

WORLD TRADE ORGANISATION

RESTRICTED

G/TBT/Notif.95.1

16 January 1995

Special Distribution

(95-0031)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>CANADA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of National Wealth and Welfare
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 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 and 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: