

# WORLD TRADE ORGANIZATION

G/TBT/N/CAN/103

23 July 2004

(04-3190)

Committee on Technical Barriers to Trade

Original: English/  
French

## NOTIFICATION

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

1.	<b>Member to Agreement notifying:</b> CANADA <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Department of Health <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> Canadian Enquiry Point, 200-270 Albert Street, Ottawa, Ontario, Canada, K1P 6N7 Tel.: +1 613 238 3222, Fax.: +1 613 569 7808, E-mail: <a href="mailto:info@scc.ca">info@scc.ca</a>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medicinal ingredients which require a prescription for both human and veterinary use (ICS : 11.120, 11.220)
5.	<b>Title, number of pages and language(s) of the notified document:</b> Proposed Amendment to the Food and Drug Regulations (1397 – Schedule F) (pages 2061-2065; English and French)
6.	<b>Description of content:</b> The Therapeutic Products Directorate (TPD) of Health Canada intends to update Schedule F to the <i>Food and Drug Regulations</i> of the <i>Food and Drugs Act</i> by adding seven medicinal ingredients to Part I of Schedule F.  Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.046 of the <i>Food and Drug Regulations</i> . Part I of Schedule F lists medicinal ingredients which require a prescription for both human and veterinary use. Part II of Schedule F lists medicinal ingredients which require a prescription for human use, but do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use. The review and introduction of new drugs on the Canadian market necessitate periodic revisions to Schedule F.  <u>New listings</u>  It is proposed that the following seven medicinal ingredients be added to Part I of Schedule F:  1. Adefovir and its salts and its derivatives — a nucleotide analogue. Adefovir dipivoxil is used to treat chronic hepatitis B.  2. Almotriptan and its salts — a selective 5-hydroxytryptamine <sub>1B/1D</sub> (5-HT <sub>1B/1D</sub> ) receptor agonist. Almotriptan malate is used for the acute treatment of migraine attacks with or without aura in adults.

./.

3.	Cetrorelix and its salts — gonadotropin-releasing hormone (GnRH) antagonist. Cetrorelix acetate injection is used to help control the release of eggs from the ovaries of women undergoing assisted conception procedures such as in-vitro fertilization.
4.	Ketanserin and its salts — serotonin S2 receptor antagonist. Ketanserin is indicated for the treatment of wounds in horses on or below the tarsal or carpal joints and to prevent the formation of excessive granulation tissue at these wound sites.
5.	Phenylpropanolamine and its salts and its derivatives for veterinary use — a sympathomimetic amine consisting of the racemic mixture of <i>d</i> - and <i>l</i> -norephedrine. Phenylpropanolamine hydrochloride (PPA) is used in female dogs for the long-term treatment of urinary incontinence associated with sphincter mechanism incompetence.
6.	Tadalafil and its salts — a cGMP-specific phosphodiesterase type 5 (PDE5) inhibitor. Tadalafil is a potent, selective, and reversible inhibitor indicated for the treatment of male erectile dysfunction (ED) at oral doses of 10 and 20 mg once daily.
7.	Teflubenzuron — antiparasite. Teflubenzuron is indicated for the treatment of parasitic infestations caused by the developing chalimus and pre-adult stages of <i>Lepeophtheirus salmonis</i> on Atlantic salmon ( <i>Salmo salar</i> ).
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human and animal health
8.	<b>Relevant documents:</b> Canada Gazette, Part I, 17 July 2004
9.	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> } Not stated
10.	<b>Final date for comments:</b> 30 September 2004
11.	<b>Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b>  The electronic version of the regulatory text can be downloaded at: <a href="http://canadagazette.gc.ca/partI/2004/20040717/pdf/g1-13829.pdf">http://canadagazette.gc.ca/partI/2004/20040717/pdf/g1-13829.pdf</a>