short-term immunostimulatory effect corroborates other studies (Double blind study) (Exhibit C).

Contrary findings were reported by Heinonen, O.P., et al., “The effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and other Cancers in Male Smokers,” *New Eng J Med*, April 1994, Vol. 330, No. 15, 1029-1035. That study examined the effects of vitamin E and beta-carotene on older Finnish male smokers and the results wouldn't apply to non-smokers, women and younger individuals. The study failed to

account for the confounding factors of high alcohol consumption (known to interfere with the antioxidative mechanisms) and other factors (Exhibit D).

The deficiencies of the Heinonen study are underscored by the results of another Finnish study of 4,438 men aged 20-69 years. The protective qualities of the antioxidants were demonstrated by the significant inverse relationship between the intake of antioxidants and the incidence of lung cancer. The inverse association was strongest among non-smokers. Knekt, Paul, et al., "Dietary Antioxidants and the Risk of Lung Cancer," *Am J Epidemiology*, 1991, Vol. 134, No. 5, 471- 479 (Exhibit E).

Taylor, Allen, et. al., "Relations among aging, antioxidant status, and cataract," *Am J Clin Nutr*, 1995 (suppl) 1439S-1447S (Exhibit F). Literature review of clinical trials and double blind intervention studies identified that:

- Increased levels of Vitamin C appear to reduce the risk of cataracts. In addition, Vitamin C supplements are more effective than increasing the intake of foods well in excess of RDA's.
- Inverse relationships noted between Vitamin E levels and the incidence of cataracts. Review of literature and Roberson and Jacques' studies found that supplements are more effective than food sources. Inconsistent findings are from studies that failed to account for major confounding factors.
- Preliminary evidence suggests that there is a lower prevalence of cataracts with higher levels of beta-carotenes (lutein, alpha carotene, lycopene, and zeaxanthin) The evidence was inconclusive as to the effect of carotenoids.

HEALTH CLAIM

Antioxidant Vitamin A and beta-carotene may reduce the risk in adults of atherosclerosis, coronary heart disease and certain cancers. Sources of Vitamin A and beta-carotene include red, yellow and green leafy vegetables, dairy products, and dietary supplements.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

"Beta-carotene and other pro-vitamin A carotenoids can be converted to vitamin A in the body. Interest in the carotenoids has increased in recent years because of the accumulation of a large body of evidence that foods high in carotenoids are protective against a variety of epithelial cancers. USDA and DHHS (PHS) *Nutrition Monitoring in the United States: An Update Report on Nutrition Monitoring*, Sept 1989, 56 (Exhibit 7).

“The antioxidant nutrients found in plant foods (e.g. vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer and certain other chronic diseases.” *Nutrition and Your Health: Dietary Guidelines for Americans*, USDA and DHHS, Fourth Edition, 1995. (Exhibit 8)

“If the findings hold up in further research, eating more vegetables rich in beta carotene and related carotenoids – lutein and lycopene – may help people ward off a cold or flu as well as protect from cancer . . . The findings also suggest that carotenoid-rich vegetables also stimulate the immune system.” *Daily servings of dark green and deep yellow vegetables and tomatoes boost immune response, a preliminary study suggests*. Human Nutrition, Agriculture Research Service (a division of USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 9).

“This research involving human cells provides data which supports the general hypothesis that beta carotene and lutein protect cells by serving as antioxidants.” *Beta-Carotene and Lutein protect the plasma membrane of HEPG2 human liver cells against oxidant-induced damage*. Agriculture Research Service Tektran, Report Number 69264, March 21, 1996 (Exhibit 10).

“[Antioxidants] may help prevent disease. Antioxidants fight harmful molecules called oxygen free radicals, which are created by the body as cells go about their normal business of producing energy . . . [S]ome studies show that antioxidants may help prevent heart disease, some cancers, cataracts, and other health problems that are more common as people get older.” *National Institute on Aging Age Page: Life Extension: Science or Science Fiction?* <http://www.aoa.dhhs.gov/lifextsn.html>, Administration on Aging, 1994 (Exhibit 2).

“As potent antioxidants, [lutein and lycopene] are thought to contribute to the lower rates of heart disease, cancer and other diseases of aging among populations that eat a lot of fruits and vegetables.” *Carotenoids Show Their Real Colors*. USDA’s BHNRG Success stories, P.2, as modified June 30, 1997 (Exhibit 11).

“Researchers also found more evidence suggesting that carotenes act as antioxidants to protect the body from harmful oxidation. Antioxidants are thought to help prevent heart attack, stroke and cancer. During the low-carotene stints, researchers recorded several biochemical signs of oxidative damage.” *Do carotenoids—the bright red, yellow and orange pigments in fruits and vegetables—warrant a Recommended Dietary Allowance?* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 12).

“[H]igh dietary carotene and possibly vitamins C and E and folate are associated with reduced risk for cervical cancer.” *Prevention of Cervical Cancer*, National Cancer Institute, PDQ Detection and Prevention, July 1997 (Exhibit 13).

“[B]eta carotene or vitamin A supplements have reversed pre-cancerous conditions in people’s mouths.” *A daily dose of blue-green algae Spirulina may help prevent cancer of the mouth, a study shows.* Human Nutrition, Agriculture Research Service (a division of USDA), Quarterly Report, 3rd Quarter of 1995 (Exhibit 14).

“Carotenoids or other plant components appear to boost the immune system.” *Consumption of carotenoid-rich vegetables increases T-Lymphocyte proliferation and plasma levels of carotenoid oxidation products.* Agriculture Research Service Tektran, Report Number 74185, August 27, 1996 (Exhibit 15).

“A wealth of epidemiological evidence has linked a high intake of green leafy and deep yellow vegetables – both rich in beta carotene—with lower rates of many types of cancer . . . Men over 65 who took a 50-milligram beta carotene supplement every other day during the 12-year study had natural killer cells that were more active than their counterparts who got a placebo. Natural killer cells – or NK cells—are the immune system’s sentinels, ever on watch for viruses and cancer cells.” *Older people who get plenty of beta carotene may have a better chance of preventing virus infections or a cancerous growth.* Human Nutrition, Agriculture Research Service (a division of USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 16).

SCIENTIFIC LITERATURE

Vitamin A and beta-carotenes are antioxidants and protect the body at the cellular level. There is a vast body of evidence supporting the antioxidative properties of Vitamin A and beta-carotenes. The controversy among nutrition and public health figures surrounds the degree to which the nutrients are beneficial and how individuals should modify their intake of them. The evidence clearly supports the health claim that Vitamin A and beta-carotenes may reduce the risk of atherosclerosis, coronary heart disease, and some cancers in adults.

The Agricultural Research Service of the USDA interpreted the study and findings of Clevidence, Beverly, et. al., *Consumption of Carotenoid-Rich Vegetables Increases T-Lymphocyte Proliferation and Plasma Levels of Carotenoid Oxidation Products*” (ARS Report 74185, 1996) (Exhibit G) stating:

“Cancer, cardiovascular disease, and age-related macular degeneration are less common in people who eat diets rich in fruits and vegetable. Many scientist[s] believe that carotenoids (the prominent yellow, orange and red pigments in plant foods) are among the plant components providing protection. We studied 12 men and women who ate 5 servings of carotenoid-rich vegetables a day for three weeks... The vegetables (sweet potato, kale, tomato juice) provided three major carotenoids - - beta-carotene, lutein, and lycopene, respectively. The level of total carotenoids was increased about 6 fold over levels typically consumed in the Americana diet. Levels of all three carotenoids increased in subjects’ plasma and

in their colon cells. Immune status, measured as the ability of T-lymphocytes to proliferate when challenged was improved during the time of treatment. This effect remained for three weeks after the treatment ended suggesting prolonged benefit. However, the carotenoid-rich vegetables did not protect DNA and plasma lipids from normal, oxidative processes. We conclude that carotenoids from common vegetables are absorbed and incorporated into tissues. Carotenoids or other plant components appear to boost the immune system. This information will be useful to consumers, plant scientists, and nutritionists interested in promoting health through diet.”

The Agricultural Research Service of the USDA also interpreted the study and findings of Keith, Martin R., et. al., “Beta-Carotene and Lutein Protect the Plasma membrane of HEPG2 Human Liver Cells against Oxidant-Induced Damage” (ARS Report 69264, 1996) (Exhibit H) stating :

The results support the concept that both B[eta]-C[arotene] and lut[ein] protect human cells against damage. In some of the tests, the carotenoids were as effective as the reference substance, vitamin E (alpha-tocopherol), which is widely recognized as an effective cell protector antioxidant. The results also demonstrated that the protective effect of B[eta] C[arotene] and lutein was not due to being converted to vitamin A ... since lut[ein] (unlike B[eta] C[arotene]) has no such potential. Thus, this research involving human cells provides data which supports the general hypothesis that B[eta] C[arotene] and lut[ein] protect the cells by serving as antioxidants. These findings will benefit other scientists working in the area.

Contrary findings were reported by Heinonen, O.P., et al., “The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers,” *New Eng J Med*, April 1994, Vol. 330, No. 15, 1029-1035. That study examined the effects of anti-oxidants on older Finnish male smokers and the results wouldn't apply to non-smokers, women and younger individuals. (See *FDA Release t-94-20, April 13, 1994*). The study failed to account for the confounding factors of high alcohol consumption (known to interfere with the antioxidative mechanisms) and other factors. (Exhibit D)

The deficiencies of the Heinonen study are underscored by the results of another Finnish study of 4,438 men aged 20-69 years. The protective qualities of the antioxidant vitamins C and E, and carotenoids were demonstrated by the significant inverse relationship between the intake of antioxidants and the incidence of lung cancer. The inverse association was strongest among non-smokers. Knekt, Paul, et al., “Dietary Antioxidants and the Risk of Lung Cancer,” *Am J Epidemiology*, 1991, Vol. 134, No. 5, 471- 479. (Cohort 20-year longitudinal study) (Exhibit E)

HEALTH CLAIM

B-Complex Vitamins - Folic Acid, Vitamin B₆, Vitamin B₁₂-- 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.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

“A research team’s new evidence confirms earlier data that elevated blood 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 B₆ contribute to increased risk of artery narrowing. Like a see-saw, homocysteine levels go up as the vitamins go down, and vice versa.” *Eating green vegetables, citrus and other foods rich in folate (folic acid) may help keep the arteries open, reducing heart disease and stroke risks.* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 1st Quarter of 1995 (Exhibit 17).

“When people don’t have enough of these [vitamin B₁₂ and folate] vitamins to metabolize homocysteine it accumulates in the blood and damages the vessels.” *One or two alcoholic drinks a day can interfere with people’s B vitamin levels, according to a study of 41 men and women.* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 18).

“[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.” *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.* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 4th Quarter of 1996 (Exhibit 19).

“Research has linked high homocysteine levels to increased risk of heart disease and stroke.” *Measuring blood levels of the amino acid homocysteine only after an overnight fast could miss nearly half of the people with elevated levels.* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 3rd Quarter of

1995. (In determining that two measurements are needed, the USDA indicated that people with high homocysteine levels were deficient in folate, vitamin B₁₂, and vitamin B₆) (Exhibit 20).

SCIENTIFIC LITERATURE

Elevated homocysteine levels are strongly implicated in cardiovascular disease. High levels of homocysteines cause vascular changes that have profound effects on an individual's health. Proper intake of Folic Acid, Vitamin B₆, Vitamin B₁₂ can reduce homocysteine levels. The scientific evidence supports the health claim that B-Complex Vitamins - Folic Acid, Vitamin B₆, Vitamin B₁₂-- may reduce the risk in adults of cardiovascular disease by lowering elevated serum homocysteine levels, one of the many factors implicated in that disease.

Dalrey, Karl, et. al., "Homocysteine and Coronary Artery Disease in French Canadian Subjects: Relation with Vitamins B₁₂, B₆, Pyridoxal Phosphate, and Folate," *Am J Cardiology* June 1995, Vol. 75, 1107-1111. The study involved male and female adults (n=734) between the ages of 20 and 59 years. The study examined the homocysteine levels in patients with premature coronary artery disease (CAD) compared to a group of healthy subjects and determined the relation among the plasma levels of vitamins B₁₂ and B₆, folic acid, and homocysteine. The results confirmed earlier findings that homocysteine is an independent risk factor for CAD. The study showed a significant difference in the levels of vitamin B₆ derivative pyridoxal phosphate between the two groups with pyridoxal phosphate being higher in the healthy patients than in those with CAD. There was a strong inverse association between the levels of pyridoxal phosphate and homocysteine, especially in men. A significant number of patients with high homocysteine levels had lower folate levels than those with normal homocysteine levels (Controlled Case Study) (Exhibit I).

USDA Human Nutrition Research Center on Aging, Boston, Andrew, et. al., "High dose B-vitamin treatment of hyperhomocysteinemia in dialysis patients," *Kidney International*, January 1996, Vol. 49, 147-152. This study of maintenance dialysis patients demonstrated that higher than physiologic dose supplementation of vitamins B₁₂, and B₆ and folic acid significantly increased the lowering of homocysteines. (The control group in this study had higher vitamin B₁₂ and B₆ and folic acid levels than would be found in a general population) (Double blind placebo study) (Exhibit J).

Selhub, Jacob, et. al., "Relationship between Plasma Homocysteine, Vitamin Status and Extracranial Carotid-Artery Stenosis in the Framingham Study Population," *J of Nutrition*, Vol. 126, 1258S-1265S. This cohort study of Framingham subjects (n=1041) demonstrated that homocysteine exhibited a strong inverse association with plasma folate. Inverse associations were also exhibited between homocysteine and intake of vitamin B₆ and folate. The study further demonstrated the inverse association between folate intake and the incidence of carotid artery stenosis (Longitudinal and Case Controlled Cohort Study) (Exhibit K).

Herzlich, Barry B., et. al., "Relationship among Homocyst(e)ine, Vitamin B-12 and Cardiac Disease in the Elderly: Association between Vitamin B-12 Deficiency and Decreased Left Ventricular Ejection Fraction," *J of Nutrition*, Vol. 126, 1249S-1253S. The complicated interaction between homocysteine levels and coronary health is further demonstrated in this study of older adults undergoing angiography (n=367). Results revealed an association between Vitamin B₁₂ deficiency and decreased left ventricular ejection fractions (Case Controlled Study) (Exhibit L).

HEALTH CLAIM

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.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

"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." "Inadequate dietary calcium consumption in the first three to four decades of life may be associated with increased risk of osteoporosis in later life." "Evidence shows that chronically low calcium intake especially during adolescence and early adulthood, may compromise development of peak bone mass." *The Surgeon General's Report on NUTRITION AND HEALTH Summary and Recommendations*, 1988, U.S. Department of Health and Human Services, Public Health Service, DHHS (PHS) Publication No. 88-50211 (Exhibit 21).

"[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." *Secretary Shalala Announces Partnership to Increase Teen Calcium Consumption*, NICHD, Press Release, November 12, 1997 (Exhibit 22).

"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." *News Report Recasts Dietary Requirements for Calcium and Related Nutrients*. National Academy of Science, Institute of Medicine News, August 13, 1997 (Exhibit 23).

“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.” *Calcium, Vitamin D Combo Reduces Bone Loss, Fracture Rate for Older People.* National Institute of Aging, Press Release, September 3, 1997 (Exhibit 24).

“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.” *Women and Nutrition: A Menu of Special Needs.* FDA, in FDA Consumer, January-February 1991 issue (Exhibit 25).

SCIENTIFIC LITERATURE

Most authorities promote the important role that calcium plays in maintaining bone density and the prevention of osteoporosis. Scientific evidence demonstrates that as a direct consequence of this mechanism and process, proper calcium intake at each stage of one’s life can reduce the risk of future fractures. The literature clearly supports the health claim that calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures.

Dawson-Hughes, Bess, et. al., “Effect of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years Old or Older,” *New England J of Med*, September, 1997, Vol. 10, 670-676. This study sponsored by and conducted through the U.S. Department of Agriculture Human Nutrition Research Center on Aging. The results of the study indicate that in older adults, both male and female (n=389), the rate of fractures is significantly reduced in the individuals receiving calcium and vitamin D supplements. This reduction in risk of fractures is attributed to an increase in, and maintenance of, bone mineral density. The study was conducted over a three-year period and the benefits of mineral supplementation may be even greater over the long term (Double Blind placebo study) (Exhibit M). See also Dawson-Hughes, Bess, “*Calcium and Vitamin D Nutritional needs of Elderly Women*, *J of Nutrition*, April 1996, Vol. 126, 1165S-1167S.

Cumming, R.G. and Nevit, M.C., “Calcium for prevention of osteoporotic fractures in postmenopausal women,” *J of Bone and Mineral Research*, Sep. 1997, Vol. 12, No. 9, 1321-9. The authors conducted a systematic, meta-analytical review of studies performed during the years of 1996-1997. The investigators focused the analysis on those studies with “fracture” outcomes. Pooling of all study results lead the authors to conclude that the data supports the clinical and public health policy of “recommending increased calcium intake among older women for fracture prevention” (Exhibit N). See also Lindsey, Robert, “*Prevention and treatment of osteoporosis*, *Lancet*, March 27, 1993, Vol. 341, No. 8848, 801-805; Myer, H.E., et. al., “*Dietary factors and the incidence of hip-fractures in middle-aged Norwegians. A Prospective Study*,” *Am J of Epidemiology*, Jan 1997, Vol. 145, No. 2, 117-123; and Looker, A.C., et. al., “*Dietary*

calcium and hip fracture risk: the NHANES I Epidemiological Follow-Up Study,”
Osteoporosis Internat’l (Exhibit AA).

HEALTH CLAIM

In adults chromium may decrease the risk of hyperglycemia and the effects of glucose intolerance. Sources of chromium include whole grains, brewer’s yeast, cheese, and dietary supplements.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

“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.” Human Nutrition, Agriculture Research Service (a division of USDA), Quarterly Report, 3rd Quarter of 1997 (Exhibit 26).

“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 signs of toxicity.” “[The findings] bring into question the relevance of a study done 2 years ago . . . that reported DNA damage.” *There’s good news for people concerned about the safety of taking chromium supplements.* Human Nutrition, Agriculture Research Service (a division of USDA), Quarterly Report, 3rd Quarter of 1997 (Exhibit 27).

(In 1988, *The Surgeon General’s Report on NUTRITION AND HEALTH Summary and Recommendations* stated that “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”) (Exhibit 21).

SCIENTIFIC LITERATURE

Chromium is a trace mineral integral to proper glucose metabolism. All individuals must have sustained proper levels of this nutrient. However, as individuals age, the risks of diabetes and other forms of glucose intolerance increase. It is especially important for adults to maintain adequate levels of chromium to counteract those increased risks of aging. The scientific

literature supports the health claim that in adults chromium may decrease the risk of hyperglycemia and the effects of glucose intolerance.

Anderson, Richard A., et. al., "Elevated Intakes of Supplemental Chromium Improve Glucose and Insulin Variables in Individuals with Type 2 Diabetes," *Diabetes* Vol. 16, November 1997, 1786-1791. This USDA sponsored study examined adults with Type II Diabetes Mellitus (n=180) and the impact chromium supplements had in the control of diabetes. The study demonstrated that the presence of chromium in a usable form potentiates the action of insulin. The levels of chromium required to obtain results are higher than would be found in a normal diet. Supplemental chromium leads to increased insulin binding to cells. The effect is not only on insulin but also on glucose metabolism. The overall effect of chromium is to increase insulin sensitivity, which is associated with decreased glucose intolerance, decreased risk factors associated with cardiovascular disease, improved immunity, and increased life span (Double Blind Study) (Exhibit O).

Dr. Anderson and the researchers at the USDA's Human Nutrition Research Center in Beltsville, MD have conducted numerous studies that confirm these findings. The studies were case controlled and double blinded in humans as well as animals. William Cefalu, M.D. and the team of researchers at the Diabetes Comprehensive Care and Research Program of Wake Forest University found that supplemental chromium reduced insulin resistance by as much as forty percent. That was the finding of a double blind, placebo study of twenty-nine adults who were deemed "at risk" for diabetes by their overweight status and positive family history. The study was reviewed and praised by Dr. Anderson of the USDA (Exhibit P).

USDA Human Nutrition Research Center, Walter Mertz, "Confirmation: Chromium Levels in Serum, Hair, and Sweat Decline with Age," *Nutrition Reviews*, October 1997, Vol. 55, N. 10, 373-375. Critical review of Davis, S., et. al., "Age related decreases in chromium levels in 51,665 hair, sweat, and serum samples from 40,872 patients: implications for the prevention of cardiovascular disease and type II diabetes mellitus," *Metabolism*, 1997, v. 46, 469-73. The research was gathered not from "an ideal, healthy population but a more realistic mixture of people who sought medical advice for prevention or therapy." The study demonstrated a significant negative correlation between age and chromium concentrations in all three tissues studied. According to Dr. Mertz of the USDA, "this is the first study using reliable analytical methods in a very large number of subjects to demonstrate a marked, continuous decline of chromium in three tissues." The study's authors postulate that a cause of the decline is "poor nutrition, especially excessive consumption of refined carbohydrates³" and Dr. Mertz confirmed that that opinion is consistent with other studies. Other causes need to be investigated to determine why a large population of a country without severe malnutrition uniformly developed a deficiency (Exhibit Q).

³ Milling and refining of grains removes more than 80% of chromium, none of which is replaced during the enrichment process.

HEALTH CLAIM

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.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

“Intake of particular polyunsaturated fats, the omega-3 fatty acids, may offer some protection against the development of clinical manifestations of atherosclerosis by decreasing platelet aggregation and clotting activity and preventing arterial thrombosis.” USDA and DHHS (PHS) *Nutrition Monitoring in the United States: An Update Report on Nutrition Monitoring*, Sept 1989, 96 (Exhibit 7).

In new soybean oil varieties developed by the USDA’s Agriculture Research Service “palmitic acid is replaced with oleic acid, which has some health benefits. In addition, omega-3 and omega-6 fatty acids, which can actually lower cholesterol levels, are at 7 and 60 percent respectively—essentially the same as regular soybeans.” *New Soybeans Have Saturated Fat, Keep Nutrition*. ARS Press Release, November 26, 1996 (Exhibit 28).

SCIENTIFIC LITERATURE

High serum lipids are strongly implicated in cardiovascular diseases. Omega-3 fatty acid reduces serum levels of the offending lipids. The scientific evidence overwhelmingly supports the health claim that in adults Omega –3 Fatty Acids may reduce the risk of cardiovascular disease.

Layne, Kim S., et al “Normal Subjects Consuming Physiological levels of 18:3 (n-3) and 20:5 (n-3) from Flaxseed or Fish Oils Have Characteristic Differences in Plasma Lipid and Lipoprotein Fatty Acid Levels,” *J of Nutrition*. (1996), 2130-2140. In healthy adults (n=37) high doses of fish oil for three months resulted in a significant lowering of total cholesterol and triglycerides. At lower levels, fish oil demonstrated a significant decrease in triglycerides, an insignificant effect on cholesterol, and an inconclusive effect on lipoprotein (Double blind study) (Exhibit R).

Adler, Adam J., and Holub, Bruce J., “Effect of garlic and fish-oil supplementation on serum lipid and lipoprotein concentrations in hypercholesterolemic men.” *Am J Clin Nutr*. (1997) 65:445-50. In men with cholesterol levels greater than 200mg/dL (n=46) fish oil alone demonstrated a decrease in triglycerides. When fish oil (combined EPA

and DHA fatty acids) combined with garlic, a decrease in triglycerides, lipids and LDL's were demonstrated. There were significant improvements in the LDL to HDL ratios and the total cholesterol to HDL ratios (Double blind placebo study) (Exhibit S).

Blonk, Marion C., et. al., "Dose Response effects of fish oil supplementation in healthy volunteers," *Am J Clin Nutr*. In healthy adults (n=45) normal and low doses of fish oil (combined DHA and EPA fatty acids) resulted in decrease of serum triglycerides. However, to obtain significant changes in phospholipid and lipoprotein ratio patterns much higher doses are required. The potential benefits of those higher doses may be outweighed by risks attached to them (Randomized Controlled Study) (Exhibit T).

These studies confirmed results of earlier studies by Bang (1976), Sanders (1981), Von Lossonczy (1978), Phillipson (1985).

Adults suffering from hyperlipidemia or hypercholesteremia would benefit from the supplementation of their diet with fish oil. Caution is recommended when prescribing the same therapy to diabetics. The non-diabetic would not be at risk of harm from slight rises in serum glucose but DM sufferers cannot tolerate the unknown and unpredictable minor glucose fluctuations. (See Axelrod, Lloyd "Omega-3 Fatty Acids in Diabetes Mellitus: A Gift from the Sea?" *Diabetes*, vol. 38, May 1989, 539-543) (Exhibit U)

HEALTH CLAIM

In adults garlic may reduce serum cholesterol and the risk of cardiovascular disease.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

"Garlic is well-known for its medicinal benefits: lowering blood cholesterol, fighting off infections and boosting the immune system." *Nation's First Garlic From True Seed Produced by USDA Scientist*. USDA, Press Release No. 0102.95, February 7, 1995 (Exhibit 29).

SCIENTIFIC LITERATURE

Reduction of serum cholesterol is just one of the health benefits for which garlic has historically been consumed. Garlic reduces serum lipid levels that

are most commonly associated with high cholesterol and cardiovascular disease. Scientific evidence supports the health claim that in adults garlic may reduce serum cholesterol and the risk of cardiovascular disease.

Adler, Adam J., and Holub, Bruce J., "Effect of garlic and fish-oil supplementation on serum lipid and lipoprotein concentrations in hypercholesterolemic men." *Am J Clin Nutr.* (1997) 65:445-50. In men with cholesterol levels greater than 200mg/dL (n=46) fish oil alone demonstrated a decrease in triglycerides. When fish oil (combined EPA and DHA fatty acids) was combined with garlic, decreases in triglycerides, lipids and LDL's were demonstrated. There were significant improvements in the LDL to HDL ratios and the total cholesterol to HDL ratios (Double Blind Placebo Study) (Exhibit S).

Jain, Adesh K., et. al., "Can Garlic Reduce Levels of Serum Lipids A Controlled Study," *Am J Med.* Vol 94, June 1993, 632-635. In healthy adults (n=42) with total cholesterol levels greater than 220 mg/dL in a 12 week double blind study a decrease in total cholesterol and LDL's was demonstrated. There appeared to be no effect on serum glucose, blood pressure or EKG results (Double Blind Placebo Study) (Exhibit V).

Steiner, Manfred, et. al. , "A double-blind crossover study in moderately hypercholesterolemic men that compared the effect of aged garlic extract and placebo administration of blood lipids," *Am J of Clin Nutr*, 1996, 64, 866-70. This rigidly controlled study demonstrated that garlic had significant lipid lowering effects on men with elevated cholesterol (n=56). Those findings confirmed the earlier results of Heinle and Betz from their study of the effect of garlic in rats. "Effects of Dietary Garlic Supplementation in a Rat Model of Atherosclerosis," *Drug Research*, 1994, Vol. 44, No. 5 614-617, (Exhibit W-1). Steiner's double blind study of men corroborated the meta-analysis of British researchers who distilled data from 952 subjects and found that garlic supplementation was associated with lipid reduction. (Silagy, Christopher and Neil, Andrew, "Garlic as a lipid lowering agent- a meta-analysis," *Journal of the Royal College of Physicians of London*, Jan-Feb 1994, Vol. 28, No. 1, 39-45) (Exhibit W-2).

HEALTH CLAIM

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.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

“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 protein synthesis, wound healing, immune function, growth and maintenance of tissues.” USDA and DHHS (PHS) *Nutrition Monitoring in the United States: An Update Report on Nutrition Monitoring*, Sept 1989, 71 (Exhibit 7).

“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.” *Boosting a key amino acid in plants could help people get more zinc in their diets*. Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 1st Quarter of 1995 (Exhibit 30).

SCIENTIFIC LITERATURE

Zinc is a critical component of the early infection response and wound healing processes of the body. A growing body of clinical evidence supports the health claim that in adults zinc may increase the body’s ability to fight infection and heal wounds.

Braunschweig, et. al., “Parenteral Zinc Supplementation in Adult Humans During the Acute Phase Response Increases the Febrile Response,” *J of Clin Nutr*, Jan 1997, Vol. 127, 70-74. A study of adults receiving total parenteral nutrition (TPN) who had either a catheter sepsis or pancreatitis (n=43) demonstrated that patients who received a zinc supplement experienced an increased anti-infection response as compared to the control group (Double blind Placebo Study) (Exhibit X).

Cleveland Clinic Foundation, “Zinc Gluconate Lozenges for Treating the Common Cold,” *Annals of Internal Medicine*, Vol. 125, No. 2, July 1996 (Exhibit Y). In this double blind placebo study, 100 adults were studied to determine the effect of zinc lozenges on the severity of cold symptoms. The zinc lozenges significantly decreased the clinical symptoms of the colds and those subjects receiving zinc had colds that resolved sooner than the control group.

Lansdown, A. B. G., “Zinc in the healing wound,” *Lancet*, March 16, 1996, Vol. 347, No. 9003, 706-707. A review of the status and the use of zinc to enhance wound healing from 1869 to 1996 reveals that there is a large body of evidence supporting the healing properties of zinc. Slower wound healing is noted in those with zinc deficiencies (Exhibit Z).

Shi, Hai N., et. al., “Energy Restriction and Zinc Deficiency Impair the Functions of Murine T Cells and Antigen-Presenting Cells during Gastrointestinal Nematode Infection,” *Journal of Nutrition*, January 1998, 20-27. The study demonstrated the

important role played by zinc in the body's macrophage and other immune responses. The study of nematode infection of mice resulted treated with zinc compared with control groups of mice. The study showed that zinc deficiency played a distinct role in regulating host immune responses against the infection (Exhibit BB).

Additional Studies: Godfrey, J.C., et. al., "Zinc Gluconate and the Common Cold: A Controlled Clinical Study," *J of Internat'l Medical Research*, June 1992, vol. 20, no. 3.

Additional Studies from USDA Researcher H.H. Sandstead:

"Some trace elements which are essential for human nutrition: Zinc, copper, manganese, and chromium," *Progress in Food and Nutrition Science*, 1975 Vol. 1, 371-391.

"Zinc in human nutrition," *Disorders of Mineral Metabolism*, Vol. 1, 1981, 93-157.

"Zinc Nutrition in the United States," *Am J Clin Nutr*, Vol. 26, 1973, 1251-1260.

Greely, S., "Zinc in Human nutrition," *Contemporary Nutrition*, Vol. 5 No.4 April 1980.

HEALTH CLAIM

In adults Vitamin K promotes proper blood clotting and may improve bone health. Sources of Vitamin K include spinach, cabbage, turnip greens, broccoli, tomatoes, and dietary supplements.

This health claim is based on authoritative statements published by a scientific body of the United States Government with official responsibility for public health protection or research directly related to human nutrition. The following authoritative statements that describe a relationship between a nutrient and a disease or health related condition are currently in effect.

AUTHORITATIVE GOVERNMENT STATEMENTS

"The vitamin [K] activates at least three proteins involved in bone formation." "The vitamin is well known for its role in blood clotting." *Preliminary evidence suggests that people may need more vitamin K than the current Recommended Dietary Allowance to maintain strong, healthy bones.* Human Nutrition, Agriculture Research Service (a division of the USDA), Quarterly Report, 3rd Quarter of 1996 (Exhibit 31).

SCIENTIFIC LITERATURE

Vitamin K has long been known for its critical role in blood clotting. However, its role in calcium homeostasis is not limited to blood coagulation. Vitamin K plays a key role in maintaining bone health. The scientific literature supports the claim that in adults Vitamin K promotes proper blood clotting and may improve bone health.

Kohlmeier, Martin, et. al. "Transport of Vitamin K to Bone in Humans," *J of Nutr*, April 1996 (Suppl.), 1192S-1196S. "Until recently, the only known function of vitamin K was its role in blood coagulation...[I]t has been recognized that vitamin K supplies may be suboptimal in bone but sufficient to maintain normal blood coagulation." An exhaustive review of scientific literature demonstrates that the process of bone formation is impaired in individuals with low levels of vitamin K. Those with low vitamin K have been identified by research to have a greatly increased prospective bone fracture risk (Exhibit CC).

Vermeer, Cees, et. al., "Effects of Vitamin K on Bone Mass and Bone Metabolism," *J of Nutr*, April 1996 (Suppl.), 1187S-1191S. Based on a review of scientific studies and the new appreciation for the role and function of vitamin K, the authors present information that supports the concern of many in the nutrition field that 'a substantial part of the population must be characterized as bio-chemically vitamin K deficient.' The levels of vitamin K required for proper bone health are higher than those required for normal blood coagulation (Exhibit DD).

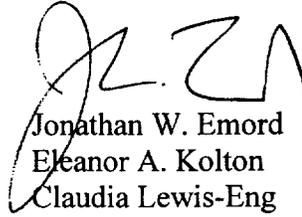
Shearer, Martin J., et. al., "Chemistry, Nutritional Sources, Tissue Distribution and Metabolism of Vitamin K with Special Reference to Bone Health," *J of Nutr*, April 1996 (Suppl.), 1181S-1186S. The authors present data and information to support increasing intake of vitamin K for maintaining proper bone and skeletal health in adults. The fact that "a majority of the daily intake of Vitamin K is lost to the body by excretion... emphasizes the need for continuous dietary supply to maintain tissue reserves" (Exhibit EE).

USDA Jean Mayer Human Nutrition Center on Aging, Sara L. Booth, "Skeletal Functions of Vitamin K-Dependent Proteins: Not Just for Clotting Anymore" *Nutrition Reviews*, July 1997, Vol.55, No. 7, 282-4. "Historically, vitamin K has been identified exclusively for its role in blood coagulation." The author conducted a critical review of recent scientific literature regarding the bio-chemical function of vitamin K and bone formation mechanisms and the validity of experiments in mice. The transgenic mouse model is appropriate for further identifying biologic functions of vitamin K in bone formation and important implications for skeletal health (Exhibit FF).

Shaerer, M.J. "Vitamin K," *Lancet*, January 28, 1995, Vol. 345, 229-234. In this comprehensive review of recent scientific literature, strong evidence emerges that vitamin K is essential not only for proper blood clotting processes in infants and adults, but also for proper bone formation. The complicated bone formation mechanism is dependent upon numerous enzymes, metabolites, nutrients and minerals. Hip fracture patients' plasma phylloquinone (vitamin K) (and thus proper bone metabolism) was

markedly decreased prior to the trauma or fracture. The interaction of proper amounts of both vitamin D and K is needed for more discreet conclusions (Exhibit GG).

Sincerely,

A handwritten signature in black ink, appearing to read 'J.W. Emord', written over the printed name.

Jonathan W. Emord
Eleanor A. Kolton
Claudia Lewis-Eng
Andrea G. Ferrenz
Julie E. Gossman
Counsel for
Weider Nutrition International, Inc.

6

federal register

Ref 6

Monday
June 22, 1998

Part IV

Department of
Health and Human
Services

Food and Drug Administration

21 CFR Part 101
Food Labeling: Health Claims; Interim
Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N-0426]

Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts

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 antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts. 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. These provisions of FDAMA supplement the petition process for nutrient content and health claims provided by section 403(r)(4) (21 U.S.C. 343(r)(4)) and §§ 101.69 and 101.70 (21 CFR 101.69 and 101.70, respectively) by providing an alternative for establishing the scientific basis for such claims by reliance 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. The notification must contain specific information including: (1) The exact wording of the prospective nutrient content claim or health claim; (2) a concise description of the basis upon which the petitioner relied for determining that the requirements of section 403(r)(2)(G)(i) of the act for nutrient content claims or section 403(r)(3)(C)(i) for health claims have been satisfied; (3) a copy of the authoritative statement that serves as the basis for the claim; and (4) a balanced representation of the scientific literature relating to the nutrient level for a prospective nutrient content claim or relating to the relationship between the nutrient and the disease or health-related condition for a prospective health claim. For a prospective nutrient content claim, the authoritative statement must identify the nutrient level to which the claim refers. For a prospective health claim, the authoritative statement must be a statement about the relationship between a nutrient and a disease or health-related condition to which the claim refers. For both types of claims, the authoritative statement must be currently in effect and it must have been published either by a scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition (e.g., the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC)) or by the National Academy of Sciences (NAS) or any of its subdivisions (hereinafter referred to as a "scientific body").

Under new section 403(r)(2)(H) and (r)(3)(D) of the act, such a claim may be made beginning 120 days after submission of the notification until: (1) FDA has issued an effective regulation that prohibits or modifies the claim; (2)

the agency has issued a regulation finding that the requirements under section 403(r)(2)(G) for a prospective nutrient content claim or under section 403(r)(3)(C) for a prospective health claim have not been met; or (3) a district court of the United States in an enforcement proceeding under chapter III of the act has determined that the requirements under section 403(r)(2)(G) for a prospective nutrient content claim or under section 403(r)(3)(C) for a prospective health claim have not been met. During the 120 days following submission of a notification and before the claim may appear on a food, the agency may also notify any person who is making the claim that the notification did not include all of the required information.

Section 304 of FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and for dietary supplements because section 304 amended section 403(r)(2) of the act, which provides for nutrient content claims on both conventional foods and dietary supplements. Section 303 of FDAMA does not include provisions for health claims for dietary supplements based on authoritative statements, however. In particular, section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(5)(D)) specifies that health claims for dietary supplements shall not be subject to section 403(r)(3) of the act, but rather to a procedure and standard that FDA establishes by regulation. In section 303 of FDAMA, Congress amended section 403(r)(3) of the act, which provides for procedures and standards for health claims for conventional foods, to allow for health claims based on authoritative statements for conventional foods, but Congress did not amend section 403(r)(5)(D) of the act.

Therefore, FDA believes that section 403(r)(3)(C) of the act authorizes use of a health claim based on an authoritative statement only on any conventional food that provides an appropriate level of the nutrient that is the subject of the health claim, that does not exceed the disqualifying levels identified in § 101.14(a)(5) (21 CFR 101.14(a)(5)), and that otherwise complies with section 403(r)(3)(C) and all other provisions of the act. Nevertheless, FDA has tentatively concluded that, for health claims authorized via the authoritative statement procedure provided by FDAMA, conventional foods and dietary supplements should be subject to the same standards and procedures. This position is consistent with the agency's final rule that made dietary supplements subject to the same general

requirements as apply to conventional foods with respect to health claims (59 FR 395, January 4, 1994). This approach is also consistent with the guidance of the Commission on Dietary Supplement Labels, which stated in its 1997 report (Ref. 1) that the process for the approval of health claims should remain the same for dietary supplements and conventional foods. Therefore, FDA intends to issue a proposed rule to provide for health claims based on authoritative statements for dietary supplements.

A. Authoritative Statements

Sections 303 and 304 of FDAMA authorize the use of a health or nutrient content claim based, in part, on an "authoritative statement." In particular, new section 403(r)(3)(C)(i) and (r)(2)(G)(i) of the act states that such claims are authorized and may be made when "a scientific body * * * has published an authoritative statement, which is currently in effect." For a health claim, section 403(r)(3)(C)(i) of the act requires that the statement must be "about the relationship between a nutrient and a disease or health-related condition to which the claim refers." For a nutrient content claim, section 403(r)(2)(G)(i) of the act requires that the statement must be one "that identifies the nutrient level to which the claim refers."

Section 403(r)(3)(C) and (r)(2)(G) of the act further requires that:

* * * [a] statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include the statement of an employee of the scientific body made in the individual capacity of the employee.

Although Congress did not explicitly define the term "authoritative statement," section 403(r)(3)(C) and (r)(2)(G) of the act and the legislative history clarify several characteristics that Congress intended an "authoritative statement" to have. Most significantly, to be the basis for a health or nutrient content claim, a statement must: (1) Address certain subjects, namely, for a health claim, it must be about the relationship between a nutrient and a disease or health-related condition to which the claim refers, or, for a nutrient content claim, it must identify the nutrient level to which the claim refers; (2) be published by an appropriate scientific body and represent its official position, and may not be, for example, a statement of individual employees of the scientific body made in the individual capacities of the employees; (3) be based on a deliberative review of the scientific evidence on the subject of

the statement and not indicate that the scientific evidence about the subject of the statement is preliminary or inconclusive; and (4) be currently in effect. The aspects of these requirements relevant to this rulemaking, and its companion rulemakings publishing elsewhere in this issue of the **Federal Register**, are discussed in greater detail in section I.A.1 of this document.

1. To Be the Basis for a Health or Nutrient Content Claim, a Statement Must Address One of Two Subjects

For a statement to be eligible for consideration as an "authoritative statement," it must address certain subjects. Section 403(r)(3)(C) of the act provides that, for a health claim, it must be "about the relationship between a nutrient and a disease or health-related condition to which the claim refers." Section 403(r)(2)(G) of the act provides that, for a nutrient content claim, it must "identify the nutrient level to which the claim refers."

There are several aspects to these requirements. First, a statement cannot be an "authoritative statement" under section 403(r)(2)(G) or (r)(3)(C) of the act if it identifies no nutrient level or if it is not about the relationship between a nutrient and a disease or health-related condition. For example, if a statement refers to no nutrient, to no disease or health-related condition, or to neither a nutrient nor a disease or health-related condition, it cannot be an authoritative statement under section 403(r)(3)(C) of the act. Second, if a statement is "about the relationship between a nutrient and a disease or health-related condition," or if it "identif[ies] the nutrient level," it must be about the relationship or nutrient "to which the claim refers." Moreover, the statement must be about the relationship between a nutrient and a disease or health-related condition in humans or it must identify a nutrient level for total daily consumption by humans.

When evaluating what relationship a statement is about, or what nutrient level a statement identifies, it may be necessary to consider the context in which the statement appears. It is likely that a submitter will identify excerpted sentences as an "authoritative statement." The context in which these excerpted sentences appears can be relevant when determining the subject of the statement. For example, sentences immediately adjoining the excerpted sentences or in a summary statement in the document may clarify the disease that is the subject of the excerpted sentences.

Accordingly, the statutory requirement in section 403(r)(3)(C)(ii)(II)

and (r)(2)(G)(ii)(II) of the act that a notification include "a copy of the statement referred to in subclause (i) upon which [the] person [who submitted the notification] relied in making the claim," means that the entire document from which the statement is excerpted should be included in a notification. The agency notes that submission of the entire document is also relevant to other determinations under section 403(r)(3)(C) and (r)(2)(G), such as whether the scientific evidence about the relationship or nutrient level at issue is preliminary or inconclusive, as discussed in section I.A.3 of this document, and whether a health or nutrient content claim is "stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i)," as required by section 403(r)(3)(C)(iv) and (r)(2)(G)(iv) of the act.

2. To Be the Basis for a Health or Nutrient Content Claim, a Statement Must Be Published by an Appropriate Scientific Body and Represent the Official Policy of That Body.

Section 403(r)(3)(C) and (r)(2)(G) of the act requires that an "authoritative statement" be "published." The agency understands the use of "published" in section 403(r)(3)(C)(i) and (r)(2)(G)(i) to mean that the statement must be publicly available in print form (paper or electronic).

The identical last sentence of section 403(r)(3)(C) and (r)(2)(G) of the act states that:

* * * [a] statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include the statement of an employee of the scientific body made in the individual capacity of the employee. "Published" as used in this sentence means that the scientific body can be considered to be the author of the statement, in that the statement represents the official policy of the scientific body. Of course, the statements of scientific bodies—indeed, of organizations generally—are authored by individuals. Yet statements that are merely those of individual employees made in the individual capacities of the employees are not statements that have been authored by, and so represent the official policy of, the scientific body. Similarly, in the case of Federal scientific bodies with subdivisions, such as NIH and CDC, section 403(r)(3)(C) and (r)(2)(G) indicates that the scientific body, and not merely the subdivision, can be considered to have "published" a statement within the

meaning of those sections only if, as the legislative history indicates, "statements issued by entities such as NIH and CDC reflect consensus within those institutions" (H. Conf. Rept. 105-399, at 98 (1997)). Accordingly, to be considered an "authoritative statement" under section 403(r)(3)(C) and (r)(2)(G), a statement must represent the official policy of a scientific body.

3. To Be the Basis for a Health or Nutrient Content Claim, a Statement Must Be Based on a Deliberative Review of the Scientific Evidence on the Subject of the Statement, and It Should Not Indicate That the Scientific Evidence Is Preliminary or Inconclusive

In section 403(r)(3)(C)(i) and (r)(2)(G)(i) of the act, Congress required that claims may be authorized only when "a scientific body * * * has published an *authoritative statement*," not merely when a scientific body has published a statement (emphasis added). The use of "authoritative" here indicates that a statement may not be the basis for a health or nutrient content claim merely because its source is a scientific body, an authority on the subject of the statement. A review of the legislative history of sections 303 and 304 of FDAMA indicates that, to be "authoritative," Congress intended that a statement must be the product of a deliberative review of the scientific evidence on the subject of the statement. In addition, the statement should not indicate that the scientific evidence about the subject of the statement is preliminary or inconclusive.

Congress intended both that claims based on authoritative statements should have "a presumption of validity" (H. Rept. 105-306, at 16 and 17 (1997)) and that "more *scientifically sound* nutrition information * * * be provided to consumers through health and nutrient content claims" based on authoritative statements (H. Conf. Rept. 105-399, at 98 (1997) (emphasis added); see also H. Rept. 105-306, at 16 (1997) and S. Rept. 105-43, at 49 (1997)).

When FDA authorizes a health claim by regulation under section 403(r)(3)(B) of the act or establishes a Daily Value that can serve as the basis for a nutrient content claim, it conducts a deliberative review of the scientific evidence about the relationship between a nutrient and a disease or health-related condition or about the nutrient level at issue and concludes that there is significant scientific agreement about the relationship or appropriate scientific consensus about the nutrient level. Congress intended that an "authoritative statement" published by a scientific body could be the basis for health and

nutrient content claims because the "authoritative statement" is to serve as a presumptive surrogate for FDA's deliberative review of the scientific evidence.

Congress therefore intended that an "authoritative statement" must be the product of a deliberative review of the scientific evidence on the subject of the statement. For example, the House Report states that:

[a]uthoritative scientific bodies, as part of their official responsibilities for public health protection, regularly undertake deliberative reviews of the scientific evidence to evaluate potential diet/disease relationships, and issue authoritative statements concerning such relationships.

(H. Rept. 105-306, at 16 (1997)). The Senate Report repeats this idea, noting that scientific bodies engage in:

* * * deliberative processes * * * in issuing statements on matters of public health. Important Federal public health organizations, as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews.

(S. Rept. 105-43, at 49 (1997)). Moreover, only a statement that a relationship between a nutrient and a disease or health-related condition exists or that identifies a level of a nutrient—and not merely statements about a possible relationship or level—can serve as the basis for claims that will provide consumers with scientifically sound information. Only a claim based on such a statement can be accorded a presumption of validity.

Accordingly, a statement that indicates, for example, that research about a nutrient level or a relationship between a nutrient and a disease or health-related condition is preliminary or inconclusive, that indicates that such a relationship or a nutrient level is or should be the subject of ongoing scientific study, or that indicates the direction for future research about such a relationship or a nutrient level is not "authoritative." When evaluating whether a statement about a relationship or nutrient level indicates that the scientific evidence is preliminary or inconclusive, the agency intends to consider the context in which the statement appears, as discussed in section I.A.1 of this document. For example, a statement of excerpted sentences might not indicate that research is preliminary or that there are unresolved questions that require additional study, but such qualifiers could be found elsewhere in the document.

The agency notes that, even if a statement meets the criteria to be an "authoritative statement," Congress also

provided under new section 403(r)(3)(D)(i) of the act that FDA have the authority to prohibit a health claim based on an authoritative statement when there is not significant scientific agreement that there is a relationship between the nutrient and the disease or health-related condition in question. As the Senate Report on the provision explains, in an agency rulemaking to prohibit or modify a health claim based on an authoritative statement, "the standards and criteria for health claims prescribed by section 403(r)(3) and implementing regulations, including the significant[t] scientific agreement standard, would be fully applicable" (S. Rept. 105-43, at 51 (1997); see also H. Rept. 105-306, at 15 (1997)).

With respect to nutrient content claims, Congress indicated that the agency is to determine "whether the authoritative statement upon which the notification is based is supported by scientific consensus to the extent * * * appropriate to allow the claim" (H. Rept. 105-306, at 17-18 (1997)), an evaluation that FDA would make under section 403(r)(2)(f) of the act, after the Federal scientific body that is the source of a statement determines that the statement reflects consensus within it, as discussed in section I.A.2 of this document.

B. Review Process

As allowed by sections 303 and 304 of FDAMA, health claims and nutrient content claims based on authoritative statements from Federal scientific bodies or NAS may be made on foods in interstate commerce as soon as 120 days after submission of a notification of the claim to FDA. Upon receipt of a notification, FDA intends to review the notification to determine whether the components specified in section 403(r)(2)(G) and (r)(3)(C) are present within the submission packet. When such components are missing, FDA intends to notify the submitter by letter identifying one or more of these components that is absent from the notification packet.

If the necessary components are present, FDA intends to determine, for a health claim, what relationship between a nutrient and disease or health-related condition is at issue, or, for a nutrient content claim, what nutrient is at issue. If, by regulation under section 403(r)(3)(B) of the act, the agency has already authorized a health claim about the relationship at issue, then the notification provisions of section 403(r)(3)(C) of the act may not be used to modify the existing health claim or to authorize the prospective health claim. Similarly, if by rulemaking the

agency has already established a Daily Value for the nutrient at issue, then the notification provisions of section 403(r)(2)(G) of the act may not be used to modify the existing Daily Value. Instead, a health claim about the relationship at issue or a nutrient content claim referring to the nutrient at issue may be made when the claim is consistent with the existing health claim regulation or with the established Daily Value and the authorized terms for nutrient content claims. Furthermore, if the prospective claim refers to a relationship or a nutrient that is not addressed by the statement that is identified as the "authoritative statement" on which the claim is based, then section 403(r)(3)(C) and (r)(2)(G) of the act does not authorize the health or nutrient content claim at issue. In each case, FDA intends to notify the submitter by letter that use of the claim is not authorized under section 403(r)(3)(C) or (r)(2)(G) of the act, as appropriate.

If, however, a prospective claim could be authorized based on an appropriate authoritative statement, and if the prospective claim refers to a relationship or nutrient that is addressed by the statement that is identified in the notification as the "authoritative statement," FDA then intends to evaluate further whether the statement is an "authoritative statement." In particular, FDA intends to determine for a statement, as a threshold matter, whether: (1) It may be attributable to a scientific body or to one or more of its employees; (2) it is publicly available in print form (paper or electronic); and (3) the statement indicates that the scientific evidence about the relationship between a nutrient and a disease or health-related condition or a nutrient level is preliminary or inconclusive. With respect to the first of these issues, FDA notes that it can determine that a statement from a non-Federal body or agency—such as a state university school of public health—is not an "authoritative statement," or that a statement from a scientist who was not an employee of an appropriate scientific body is not an "authoritative statement." As a general matter, however, only a scientific body can state whether a statement that is attributable to it or to one or more of its employees actually represents the official policy of the scientific body or not, and FDA would therefore consult with the scientific body if necessary.

If a statement fails to meet any of these criteria, FDA would normally conclude that the statement is not an authoritative statement. In any case the

agency may, and, when a statement meets these three criteria, the agency would normally, consult with the scientific body to which the statement is attributed. FDA would request that the scientific body determine, for example, whether the statement is currently in effect; whether the statement represents the official policy of the scientific body, for example, by reflecting consensus within that body, as opposed to being the statement of individual employees made in the individual capacities of those employees; and whether the statement is based on a deliberative review of the scientific evidence.

If the statement is found to be issued by an appropriate scientific body and determined to be an "authoritative statement" under section 403(r)(2)(G) or (r)(3)(C) of the act, the agency intends to review the wording of the claim to determine if it is in accordance with section 403(r)(3)(C)(iv) or (r)(2)(G)(iv) of the act. These provisions of the act require that the claim be stated in a manner so that it is an accurate representation of the authoritative statement and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For health claims, FDA also intends to consider the requirement of section 403(r)(3)(C)(iii) of the act that there be compliance with, for example, sections 403(a) and 201(n) of the act (21 U.S.C. 321(n)), which require that the claim be truthful and not misleading, including compliance as appropriate with existing § 101.14. FDA would also determine whether there is significant scientific agreement concerning the authoritative statement, as provided for under new section 403(r)(3)(D)(i) of the act. For nutrient content claims, FDA intends to consider the requirements of section 403(r)(2)(G)(iii) of the act that there be compliance with, for example, section 403(r)(2)(A)(i) of the act, which requires that nutrient content claims use the terms defined in FDA's regulations, and sections 403(a) and 201(n) of the act, including compliance as appropriate with existing § 101.13 (21 CFR 101.13). If, after this review, FDA has no objections to the claim, then the statute provides that the claim may be used on food labels 120 days after submission of a complete notification.

By contrast, if the statement is not from an appropriate scientific body or is found not to be an "authoritative statement" from a Federal scientific body or NAS (or any of its subdivisions), the agency intends to determine that the notification does not

meet the requirements of section 403(r)(3)(C) or (r)(2)(G) of the act in that the submitter has not submitted a statement from a Federal scientific body or NAS, or an authoritative statement from such a body. The agency may notify the submitter of this determination, and its basis, by letter. Alternatively, the agency may issue an interim final rule to prohibit the claim.

Generally, the agency would notify the submitter by letter when, for example, the notification is deficient on its face, and the agency would use the rulemaking process when substantial scientific or legal questions are presented by the notification. The agency intends to elaborate further on these issues in implementing regulations. The agency has chosen to respond with nine interim rules publishing in this issue of the **Federal Register** to a notification for nine claims to specify the approach used by the agency to review this notification in the absence of implementing regulations, and to provide opportunity for public comment. In the future, the agency anticipates that it may respond to similar notifications by letter. Whether FDA sends a letter or acts by rulemaking to prohibit a claim, the agency may begin an enforcement action under the act in a U. S. district court if such a claim is used in food labeling.

The agency notes that, when it sends such a letter or acts by regulation to prohibit the use of a claim, a person nonetheless may submit in the future a notification that bases the claim on a statement that meets the requirements of section 403(r)(3)(C) or (r)(2)(G) of the act. If there is no authoritative statement that may serve as a basis for the claim, an interested person may petition the agency under section 403(r)(4) of the act and § 101.70 to authorize the health claim by regulation under section 403(r)(3)(B) of the act. For a nutrient content claim, an interested person may submit a citizen petition under 21 CFR 10.30 that requests the agency to establish the Daily Value to which the claim would refer.

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. 2). 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 first claim in the notification. The notification included six statements that the petitioner identified as authoritative statements on which the following claim is based: "Antioxidant vitamins C and E may reduce the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts. Sources of Vitamin C and E include fruits, vegetables, and dietary supplements."

The first sentence of this claim will be discussed in greater detail in section III of this document. FDA notes that this claim describes the relationship between vitamins C and E and a number of different diseases and, thus, in point of fact, reflects several prospective health claims. The second sentence, "Sources of Vitamin C and E include fruits, vegetables, 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.

With respect to nutrient content claims, FDA concluded in comment 152 of its final rule for nutrient content claims (58 FR 2302 at 2345, January 6, 1993) that the term "source" alone merely connotes that a nutrient is present and does not provide consumers with meaningful information about the level of the nutrient. Therefore, FDA did not define the term "source," although it did define several other terms that include the word "source." For example, a food is defined as a "good source" of a nutrient if it contains 10 to 19 percent of the Reference Daily Intake (RDI) for that nutrient per reference amount customarily consumed (§ 101.54(c) (21 CFR 101.54(c))), or as an "excellent source" if it contains 20 percent or more of a nutrient's RDI per reference amount customarily consumed (§ 101.54(b)). In addition, "trivial source" is defined as a synonym for "free" and "low source" as a synonym for "low" (see, for example, 21 CFR 101.61(b)(1) and (b)(4)).

Information regarding the agency's position on nutrient content claims is included in the preamble to the proposed and final rules for nutrient content claims (56 FR 60421, November 27, 1991, and 58 FR 2302, January 6, 1993) and in the agency guidance document, "Food Labeling—Questions and Answers—Volume I—For Guidance to Facilitate the Process of Developing or Revising Labels for Foods Other than Dietary Supplements" (Ref. 3).

As for statements that constitute dietary guidance, such label information must be truthful and not misleading as discussed in section II.D.6 of the preamble to the final rule for general requirements for health claims (58 FR 2478 at 2487, January 6, 1993) and in the agency guidance document, "Food Labeling—Questions and Answers—Volume II—A Guide for Restaurants and Other Retail Establishments" (Ref. 4). The agency notes that in the case of the subject sentence, not all fruits, vegetables, and dietary supplements contain significant amounts of vitamins C and E, and therefore if the statement were intended to reflect dietary guidance it cannot be considered to be truthful and not misleading. In addition, to be truthful and not misleading when used on a particular food's labeling, that food must contain significant amounts of vitamins C and E.

III. Basis for the Action

FDA has reviewed the notification submitted in support of the prospective claim: "Antioxidant vitamins C and E may reduce the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts." The agency has determined that none of the six 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 six 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 statements from: (1) A published article authored by two employees of CDC; (2) public information provided on the Internet by an institute of NIH; (3) an electronic version provided on the Internet of "Nutrition and Your Health: Dietary Guidelines for Americans," (Home and Garden Bulletin No. 232, Fourth Edition, 1995) (hereinafter, referred to as "the dietary guidelines") recommendations developed by a group of Federal agencies and issued jointly by the Department of Health and Human Services (DHHS) and the United States Department of Agriculture (USDA); (4) public information provided on the Internet by CDC's Office of Women's Health; (5) a NIH press release provided on the Internet; and (6) an electronic version provided on the Internet of a quarterly report from USDA's Agricultural Research Service (ARS). Thus, the statements in the notification are attributable to NIH, CDC, and USDA/ARS, as well as a group of Federal agencies that included NIH, CDC, and USDA/ARS. Two of the scientific bodies identified, NIH and CDC, are highlighted in the statute as Federal 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. The group that developed the dietary guidelines included Federal agencies that are such scientific bodies. 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 six statements discussed in A. through F. of this section of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: "Antioxidant micronutrients, especially carotenes, vitamin C, and vitamin E, appear to play many important roles in protecting the body against cancer. They block the formation of chemical carcinogens in the stomach, protect DNA and lipid membranes from oxidative damage, and enhance immune function." 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 the conclusion section of an article published in *The Annual Review of Nutrition* (12:139-59:1992), entitled: "Dietary Carotenes, Vitamin C, and Vitamin E as Protective Antioxidants in

Human Cancers," and authored by two persons, T. Byers and G. Perry, who are identified in the article as employees of CDC at the time of publication of the article. *The Annual Review of Nutrition* is published periodically by Annual Reviews, Inc., in Palo Alto, CA. Editors for each volume serve as reviewers for the various articles included in the volume and contributors are asked to submit articles for consideration for publication. The subject article is 20 pages of a review of the literature that includes a section on the theoretical roles of dietary oxidants in cancer prevention and focuses on the outcomes of laboratory animal research and epidemiologic studies conducted since 1987. The subject statement appears in the conclusion section of the paper. The agency notes that the next sentence in the conclusion section states: "Nevertheless, many important questions need to be answered before either micronutrient supplements or food fortification can be recommended as a cancer prevention strategy to the general population."

The noted qualifying sentence, as well as the wording of the statement itself (i.e., "appear to play"), suggests that the scientific evidence about the relationship in question is preliminary or inconclusive, as discussed in section I.A.3 of this document.

FDA asked CDC whether the statement is an "authoritative statement" under FDAMA. CDC responded to FDA that the statement is not an authoritative statement of CDC because it does not reflect consensus within CDC and was not published by CDC (Ref. 5). CDC indicated that the article was authored by individual employees made in the individual capacity of those employees. Therefore, FDA has concluded that the statement is not an "authoritative statement" under section 403(r)(3)(C) of the act because the statement was not published by CDC and is instead the statement of individual employees of CDC made in their individual capacities, as discussed in section I.A.2 of this document.

B. Statement 2

Statement 2 reads: "[Antioxidants] may help prevent disease. Antioxidants fight harmful molecules called oxygen free radicals, which are created by the body as cells go about their normal business of producing energy * * * [Some] studies show that antioxidants may help prevent heart disease, some cancers, cataracts, that are more common as people get older." 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 within an information piece entitled "Life Extension: Science or Fiction?" that is provided on the Internet by the Administration on Aging and which includes statements from the "Age Page" of the National Institute on Aging (an Institute of NIH) ("<http://www.aoa.dhhs.gov/aoa/pages/agepages/lifextsn.html>" accessed on 12/2/97). This electronically available information (submitted to the agency as a hardcopy reprint from the Internet information) is dated 1994, is approximately two standard printed pages in length, and is described as being intended to inform the reader about chemicals being studied that may play a role in aging and what scientists have learned about them so far. Topics covered include antioxidants, deoxyribonucleic acid (DNA), dehydroepiandrosterone (DHEA), and other hormones. Ten tips for healthy aging are also included. The section on antioxidants is 14 sentences in length and includes the three sentences identified as the subject statement. The agency notes that the last sentence of the antioxidant section is: "More research is needed before specific recommendations can be made."

FDA asked NIH whether the statement is an "authoritative statement" under FDAMA. NIH responded to FDA that the statement is not an authoritative statement of NIH because it was prepared by an individual from the National Institute on Aging and is not based on a deliberative review of the scientific evidence regarding the nutrient-disease relationship in question (Ref. 6). 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 this document.

C. Statement 3

Statement 3 reads: "The antioxidant nutrients found in plant foods (e.g., vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer and certain other chronic diseases." 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 from an electronic version of the dietary guidelines issued jointly by DHHS and USDA and provided on the Internet ("<http://www.usda.gov/fcs/library/0102-1.txt>" accessed on 12/5/97). The submitted material consists of selected

pages reprinted from the Internet information, which identifies the seven dietary guidelines and gives background information on the use of, and reasons for, the guidelines. The dietary guidelines reflect the findings of a panel of scientists concerning the dietary recommendations to be made to the U.S. population, and the guidelines are based on a deliberative review of the scientific evidence about the nutrient/disease relationships that the guidelines address. The subject statement is found within the discussion that accompanies the recommendation to "Choose a diet with plenty of grain products, vegetables, and fruits."

The statement indicates that a relationship between antioxidant nutrients and cancer and other chronic disease is "of great interest" because of a "potentially beneficial role." The statement points to the need for future research and suggests that whether a relationship exists should be the subject of scientific study, but does not indicate that there exists a scientifically sound relationship that should be accorded a presumption of validity. This assessment is further supported by the fact that the subject of the dietary guidelines recommendation that the text is intended to clarify is the dietary importance of grain products, vegetables, and fruits, not the specific impact of antioxidant nutrients, vitamins C and E, per se. FDA notes that, consistent with the dietary guidelines, the agency has authorized a health claim for the relationship between cancer and fruits and vegetables that contain vitamin C (as well as vitamin A (as beta-carotene) and dietary fiber) (21 CFR 101.78).

On this basis, FDA has concluded that the statement is not an "authoritative statement" under section 403(r)(3)(C) of the act because the statement indicates that the scientific evidence about the relationship in question is preliminary or inconclusive, as discussed in section I.A.3 of this document.

The dietary guidelines is the product of a periodic review by a group of Federal agencies, the most recent review having been completed in 1995. FDA did not attempt to reconvene this group of Federal agencies to consult with it about whether the statement is an authoritative statement because, as discussed previously, the wording and context of the statement show that it is not an authoritative statement under section 403(r)(3)(C) of the act.

D. Statement 4

Statement 4 reads: "A diet high in fiber, high in antioxidants, and low in fat may play an important role in

preventing the development of atherosclerosis, coronary heart disease, and some cancers." 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 information on "Health in Later Years" provided on the Internet by CDC's Office of Women's Health in a section entitled: "Health Problems among Older Women," and is included in the subsection "Improving Health and Quality of Life" ("<http://www.cdc.gov/od/owh/whily.htm>" accessed on 11/26/97). This electronically available information (submitted to the agency as a hardcopy reprint from the Internet information) is not dated, is approximately three standard printed pages in length, and covers the topics of coronary heart disease, cancer, stroke, and other diseases.

FDA asked CDC whether this statement is an "authoritative statement" under FDAMA. CDC responded that the statement is not an authoritative statement of CDC because, although it is a statement from CDC, it is not based upon a deliberative review of the scientific evidence regarding the nutrient-disease relationship in question; rather, it is a statement from an educational fact sheet developed by CDC's Office of Women's Health to convey information to the public (Ref. 5). Therefore, FDA has concluded that the statement is not an "authoritative statement" under section 403(r)(3)(C) of the act because the statement is not based on a deliberative review of the scientific evidence.

E. Statement 5

Statement 5 reads: "[It] is likely that certain antioxidants, such as vitamins C and E, may destroy the oxygen radicals, retard molecular damage, and perhaps slow the rate of aging." The notification identified Statement 5 as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is contained in an undated press release from the National Institute on Aging at NIH, which was provided on the Internet ("<http://www.nih.gov/nia/newpress/agingcau.htm>" accessed on 12/1/97). The press release (submitted to the agency as a hardcopy reprint from the Internet) states that it is a synopsis of a recent publication entitled: "Aging—Causes and Defenses," which had been authored by R. Martin, D. Danger, and N. Holbrook and published in *The Annual Review of Medicine* (44:419,429:1993). The press release indicates that it is providing a synopsis

of the publication but does not clarify if the authors are associated with, or are staff of, NIH. *The Annual Review of Medicine* is published periodically by Annual Reviews, Inc., in Palo Alto, CA. Editors for each volume serve as reviewers for the various articles included in the volume and contributors are asked to submit articles to be considered for publication.

The statement is not "about the relationship between a nutrient and a disease or health-related condition" because aging, the absence of oxygen radicals, and the presence of molecular damage are not diseases or health-related conditions. FDA has therefore concluded that the statement does not address a disease or health-related condition and therefore, as discussed in section I.A.1 of this document, is not an "authoritative statement" under section 403(r)(3)(C) of the act.

F. Statement 6

Statement 6 reads: "Antioxidants are thought to help prevent heart attack, stroke and cancer." The notification identified Statement 6 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) 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). *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: "Do carotenoids—the bright red, yellow and orange pigments in fruits and vegetables—warrant a Recommended Dietary Allowance?" The paragraph describes the nature and outcome of two ARS studies and is attributed to Betty J. Burr at the USDA Western Human Nutrition Research Center in San Francisco. The agency notes that the last sentence of the paragraph is: "Further ARS studies will try to shed more light on whether a specific minimum daily intake of carotenoids is important for good health."

The context of the paragraph, as well as the wording of the statement (i.e., "are thought"), suggests that the scientific evidence about the relationship in question is preliminary or inconclusive.

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. 7). 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.

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 antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts 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 § 101.70 to authorize the 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 this 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 (21 U.S.C. 343(r)(7)(B)), 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 antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts 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 vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts 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 antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers, and cataracts 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. Commission on Dietary Supplement Labels, "Report of the Commission on Dietary Supplement Labels," November 1997, p. vii.
2. 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.
3. "Food Labeling—Questions and Answers—Volume I—For Guidance to Facilitate the Process of Developing or Revising Labels for Foods Other than Dietary Supplements," August 1993, Questions C1-C54.
4. "Food Labeling—Questions and Answers—Volume II—A Guide for Restaurants and Other Retail Establishments," August 1995, Questions R117-R127.
5. Letter to Christine J. Lewis, CFSAN, FDA, from Dixie E. Snider, CDC, April 21, 1998.
6. Letter to Christine Lewis, CFSAN, FDA, from William R. Harlan, NIH, April 30, 1998.
7. 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. 98-16454 Filed 6-19-98; 8:45 am]

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Ref 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N-0428]

Food Labeling: Health Claims; Antioxidant Vitamin A and Beta-Carotene and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, and Certain Cancers

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 antioxidant vitamin A and beta-carotene and the risk in adults of atherosclerosis, coronary heart disease, and certain cancers. 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 second claim in the notification. The notification included 11 statements that the petitioner identified as authoritative statements on which the following claim is based: "Antioxidant vitamin A and beta-carotene may reduce the risk in adults of atherosclerosis, coronary heart disease and certain cancers. Sources of Vitamin A and beta-carotene include red, yellow and green leafy vegetables, dairy products, and dietary supplements."

The first sentence of this claim will be discussed in greater detail in section III of this document. FDA notes that this claim describes the relationship between vitamin A and beta-carotene and a number of different diseases and, thus, in point of fact, reflects several prospective health claims. The second sentence, "Sources of Vitamin A and

beta-carotene include red, yellow and green leafy vegetables, dairy products, 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: "Antioxidant vitamin A and beta-carotene may reduce the risk in adults of atherosclerosis, coronary heart disease and certain cancers." The agency has determined that none of the 11 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 11 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 statements from: (1) A report on nutrition monitoring prepared for the Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA); (2) an electronic version provided on the Internet of "Nutrition and Your Health: Dietary Guidelines for Americans,"

recommendations developed by a group of Federal agencies and issued jointly by DHHS and USDA; (3) electronic versions provided on the Internet of four quarterly reports from USDA's Agricultural Research Service (ARS) (statement 3, 7, 9, and 11); (4) electronic versions provided on the Internet of two interpretative summaries from USDA/ARS Technology Transfer Information Center (statements 4 and 10); (5) public information provided on the Internet by an institute of the National Institutes of Health (NIH); (6) public information provided on the Internet by USDA/ARS Beltsville Human Nutrition Research Center; and (7) public information provided on the Internet by the National Cancer Institute (NCI), an institute within NIH. Thus, nine statements in the notification are attributable to either NIH or USDA/ARS. A 10th statement is attributable to USDA and DHHS and is intended for use by Federal agencies including NIH, the Centers for Disease Control and Prevention (CDC), and USDA/ARS. An 11th statement from the Dietary Guidelines for Americans is attributable to a group of Federal agencies that included NIH, CDC, and USDA/ARS. Two of the agencies, NIH and CDC, are highlighted in the statute as Federal 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. The agencies that were identified as users of the "Nutrition Monitoring Report" as well as the group that developed the dietary guidelines included Federal agencies that are such scientific bodies, including NIH, CDC, and USDA/ARS. 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 11 statements discussed in sections III.A through III.K of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: "Beta-carotene and other pro-vitamin A carotenoids can be converted to vitamin A in the body. Interest in the carotenoids has increased in recent years because of the accumulation of a large body of evidence that foods high in carotenoids are protective against a variety of epithelial cancers." 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 vitamins 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 (SRO) 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 statement indicates that there is interest in the relationship because of a growing body of evidence, but does not confirm that the relationship is considered scientifically valid or well established. Rather, the context suggests that further research would be worthwhile and that the scientific evidence about the relationship is preliminary or inconclusive, 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**.

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 (NAS). Contractual activities involved in the 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 of "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 of "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 indicates that the scientific evidence is preliminary or inconclusive, that it does not reflect the official policy of an appropriate scientific body, and that no appropriate scientific body has conducted a deliberative review of the scientific evidence.

B. Statement 2

Statement 2 reads: "The antioxidant nutrients found in plant foods (e.g., vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer and certain other chronic diseases." 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 from an electronic version of "Nutrition and Your Health: Dietary Guidelines for Americans" (Home and Garden Bulletin No. 232, Fourth Ed., 1995), hereinafter referred to as the "dietary guidelines," issued jointly by DHHS and USDA and provided on the Internet ("<http://www.usda.gov/fcs/library/0102-1.txt>" accessed on 12/5/97). The submitted material consists of selected pages reprinted from the Internet information, which identifies the seven dietary guidelines and gives background

information on the use of, and reasons for, the guidelines. The dietary guidelines reflect the findings of a panel of scientists concerning the dietary recommendations to be made to the U.S. population, and the guidelines are based on a deliberative review of the scientific evidence about the nutrient/disease relationships that the guidelines address. The subject statement is found within the discussion that accompanies the recommendation to "Choose a diet with plenty of grain products, vegetables, and fruits."

The statement indicates that a relationship between antioxidant nutrients and cancer and other chronic disease is "of great interest" because of a "potentially beneficial role." The statement points to the need for future research and suggests that whether a relationship exists should be the subject of scientific study, but does not indicate that there exists a scientifically sound relationship that should be accorded a presumption of validity. This assessment is further supported by the fact that the subject of the dietary guideline is the dietary importance of grain products, vegetables, and fruits, not the specific impact of antioxidant nutrients, vitamin A and beta-carotene, per se. FDA notes that, consistent with the dietary guidelines, the agency has authorized a health claim for the relationship between cancer and fruits and vegetables that contain vitamins A (as beta-carotene) as well as vitamin C and dietary fiber (21 CFR 101.78).

On this basis, FDA has concluded that the statement is not an "authoritative statement" under section 403(r)(3)(C) of the act because the statement indicates that the scientific evidence about the relationship in question is preliminary or inconclusive, as discussed in section I.A.3 of the **Federal Register** "Health Claims; Vitamins C and E," which is published elsewhere in this issue of the **Federal Register**.

The dietary guidelines is the product of a periodic review by a group of Federal agencies, the most recent review having been completed in 1995. FDA did not attempt to reconvene this group of Federal agencies to consult with it about whether the statement is an authoritative statement because, as discussed previously, the wording and context of the statement show that it is not an authoritative statement under section 403(r)(3)(C) of the act.

C. Statement 3

Statement 3 reads: "If the findings hold up in further research, eating more vegetables rich in beta-carotene and related carotenoids—lutein and lycopene—may help people ward off a

cold or flu as well as protect from cancer * * *. The findings also suggest that carotenoid-rich vegetables also stimulate the immune system." 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) 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).

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: "Daily servings of dark green and deep yellow vegetables and tomatoes boost immune response, a preliminary study suggests." The paragraph describes the nature and outcome of one ARS study and is attributed to Tim R. Kramer and Beverly Clevidence of the USDA Beltsville Human Nutrition Research Center in Beltsville, MD. The agency notes that the research is identified as a "preliminary study."

The context of the paragraph, as well as the wording of the statement (i.e., "if the findings hold up"), suggests that the statement is based on preliminary research and that further study is needed. As such, the statement appears to indicate that the scientific evidence about the relationship is preliminary or inconclusive.

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. 3). 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.

D. Statement 4

Statement 4 reads: "This research involving cells provides data which supports the general hypothesis that beta-carotene and lutein protect cells by serving as antioxidants." 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 a one paragraph interpretative summary of a research report from Technology Transfer Information Center, TEKTRAN of USDA/ARS entitled "Beta-carotene and Lutein Protect the Plasma Membrane of HEPC2 Human Liver Cells Against Oxidant-induced Damage," and provided on the Internet ("<http://www.nalusda.gov/ttic/tektran/data/000006/92/0000069264.html>" accessed on 12/3/97) (ARS Report Number 69264). It describes the nature and outcome of one study, which is attributed to Keith J. Martin, Mark L. Failla, and James C. Smith, Jr.

The statement is not "about the relationship between a nutrient and a disease or health-related condition" because no disease is identified in the statement. Therefore, FDA has concluded that the statement does not address a disease or health-related condition and therefore is not an "authoritative statement" under section 403(r)(3)(C) of the act, 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**.

E. Statement 5

Statement 5 reads: "[Antioxidants] may help prevent disease. Antioxidants fight harmful molecules called oxygen free radicals, which are created by the body as cells go about their normal business of producing energy * * *. [S]ome studies show that antioxidants may help prevent heart disease, some cancers, cataracts, and other health problems that are more common as people get older." The notification identified statement 5 as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is found within an information piece entitled: "Life Extension: Science or Fiction?" that is provided on the Internet by the Administration on Aging and which includes statements from the "Age Page" of the National Institute on Aging (an Institute of the NIH) ("<http://www.aoa.dhhs.gov/aoa/pages/agepages/lifextsn.html>" accessed on 12/2/97). This electronically available information (submitted to the agency as a hardcopy reprint from the Internet information) is dated 1994, is approximately two standard printed pages in length, and is described as being intended to inform the reader about chemicals being studied that may play a role in aging and what scientists have learned about them so far. Topics

covered include: Antioxidants, DNA, DHEA, and other hormones. Ten tips for healthy aging are also included. The section on antioxidants is 14 sentences in length and includes the 3 sentences identified as the subject statement. The agency notes that the last sentence of the antioxidant section is: "More research is needed before specific recommendations can be made."

FDA asked NIH whether the statement is an "authoritative statement" under FDAMA. NIH responded to FDA that the statement is not an authoritative statement of NIH because it was prepared by an individual from the National Institute on Aging and is not based on a deliberative review of scientific evidence regarding the nutrient-disease relationship in question (Ref. 4). 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.

F. Statement 6

Statement 6 reads: "As potent antioxidants, [lutein and lycopene] are thought to contribute to the lower rates of heart disease, cancer and other diseases of aging among populations that eat a lot of fruits and vegetables." The notification identified statement 6 as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is found within an information piece, "BHNRC Success Stories," provided on the Internet by USDA/ARS Beltsville Human Nutrition Research Center and entitled: "Carotenoids Show Their Real Colors" ("<http://www.barc.usda.gov/bhnrc/success.htm>" accessed on 12/4/97). This electronically available information (submitted to the agency as a hardcopy reprint from the Internet information) is undated. The section on carotenoids is three brief paragraphs in length and describes the nature and outcome of a single ARS study attributed to Tim Kramer and Beverly Clevidence. The same study was also referenced in ARS's *Human Nutrition* quarterly report as noted in the discussion of statement 3 in section III.C of this document.

The context of the section, as well as the wording of the statement (i.e., "are thought"), suggests that the statement is based on preliminary research and that further study is needed. As such, the statement appears to indicate that the scientific evidence about the relationship is preliminary or inconclusive.

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. 3). USDA explained that the ARS "BHNRC Success Stories" 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.

G. Statement 7

Statement 7 reads: "Researchers also found more evidence suggesting that carotenes act as antioxidants to protect the body from harmful oxidation. Antioxidants are thought to help prevent heart attack, stroke and cancer. During the low-carotene stints, researchers recorded several biochemical signs of oxidative damage." The notification identified statement 7 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 3 in section III.C 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: "Do carotenoids—the bright red, yellow and orange pigments in fruits and vegetables—warrant a Recommended Dietary Allowance?" The paragraph describes the nature and outcome of two ARS studies and is attributed to Betty Burri of the Western Human Nutrition Research Center in San Francisco, CA. The agency notes that the final sentence states: "Further ARS studies will try to shed more light on whether a specific minimum daily intake of carotenoids is important for good health."

The context of the paragraph, as well as the wording of the statement (i.e., "are thought"), suggests that the statement is based on preliminary research and that further study is needed. As such, the statement appears to indicate that the scientific evidence about the relationship is preliminary or inconclusive.

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. 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.

H. Statement 8

Statement 8 reads: "[H]igh dietary carotene and possibly vitamins C and E and folate are associated with reduced risk for cervical cancer." The notification identified statement 8 as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is found in information provided on the Internet by the NCI, an institute of NIH, in an article entitled: "Prevention of Cervical Cancer" and disseminated as part of "PDQ—Detection & Prevention—Health Professionals" (PDQ stands for physicians data query) ("http://cancer.net.nci.nih.gov/clinpdq/screening/Prevention_of_cervical_cancer_Physician.html" accessed on 12/1/97). This electronically available information (submitted as a hardcopy reprint from the Internet information) is undated, approximately nine standard printed pages in length, and is described as intended for use by doctors and other health care professionals. The subject sentence is one of several sentences summarizing research on the intake of micronutrients and the risk of squamous intraepithelial lesion (SIL) and cervical cancer.

FDA asked NIH whether this was an "authoritative statement" under FDAMA. NIH responded that the statement was not an authoritative statement of NIH and does not reflect consensus within NIH (Ref. 4). NIH explained that the evidence was reviewed by an editorial board for PDQ, and the majority of the members are not Federal employees. The statements contained in PDQ were reported by NIH to be "state of the art" educational statements developed by an editorial board that assesses the levels of scientific evidence supporting the statements. In this instance, the scientific evidence for the nutrient-disease relationship was not considered to be strong since it was based on observational studies. NIH reiterated that the statement is not the product of consensus process within the NCI and the statement has not undergone formal review and clearance by the Director of the National Institutes of Health.

Therefore, FDA has concluded that the statement is not an "authoritative statement" under section 403(r)(3)(C) of

the act because it does not reflect consensus within NIH, as discussed in section I.A.2 of "Health Claims: Vitamin C and E," which is published elsewhere in this issue of the **Federal Register**.

I. Statement 9

Statement 9 reads: "[B]eta carotene or vitamin A supplements have reversed pre-cancerous conditions in people's mouths." The notification identified statement 9 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, 3rd quarter 1995) (see discussion of statement 3 in section III.C 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: "A daily dose of blue-green algae *Spirulina* may help prevent cancer of the mouth, a study shows." The paragraph describes the nature and outcome of an ARS study and is attributed to Padmanabhan P. Nair of the Beltsville Human Nutrition Research Center, Beltsville, MD.

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. 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.

J. Statement 10

Statement 10 reads: "Carotenoids or other plant components appear to boost the immune system." The notification identified statement 10 as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is found in a one-paragraph interpretative summary of a research report from Technology Transfer Information Center, TEKTRAN of USDA/ARS entitled: "Consumption of Carotenoid-Rich Vegetables Increases T-Lymphocyte Proliferation and Plasma Levels of Carotenoid Oxidation Products" and provided on the Internet ("<http://www.nalusda.gov/ttic/tektran/data/000007/41/0000074185.html>" accessed on 12/3/97) (ARS Report Number 74185). It describes the nature

and outcome of one study, which is attributed to ten researchers, the first author being Beverly Clevidence.

FDA finds that the statement is not "about the relationship between a nutrient and a disease or health-related condition" because no disease is identified in the statement. Therefore, FDA has concluded that the statement does not address a disease or health-related condition and therefore is not an "authoritative statement" under section 403(r)(3)(C) of the act.

K. Statement 11

Statement 11 reads: "A wealth of epidemiological evidence has linked a high intake of green leafy and deep yellow vegetables—both rich in beta-carotene—with lower rates of many types of cancer * * *. Men over 65 who took a 50-milligram beta-carotene supplement every other day during the 12-year study had natural killer cells that were more active than their counterparts who got a placebo. Natural killer cells—or NK cells—are the immune system's sentinels, ever on watch for viruses and cancer cells." The notification identified statement 11 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 3 in section III.C 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: "Older people who get plenty of beta carotene may have a better chance of preventing virus infections or a cancerous growth." The paragraph describes the nature and outcome of a study and is attributed to Simin Nikbin Meydani of the 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. 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 statements 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 antioxidant vitamin A and beta-carotene and the risk in adults of atherosclerosis, coronary heart disease, and certain cancers 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) and 21 CFR 10.70 to authorize the health claim or claims by regulation under section 403(r)(3)(B).

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

For the reasons described in this section of this 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. No. 105-399, at 98 (1997)).

As described previously 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 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 B₆, vitamin B₁₂), 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

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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 B₆, vitamin B₁₂), 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 B₆, Vitamin B₁₂—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 B₆, Vitamin B₁₂—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 B₆ 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 B₁₂ 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 B₆, vitamin B₁₂), 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 B₆, vitamin B₁₂), 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 B₆, vitamin B₁₂), 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 B₆, vitamin B₁₂), 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

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Ref 9

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:

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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 osteoporosis nor fractures related to osteoporosis. 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

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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

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VIII. Reference

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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]

BILLING CODE 4160-01-F

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

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Ref 11

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.

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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.

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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

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: "In adults, Omega-3 Fatty Acids may reduce the risk of cardiovascular disease." 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 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 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 statements from: (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) a USDA's Agriculture Research Service (ARS) press release provided on the Internet. 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 section III.A and III.B of this document was found to be an authoritative statement.

A. Statement 1

Statement 1 reads: "Intake of particular polyunsaturated fats, the omega-3 fatty acids, may offer some protection against the development of clinical manifestations of atherosclerosis by decreasing platelet aggregation and clotting activity and preventing arterial thrombosis." 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 coronary heart disease 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 wording and context of the statement indicates that arterial thrombosis as affected by omega-3 fatty acids is a preliminary, albeit promising, relationship, and does not yet constitute an established relationship between omega-3 fatty acids and heart disease. As such, the statement appears to indicate that the scientific evidence about the relationship is preliminary or inconclusive 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**.

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 the 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 of "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 of "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 indicates that the scientific evidence is preliminary or inconclusive, that it does not reflect the official policy

of an appropriate scientific body, and that no appropriate scientific body has conducted a deliberative review of the scientific evidence.

B. Statement 2

Statement 2 reads: "In new soybean oil varieties developed by the USDA's Agriculture Research Service palmitic acid is replaced with oleic acid, which has some health benefits. In addition, omega-3 and omega-6 fatty acids, which can actually lower cholesterol levels, are at 7 and 60 percent respectively—essentially the same as regular soybeans." 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 contained in a press release from USDA's ARS, dated November 26, 1996, entitled: "New Soybeans Halve Saturated Fat, Keep Nutrition," which was provided on the Internet ("<http://www.ars.usda.gov/is/pr/soyfat1196.htm>" accessed on 12/4/97). The press release (submitted to the agency as a hardcopy reprint from the Internet) is attributed to Jill Lee of ARS and suggests that Joseph W. Burton (USDA/ARS, Raleigh, NC) or James R. Wilcox (USDA/ARS, West Lafayette, IN) be contacted for details. It is approximately two standard printed pages in length and the subject sentence is one of several sentences that summarize the nutritional differences between two new varieties of soybeans compared with regular soybeans.

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. 3). USDA explained that informational pieces such as press releases 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.

In summary, FDA has concluded that the notification does not include authoritative statements published by any scientific body as required by section 403(r)(3)(C) of the act. Accordingly, the subject claim relating to the relationship between omega-3 fatty acids 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 10.70 to authorize a health claim by regulation under section 403(r)(3)(B).

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. No. 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)(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 omega-3 fatty acids 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 omega-3 fatty acids 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 omega-3 fatty acids 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 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.

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-16459 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-0422]

Food Labeling: Health Claims; Garlic, Reduction of Serum Cholesterol, and the Risk of Cardiovascular Disease 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 garlic, decreased serum cholesterol, 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 the statement that the petitioner submitted in that notification, and, in conformity with the requirements of FDAMA, the agency is prohibiting the claim because the statement submitted as the basis of the claim is not an "authoritative statement" 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 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 seventh claim in the notification. The

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 omega-3 fatty acids 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 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)

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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.

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-16459 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-0422]

Food Labeling: Health Claims; Garlic, Reduction of Serum Cholesterol, and the Risk of Cardiovascular Disease 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 garlic, decreased serum cholesterol, 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 the statement that the petitioner submitted in that notification, and, in conformity with the requirements of FDAMA, the agency is prohibiting the claim because the statement submitted as the basis of the claim is not an "authoritative statement" 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 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 seventh claim in the notification. The

notification included one statement that the petitioner identified as an authoritative statement on which the following claim is based: "In adults, garlic may reduce serum cholesterol and the risk of cardiovascular disease." This claim will be discussed in greater detail in section III of this document.

III. Basis for the Action

FDA has reviewed the notification submitted in support of the prospective claim: "In adults, garlic may reduce serum cholesterol and the risk of cardiovascular disease." The agency has determined that the one statement submitted as a basis for this claim does not meet 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, the statement 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 a statement from a U.S. Department of Agriculture (USDA) press release provided on the Internet that refers to USDA's Agricultural Research Service (ARS) for further information. Thus, the statement in the notification is 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). Accordingly, the statement provided in the notification in support of the claim may be attributable to an appropriate Federal scientific body or to its employees.

Finally, however, the statement discussed in this section of this document was not found to be an authoritative statement.

Statement

The statement reads: "Garlic is well-known for its medicinal benefits: Lowering blood cholesterol, fighting off infections and boosting the immune system." The notification identified the

statement as an "authoritative statement" for purposes of making the claim that is the subject of this rulemaking. The statement is contained in a press release from USDA, dated February 7, 1995, entitled: "Nation's First Garlic from True Seed Produced by USDA Scientist" (Release No. 0102.95), which was provided on the Internet ("http://www.usda.gov/news/releases/1995/02/0102" accessed on 12/16/97). The press release (submitted to the agency as a hardcopy reprint from the Internet) is attributed to Linda Cooke and Maria Bynum (affiliation unknown), but refers editors to Philip W. Simon at ARS for details. The press release summarizes the development of the first garlic seeds and is approximately two standard printed pages in length. The subject sentence is included in a description of garlic and its uses.

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 informational pieces such as press releases 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 discussed in section I.A.3 of "Health Claims; Vitamins C and E," which is published elsewhere in this issue of the **Federal Register**.

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 garlic, decreased serum cholesterol, 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 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 statement submitted in support of the prospective health claim does not meet the requirements for an authoritative statement 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 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]

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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

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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.

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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]

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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]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N-0420]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to prohibit the use on foods of a health claim relating to relationships between vitamin K and the promotion of proper blood clotting and improvement in bone health in adults. This interim final rule is in response to a notification of a health claim submitted under section 303 of the FDA Modernization Act of 1997 (FDAMA). FDA has reviewed the notification, and, in conformity with the requirements of FDAMA, the agency is prohibiting the claim as a health claim because the claim does not characterize the relationship of the nutrient vitamin K to a disease or health-related condition, as required by section 303 of FDAMA; therefore, section 303 of FDAMA does not authorize use of this claim as a health claim. Although the claim is not a health claim, it may be the type of claim permissible as a structure/function claim. As provided for in section 301 of FDAMA, this rule is effective immediately upon publication. **DATES:** The interim final rule is effective June 22, 1998; comments by September 8, 1998.

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

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

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Ref 14

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.

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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.

SUPPLEMENTARY INFORMATION:**I. The FDA Modernization Act of 1997**

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

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

II. The Notification

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

interim final rule responding to each claim.

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

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

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

III. Basis for the Action

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

clotting and improvement in bone health is not authorized as a health claim under section 403(r)(3)(C) of the act and is, therefore, prohibited as a health claim.

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

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

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

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

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

by that date. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of this interim final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. FDA finds that this interim final rule is not a significant regulatory action as defined by Executive Order 12866. In

addition, it has been determined that this interim final rule is not a major rule for the purpose of congressional review.

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

B. Small Entity Analysis

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

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

U.S.C. 601-612), the agency certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

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

VII. The Paperwork Reduction Act of 1995

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

VIII. References

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

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

Dated: June 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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Ref 15

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ONE HUNDRED FIFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

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BERNARD SANDERS, VERMONT
INDEPENDENT

August 13, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner
and Deputy Commissioner of Operations
Food and Drug Administration
5600 Fishers Lane
Mail Code: HF-28/14-71/PKLN
Rockville, MD 20857

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Docket Nos. 9N-0419; 98N-0420; 98N-0421; 98N-0422; 98N-0423; 98N-0424; 98N-0426; 98N-0427; and 98N-0482

Dear Dr. Friedman:

Pursuant to its authority under Rules X and XI of the House of Representatives and the oversight responsibilities of the Committee on Government Reform and Oversight, this Committee has jurisdiction over the Food and Drug Administration. On June 22, 1998, the Food and Drug Administration (FDA) published nine Interim Final Rules forbidding specific health claims that accurately represented published statements of federal government health agencies. As a member of Congress with oversight responsibility of the FDA, I object strenuously to FDA's interim final rules. If left unchanged, those rules will defeat the vital purpose of Section 303 of the FDA Modernization Act.

Congress intended Section 303 to provide a meaningful alternative to the agency's overly restrictive health claims review procedure and standard. We sought to allow parties to avoid that procedure and standard if they used health claims that accurately state nutrient-disease

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relationships published by other federal government health agencies. Despite the intent of Congress, you have interpreted Section 303 to require adherence to your existing health claims review procedure and standard, defeating the very purpose of Section 303 and rendering it superfluous.

Congress enacted Section 303 in reaction to FDA's poor track record on the folic acid/neural tube defect claim. FDA's interpretation of the scientific agreement standard could have contributed to thousands of needless preventable deaths when, years following the public recommendations of the Public Health Service and the Centers for Disease Control (associating consumption of folic acid with a reduction in neural tube defect births), FDA continued to prohibit the claim. We sought to prevent that kind of unnecessary event from recurring by enacting Section 303. Your interim final rules, however, only reinforce the existing censorship effected by the scientific agreement standard. Consequently, I fully expect that FDA's denial of vital health information to the public will pose a continued threat to the health of the American public.

In your interim final rules you propose to define the "authoritative statement" language in Section 303 to require satisfaction of FDA's scientific agreement standard, thereby preventing that section from providing a meaningful alternative to the standard. Reading the Senate Report out of context and contrary to its plain language, you assert that Congress would not have authorized health claims published by other government agencies unless they were based on a "deliberative review of the scientific evidence" which you equate with FDA's own review under its scientific agreement standard. We did not use the quoted language nor did we equate it with FDA's standard. Rather, the Senate Report, taken in context, simply confirms Congress's view that the published nutrient-disease statements of other federal government health agencies *are in fact* products of routine reviews of scientific evidence and are thus reliable and appropriate for use as health claims.

You boldly assert that "Congress intended that an 'authoritative statement' published by a scientific body could be the basis for health and nutrient content claims because the 'authoritative statement' *is to serve as a presumptive surrogate for FDA's deliberative review of the scientific evidence.*" Nowhere does such a statement appear in the Senate Report. Indeed, we as members certainly did not expect that Section 303 would "serve as a presumptive surrogate for FDA's...review of the scientific evidence." To the contrary, we expected that Section 303 would be a meaningful alternative to FDA's health claims standard and procedure, one that would stop FDA from preventing nutrient-disease statements published by other federal health agencies from appearing in the marketplace.

Moreover, you state that even if another agency had performed the same review FDA performs and concluded that a statement were authoritative, FDA would nevertheless disallow the claim if it decided that "there is not significant scientific agreement" to support it. In short,

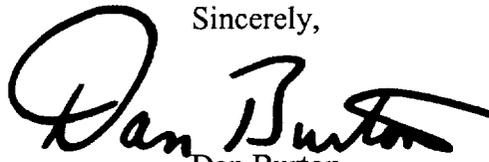
Dr. Michael A. Friedman
August 13, 1998
Page 3

FDA will not permit any nutrient-disease relationship claims from appearing on labels and in labeling unless it determines that the statement is backed by significant scientific agreement, a phrase which is undefined and subjective. You thus prevent Section 303 from providing any, let alone a meaningful, alternative to the scientific agreement standard.

FDA's interim final rules require adherence to the very same standard and procedure that resulted in its reprehensible determination not to allow the folic acid claim. Once FDA finally reversed its position on the use of health claims for folic acid supplements, it may have been too late for many unborn children. Congress enacted Section 303 precisely to prevent that kind of occurrence. The interim final rules flout the will of Congress and undo the good work we have done.

It is, of course, difficult to predict the lives that will be lost or suffering that will be incurred from the needless censorship effected by FDA's interim final rules, but I do fear that many may suffer needlessly. I cannot stress strongly enough my recommendation that FDA reconsider its course, and I would like you to address these concerns by letter by the close of business August 21, 1998. If you should have any questions with regard to the foregoing, please contact Committee Counsel Laurie S. Taylor at (202) 225-5074. Please inform the relevant staff of your agency that this Committee may convene a hearing on this matter in September, 1998.

Sincerely,



Dan Burton
Chairman

Enclosures

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT
OF 1997

NOVEMBER 9, 1997.—Ordered to be printed

Mr. BLILEY, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany S. 830]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—*This Act may be cited as the "Food and Drug Administration Modernization Act of 1997".*

(b) **REFERENCES.**—*Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).*

(c) **TABLE OF CONTENTS.**—*The table of contents for this Act is as follows:*

Sec. 1. Short title; references; table of contents.

Sec. 2. Definitions.

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs

Sec. 101. Findings.

TITLE III—IMPROVING REGULATION OF FOOD

Flexibility for regulations regarding claims (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the interim final rulemaking authority established under this section. This authority enables the Secretary to make proposed regulations on claims effective upon publication, pending consideration of public comment and publication of a final regulation. The conferees' clarifying language emphasizes that this authority may be used when the Secretary determines that it is necessary to enable the Secretary to improve consumer access to important dietary information and to ban or modify a claim in a prompt fashion. The conferees' intent in creating this expedited rulemaking authority for health and nutrient content claims is that it be used primarily to expedite the review of petitions for health and nutrient content claims based on authoritative statements.

Health and nutrient content claims (Secs. 303, 304)

The conference agreement makes streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. This process is triggered by authoritative statements of entities such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the National Academy of Sciences (NAS). Although the provision specifically permits claims to be made on the basis of a statement produced by subsidiaries of NAS, the conferees intend that the lack of similar language with respect to entities such as NIH and CDC be interpreted as a reflection of the desire of the conferees that statements issued by entities such as NIH and CDC reflect consensus within those institutions. The agreement makes minor modifications to the House provisions on health and nutrient content claims to expedite the process by which such claims are processed. As part of the submissions to the Secretary for health claims based on authoritative statements, a balanced representation of the scientific literature may include a bibliography of such literature.

Disclosure of irradiation (Sec. 306)

The conference agreement ensures that no existing provision of the Federal Food Drug and Cosmetic Act will be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. To ensure the intended effect of this provision, the conferees direct the Secretary promptly to publish for public comment proposed amendments to current regulations relating to the labeling of foods treated with ionizing radiation. The conferees expect final regulations to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. The conferees intend for any required disclosure to be of a type and

character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety.

Food contact substances (Sec. 309)

The conference agreement establishes a notification process for the regulation of components of food packaging, known as food contact substances, which is intended to expedite authorization of the marketing of a food contact substance except where the Secretary determines that submission and review of a food additive petition is necessary to provide adequate determination of safety. The agreement also authorizes appropriations to finance the costs of the new notification process. To protect the Agency from having to reallocate resources within CFSAN to meet the costs of implementation, the agreement provides that implementation is to be triggered only when the FDA receives an appropriation sufficient to fund the program. The conferees strongly encourage the House and Senate to appropriate the funds authorized. The conferees also urge the Committees of jurisdiction, when reauthorizing the notification program, to reevaluate fully its operational effectiveness, the appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

On the subject of food contact substances, the conferees wish to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from EPA to FDA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effecting this policy was considered by the conferees to be outside the scope of this conference, the conferees acknowledge the significant need for this change and urge FDA and EPA to continue to work with the Congress to identify and develop an appropriate and expeditious vehicle for action on this matter. In the interim, the conferees urge the agencies not to delay active review of pending petitions and the pursuit of the most immediate means to achieve resolution of this jurisdictional issue.

TITLE IV—GENERAL PROVISIONS

Dissemination of treatment information (Sec. 401)

The conference agreement's inclusion of this section is intended to provide that health care practitioners can obtain important scientific information about uses that are not included in the approved labeling of drug, biological products, and devices. The conferees also wish to encourage that these new uses be included on the product label. Therefore, the agreement includes strong incentives to conduct the research needed and file a supplemental application for such uses. A manufacturer who seeks to disseminate information about a new use must either certify that it will file a supplemental application or must submit a proposed protocol and schedule for conducting the necessary studies and a certification that a supplemental application will be filed.

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October 26, 1998

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Re: FDA Dockets Nos. 98N-0419; 98N-0420; 98N-0421; 98N-0422; 98N-0423; 98N-0424; 98N-0426; 98N-0427; and 98N-0482

Dear Dr. Henney:

On August 13, 1998, I sent a letter for inclusion in the above-referenced dockets, explaining that FDA's nine Interim Final Rules violated the plain meaning of Section 303 of the FDA Modernization Act 9 (FDAMA) as well as Congress's expressed intentions on how that Section should be interpreted. To avoid the need for legislative intervention, I urged Dr. Friedman to reconsider the agency's course and to revoke the Interim Final Rules. I received from your agency a responsive letter dated September 16, 1998, signed by Diane E. Thompson, Associate Commissioner for Legislative Affairs (Exhibit A). This letter evaluates your response. I ask that it too be included in, and evaluated as part of, the above-referenced dockets.

In Ms. Thompson's letter, the Agency contends that (1) FDA consulted with federal scientific bodies cited as the sources of "authoritative statements" submitted to the agency and that each body informed FDA that the statements were not "authoritative;" (2) only statements FDA finds

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to have been the results of "deliberative reviews on the part of scientific bodies" qualify as authoritative statements under FDAMA Section 303, quoting from H.Rep. 105-306 at 16; S. Rep. 105-43 at 49; H. Rep. 105-306 at 16 and 17; and H. Conf. Rep. 105-399 at 98; and (3) FDAMA Section 303 specifically permits FDA to issue a regulation prohibiting any claim that it finds not backed by significant scientific agreement.

The FDA's explanation is unpersuasive, and I continue to believe strongly that FDA's Interim Final Rules violate the plain meaning of the statute and the legislative intent underlying it. Indeed, your interpretation would render Section 303 superfluous, nothing more than a reiteration of the current health claims review process--precisely the process the Congress intended to circumvent with a less restrictive review standard under Section 303.

FDA's Consultations with other Agencies depended upon its own definition of "Authoritative Statements," not the one in Section 303. I am disturbed by your contention that the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the U.S. Department of Agriculture (USDA) each determined that the statements in question were not "authoritative" under Section 303, without revealing that the test for making that determination is not the one Congress provided in the statute but the one FDA invented and supplied to those agencies. I have examined the three letters that FDA received from the CDC, the NIH, and the USDA, respectively. They merely reflect that the definition FDA gave to those agencies of the term "authoritative statement," not the one contained in the statute itself, was not satisfied. They do not establish that Congress's definition of "authoritative statement" in Section 303 was not satisfied.

According to Section 303(C), "a statement shall be regarded as an authoritative statement of a scientific body described in subclause (I) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee." Thus, there are only two requirements to be satisfied: First, that the statement be published by a scientific body of the federal government, and second, that the statement not be one of an employee of the scientific body made in that employee's individual capacity. If those two requirements are satisfied, the statement is "authoritative" within the meaning of Section 303; there is no requirement of a subsequent written confirmation that the statement is deemed authoritative by the publishing agency and there is no requirement that any other condition be met. FDA has adopted a far different and more restrictive definition from the one we codified, one that renders Section 303 superfluous. According to FDA, a statement will only be deemed authoritative if it satisfies several highly subjective conditions nowhere present in the statute.

According to the agency, a statement is authoritative only if:

1. It represents the official policy of a scientific body (63 Fed. Reg. at 34086);
2. It is the product of a deliberative review of the scientific evidence on the subject of the statement (id.);

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3. It is not based on preliminary or inconclusive evidence (id.);
4. It documents a valid nutrient-disease relationship, one that actually exists, not merely statements about a possible relationship (id.); and
5. It satisfies the agency's "significant scientific agreement" health claims review (id.).

Using these criteria, FDA protects its previous health claims review process from the less rigorous alternative procedure we intended to make available under Section 303.

The CDC, NIH, and USDA letters respond not to the plain language of Section 303 but to the agency's own "amendment" to the statute, to its addition of these various requirements as conditions precedent to a determination that a statement is "authoritative." CDC did not find that the statements attributed to it were either not published by it or were the product of an employee acting in his or her individual capacity. Instead, CDC responded to the agency's definition, finding that the statement was not "authoritative" because "it is not based on deliberative review of the scientific evidence regarding the nutrient-disease relationship in question" and did not "reflect a consensus within the CDC." Those are the FDA's criteria, not Congress's. Likewise, NIH did not find the statements attributed to it were either not published by it or were the product of an employee acting in his or her individual capacity. Once again, NIH merely responded to the agency's definition, finding that the statement was not "based upon a deliberative review of the scientific evidence regarding the nutrient-disease relationship in question" and did not "reflect a consensus" within NIH. Likewise, USDA did not find the statements attributed to it were either not published by it or were the product of an employee acting in his or her individual capacity. USDA responded to the agency's definition, finding that the statement was not "based upon a deliberative review of the scientific evidence regarding the nutrient-disease relationship in question." The responses are identical in pertinent part, strongly suggesting that they are not the product of independent action by these agencies but rubber stamps given to questions formulated by the FDA. I consider this tactic disingenuous at best, and at worst intentionally misleading.

The legislative history you cite fails to support the view that Congress intended FDA to add to the statutory definition of "authoritative statement." I am deeply concerned by your selective excerpting from the legislative record in an attempt to suggest that Congress supports or condones your requirement of the aforementioned conditions precedent to find the existence of an "authoritative statement." Examined in context, each of the statements that you rely upon as a basis for FDA's own definition of authoritative statement does not indicate any intent by Congress to have FDA adopt such a definition. You cite the House Report (H. Rep. 105-306 at 16) which states that "[a]uthoritative scientific bodies, as part of their official responsibilities for public health protection, regularly undertake deliberative reviews of the scientific evidence to evaluate potential diet/disease relationships, and issue authoritative statements concerning such relationships." That statement in context does not call for FDA to develop its definition of the term "authoritative statement," as you contend. Rather, in context the statement is a plain recognition that authoritative scientific bodies other than FDA publish nutrient/disease relationship claims to the public as a routine matter and that those statements are scientifically valid. The quoted language underscores our view that reliance on the published statements of

scientific bodies other than FDA is appropriate "to permit more scientifically sound nutrition information to be provided to consumers" and to "prevent a reoccurrence of such problems as the one presented by the folic acid/neural tube defect claim."

Recall that the problem with the folic acid/neural tube defect claim arose precisely because FDA forbade the use on labels and in labeling of a claim published by another scientific agency precisely because FDA believed the claim not backed by adequate scientific evidence. In the record underlying Section 303, Congress determined that FDA was wrong to prevent that claim from the beginning, and that Section 303 was needed to avoid a reoccurrence. FDA's Interim Final Rules ensure a reoccurrence.

Ms. Thompson next cites the Senate Report (S. Rep. 105-43 at 49): "deliberative processes . . . in issuing statements on matters of public health. Important Federal public health organizations, as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews." Far from authorizing FDA to adopt its definition for "authoritative statements," the Senate Report recognizes that published nutrient/disease relationships are routinely the by-product of scientific reviews and, in context, plainly condemns FDA's existing system of review for keeping such statements out of labeling. Moreover, the Senate Report recognizes that a wide range of published statements are authoritative, not limited to those that could meet FDA's invented, extended definition of the term "authoritative statement." The entire paragraph from which the excerpt was selected should be taken into account:

Under existing section 403(r)(3), health claims can be made for food only after FDA issues a regulation authorizing the specific claim. This same preclearance requirement applies to all health claims--from the novel claim, to the claim that would be supported by the authoritative statement of an official public health agency of the Federal Government. This procedure is inefficient and fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health. Important Federal public health organizations, as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews. The Surgeon General and National Academy of Sciences have published authoritative reports on such relationships. The National Cancer Institute has issued pamphlets recommending food choices to reduce the risk of cancer. The National Heart, Lung, and Blood Institute has issued a range of authoritative publications aimed at reducing the risk of hypertension and heart disease in the United States population.

Ms. Thompson next indicated that Congress expected FDA to ascertain whether a published statement of a scientific body was the product of a "deliberative review" and was deserving of a "presumption of validity," based on H. Rep. 105-306 at 16 and 17. Once again, an examination of the Report on those pages reveals no statement by Congress electing to bestow

upon FDA that discretion as a condition precedent to finding an "authoritative statement." The reference to H. Conf. Rep. 105-399 at 98 is equally lacking in any textual support for FDA's definition of "authoritative statement."

In sum, the citations presented do not support the FDA's conclusion that Congress intended this agency to expand its two-part definition of "authoritative statement" in Section 303 to include the added conditional strictures placed upon the term. Indeed, far from achieving Congress's objective of providing a streamlined alternative less restrictive than FDA's existing health claims review process, FDA's Interim Final Rules create no meaningful alternative at all.

FDAMA Section 303 contemplates use of FDA's "Significant Scientific Agreement" review only in one instance, not in every case. The Interim Final Rules make it a condition of approval for any claim that it satisfy FDA's current health claims review standard ("significant scientific agreement"). That interpretation guts Section 303 of meaning, rendering it a mere duplication of the very standard we understood we were eliminating when we voted in favor of Section 303. Contrary to FDA's view, Section 303 does not permit resort to the "significant scientific agreement" review procedure except in one instance. The legislative history contemplates that Section 303 will be an alternative to the Section 403(r)(3)(B) procedure except when a claim already approved under that procedure is the subject of a claim based on an authoritative statement. In that peculiar circumstance, the Senate Report provides for use of the "significant scientific agreement" review process. The Senate Report provides:

Under this legislation, the agency retains the full range of enforcement powers it has possessed historically to remedy misleading claims. . . . In addition, new section 403(r)(3)(D) assures that FDA retains full authority to regulate health claims based on the statements of authoritative bodies through rulemaking. Once FDA regulations governing health claims concerning a particular diet/disease relationship claim (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. The legislation specifically provides that FDA may prohibit or modify such health claims through rulemaking. In any such proceeding, the standards and criteria for health claims prescribed in section 403(r)(3) and implementing regulations, including the significance [sic] scientific agreement standard, would be fully applicable.

Senate Report 105-43 at 51.

The Congress sought to eliminate the FDA's current system of review in the legislative history underlying Section 303 for its rigidity and failure to authorize claims we intended to be authorized. We created Section 303 as a meaningful alternative. FDA's interpretation of the law in the Interim Final Rules would have Section 303 be a redundancy of FDA's current overly restrictive system.

Jane Henney, M.D.
October 26, 1998
Page 6

In light of the foregoing, please respond to the following the questions:

1. If the Agency's position on this matter were correct, and we were compelled to take legislative action and mandate that the two provisions in the statute are the only two requirements that the FDA can impose, would the FDA then allow all the authoritative statements to be used in products labels and in labeling?
2. Does the FDA take the position that any publication by a scientific body of a Federal agency not meeting the requirements of your interim final rules is necessarily false and misleading? If so, is it the Agency's position that every nutrient/disease relationship published by other Federal scientific bodies is false and misleading until FDA determines otherwise?
3. Does FDA routinely review published statements of other scientific bodies associating nutrients with diseases?
4. Is the FDA aware of any published statement by another Federal health agency that would meet its standard, according to the interim final rules? If yes, provide a list of 5 authoritative statements of published by other Federal health agencies on nutrient/disease relationships that FDA would determine in compliance with the Agency's interim final rules.
5. In 1991 when the Public Health Service published the folic acid/neural tube defect relationship, FDA determined that this relationship lacked significant scientific agreement. If DSHEA had been in effect at this time and the agency was presented with CDC statement associating folic acid with the prevention of neural tube defect births, would FDA allow or disallow the claim, and why?

