WORLD TRADE ORGANIZATION

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Date

(00-0000) Page: 1/2

Committee on Technical Barriers to Trade Original:

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:** The Brazilian Health Regulatory Agency **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(s): 3003; 3004; 3005; 2941 (pharmaceutical products).
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution number 760, December 27th, 2019. **Number of pages:** 38; **Language(s):** Portuguese Draft: Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=52824
6.	**Description of content:** This Draft Resolution establishes the minimal technical requirements for relative bioavailability and bioequivalence studies that supports dossier of consent for clinical research, market authorization or post-market authorization of medicines, in the terms of this resolution.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health.
8.	**Relevant documents:** Impact Assessment Report
9.	**Proposed date of adoption:** 365 days after the date of its publication. **Proposed date of entry into force:** 365 days after the date of its publication.
10.	**Final date for comments:** April 7th, 2020
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Brazilian Health Regulatory Agency (Anvisa)

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http://portal.anvisa.gov.br/documents/10181/5740831/Consulta+P%C3%BAblica+n%C2%BA+760-2019.pdf/e7555e7d-f87d-4190-bb10-82ec5fd13e61