



15 June 2021

(21-4883)

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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: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory Agency (ANVISA) 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 2145.3817 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): Pharmaceutical preparations and products of subheadings 3006.10.10 to 3006.60.90 (HS 3006)
5. Title, number of pages and language(s) of the notified document: Resolution number 501, May 27th, 2021 (2 page(s), in Portuguese)
6. Description of content: The Resolution disposes about the mandatory execution and notification of field actions by product registration holders for health in Brazil.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: 1) Brazilian Official Gazette 103 on 02 June 2021, section 1, page 119; https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-501-de-27-de-maio-de-2021-323567020
9. Proposed date of adoption: 1 July 2021 Proposed date of entry into force: 1 July 2021
10. Final date for comments: Not applied

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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Website: www.anvisa.gov.br

http://antigo.anvisa.gov.br/documents/10181/6279622/RDC_501_2021_.pdf/1966d1de-c391-4ca3-8ed1-c73f69657ae3