WORLD TRADE ORGANIZATION

G/SPS/N/USA/699
26 March 2003

(03-1741)

Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION

1.	**Member to Agreement notifying:** UNITED STATES **If applicable, name of local government involved:**
2.	**Agency responsible:** 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):** Dietary Ingredients and Dietary Supplements (HS Section IV)
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** US Trading Partners, specifically firms and entities seeking to manufacture, pack or hold covered products for or participate in the export to or import from the United States of such products.
5.	**Title, language and number of pages of the notified document:** "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements". (Available in English, 171 pages)
6.	**Description of content:** The Food and Drug Administration (FDA) is proposing current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule is one of many actions related to dietary supplements that we (FDA) are taking to promote and protect the public health. Since 1993, FDA has received many dietary supplement-related adverse event reports. Many of these reports relate to misbranding and/or adulteration, and private laboratory studies suggest that some supplements do not contain the amount of dietary ingredients claimed in their labeling. This proposed rule will establish mandatory minimum CGMPs necessary to ensure that dietary ingredients are neither adulterated nor misbranded. The proposed rule includes requirements for designing and constructing physical plants, establishing quality control procedures and testing manufactured dietary ingredients and dietary supplements. It also includes proposed requirements for maintaining records and for handling consumer complaints related to CGMPs. It does not limit consumer access to dietary supplements nor does it ensure the safety or claimed effect of a particular dietary ingredient independent whether the product is produced under CGMPs.
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests**

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8.	**International standard, guideline or recommendation:** **[ ] Codex Alimentarius Commission, [ ] Office International des Epizooties, [ ] International Plant Protection Convention, [X] 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:** This document represents a new proposed rule and is available in English, 171 pages: http://www.cfsan.fda.gov/~lrd/fr030313.html, English. The Advanced Notice of Proposed Rulemaking (ANPR, 62FR 25:5699-5709, 6 February 1997) can be found at http://www.cfsan.fda.gov/~lrd/fr970206.html, English.
10.	**Proposed date of adoption:** To be determined
11.	**Proposed date of entry into force:** Staggered following final rule: one year large business, two years medium business, and three years small business.
12.	**Final date for comments:** Submit written or electronic comments by 11 June 2003. **Agency or authority designated to handle comments: [ ] National notification authority, [X] National enquiry point, or address, fax number and E-mail address (if available) of other body:** Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, U.S.A. It is possible to submit electronic comments to: http://www.fda.gov/dockets/ecomments. Submit comments by indicating DOCKET No. 96N-0417 and title of document "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements".
13.	**Texts available from: [ ] National notification authority, [X] National enquiry point, or address, fax number and E-mail address (if available) of other body:** United States SPS Enquiry Point / Notification Point Mr. William Janis U.S. Department of Agriculture Stop 1027 Washington, DC 20250 Tel: (202) 720-9047 Fax: (202) 720-0677 E-mail: fstsd@usda.gov Complete text can be also be found on the Internet http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm by looking under DOCKET No. 96N-0417.