

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**TBT/Notif.93.457**  
**6 December 1993**  
**Special Distribution**

(93-2091)

**Committee on Technical Barriers to Trade**

NOTIFICATION

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

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| 1.  | Party to Agreement notifying: <u>UNITED STATES</u>  |
| 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:   |