

# WORLD TRADE ORGANIZATION

RESTRICTED

**G/TBT/Notif.95.64**

8 March 1995

(95-0502)

## 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 (3)
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): Iron-containing supplements and drugs
5.	Title and number of pages of the notified document: Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements (6 pages)
6.	Description of content: The Administration is issuing a supplemental proposed rule to set forth its legal authority, after the passage of the Dietary Supplement Health and Education Act (DSHEA), to require unit-dose packaging of iron-containing dietary supplements that contain 30 milligrams (mg) or more iron per dosage unit. The Administration is proposing regulations to require label warning statements for products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes. Also proposed are regulations to require unit-dose packaging for iron-containing products that contain 30 milligrams or more of iron per dosage unit.
7.	Objective and rationale: To reduce the risk of accidental iron poisoning of young children less than six years of age and to ensure that products containing iron or iron salts do not pose a health hazard to young children and infants.
8.	Relevant documents: 60 FR 8989, 16 February 1995; 21 CFR parts 101, 111, 170, 310. TBT/Notif.94.391 issued 27 October 1994. Will appear in the Federal Register when adopted.

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9.	Proposed date of adoption and entry into force: The Agency is proposing that any final rule that may be issued based upon this proposal became effective 180 days after its publication in the Federal Register.
10.	Final date for comments: 17 April 1995
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: