WORLD TRADE ORGANIZATION

G/TBT/N/CAN/430

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(14-6210)

Committee on Technical Barriers to Trade

Original: English/French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** CANADA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Department of Health **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**: Canada's Notification Authority and Enquiry Point Foreign Affairs, Trade and Development Canada Technical Barriers and Regulations Division (TIB) 111 Sussex Drive Ottawa, ON K1A 0G2 Canada Telephone: (343)203-4273 Fax: (613)943-0346 E-mail: enquirypoint@international.gc.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):** Class II medical devices (ICS 11:040)
5.	**Title, number of pages and language(s) of the notified document:** Proposed Amendments to the Medical Devices Regulations (Non-Corrective Contact Lenses and Labelling of Class II Medical Devices) (7 pages, available in English and French)
6.	**Description of content:** This proposal would introduce two sets of amendments to the *Medical Devices Regulations*, both involving the licence application requirements for Class II medical devices. The first amendment would address the absence of therapeutic effect in non-corrective contact lenses. Non-corrective contact lenses are currently subject to the *Canada Consumer Product Safety Act* and therefore do not require a licence from Health Canada prior to being imported or sold in Canada. Bill C-313, *An Act to Amend the Food and Drugs Act (non-corrective contact lens)* received Royal Assent on December 14, 2012. Once this Act comes into force, these products would become subject to all of the licensing requirements for Class II devices under the *Medical Device Regulations.* However, an exemption would be made so that manufacturers of non-corrective contact lenses would not be required to demonstrate therapeutic effectiveness for these products. The proposed amendments to the *Medical Devices Regulations* and to the *Food and Drugs Act* would come into force at the same time. Since 2005, all contact lenses (both corrective and non-corrective) have been regulated as medical devices in the United States. The proposal would align the Canadian regulatory approach more closely with our largest trading partner.

	The objective of the proposed regulation for non-corrective lenses is to enable proportional regulatory oversight with regard to the manufacture and safe use of these products, without imposing an undue burden on the manufacturer. The second amendment to the *Medical Devices Regulations* would require manufacturers of all Class II devices to submit a copy of the product label as part of the Class II medical device licence application. Currently, manufacturers of Class II devices are not required to provide a copy of the product label with a licence application. Instead, a Class II licence application requires only an attestation that the label complies with the requirements of the *Regulations*. The regulation with respect to labelling of Class II medical devices is intended to address concerns of non-compliant labelling and inappropriate risk classification of medical devices so that the level of regulatory oversight applied to a device is proportional to the risk presented by its use.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health and safety (safe use of medical devices)
8.	**Relevant documents:** Canada Gazette, Part I, 18 October 2014, pages 2718-2725 (available in English and French)
9.	**Proposed date of adoption:** On the date the amendments are registered, Notification of registration will occur through publication in Canada Gazette, Part II, which is anticipated to be 6-9 months following publication in Canada Gazette, Part I. **Proposed date of entry into force:** The concurrent coming into force of the proposed amendments to the Medical Devices Regulations and the Food and Drugs Act for Non-Corrective Contact Lenses would come into force 12 months following publication in Canada Gazette, Part II. The amended Regulations to address Class II device labelling would come into force on the day on which they are registered.
10.	**Final date for comments:** December 31, 2014
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** The electronic version of the regulatory text can be downloaded at: http://www.gazette.gc.ca/rp-pr/p1/2014/2014-10-18/pdf/g1-14842.pdf (Canada Gazette) http://gazette.gc.ca/rp-pr/p1/2014/2014-10-18/html/reg4-eng.php http://gazette.gc.ca/rp-pr/p1/2014/2014-10-18/html/reg4-fra.php