**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 (268)

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):**
   Anorectal drug products sold over-the-counter for human use (CCCN Chapter 30)

5. **Title:** Tentative Final Monograph

6. **Description of content:** This proposed rule establishes a tentative final monograph which lists conditions under which over-the-counter (OTC) anorectal drug products for the relief of symptoms associated with haemorrhoids and other anorectal disorders are generally recognized as safe and effective and not misbranded.

7. **Objective and rationale:** This proposed rule is part of an ongoing review of OTC drug products being conducted by the Food and Drug Administration.


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

10. **Final date for comments:** 13 December 1988

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