

WORLD TRADE ORGANIZATION

G/TBT/N/CAN/79
17 October 2003

(03-5515)

Committee on Technical Barriers to Trade

Original: English/
French

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 Health 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: Canadian Enquiry Point, 200-270 Albert Street, Ottawa, Ontario, Canada, K1P 6N7 Tel.: +1 613 238 3222, Fax.: +1 613 569 7808, E-mail: info@scc.ca
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): Substances which require a prescription for both human and veterinary use (ICS : 11.120, 11.220)
5.	Title, number of pages and language(s) of the notified document: Proposed Amendment to the Food and Drug Regulations (1329 – Schedule F) (pages 3232-3240 in English and French)
6.	<p>Description of content: 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 19 medicinal ingredients to Part I of Schedule F, amending 4 medicinal ingredients in Part I of Schedule F, and transferring 1 medicinal ingredient from Part II to Part I of Schedule F.</p> <p>Schedule F is a list of substances, 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 substances that require a prescription for both human and veterinary use. Part II of Schedule F lists substances that 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 onto the Canadian market necessitates periodic revisions to Schedule F.</p> <p><u>New listings</u></p> <p>It is proposed that the following 19 substances be added to Part I of Schedule F:</p> <p>1. Alteplase and its salts and derivatives – an enzyme used to dissolve blood clots.</p>

2. Anakinra and its salts and derivatives – an interleukin-1 receptor antagonist. Anakinra is used to treat adults with active rheumatoid arthritis to reduce the signs and symptoms of the disease.
3. Atipamezole and its salts – an alpha-2 adrenergic receptor antagonist. This drug is used to reverse the effects of alpha-2 adrenergic receptor agonists which are sedative agents for minor surgical or medical procedures or used as pre-anaesthetic agents.
4. Bimatoprost and its derivatives – a drug to reduce elevated pressure within the eye. Bimatoprost is used to treat patients who have elevated pressure within the eye, including glaucoma.
5. Carprofen and its salts and derivatives – a non-steroidal anti-inflammatory drug (NSAID). Carprofen is indicated for use in dogs for the relief of pain and inflammation associated with osteoarthritis.
6. Ganirelix and its salts and derivatives – a gonadotropin-releasing hormone (GnRH) antagonist. Ganirelix is used as part of the treatment for assisted reproduction techniques including in-vitro fertilisation (IVF – fertilization of an egg in a test tube).
7. Glimepiride – an oral hypoglycemic agent. Glimepiride is used to lower the blood glucose of patients with type 2 diabetes whose high blood glucose levels cannot be controlled by diet and exercise alone.
8. Medetomidine and its salts – a alpha-2 adrenergic receptor agonist. Medetomidine is used in animals as a sedative agent for minor surgical or medical procedures or a pre-anaesthetic agent.
9. Moxidectin and its derivatives – an antiparasitic drug. This drug is used for the prevention of heartworm in dogs.
10. Orbifloxacin and its salts and derivatives – a synthetic broad spectrum antibacterial agent. Orbifloxacin is used for the treatment of skin and soft tissue infections in dogs and cats and for the treatment of urinary tract infections in dogs.
11. Palivizumab – a humanized monoclonal antibody produced by recombinant DNA technology. This drug is administered by monthly intramuscular injections to high-risk children for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus.
12. Romifidine and its salts – a potent alpha-2 adrenergic receptor agonist. Romifidine is used in animals as a sedative agent and for pain relief during minor surgical or medical procedures or as a pre-anaesthetic agent.
13. Tegaserod and its salts – a 5-HT₄ receptor partial agonist. Tegaserod is used to treat the symptoms of irritable bowel syndrome with constipation in female patients whose main symptoms are constipation and abdominal pain and/or discomfort.
14. Thyrotropin alfa – human thyroid-stimulating hormone produced by recombinant DNA technology. Thyrotropin alfa is a diagnostic tool used in conjunction with other tests in the follow-up of patients with certain kinds of thyroid cancer.

15. Tiotropium bromide – anticholinergic agent. Tiotropium bromide is a bronchodilator for the treatment of chronic obstructive pulmonary disease including chronic bronchitis and emphysema.

16. Tolfenamic acid and its salts and derivatives – a non-steroidal anti-inflammatory drug (NSAID). Tolfenamic acid is used to alleviate inflammation and pain associated with osteoarthritis in dogs with hip dysplasia. It is also used as an aid in the treatment of upper respiratory diseases and as symptomatic treatment of fever in cats.

17. Unoprostone and its salts and derivatives – a drug to reduce elevated pressure within the eye. Unoprostone is used to treat patients who have elevated pressure within the eye, including glaucoma. It is for use in patients who cannot be treated with other pressure-lowering medication due to intolerance or insufficient response.

18. Valdecoxib and its salts – a nonsteroidal anti-inflammatory drug (NSAID). Valdecoxib is used to treat the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. It is also indicated for the relief of menstrual pain.

19. Valganciclovir and its salts and derivatives – an antiviral agent. Valganciclovir is used to treat inflammation of the retina of the eye caused by cytomegalovirus (CMV) in patients with acquired immunodeficiency syndrome (AIDS).

Revised listings

It is proposed that the listings of five ingredients presently included in Schedule F be revised:

1. Amfebutamone
2. Melarsomine
3. Omeprazole
4. Praziquantel
5. Ivermectin

7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8.	Relevant documents: Canada Gazette, Part I, 11 October 2003
9.	Proposed date of adoption: not stated Proposed date of entry into force: not stated
10.	Final date for comments: 25 December 2003
11.	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: The electronic version of the regulatory text can be downloaded at: http://canadagazette.gc.ca/partI/2003/20031011/pdf/g1-13741.pdf