

WORLD TRADE ORGANIZATION

G/TBT/Notif.97.267

19 June 1997

(97-2525)

Committee on Technical Barriers to Trade

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 (11) Agency or authority designated to handle comments regarding the notification can 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 Supplements
5.	Title, number of pages and language(s) of the notified document: Dietary Supplements Containing Ephedrine Alkaloids (47 pages, English)
6.	Description of content: The Administration is proposing to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids; require that the label of dietary supplements that contain ephedrine alkaloids state "Do not use this product for more than 7 days"; prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids; prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building); require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and require specific warning statements to appear on product labels. The Administration is also incorporating by reference its Laboratory Information Bulletin No. 4053, that the Administration will use in determining the level of ephedrine alkaloids in a dietary supplement.
7.	Objective and rationale: Health and safety.
8.	Relevant documents: 62 FR 30678, 4 June 1997; 21 CFR Part 111. Will appear in the Federal Register when adopted.

9.	Proposed date of adoption: The agency proposes that any final rule that may issue based on this proposal become effective 180 days after date of publication of the final rule. Proposed date of entry into force:
10.	Final date for comments: 18 August 1997
11.	Texts available from: National enquiry point [x] or address and telefax number of other body: