NOTIFICATION

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

1. Party to Agreement notifying: AUSTRALIA

2. Agency responsible: Department of Human Services and Health

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

4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Therapeutic goods, where a test for pyrogen or endotoxin content is part of a statutory requirement.

5. Title and number of pages of the notified document: Therapeutic Goods Order No. 50, General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods

6. Description of content: Describes legal standard for the supply of goods in Australia where test for pyrogen or endotoxin content is part of a statutory requirement.

7. Objective and rationale: To ensure the safety of therapeutic goods.

8. Relevant documents: Therapeutic Goods Order No. 50, available from Therapeutic Goods Administration

9. Proposed date of adoption and entry into force: 30 December 1994

10. Final date for comments: 15 December 1994

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

   The Information Officer
   Therapeutic Devices Branch
   Therapeutic Goods Administration
   PO Box 100
   Woden, ACT 2606
   AUSTRALIA

   Telefax (61) 6 239 8687