

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**TBT/Notif.95.5**  
12 January 1995  
Special Distribution

(95-0023)

**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. ICS numbers may be provided in addition, where applicable): Drugs
5.	Title and number of pages of the notified document: Proposed Amendment to the Food and Drug Regulations, pages 4787-4799
6.	Description of content: This initiative establishes a regulatory framework for abbreviated new drug submissions. The Amendment provides a definition for a Canadian reference product thereby providing manufacturers and consumers with a clearly defined standard. This regulatory initiative also defines specific requirements for an abbreviated new drug submission.
7.	Objective and rationale: Protection of human safety
8.	Relevant documents: Canada Gazette, Part I, 24 December 1994
9.	Proposed date of adoption and entry into force: Not stated
10.	Final date for comments: 22 February 1995
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: