NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: JAPAN

2. Agency responsible: Evaluation and Registration Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare

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):
   Pharmaceuticals

5. Title: Establishment of Manufacturing Guideline for Pharmaceuticals Produced by Using Recombinant DNA Technique

6. Description of content: This proposal is to establish following standards on manufacturing facility where pharmaceuticals are produced by using recombinant DNA technique.
   A. Standards for building and facility
   B. Standards for organization of manufacturing control
   C. Matters to be obeyed by workers

7. Objective and rationale: To ensure the quality of the pharmaceutical mentioned 6. above and to prevent danger and injury caused by production.

8. Relevant documents: The Pharmaceutical Affairs Law and the Regulations for Buildings and Facilities for Pharmacies, etc.

9. Proposed dates of adoption and entry into force: Not yet determined

10. Final date for comments: 31 July 1984

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