

GENERAL AGREEMENT ON

RESTRICTED

TBT/Notif.90.353

12 December 1990

Special Distribution

TARIFFS AND TRADE

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 (319)
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): Medical devices (HS Chapter 9018)
5. Title: Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations Document; Suggested Changes; Availability (5 pages)
6. Description of content: The administration is announcing the availability of an information document created to facilitate the development of changes to the Medical Devices Current Good Manufacturing Practices (CGMP) Regulations. The information document is intended to facilitate discussion of suggested changes and to generate comments for consideration by the agency when drafting language for changing the CGMP Regulations.
7. Objective and rationale: Safety
8. Relevant documents: 55 FR 24544, 15 June 1990; 55 FR 49644, 30 November 1990; 21 CFR Part 820. Will appear in the Federal Register when adopted.
9. Proposed dates of adoption and entry into force: Not yet determined
10. Final date for comments: 29 January 1991
11. Texts available from: National enquiry point [<input checked="" type="checkbox"/> , or address of other body: