WORLD TRADE ORGANIZATION

G/TBT/N/BRA

Committee on Technical Barriers to Trade Original: English

NOTIFICATION

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

1.	**Member to Agreement notifying:** 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, Standardization and Industrial Quality-INMETRO Telephone: +(55) 21 2563.2821 Telefax: +(55) 21 2502.6542 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):** Medicines, Health Products, Cosmetics, Perfumes, Personal Care Products, Sanitizing and Pharmaceutical Active Ingredients.
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 02, January 7th 2013 – Granting of Certificate of Good Manufacturing Practices and Certification of Good Distribution Practices and/or Storage (11 pages, Portuguese)
6.	**Description of content:** This draft technical regulation establishes conditions for the granting of Certification of Good Manufacturing Practices for Medicines, Health Products, Cosmetics, Perfumes, Personal Care Products, Sanitizing and Pharmaceutical Active Ingredients. It also establishes the conditions for the granting of Certification of Good Distribution Practices and/or Storage for Medicines, Health Products and Active Ingredients. This draft technical regulation revokes Resolution RDC 460, September 14th 1999; Annex II of Resolution RDC 25, December 9th 1999; Resolution RDC 95, November 08th 2000; Resolution RE 1.450, September 11th 2001; Resolution RDC 354, December 23rd 2002; Resolution RDC 225, August 25th 2003; Resolution RDC 66, October 05th 2007; Resolution RDC 16, April 23rd 2009; Resolution RDC 68, December 21st 2009, and Resolution RDC 29, August 10th 2010.

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	Petitions for extension of the Certificate of Good Manufacturing Practices for Health Products filed until the date of publication of this Resolution shall be evaluated in accordance with the requirements of Resolution RDC 16, April 23rd, 2009.
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 8th 2013; Section 1 p. 35 Draft Resolution (Consulta Pública) number 02, January 7th, 2013, issued by Brazilian Health Regulatory 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:** on the date of adoption.
10.	**Final date for comments:** March 18th, 2013
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: National enquiry point 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 E-mail: rel@anvisa.gov.br Website: www.anvisa.gov.br http://portal.anvisa.gov.br/wps/wcm/connect/fcd35d004e1b2885a1feb3c09d49251b/Consulta+P%C3%BAblica+n%C2%B0+2+GGIMP.pdf?MOD=AJPERES