

WORLD TRADE ORGANIZATION

G/SPS/N/USA/84/Add.5
10 March 2003

(03-1357)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, dated 7 March 2003, has been received from the United States.

Comment Period For A Proposed Rule Entitled "Dietary Supplements Containing Ephedrine Alkaloids"

Dietary Supplements Containing Ephedrine Alkaloids, Reopening the Comment Period.

Federal Register Vol. 68, No. 43, pages 10417-10420 (4 pages; available in English)
<http://www.fda.gov/OHRMS/DOCKETS/98fr/03-5072.pdf>

The US Food and Drug Administration (FDA) has reopened for 30 days the comment period for a proposed rule entitled "Dietary Supplements Containing Ephedrine Alkaloids" that published in the Federal Register of 4 June 1997 (62 FR 30678) (the June 1997 proposal). In that document, FDA proposed a number of requirements relating to dietary supplements containing ephedrine alkaloids, including a requirement for a warning statement on the product label. Since publication of the June 1997 proposal, new scientific evidence has come to light concerning health risks associated with the use of dietary supplements containing ephedrine alkaloids. FDA is reopening the comment period to receive comment on this new evidence, as well as on the warning statement it is now considering for dietary supplements containing ephedrine alkaloids. FDA also intends to consider, to the extent possible, whether in light of current information FDA should determine that dietary supplements containing ephedrine alkaloids present a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."

Final date for comments: Submit written or electronic comments by 4 April 2003.

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, USA.

It is possible to submit electronic comments to:
<http://www.fda.gov/dockets/ecomments>

Submit comments by indicating DOCKET Number 95N-0304 and Title of document "Dietary Supplements Containing Ephedrine Alkaloids."

Mr. William Janis
US Department of Agriculture
Stop 1027
Washington, DC 20250
Tel (202) 720-9047, (202) 720-0677
fstd@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. 95N-0304
