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 (190)

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): Aspartame

5. Title: Aspartame as an inactive ingredient in human drug products. Labelling requirements.

6. Description of content: The Food and Drug Administration (FDA) is proposing to declare aspartame suitable for use as an inactive ingredient in human drug products provided that the label and labelling of the drug products declare the presence and amount of the component phenylalanine that is contained in the drug product per dosage unit. Data show that aspartame can be safely used as a sweetening agent in human drug products provided that persons with phenylketonuria are alerted to the presence and the amount of phenylalanine in the product.

7. Objective and rationale: Health and safety


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

10. Final date for comments: 6 February 1984

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