

WORLD TRADE ORGANIZATION

G/SPS/N/USA/825

11 November 2003

(03-6043)

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): Iron-containing dietary supplements and drug products in solid oral dosage form
4.	Regions or countries likely to be affected, to the extent relevant or practicable: All US trading partners
5.	Title, language and number of pages of the notified document: Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Removal of Regulations for Unit-Dose Packaging Requirements for Dietary Supplements and Drugs; Final rule; removal of regulatory provisions in response to court order (available in English, 2 pages)
6.	Description of content: FDA is removing a part of a final rule that required unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 milligrams or more of iron per dosage unit. The action was taken in response to the Court's ruling in Nutritional Health Alliance v. FDA, in which the court concluded that the Federal Food, Drug, and Cosmetic Act does not provide FDA the authority to require unit-dose packaging for poison control purposes. The final rule removes the requirement for unit-dose packaging of dietary supplements and drug products from the agency's regulations in Title 21 of the Code of Federal Regulations Part 111.50 and 310.518.
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"/> Office International des Epizooties, <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: The final rule was published in the 17 October 2003 Federal Register (68 FR 59714); in English. http://www.fda.gov/OHRMS/DOCKETS/98fr/03-26188.pdf
10.	Proposed date of adoption: 17 October 2003

11.	Proposed date of entry into force: 17 October 2003
12.	<p>Final date for comments: There is no comment period</p> <p>Agency or authority designated to handle comments: <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:</p> <p>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 Numbers 91P-0186 and 93P-0306.</p>
13.	<p>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:</p> <p>U.S. Enquiry Point, U.S. Department of Agriculture, Stop 1027, Washington, DC 20250. Tel (202) 720-1301, fstsd@usda.gov. Complete text can be also be found on the Internet http://www.fda.gov/OHRMS/DOCKETS/98fr/03-26188.pdf or http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm by looking under DOCKET Nos. 91P-0186 and 93P-0306.</p>