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) (270)

3. Notified under Article 2.5.2 [x], 2.6.1 [], 7.3.2 [], 7.4.1 [], Other:

4. Products covered (HS where applicable, otherwise national tariff heading):
   Antacid drug products for over-the-counter (OTC) human use (HS Chapter 30)

5. Title: Proposed Amendment to the Monograph

6. Description of content: The purpose of this proposed regulation is to revise the conditions for marketing combination antacid/analgesic drug products; to add a section on the labelling of permitted active ingredients; and to revise the professional labelling section to conform to the format of other OTC drug final monographs.

7. Objective and rationale: Safety


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

10. Final date for comments: 16 March 1989

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

88-1838