GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.88.32
9 February 1988

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 (FDA) (257)
3. Notified under Article 2.5.2 [X], 2.6.1 [ ], 7.3.2 [ ], 7.4.1 [ ], Other:
4. Products covered (CCCN where applicable, otherwise national tariff heading: Digestive aid products for over-the-counter use (CCCN Chapter 30)
5. Title: Tentative Final Monograph
6. Description of content: The purpose of this proposed regulation is to issue a monograph that would establish conditions under which over-the-counter (OTC) digestive aid drug products are generally recognized as safe and effective and not misbranded.
7. Objective and rationale: Safety
8. Relevant documents: 21 CFR 357, 53 FR 2706, 29 January 1988. Will appear in the Federal Register when adopted.
9. Proposed dates of adoption and entry into force: To be determined
10. Final date for comments: 29 March 1988
11. Texts available from: National enquiry point [X] or address of other body: