Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **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:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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):**
5.	**Title, number of pages and language(s) of the notified document:** Resolution - RDC n. 219, February 26th, 2018. Portuguese, 8 pages – post-registration of medicines
6.	**Description of content:** This Resolution applies to requests for post-registration alteration of medicines and biological products filed with Anvisa before and after Law 13.411 of December 28, 2016. Art. 2. The maximum period for the final decision in the post-registration change processes of medicines and biological products will be, respectively: I - for the priority category, of sixty days, counted from the date of the respective prioritization protocol; II - for the ordinary category, one hundred and eighty days, counted from the date of the respective post-registration change protocol. Paragraph 1. The aforementioned period may be extended by up to one-third of the original term, once, by means of a reasoned decision of Anvisa issued at least fifteen business days before the end of the original term. Paragraph 2. The aforementioned period will have their countdown suspended when they request information or requirements, until they are attended to. Art. 6. Petitions for post-registration changes petitioned before the enactment of Law nº 13.411, of 2016, for which a safety and efficacy report is required, will have its analysis procedures maintained and can only be implemented after approval by Anvisa. Art. 8. The Anvisa areas responsible for medicine registration, inspection, monitoring and

	monitoring will establish a program to monitor post-registration changes implemented in accordance with the conditional approval set forth in this Resolution. Art. 9. During follow-up inspections or inspection actions, the company must provide all documentation related to the complete technical dossier, required by the health regulations in force at the time of the petition, which deals with post-registration changes. Art. 17. This Resolution comes into force on the date of its publication.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** 1) Brazilian Official Journal (Diário Oficial da União) Nº 39, 28 February 2018, section 1, page 79; 2) Law No. 13.411 28 December 2016; Law 6.437, 20 August 19773) Brazilian Official Journal; 4) Not applicable
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** On the date of its publication
10.	**Final date for comments:**
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:** Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/4106210/%281%29RDC_219_2018_.pdf/e2a0ae4f-8998-4ebf-b37c-03dabb3ad87e