GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.91.66
28 February 1991

Special Distribution

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 (325)
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): Drugs and finished pharmaceuticals
5. Title: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals (4 pages)
6. Description of content: The Food and Drug Administration is proposing to amend certain requirements of the Current Good Manufacturing Practice (CGMP) Regulations for finished human and veterinary pharmaceuticals. The proposed amendments would provide manufacturers with more flexibility and discretion in manufacturing drug products while maintaining those CGMP requirements that are necessary to assure drug product quality.
7. Objective and rationale: Drug safety
8. Relevant documents: 56 FR 5671, 12 February 1991; 21 CFR Part 211. Will be published in the Federal Register when adopted.
9. Proposed date of adoption and entry into force: Not yet determined
10. Final date for comments: 15 April 1991
11. Texts available from: National enquiry point [X] or address of other body: