

WORLD TRADE ORGANIZATION

G/SPS/N/USA/855

18 February 2004

(04-0696)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved:
2. Agency responsible: US Food and Drug Administration (FDA)
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Food (including dietary supplements) for human consumption in the United States, except for meat, poultry and egg products that are exclusively regulated by the U.S. Department of Agriculture
4. Regions or countries likely to be affected, to the extent relevant or practicable: Trading partners who import food into the United States
5. Title, language and number of pages of the notified document: Food Labelling: Health Claims; Dietary Guidance (8 pages, available in English).
6. Description of content: The US Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labelling of conventional human foods and dietary supplements. FDA solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on food labels. Comments on the regulatory alternatives and the additional topics informed FDA's rulemaking to establish regulations for qualified health claims, as well as any policy initiatives(s) that FDA may undertake to give consumers information to help them make wise food choices.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests
8. International standard, guideline or recommendation: <input type="checkbox"/> Codex Alimentarius Commission, <input type="checkbox"/> World Organization for Animal Health (OIE), <input type="checkbox"/> International Plant Protection Convention, <input checked="" type="checkbox"/> None If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:
9. Relevant documents and language(s) in which these are available: Notice in the <i>Federal Register</i> (FR), 68 FR No. 227, pages 66040-66048, http://www.fda.gov/OHRMS/DOCKETS/98fr/03-29448.pdf (available in English)

10. Proposed date of adoption: FDA intends, within one year, to initiate notice-and-comment rulemaking to establish scientific review criteria and procedures for qualified health claim petitions. FDA intends to complete its notice-and-comment rulemaking process in the Fall of 2005.
11. Proposed date of entry into force: Fall of 2005
12. Final date for comments: 26 January 2004 Agency or authority designated to handle comments: <input type="checkbox"/> National notification authority, <input type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body: Submit written comments to the Division of Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, U.S.A. Submit electronic comments to: http://www.fda.gov/dockets/ecomments by indicating Docket No. 2003N-0496.
13. Texts available from: <input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body: U.S. Department of Agriculture, Stop 1027, Washington, DC 20250. Tel (202) 720-4051, (202) 720-0677, fstd@usda.gov . Complete text can also be found on the Internet http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm by looking under the date of publication in the Federal Register, which is 25 November 2003.