

information with respect to transactions executed in reliance on the exemption:

(A) Contract terms and conditions, or a product description, and trading conventions, mechanisms and practices;

(B) Trading volume by commodity and, if available, open interest; and

(C) The opening and closing prices or price ranges, the daily high and low prices, a volume-weighted average price that is representative of trading on the market, or such other daily price information as proposed by the facility and approved by the Commission.

(v) *Modification of price discovery determination.* A trading facility that the Commission has determined performs a significant price discovery function under paragraph (c)(2)(iii) of this section may petition the Commission at any time to modify or vacate that determination. The petition shall contain an appropriate justification for the request. The Commission, after notice and opportunity for a hearing through the submission of written data, views and arguments, shall grant, subject to conditions, or deny such request.

(3) *Required representation.* * * *

Issued in Washington, DC, on November 20, 2003, by the Commission.

Jean A. Webb,

Secretary of the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N-0496]

RIN 0910-AF09

Food Labeling: Health Claims; Dietary Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also is soliciting comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels.

Comments on the regulatory alternatives and the additional topics will inform FDA's rulemaking to establish regulations for qualified health claims, as well as any policy initiative(s) that FDA may undertake to provide information to consumers to help them make wise food choices.

DATES: Submit written or electronic comments by January 26, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Paulette Gaynor, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1450.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535)¹ directed FDA to issue regulations authorizing health claims (i.e., labeling claims that characterize the relationship of a substance to a disease or health-related condition) only if the agency determines, based upon 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 (SSA), among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (21 U.S.C. 343(r)(3)(B)(i)). Congress delegated to FDA the authority to establish the procedure and standard for health claims for dietary supplements (21 U.S.C. 343(r)(5)(D)). In accordance with the NLEA, FDA issued regulations establishing general requirements for health claims in labeling for conventional foods (58 FR 2478, January 6, 1993). By regulation (59 FR 395,

January 4, 1994), and under Congressional authority², FDA adopted the same general requirements, including the procedure and standard, for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods. (See 21 U.S.C. 343(r)(3) and (r)(4).)

The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) and 101.70) (21 CFR 101.14(d) and (e), 101.70)). The standard requires a finding of "significant scientific agreement" (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§§ 101.14(c) and 101.70(f)).

Among its provisions regulating claims, the NLEA required FDA to determine whether claims respecting 10 specific substance/disease relationships met the requirements for a health claim (NLEA section 3(b)(1)(A)(vi) and (x), Pub. L. 101-535). FDA conducted these statutorily required analyses. Not all relationships that Congress required the agency to consider were found to meet the standard of SSA, and, so, not all were authorized by FDA. Some of the substance/disease relationships that were found to lack SSA became the subject of a lawsuit, *Pearson v. Shalala* (*Pearson*), brought by dietary supplement marketers and health advocacy organizations.

In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. Although the U.S. District Court for the District of Columbia initially ruled in favor of FDA (14 F. Supp. 2d 10 (D.D.C. 1998)), the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).³ The appeals court held

¹ The NLEA authorized health claims in food labeling by amending the Federal Food, Drug, and Cosmetic Act (the act) to add section 403(r) to the act (21 U.S.C. 343(r)). This section specifies, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) (for conventional foods) or 403(r)(5)(D) (for dietary supplements).

² FDA issued regulations establishing general requirements for health claims in dietary supplement labeling (59 FR 395) under the NLEA and the Dietary Supplement Act of 1992 (Public Law 102-571).

³ The appellate court decided the case on January 15, 1999. On March 1, 1999, the Government filed a petition for rehearing en banc. The U.S. Court of Appeals for the D.C. Circuit denied the petition for