GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.88.180
7 September 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 (269)
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: External analgesic drug products sold over-the-counter for human use (CCCN: Chapter 30)
5. Title: Tentative Final Monograph
6. Description of content: This proposed rule modifies the indications for which over-the-counter (OTC) hydrocortisone-containing external analgesic drug products are generally recognized as safe and effective and not misbranded by including additional warnings and directions for products labelled for "external anal itching".
7. Objective and rationale: This proposed rule is part of an ongoing review of over-the-counter drug products conducted by the Food and Drug Administration.
8. Relevant documents: 21 CFR Part 348, 53 FR 32592, 25 August 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: 24 October 1988
11. Texts available from: National enquiry point [X] or address of other body: