that has received a section 4(c) exemption order in accordance with this section or a board of trade the products of which are accessible as part of an automated trading system operated pursuant to specific rules regarding the particular linkage arrangement that have been submitted by a designated contract market to the Commission and are in effect pursuant to section 5a(a)(12)(A) of the Act and § 1.41 of this chapter and which otherwise operates primarily outside the United States shall be deemed to involve the trading of foreign futures or foreign options, as appropriate, under the definitions of § 30.1(a) and (b) and under any provisions that refer to those definitions. A person located in the United States, its territories or possessions engaged in such trading shall be deemed to be a foreign futures or foreign options customer under § 30.1(c).

Issued in Washington, DC on March 16, 1999 by the Commission.

Jean A. Webb,

Secretary of the Commission.

Commissioner Barbara P. Holum joining in the concurring opinions of Commissioners Spears and Newsome.

Dated: March 16, 1999.

Commissioner Barbara P. Holum.

Concurring Opinion of Commissioner David D. Spears—Proposed Rules Concerning Access to Automated Boards of Trade

I have significant reservations about the complexity of the proposed rules. I believe the elaborate regulatory system this proposal envisions could impose unnecessary burdens on US FCMs and could be cited by foreign regulators as justification for imposing unnecessarily restrictive requirements on US exchanges. However, I also recognize that the Commission needs to act as quickly as possible to address issues relating to access to foreign boards of trade from within the US. Further delay in issuing proposed rules to allow for additional revisions or refinements in the proposal would be a disservice to those affected by the proposal. The investing public and the futures industry have every right to expect this agency to act expeditiously in bringing legal certainty to this area. Therefore, I have voted to issue the proposed rules in the form presented. However, I would urge commenters to review the proposal carefully with an eye toward suggesting revisions that would make the rules simpler without detracting from adequate customer protection or the fair and even-handed treatment of all affected parties.

Concurring Opinion of Commissioner James E. Newsome—Proposed Rules Concerning Automated Trading System Use in the United States

I respectfully concur in the issuance of the proposed rules concerning automated trading system use in the United States. I agree that the proposal should be released for public comment, but I do not agree with the approach detailed therein, for the reasons stated below.

My concerns are twofold: first, I believe that the proposal is overly regulatory in approach, and secondly, I believe that there are troublesome jurisdictional issues inherent in the proposed regulation, specifically, the use of the Commodity Exchange Act's § 4(c) exemptive authority and the possible conflict with the Act's § 4(b) jursidictional limitations. I do not believe that the proposal appropriately mitigates the competitive concerns of our domestic exchangers, and, indeed, may well exacerbate the issue of inequitable regulatory treatment. Moreover, I believe that there are unnecessary additional burdens included in this proposal that would negatively affect the futures commission merchant community.

Given the widespread interest in this issue and the unfortunate delay in its release, I support moving forward expeditiously and giving the public another opportunity to comment on the proposal. However, I strongly urge interested parties to comment particularly on the issues I have mentioned, as well as alternative methods of addressing this issue, including, for example, the use of no-action procedures or the CEA's Part 30 Regulations.

Dated: March 15, 1999.

James E. Newsome,

Commissioner.

[FR Doc. 99–6829 Filed 3–23–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 99N–0554]

How to Use Health Claims and Nutrient Content Claims in Food Labeling; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public meeting concerning implementation of sections 303 and 304 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Those provisions provide for use, in food labeling, of health claims and nutrient content claims based on authoritative statements published by certain Federal scientific bodies or the National Academy of Sciences (NAS) or any of its subdivisions. We are holding the meeting to allow you to provide information and recommendations to assist us in identifying appropriate approaches for implementing sections 303 and 304 of FDAMA. We anticipate that the discussion will include presentations from people whom we invite to participate as well as from members of the public.

DATES: We will hold the meeting on May 11, 1999, 8 a.m. to 5 p.m. Please register by April 27, 1999. Written comments should be submitted by May 11, 1999.

ADDRESSEES: The meeting will be held at the Jefferson Auditorium, U.S. Department of Agriculture, South Bldg., 1400 Independence Ave. SW., Washington, DC.

You may submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: ''FDADockets@bangate.fda.gov'' or via the FDA Website ''http://www.fda.gov''.

FOR FURTHER INFORMATION CONTACT: Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4697, or e-mail to ''JLatham@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed FDAMA (Pub. L. 105–115) into law. FDAMA made amendments to the Federal Food, Drug, and Cosmetic Act (the act). In particular, sections 304 and 303 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). These new paragraphs provide for the use in food labeling of nutrient content claims and health claims, respectively,

based on authoritative statements 120 days after a notification of the claim is submitted to the agency. This notification process added by FDAMA supplements the petition process for nutrient content and health claims provided by section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) and §§ 101.69 and 101.70 (21 CFR 101.69 and 101.70, respectively). It does so by providing a less time-consuming and less burdensome alternative for establishing the scientific basis for such claims through use of authoritative statements of certain scientific bodies.

Since the passage of FDAMA, FDA has been reviewing both the statute and the accompanying legislative history to determine the most appropriate approach for implementing these new provisions. We issued a guidance document in early June 1998 (Ref. 1). In this guidance, we focused on the submission procedures for notifications of claims, identified appropriate Federal scientific bodies, discussed the nature of authoritative statements and the scientific standard with respect to health claims, outlined the content of a notification and other statutory requirements, and indicated that we intended to propose that health claims based on authoritative statements be permitted for use in dietary supplement labeling. We published that proposed rule in the **Federal Register** of January 21, 1999 (64 FR 3250) (Ref. 2).

Moreover, because section 403(r)(2)(G) and (r)(3)(C) of the act provide that authoritative statements from appropriate Federal scientific bodies may be the basis of nutrient content claims and health claims, we believed there was benefit in identifying key persons within each such Federal body who could provide us with information on authoritative statements if needed. At our request, the Secretary of Health and Human Services sent a letter to scientific bodies within the Public Health Service (Ref. 3) and to the U.S. Department of Agriculture (Ref. 4) requesting that they identify such a contact person.

On February 23, 1998, we received a notification containing nine prospective claims that were identified in the notification as health claims (Ref. 5). We created nine separate dockets, one for each claim, and issued a separate interim final rule responding to each claim (Refs. 6 through 14). In one of these rules (Ref. 6), we included in the preamble our thinking about the requirements of section 403(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D) of the act as well as procedures that we would use to review notifications for claims under those provisions.

We received a number of comments on these nine interim final rules. Some comments supported the approach that we had taken and others opposed it. Some comments offered alternative approaches for our consideration. You can find these comments in Docket Nos. 98N–0419 through 98N–0424 and 98N–0426 through 98N–0428 at our Dockets Management Branch (see address in section IV of this document). In addition, on August 13, 1998 (Ref. 15), and October 26, 1998 (Ref. 16), we received congressional requests for information about the nine interim final rules. We responded to these requests on September 16, 1998 (Ref. 17), and December 8, 1998 (Ref. 18).

We believe that our efforts to implement section 304(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D) of the act would benefit from a public meeting and an open discussion of all possible approaches to implementing these provisions. We anticipate that this discussion will be most useful to us if it involves those that commented on FDA's tentative approach and other members of the public, as well as representatives of scientific bodies that may be sources of authoritative statements.

II. Scope of Discussion

We intend that the scope of the meeting be limited to issues related to implementing section 403(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D) of the act. More specifically, comments to the nine interim final rules raised questions concerning both the need for and the nature of a definition for ''authoritative statement.'' We seek clarification of issues and approaches that relate to these questions. These questions focused on FDA's role in overseeing the provisions that allow such claims, as well as our role in relation to the Federal scientific bodies and NAS. In addition, we seek input about which of the regulatory requirements applicable to health claims and nutrient content claims that FDA authorizes by regulation under the petition process in section 403(r)(4) of the act should apply to health claims and nutrient content claims authorized based on authoritative statements. Finally, we seek input on several definitional and procedural issues. Based on the questions and comments that we have already received, we are particularly interested in discussions of the following questions:

1. The Scientific Basis for Claims

a. What is an ''authoritative statement''?

b. Who defines ''authoritative statement''?

c. Who decides if a particular statement is an ''authoritative statement''?

d. Is the ''context'' of a statement in the publication in which it appears relevant to that determination? If so, how?

e. How does the significant scientific agreement standard apply to health claims based on authoritative statements?

2. Existing Regulatory Requirements

a. What requirements of 21 CFR 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?

b. What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?

3. Procedural and Definitional Issues

a. Which agencies should we identify as scientific bodies of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition under section 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act?

b. Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?

c. What should we require that you submit with a notification of a health or nutrient content claim based on an authoritative statement?

d. Should we require you to submit in a notification an analytical methodology for measuring the substance that is the subject of your submitted claim?

e. What is a balanced presentation of the scientific literature relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?

f. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?

g. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?

III. Registration and Requests to Make Oral Presentation

If you would like to attend the meeting, you must register with the contact person (address above) by April 27, 1999, by providing your name, title, business affiliation, address, telephone and fax number. To expedite processing, registration information may also be

faxed to 202–260–8957. If you need special accommodations due to disability, please inform the contact person when you register. If, in addition, you desire to make an oral presentation during the meeting, when you register to attend you must inform the contact person of that desire and submit: (1) A brief written statement of the general nature of the evidence or arguments that you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each such presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

You may, by May 11, 1999, submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: ''FDADockets@bangate.fda.gov'' or via the FDA Website ''http://www.fda.gov''. You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of any comments, identified with the docket number found in brackets in the heading of this document, except that you may submit only one copy if you are an individual. You may see received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting after May 21, 1999, at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website ''http://www.fda.gov''.

VI. References

We have placed the following references on display in the Dockets Management Branch (address above). You may see them at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body,'' June 11, 1998.

2. Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements (64 FR 3250, January 21, 1999).

3. Memorandum from Donna E. Shalala, DHHS, to scientific bodies within the Public Health Service, March 17, 1998.

4. Memorandum from Donna E. Shalala, DHHS, to The Honorable Dan Glickman, USDA, March 17, 1998.

5. 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.

6. Food Labeling: Health Claims; Interim Final Rule; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts (63 FR 34084, June 22, 1998).

7. Food Labeling: Health Claims; Interim Final Rule; Antioxidant Vitamin A and Beta-Carotene and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, and Certain Cancers (63 FR 34092, June 22, 1998).

8. Food Labeling: Health Claims; Interim Final Rule; B-Complex Vitamins, Lowered Homocysteine Levels, and the Risk in Adults of Cardiovascular Disease (63 FR 34097, June 22, 1998).

9. Food Labeling: Health Claims; Interim Final Rule; Calcium Consumption by Adolescents and Adults, Bone Density and The Risk of Fractures (63 FR 34101, June 22, 1998).

10. Food Labeling: Health Claims; Interim Final Rule; Chromium and the Risk in Adults of Hyperglycemia and the Effects of Glucose Intolerance (63 FR 34104, June 22, 1998).

11. Food Labeling: Health Claims; Interim Final Rule; Omega-3 Fatty Acids and the Risk in Adults of Cardiovascular Disease (63 FR 34107, June 22, 1998).

12. Food Labeling: Health Claims; Interim Final Rule; Garlic, Reduction of Serum Cholesterol, and the Risk of Cardiovascular Disease in Adults (63 FR 34110, June 22, 1998).

13. Food Labeling: Health Claims; Interim Final Rule; Zinc and the Body's Ability to Fight Infection and Heal Wounds in Adults (63 FR 34112, June 22, 1998).

14. Food Labeling: Health Claims; Interim Final Rule; Vitamin K and Promotion of Proper Blood Clotting and Improvement in Bone Health in Adults (63 FR 34115, June 22, 1998).

15. Letter of August 13, 1998, to Michael A. Friedman, FDA, from The Honorable Dan Burton, House of Representatives, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

16. Letter of October 26, 1998, to Jane Henney, FDA, from The Honorable Dan Burton, House of Representatives, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

17. Letter of September 16, 1998, to The Honorable Dan Burton, House of Representatives, from Diane E. Thompson, FDA, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

18. Letter of December 8, 1998, to The Honorable Dan Burton, House of Representatives, from Diane E. Thompson, FDA, regarding the nine interim final rules that FDA published in the **Federal Register** of June 22, 1998.

Dated: March 18, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7115 Filed 3–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1010 and 1040

[Docket No. 93N–0044]

Laser Products; Proposed Amendment to Performance Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the performance standard for laser products to achieve harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. FDA is proposing additional changes that reflect FDA's understanding of how photobiological and behavioral factors, such as involuntary eye and body motion, affect the risk of injury from exposure. In addition, FDA is clarifying the requirement that manufacturers provide certain information to servicers. Generally, the proposed amendments will reduce the regulatory burden on affected manufacturers and improve the effectiveness of FDA's regulation of laser products. This action is being taken under the Federal Food, Drug, and Cosmetic Act as amended by Radiation Control for Health and Safety Act of 1968.

DATES: Written comments on the proposed rule should be submitted by June 22, 1999. See section IV of this document for the proposed effective date of a final rule based on this document.

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.