

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: Health Canada Agency or authority designated to handle comments regarding the notification can be indicated if different from above:
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, number of pages and language(s) of the notified document: Proposed Amendment to the Food and Drug Regulations (Schedule No. 624)
6.	Description of content: This regulatory amendment is intended to improve the management of the risks associated with the fabrication, packaging, testing, importation, and distribution for sale of drugs in Canada. It will accomplish this by rationalizing the current patchwork of regulatory controls into a common establishment licensing framework. In addition to the framework rationalization, a number of incidental regulatory amendments are being proposed to deal with specific concerns identified by manufacturers. In addition this amendment will bring Canadian requirements into line with those of most developed countries.
7.	Objective and rationale: Protection of human safety
8.	Relevant documents: Canada Gazette, Part I, 10 August 1996
9.	Proposed date of adoption: } Proposed date of entry into force: } Not stated
10.	Final date for comments: 9 October 1996
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: