NOTIFICATION

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

1. Party to Agreement notifying: JAPAN


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

4. Products covered (CCCN where applicable, otherwise national tariff heading):
   Pharmaceuticals (CCCN: 30) Cosmetics (CCCN: 33) Quasi drugs (CCCN: 34) Medical devices (CCCN: 30.90) Pharmaceuticals, quasi drugs and medical devices for animals.

5. Title: Amendment to a part of the Enforcement Order of the Pharmaceutical Affairs Law.
   Amendment to a part of the Enforcement Regulation of the Pharmaceutical Affairs Law.
   Amendment to a part of the Control Regulation for Animal Pharmaceuticals, etc.

6. Description of content:
   (1) The amount of fees payable on application for approval by foreign manufacturers will be set.
   (2) The matters to be applied for and the application form for foreign manufacturers will be set.
   (3) The qualification for the agent whom the applicant will have to designate and the procedures to designate or to amend the agent will be set.
   (4) The matters to be obeyed by the applicant and his agent will be set.

7. Objective and rationale: To amend the cabinet orders, ministerial ordinances etc. concerned following the enactment of "the Law to Amend a Part of the Related Laws to Facilitate the Obtaining of Type Approval, etc. by Foreign Manufacturers."

8. Relevant documents: Basic document is the Pharmaceutical Affairs Law.


10. Final date for comments: 30 July 1983

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

83-1155