**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 (217)

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):**
   - Not applicable

5. **Title:** Good laboratory practices regulations

6. **Description of content:** The Food and Drug Administration (FDA) is proposing to revise the regulations that specify good laboratory practices for non-clinical laboratory studies. The revisions are based on an agency determination that several provisions of the regulations should be clarified, amended, or deleted to reduce regulatory burdens on testing facilities. Major changes are proposed in the provisions on quality assurance, protocol preparation, test and control article characterization, and retention of specimens and samples. The changes proposed will not compromise the regulations' objective, which is to ensure the quality and integrity of the safety data submitted in support of the approval of regulated products.

7. **Objective and rationale:** To reduce the burden of compliance with the regulations


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

10. **Final date for comments:** 28 December 1984

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