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:** ANVISA – Brazilian Health Surveillance Agency **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 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Website: http://www.inmetro.gov.br/barreirastecnicas **The comments to this Draft Regulation shall be sent to** http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=19091
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):** Pharmaceutical substances under special control and medicines containing them.
5.	**Title, number of pages and language(s) of the notified document:** Draft Technical Resolution Nº 05, January 28th 2015, regarding the control of substances under special control, and medicines containing them, in Pharmaceutical Equivalence centres and centres of Bioavailability/Bioequivalence. (7 pages, Portuguese).
6.	**Description of content:** Draft Technical Resolution Nº 05, January 28th 2015, regarding the control of substances under special control, and medicines containing them, in Pharmaceutical Equivalence centres and centres of Bioavailability/Bioequivalence. According to this draft Technical Resolution, the licensed Pharmaceutical Equivalence centres and the centres of Bioavailability/Bioequivalence certified by Anvisa must obtain Special Authorization to the execution of any activities which involve substances under special control, and the medicines containing them as well. The establishments have 1 (one) year to ask for the Special Authorization and 3 (three) months to adapt themselves to the other requirements of this draft Technical Resolution. This Draft Technical Resolution revokes the Resolution RDC Nº 197/2004.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), January 29th 2015; Section 1, p. 69, Draft Resolution (Consulta Pública) Nº 05, January 28th 2015, issued by Brazilian Health Surveillance Agency – Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
9.	**Proposed date of adoption:** **Proposed date of entry into force:** } To be determined after the end of the consultation period.
10.	**Final date for comments:** March 06th, 2015.
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:** Agency Responsible Brazilian Health Surveillance 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/wps/wcm/connect/e87c3b80471d65db9a589b41cdd33a01/Consulta+P%C3%BAblica+n%C2%B0+05+GGREG.pdf?MOD=AJPERES