GENERAL AGREEMENT

ON TARIFFS AND TRADE

RESTRICTED
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(93-2091)

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 (440)
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): Medical devices (HS Chapter 9018)
5.	Title and number of pages of the notified document: Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments (35 pages)
6.	Description of content: The Administration is proposing to revise the Current Good Manufacturing Practice Regulations for medical devices to: replace quality assurance programme requirements with quality system requirements that include design, purchasing, and servicing controls; clarify record-keeping requirements for device failure and complaint investigations; clarify requirements for qualifying, verifying, and validating processes and specification changes; and clarify requirements for evaluating quality data and correcting quality problems.
7.	Objective and rationale: Safety
8.	Relevant documents: 58 FR 61952, 23 November 1993; 21 CFR Part 820. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption and entry into force: The Administration is proposing that any final rule that may be issued based upon this proposal become effective 180 days following its publication.
10.	Final date for comments: 22 February 1994
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: