



11 January 2018

(18-0357)

Page: 1/2

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: <u>CANADA</u> 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 Global Affairs Canada Technical Barriers and Regulations Division 111 Sussex Drive, Ottawa, ON K1A 0G2 Canada Telephone: (343) 203-4273 Fax: (613) 943-0346 E-mail: enquiry@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): Drugs and Medical Devices (ICS: 11.120; 11.040)
5. Title, number of pages and language(s) of the notified document: Notice - Amendments to the Food and Drug Regulations for Mica (1 page(s), in English; 1 page(s), in French)
6. Description of content: This Notice communicates Health Canada's intent to amend the <i>Food and Drug Regulations</i> to permit the use of mica coated with titanium dioxide and/or iron oxide as colouring agents in drugs for both internal and external use. The regulatory proposal would also establish concentration limits for this inactive ingredient when it is used in different dosage forms.
7. Objective and rationale, including the nature of urgent problems where applicable: This proposal responds to a request and supporting data provided by a manufacturer of mica coated with titanium dioxide and/or iron oxide.
8. Relevant documents: The Notice of Intent for this regulatory proposal is available from the following websites, in English and French: http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-amendment-food-drug-regulations-mica.html https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/annonces/avis-modifications-reglement-aliment-droques-mica.html

9. Proposed date of adoption: Not stated
Proposed date of entry into force: The regulations will come into force on the day they are published in Canada Gazette Part II.

10. Final date for comments: 11 March 2018

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

The electronic version of this notice is available from the following websites, in English and French:

<http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-amendment-food-drug-regulations-mica.html>

<https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/annonces/avis-modifications-reglement-aliment-drogues-mica.html>