The system contemplated by Congress should be put in place, and the interim final rules appropriately changed or revoked. The Committee will elect to hold hearings on this issue if necessary. Please respond to the issues raised in this letter by the close of business November 11, 1998. If you have any questions, you may contact Professional Staff Member, S. Elizabeth Clay at 202-225-5074.

Sincerely,



Dan Burton
Chairman

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Ref 17
Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 1998

6 4 4 9 '98 SEP 21 P 2:15

The Honorable Dan Burton
Chairman, Committee on Government
Reform and Oversight
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for your letter of August 13, 1998, to Dr. Michael A. Friedman, Acting Commissioner of Food and Drugs, regarding the nine interim final rules that the Food and Drug Administration (FDA or the Agency) published to prohibit the use of certain health claims. These rules were published in the June 22, 1998, Federal Register in response to a notification of health claims submitted under section 303 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

As you know, prior to FDAMA, companies could not use a health claim in food labeling unless FDA published a regulation authorizing the claim. Section 303 of FDAMA permits manufacturers to use such claims if they are based on current, published, authoritative statements from certain Federal scientific bodies, as well as from the National Academy of Sciences or any of its subdivisions. Under the FDAMA provisions, 120 days after submission to the Agency of a complete notification that includes the exact words used in the claim and the authoritative statement on which it is based, manufacturers may use the claim unless and until the Agency issues a regulation prohibiting or modifying the claim or a United States district court determines that the requirements of Section 303 have not been met. FDA conducted a careful review of the nine health claims received and determined that the claims were not based on authoritative statements. Below we explain the reasons for FDA's actions in these nine interim final rules.

First, the nine interim final rules reflect a belief that federal agencies publishing statements about nutrient-disease relationships are, in the first instance, best positioned to assess whether their statements are "authoritative statements" within the meaning of section 303 of FDAMA. Where possible, FDA consulted with the federal scientific bodies cited as the sources of the "authoritative statements" about nutrient-disease relationships used to support the claims covered in the interim

final rules. In each and every instance, the agencies identified reasons, for example, the statement was not based on deliberative review, for why the statements were not "authoritative" within the meaning of FDAMA.

Second, in the preambles to the interim final rules, FDA examined the legislative history to clarify the nature of an authoritative statement. The legislative history does not indicate that all statements issued by a scientific body are authoritative; rather, it indicates that authoritative statements are derived from deliberative reviews on the part of scientific bodies. For instance, the House Report states that "[a]uthoritative scientific bodies, as part of their official responsibilities for public health protection, regularly undertake deliberative reviews of the scientific evidence to evaluate potential diet/disease relationships, and issue authoritative statements concerning such relationships" [H.Rept. 105-306, at 16 (1997)]. The Senate Report echoes this idea, noting that scientific bodies engage in "deliberative processes . . . in issuing statements on matters of public health. Important Federal public health organizations, as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews" [S.Rept. 105-43, at 49 (1997)]. Therefore, the Agency incorporated the concept of a deliberative review into the tentative definition of authoritative statement. FDA also pointed out that a deliberative review was consistent with Congressional interest in the "presumption of validity" for authoritative statements [H.Rept. 105-306, at 16 and 17 (1997)] and with the purpose of health and nutrient content claims: to provide "scientifically sound nutrition information" to consumers [H.Conf.Rept. 105-399, at 98 (1997)]. Thus, in the nine interim final rules, the Agency indicated that deliberative scientific reviews are a necessary element of authoritative statements used as a basis of health claims. As noted above, for these rules, the scientific bodies who authored the statements at issue concluded, and FDA agreed, that not all of their published statements are "authoritative statements" within the meaning of FDAMA.

Moreover, the Agency highlighted this language from the legislative history to acknowledge and underscore Congress' determination that other Federal scientific bodies are fully capable of conducting deliberative scientific reviews, and that such reviews are entirely appropriate surrogates, substitutes, or alternates to the FDA review. In short, Congress clearly concluded that other scientific bodies conduct deliberative reviews of the scientific evidence about the relationship between a nutrient and a disease or health-related condition, and that such reviews could be the basis of a health claim instead of FDA reviews. The Agency believes that its nine interim final rules support these conclusions. For those rules, each scientific body determined if, in fact, it had conducted a

deliberative review of the scientific evidence. In the rules, FDA relied on the scientific body's determination of this issue. FDA believes that the principles outlined in the preambles to the interim rules do acknowledge and readily allow for an alternative process, external to FDA, for conducting a review of the science establishing a relationship between a food component and the reduction of risk for a disease.

Third, in the interim final rules, FDA stated that FDAMA retained the standard of "significant scientific agreement" for health claims established by the Nutrition Labeling and Education Act of 1990 (NLEA). New section 403(r)(3)(D)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which section 303 of FDAMA added, reads:

A claim submitted under the requirements of clause (C) may be made until such time as the Secretary issues a regulation *under the standard in clause (B)(i)* (emphasis added) —

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause.

Section 403(r)(3)(B)(i) of the FD&C Act reads:

"The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is *significant scientific agreement* (emphasis added), among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Thus, section 303 of FDAMA specifically permits FDA to issue a regulation to prohibit a health claim based on an authoritative statement when there is not significant scientific agreement that there is a relationship between the nutrient and the disease or health-related condition in question.

It is important to point out that, in the interim final rules, significant scientific agreement was not an issue because the Agency concluded, based in significant part on the determinations made by the scientific bodies that were sources

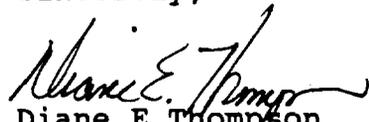
for the statements, that the statements submitted were not authoritative statements.

Finally, the Agency issued guidance entitled "Guidance for Industry: Notification of Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" (a copy of which is enclosed) for which a notice of availability was published in the Federal Register on June 11, 1998, shortly before publication of the nine interim final rules. The Agency currently is seeking comments on both this guidance and the nine interim final rules. Comments on the interim rules, including those in your letter, will be duly considered before finalizing the interim rules. We anticipate that the comments also will be helpful in developing implementing regulations that eventually will replace the guidance document. The Agency believes that these opportunities for comment from the public will assist its implementation of these FDAMA provisions in a fashion consistent with and fully supportive of Congress' intent for the use of authoritative statements as bases for health and nutrient content claims.

In the interim, the guidance and the interim final rules should help interested parties to identify statements issued by scientific bodies that are likely to be "authoritative statements." Such statements may provide the bases for additional health and nutrient content claims, so as to provide consumers with additional scientifically valid information on food labeling, as Congress intended.

We hope this information is helpful and we very much appreciate your interest in this important issue. As requested, a copy of your letter has been forwarded to the dockets for the nine interim final rules. You may be interested to know that, in response to requests, the comment period has been reopened. Comments now will be received through October 8, 1998.

Sincerely,



Diane E Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: Dockets Management Branch (HFA-305)

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
and Oversight

18

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Ref 18
Food and Drug Administration
Rockville MD 20857

DEC - 8 1998

The Honorable Dan Burton
Chairman, Committee on Government
Reform and Oversight
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for your letter of October 26, 1998, to Dr. Jane Henney, Commissioner of Food and Drugs, regarding the nine interim final rules that the Food and Drug Administration (FDA or the Agency) published prohibiting the use of certain health claims. These rules, which responded to a notification for nine health claims based on "authoritative statements" submitted under the Food and Drug Administration Modernization Act of 1997 (FDAMA), were published in the June 22, 1998 Federal Register. Your letter has been included in the appropriate dockets pertaining to the nine claims. To the extent the issues you raise are not addressed in the final rules on these claims, we will respond to you separately on them.

You also asked for responses to five questions. Your questions are shown below in bold, followed by our responses:

1. If the Agency's position on this matter were correct, and we were compelled to take legislative action and mandate that the two provisions in the statute are the only two requirements that the FDA can impose, would the FDA then allow all the authoritative statements to be used in products labels and in labeling?

If Congress were to amend section 303 of FDAMA to restrict the definition of authoritative statement to the two requirements that "the statement is published by the scientific body" and that it "not include the statement of an employee of the scientific body in the individual capacity of the employee," FDA would implement only those requirements.

If the statements submitted in support of the nine claims addressed in the interim final rules were resubmitted under section 303 so amended, FDA would evaluate each of the statements in light of the amended statutory requirements. In the absence of specific statutory language, however, it is not possible to give a definitive answer. With that caveat, it appears that some of the statements might be authoritative

statements under such an amended statute. Others of those statements, however, may still fail to qualify as authoritative statements. For example, Statement 1 submitted to support the claim for antioxidant vitamins C and E and the risk of atherosclerosis, coronary heart disease, and certain cancers was not published by a Federal scientific body or the National Academy of Sciences, but by a private commercial concern, and was authored by individual employees of the Centers for Disease Control and Prevention (CDC) in their individual capacities.

Of course, section 303 of FDAMA also requires that an authoritative statement be "about the relationship between a nutrient and a disease or health-related condition to which the claim refers." Whether particular claims based on statements that satisfied the requirements for authoritative statements could be used on labels and in labeling would depend on their satisfying the further requirements of section 303 of FDAMA that "the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement . . . and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

2. Does the FDA take the position that any publication by a scientific body of a Federal agency not meeting the requirements of your interim final rules is necessarily false and misleading? If so, is it the Agency's position that every nutrient/disease relationship published by other Federal scientific bodies is false and misleading until FDA determines otherwise?

It is not the position of FDA that any publication by a scientific body of a Federal agency not meeting the requirements for an authoritative statement advanced in the interim final rules is necessarily false and misleading. When a claim based on such a publication is included in a product's labeling, however, it must be evaluated in light of the statutory and regulatory requirements that apply to such claims.

3. Does FDA routinely review published statements of other scientific bodies associating nutrients with diseases?

FDA scientists routinely review published statements of other scientific bodies associating nutrients with diseases for the purpose of keeping abreast of new scientific information and expert evaluation of the scientific evidence about diet and health relationships. FDA staff do not routinely review such statements for the purpose of determining whether they are authoritative within the meaning of FDAMA.

4. Is the FDA aware of any published statement by another Federal health agency that would meet its standard, according to the interim final rules? If yes, provide a list of 5 authoritative statements published by other Federal health agencies on nutrient/disease relationships that FDA would determine in compliance with the Agency's interim final rules.

In assessing the evidence for the 10 original health claims included in the Nutrition Labeling and Education Act (NLEA) of 1990, the Agency gave considerable weight to the conclusions and recommendations of authoritative bodies articulated in publications such as The Surgeon General's Report on Nutrition and Health and the National Academy of Sciences' Diet and Health. These conclusions and recommendations, many of which likely would meet the definition of authoritative statements within the meaning of FDAMA, were used by FDA as part of its health claim review that led to authorization of a number of claims, including those for dietary saturated fat and cholesterol and heart disease; fat and cancer; fruits, vegetables, and grain products that contain soluble fiber and heart disease; fiber-containing grain products, fruits, and vegetables and certain cancers; and calcium and osteoporosis.

As indicated earlier, the Agency does not routinely review statements to assess whether they are authoritative within the meaning of FDAMA. One example of an authoritative statement, however, that the Agency has noted is the following from the 1995 Dietary Guidelines for Americans, published jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services: "Eating a variety of fiber-containing plant foods is important for proper bowel function, can reduce the symptoms of chronic constipation, diverticular disease, and hemorrhoids, and may lower the risk for heart disease and some cancers. However, some of the health benefits associated with a high-fiber diet may come from other components present in these foods, not just from the fiber itself." This statement could be cited in support of a claim regarding fiber-containing foods and constipation. The Agency anticipates that other such statements could be identified and that scientific bodies will issue additional authoritative statements in the near future.

5. In 1991 when the Public Health Service published the folic acid/neural tube defect relationship, FDA determined that this relationship lacked significant scientific agreement. If DSHEA had been in effect at this time and the agency was presented with CDC statement associating folic acid with the prevention of neural tube defect births, would FDA allow or disallow the claim, and why?

To clarify, in 1991 it was CDC, not the Public Health Service (PHS), that published an interim recommendation, pending further research, for 4 mg per day (a high dose) of folic acid supplementation only for women who previously had had an infant or fetus with a neural tube defect. After consulting other agencies, FDA, in its 1991 proposed rule published in response to the requirements of the NLEA, proposed not to authorize a health claim for folic acid because of the inability to generalize results obtained from studies of women at high risk of giving birth to a child with a neural tube defect to the much larger population of all women of child-bearing age who would be the target of the claim. As mentioned above, given this uncertainty, CDC's interim guidelines targeted only women who had had a fetus or infant with a neural tube defect. In 1992, just as the comment period for the 1991 proposal was closing, information from a major new study concerning the effect of folic acid on neural tube defects became available. FDA immediately responded by reopening the comment period for the 1991 proposal and, at approximately the same time, PHS, of which FDA and CDC are components, issued a recommendation for the consumption of folic acid by all women of childbearing age. Following through on this recommendation, FDA proposed in 1993 to authorize a health claim for the relationship for both dietary supplements and conventional foods. FDA was part of the PHS recommendation and, therefore, never rejected nor operated outside the PHS recommendation, but rather took immediate action to implement a health claim for the relationship. The authorization of the claim on dietary supplements was finalized within a few months of the 1993 proposal. In that same January 4, 1994 notice (59 FR 433), FDA advised that, "given the PHS recommendation and the results of FDA's preliminary review of the evidence on this claim, at this time it has no intention of taking action against foods in conventional food form that are naturally high in folate that bear a claim on this nutrient-disease relationship, so long as the claim fully complies with the provisions of the regulation that has become final for dietary supplements by operation of law."

The final regulation to allow a health claim for the relationship between folic acid and neural tube defects was delayed due to the consideration of issues of safety relative to addition of folic acid to foods. This delay was not in any way due to failure on the part of FDA to recognize or act upon the agreement concerning the scientific validity of the relationship. Rather, consistent with the PHS recommendation on folic acid consumption, FDA needed to address how to increase folic acid intake through the food supply while ensuring that over-fortification and consequently over-consumption of folic acid did not occur as an unintended consequence to a non-target population. A major concern

regarding over-consumption of folic acid, recognized by the PHS in its 1992 recommendation, was the potential for progressive neurologic damage resulting from undiagnosed vitamin B-12 deficiency in both the target population of women of child-bearing age and the elderly and other sub-populations. FDA addressed the concerns by modifying the food additive regulations for folic acid and the standards of identity for specific enriched cereal grain products so as to provide for appropriate and safe fortification of the food supply. We also issued a final regulation for the health claim for conventional foods about the relationship between folic acid and neural tube defects.

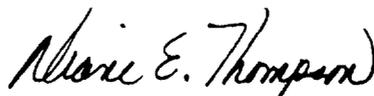
It is, of course, difficult to assess what would have happened with the health claim for folic acid and neural tube defects had the FDAMA provisions been in effect in 1992. As explained above, however, it seems reasonable to assume that FDA would have acted as it did, in fact, act: consistent with the PHS recommendation, including the concerns about safety.

With respect to conventional foods, had a notification based on the PHS recommendation been submitted to the Agency, it is likely that FDA would not have objected to the use of the claim on conventional foods that were naturally high in folate, and the claim would have been able to appear on such foods at least several months earlier than January 1994, when the Agency stated it would not object to the use of the claim on such foods. Because of the safety concerns about the addition of folic acid to foods, however, the Agency likely would have objected to the use of the claim on other conventional foods (i.e., foods fortified with folate) until the Agency was able to resolve those safety concerns. In all probability, the claim would not have been able to appear on such foods any sooner than it did.

Regarding dietary supplements, neither FDAMA nor DSHEA includes provisions that would have affected the authorization of the folic acid/neural tube defect claim. Therefore, the claim would not have appeared on dietary supplements any sooner than January 1994, when the claim, in fact, became authorized for use on dietary supplements.

We hope this information is helpful. Please contact us if we may be of further assistance.

Sincerely,



Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Page 6 - The Honorable Dan Burton

cc: Dockets Management Branch (HFA-305)

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government
Reform and Oversight