## **GENERAL AGREEMENT ON**

## TARIFFS AND TRADE

RESTRICTED

TBT/Notif.90.5 18 January 1990 Special Distribution

Committee on Technical Barriers to Trade

## NOTIFICATION

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

| 1.   | Party to Agreement notifying: <u>CANADA</u>   |
|------|---|
| 2.   | Agency responsible: Department of National Health and Welfare   |
| 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):  Pharmaceutical products   |
| 5.   | Title: Food and Drug Regulations - Amendment (10 pages)   |
| 6.   | Description of content: These amendments require pharmaceutical manufacturers to declare all non-medicinal ingredients on the inner and outer labels of all drug products for human use, both prescription and non-prescription. Corresponding requirements are also included for veterinary drug products for parenteral use only. The submission of non-medicinal ingredient information will also be required at the time of application for a Drug Identification Number. |
| 7.   | Objective and rationale: Protection of human health   |
| 8.   | Relevant documents: Canada Gazette, Part I, 2 December 1989, pages 5215-5224  |
| 9.   | Proposed dates of adoption and entry into force: 1 January 1991   |
| 10.  | Final date for comments: 1 March 1990   |
| 11.  | Texts available from: National enquiry point [X] or address of other body:  |
| 20.0 |   |