GENERAL AGREEMENT

ON TARIFFS AND TRADE

RESTRICTED
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(94-0226)

Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	Party to Agreement notifying: UNITED STATES
2.	Agency responsible: Food and Drug Administration (5)
3.	Notified under Article 2.5.2 [x], 2.6.1 [ ], 7.3.2 [ ], 7.4.1 [ ], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Drug products
5.	Title and number of pages of the notified document: Tamper-Evident Packaging Requirements For Over-The-Counter Human Drug Products (6 pages)
6.	Description of content: The Administration is proposing to amend its tamper-resistant packaging requirements to require all over-the-counter human drug products marketed in two-piece, hard gelatin capsules be sealed. The Administration is also proposing a change in terminology throughout its regulatory programme from "tamper-resistant" to "tamper-evident". The agency is also soliciting comments on whether additional regulatory changes, such as packaging performance standards, may be necessary.
7.	Objective and rationale: Public health
8.	Relevant documents: 59 FR 2542, 18 January 1994; 21 CFR Part 211. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption and entry into force: The Administration proposes that any final rule that may be issued based on this proposal have an initial effective date of one year after its date of publication in the Federal Register
10.	Final date for comments: 21 March 1994
11.	Texts available from: National enquiry point [x] or address and telefax number of other body: