Committee on Technical Barriers to Trade

Original:

NOTIFICATION

Addendum

The following communication, dated 8 June 2021, is being circulated at the request of the delegation of Brazil.

Title: Amendment of Resolution – RDC number 283, 17 May 2019

Reason for Addendum:	
[]	Comment period changed - date:
[]	Notified measure adopted - date:
[X]	Notified measure published - date: 02 June 2021
[X]	Notified measure enters into force - date: 02 June 2021
[]	Text of final measure available from[1]:
[]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[X]	Content or scope of notified measure changed https://www.in.gov.br/web/dou/-/resolucao-rdc-n-500-de-27-de-maio-de-2021-323570081 http://antigo.anvisa.gov.br/legislacao#/visualizar/451744 New deadline for comments (if applicable):
[]	Interpretive guidance issued and text available from:
[]	Other:

Description:

ANVISA Resolution RDC number 283, 4 May 2019, which establishes technical requirements for investigation, control and elimination of nitrosamines potentially carcinogenic in active pharmaceutical ingredients (IFA) which are angiotensin II receptor antagonists; and is applied to companies that manufacture, import and fractionate active pharmaceutical ingredients (IFA), - previously notified through G/TBT/N/BRA/871, was amended by the Resolution - RDC number 500, 27 May 2021.

The new text establishes that:

The final text is available only in Portuguese and can be downloaded at:

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http://antigo.anvisa.gov.br/legislacao#/visualizar/451744