WORLD TRADE ORGANIZATION

G/TBT/N/BRA/611

28 October 2014

(14-6250)

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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:** ANVISA - Brazilian Health Surveillance 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 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br Web-site: 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=17911
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):** Centres of pharmaceutical equivalence
5.	**Title, number of pages and language(s) of the notified document:** Draft Technical Resolution nº 95, October 9th 2014, Regarding the Petitions of Request for Qualification, License Renewal, Post-License Changes, Outsourcing Trial, Suspensions and Cancellations of Centres of Pharmaceutical Equivalence (22 pages, in Portuguese)
6.	**Description of content:** Draft Technical Resolution nº 95, 9 October 2014, regarding the petitions of request for qualification, license renewal, post-license changes, outsourcing trial, suspensions and cancellations of Centres of Pharmaceutical Equivalence (22 pages, in Portuguese). This draft Technical Resolution establishes the minimum requirements and procedures to be attended by laboratories that intend to become Centres for Pharmaceutical Equivalence, and by the ones that are already licensed, to the request for qualification, license renewal, post-license changes, outsourcing trial, suspensions and cancellations of Centres of Pharmaceutical Equivalence. The Centres of Pharmaceutical Equivalence already qualified have 120 days after the publication of the regulation to make the necessary adjustments, in order to comply with this Draft Technical Resolution. This Draft Technical Resolution revokes article 4th and its paragraphs 1st and 2nd, of the Resolution RDC n. 41/2000.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), 10 October 2014; Section 1, p. 45, Draft Resolution (Consulta Pública) number 95, 9 October 2014, 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:** To be determined after the end of the consultation period **Proposed date of entry into force:** To be determined after the end of the consultation period
10.	**Final date for comments:** 17 November 2014
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 Surveillance Agency - ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 Website: http://www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/cb9eab8045c7dcc89f87ffd10ee53f37/Consulta+P%C3%BAblica+n%C2%B0+95+GGMED.pdf?MOD=AJPERES