WORLD TRADE ORGANIZATION

G/TBT/N/BRA/757

24 November 2017

(17-6419)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **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:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563 2840 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):** HS CODE: 98041000
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution 416, 8 November 2017 (Consulta Pública N° 416, de 8 de novembro de 2017) (12 page(s), in Portuguese)
6.	**Description of content:** This Draft Resolution defines the procedures and regulatory requirements for the reporting of clinical trials with Products Advanced Research Therapies in Brazil, including the Clinical Development Dossier (DDCTA), to be submitted to Anvisa for consent purposes. This Resolution DOES NOT APPLY to: I - clinical trials with the drugs referred to in Resolution RDC No. 9 of February 2, 2015 and their updates; and II - to post-marketing clinical trials (phase IV) This Resolution is applicable to clinical trials for the purpose of proving safety and efficacy, with Products of Advanced Research Therapies that can be registered and that will have their clinical development in Brazil.
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 215), 9 December 2017; Section 1 page 60. (2) Draft Resolution n° 416, 8 December 2017, Resolution RDC 63, 25 November 2011; Resolution RDC 172, 12 September 2017; (3) Brazilian Official Journal. Available in Portuguese;(4) Not stated.

9.	**Proposed date of adoption:** To be determined after the end of consultation period **Proposed date of entry into force:** To be determined after the end of consultation period
10.	**Final date for comments:** 15 December 2017
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of 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/10181/3428326/CONSULTA+PUBLICA+N+416+GSTCO.pdf/21c3011c-a7b2-483e-9a3c-1d02766c67fd