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 (336)

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

4. Products covered (HS or CCCN where applicable, otherwise national tariff heading):

   Over-the-counter drugs

5. Title: Drug Labelling; Sodium Labelling for Over-the-Counter Drugs; Proposed Amendment (5 pages)

6. Description of content: The Food and Drug Administration is proposing to amend the general labelling provisions for over-the-counter (OTC) drug products to:

   (1) require that the sodium content of all orally administered OTC drug products be included in labelling when the product contains 5 milligrammes (mg.) or more sodium per a single recommended dose, (2) require that orally administered OTC drug products containing more than 140 mg. sodium in the maximum recommended daily dose be labelled with a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor; and (3) provide for the voluntary use of certain descriptive term relating to the product's sodium content.

7. Objective and rationale: To provide uniform sodium content labelling for all orally administered OTC drug products and to provide for the voluntary use in OTC drug labelling of the same terms used to describe sodium content in food labelling.


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

10. Final date for comments: 24 June 1991

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

   91-0651