

WORLD TRADE ORGANIZATION

G/TBT/N/BRA/75

13 January 2003

(03-0153)

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: <u>BRAZIL</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: 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 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: Brazilian Sanitary Surveillance Agency - ANVISA Telephone: +(55) 61 448.1078 Fax: +(55)61 448.1089 E-mail: rel@anvisa.gov.br
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): Ganglioside-based drugs (HS Chapter 30)
5. Title, number of pages and language(s) of the notified document: Resolution number 298, 6 November 2002 (Resolução RDC no. 298, de 6 de novembro de 2002) issued by the Brazilian Sanitary Surveillance Agency on ganglioside-based drugs. (4 pages, in Portuguese).
6. Description of content: This technical regulation establishes that requirements concerning raw material importation, ganglioside-based drugs manufacturing, distribution, trading and prescription as well as drug usage will be subject to the control of the Brazilian Sanitary Surveillance Agency. It also includes ganglioside-based drugs in the list C1 - Substances Subject to Special Control, found in Annex I of Ministerial Act number 344, 12 May 1998 (Portaria SVS/MS no. 344 de 12 de maio de 1998). In addition, the directions of the above mentioned drugs must contain the following warnings in Portuguese: <i>- Medicamento a base de tecido nervoso que pode desencadear a Síndrome de Guillan Barre (SGB).</i> ("Nervous tissue based drugs which can arouse Guillain-Barré

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<p>Syndrome (SGB)” and</p> <p><i>- Medicamento a base de tecido nervoso bovino. Os tecidos bovinos estão associados à aparição da Encefalite Espongiforme Bovina, variável humana. (“Bovine nervous tissue based drugs. The nervous tissues are associated with the appearance of bovine spongiform encephalopathy, human variant”)</i></p> <p>It also revokes the following Resolutions:</p> <ol style="list-style-type: none"> 1. Resolution number 527, 17 April 2001 (Resolução RE no. 527 de 17 de abril de 2001) 2. Resolution number 2, 5 March 2002 (Resolução RE no. 2 de 5 de março de 2002) 3. Resolution number 198, 12 July 2002 (Resolução RDC no. 198 de 12 de julho de 2002) 4. Resolution number 278, 24 October 2002 (Resolução RDC no. 278 de 24 de outubro de 2002) <p>Obs: Also notified under SPS Agreement</p>	<p>7. Objective and rationale, including the nature of urgent problems where applicable: Consumer’s health and safety and directions requirements</p>
<p>8. Relevant documents: Ministerial Act number 344, 12 May 1998 (Portaria SVS/MS no. 344 de 12 de maio de 1998)</p>	<p>9. Proposed date of adoption: Proposed date of entry into force: Not stated</p>
<p>10. Final date for comments: Not stated</p>	<p>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 Institute of Metrology, Standardization and Industrial Quality-INMETRO</p> <p>Telephone: +(55) 21 2563.2821 Telefax: +(55) 21 2502.6542 Email: barreirastecnicas@inmetro.gov.br</p> <p>Brazilian Sanitary Surveillance Agency – ANVISA</p> <p>Telephone: +(55) 61 448.1078 Telefax: +(55) 21 2502.6542 Email: rel@anvisa.gov.br</p> <p>Or at the following link: http://www.anvisa.gov.br/legis/resol/2002/298_02rdc.htm</p>