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 (267)

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):
   Over-the-counter cold, cough, allergy, bronchodilator and anti-asthmatic drug products (CCCN Chapter 30)

5. Title: Tentative Final Monograph

6. Description of content: This proposed rule would establish a monograph which would define conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator and anti-asthmatic drug products for human use are generally recognized as safe and effective and not misbranded.

7. Objective and rationale: This proposal is part of the ongoing review of OTC drug products being conducted by the Food and Drug Administration to ensure their effectiveness.


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

10. Final date for comments: 12 December 1988

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

88-1249