

WORLD TRADE ORGANIZATION

G/TBT/N/USA/38

1 April 2003

(03-1839)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (38) Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Dietary Ingredients and Dietary Supplements (HS Section IV) (ICS 71)
5.	Title, number of pages and language(s) of the notified document: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (106 pages, in English)
6.	Description of content: The Administration 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.
7.	Objective and rationale, including the nature of urgent problems where applicable: To promote and protect the public health
8.	Relevant documents: 68 Federal Register (FR) 12158, 13 March 2003; Title 21 Code of Federal Regulations (CFR) Parts 111 and 112. Will appear in the Federal Register when adopted
9.	Proposed date of adoption: Proposed date of entry into force: } To be determined
10.	Final date for comments: 11 June 2003

- 11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:**

<http://www.access.gpo.gov/nara/index.html>

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