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 (286)

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):
   
   Hormone-Containing Drug Products (HS Chapter 30)

5. Title: **Topically Applied Hormone-Containing Drug Products For Over-The-Counter Human Use**

6. Description of content: This proposed rule would establish that topically applied hormone-containing drug products for over-the-counter human use are not generally recognized as safe and effective and are misbranded.

7. Objective and rationale: To promote health and safety


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

10. Final date for comments: 1 December 1989

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