

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
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27 October 1994
Special Distribution

(94-2190)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1.	Party to Agreement notifying: <u>UNITED STATES</u>
2.	Agency responsible: Food and Drug Administration (52)
3.	Notified under Article 2.5.2 [<input checked="" type="checkbox"/>], 2.6.1 [<input type="checkbox"/> , 7.3.2 [<input type="checkbox"/> , 7.4.1 [<input type="checkbox"/> , 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 (29 pages)
6.	Description of content: 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 poisonings 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: 59 FR 51030, 6 October 1994; 21 CFR 101, 170 and 310. Will appear in the Federal Register when adopted.
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 become effective 180 days after its publication in the Federal Register.
10.	Final date for comments: 20 December 1994
11.	Texts available from: National enquiry point [<input checked="" type="checkbox"/>] or address and telefax number of other body: