



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 (Articles 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): 3003-3004 (HS)
5. Title, number of pages and language(s) of the notified document: Resolution – RDC number 517, 10 June 2021. Language(s): Portuguese. Number of pages: 4.
6. Description of content: Due to the international public health emergency resulting from the new Coronavirus, this resolution establishes exceptional and temporary criteria and requirements for exemption from package inserts and labeling information for the presentation of medicines for use restricted to hospitals, clinics and services of home care, except pharmacies and drugstores.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8. Relevant documents: 1) Brazilian Official Gazette 111 on 16 June 2021, section 1, page 243 https://www.in.gov.br/web/dou/-/resolucao-rdc-n-517-de-10-de-junho-de-2021-326187747
9. Proposed date of adoption: 16 June 2021 Proposed date of entry into force: 16 June 2021 This Resolution is valid for 180 days, and may be extended at the discretion of Anvisa.
10. Final date for comments: Not applied

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

http://antigo.anvisa.gov.br/documents/10181/6285580/RDC_517_2021_.pdf/21a88996-5a12-4eb5-9979-fdf418745f5e

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