Committee on Technical Barriers to Trade

Original:

NOTIFICATION

Addendum

The following communication, dated 9 June 2021, is being circulated at the request of the delegation of Brazil.

Title: ANVISA RDC number 505, 27 May 2021

Reason for Addendum:	
[]	Comment period changed - date:
[]	Notified measure adopted - date:
[X]	Notified measure published - date: 31 May 2021
[X]	Notified measure enters into force - date: 01 July 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[]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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-505-de-27-de-maio-de-2021-323002775 http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255 New deadline for comments (if applicable):
[]	Interpretive guidance issued and text available from:
[]	Other:

Description:

ANVISA issued Resolution RDC number 505, 27 May 2021, which establishes minimum requirements for the registration of an advanced therapy product, with a view to proving its effectiveness, safety and quality for use and commercialization in Brazil. Resolution RDC No. 383 of 20 February 2020 notified through G/TBT/N/BRA/911/Add.1 and Resolution RDC No. 363 of 01 April 2020, notified through G/TBT/N/BRA/911/Add.2 were revoked.

The final text is available only in Portuguese and can be downloaded at:
http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_505_2021_.pdf/43ac298e-1ade-44f0-9f98-22f0b2477255
