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)

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):
   Oral health care drug products (CCCN Chapter 30)

5. Title: Oral Health Care Drug Products for Over-The-Counter Human Use, Tentative Final Monograph

6. Description of content: This is a proposal for a monograph that would establish conditions under which over-the-counter (OTC) oral health anesthetic/analgesic, astringent, debriding agent/oral wound cleanser and demulcent drug products, products for use in the mouth and throat are generally recognized as safe and effective and not misbranded.

7. Objective and rationale: Human health and safety


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

10. Final date for comments: 26 May 1988

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

88-0217