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 (174)

3. **Notified under Article 2.5.2**, 2.6.1, 7.3.2, 7.4.1, Other:

4. **Products covered (CCCN where applicable, otherwise national tariff heading):** Drugs and antibiotic (CCCN Chapter 30)

5. **Title:** New drug and antibiotic regulations

6. **Description of content:** FDA is proposing to revise its regulations governing the approval for marketing of new drugs and antibiotic drugs for human use. The improvements will help applicants prepare and submit higher quality applications and permit FDA to review them more efficiently and with fewer delays. An application based solely on foreign clinical data meeting United States criteria for marketing approval may be approved if: (i) the foreign data are applicable to the United States population and medical practice, (ii) studies have been performed by clinical investigators of recognized competence, and (iii) the data may be considered valid without the need for an on-site inspection or other appropriate means.

7. **Objective and rationale:** To improve efficiency of the drug approval process and dealings with applicants for marketing approval.


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

10. **Final date for comments:** 20 December 1982

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