GENERAL AGREEMENT ON
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: UNITED STATES

2. Agency responsible: Food and Drug Administration, DHHS (262)

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):
   Drugs sold over-the-counter (CCCN Chapter 30)

5. Title: Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products

6. Description of content: This proposal will require manufacturers and packagers to market two-piece hard gelatin capsules in packaging using a minimum of two tamper-resistant packaging features, unless the capsules are sealed by a tamper-resistant packaging technology, in which case a minimum of one tamper-resistant packaging feature will be required.

7. Objective and rationale: Safety


9. Proposed date of adoption and entry into force: To be determined

10. Final date for comments: 5 July 1988

11. Texts available from: National enquiry point [X] or address of other body: