WORLD TRADE ORGANIZATION

G/TBT/N/

Date

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Committee on Technical Barriers to Trade Original:

NOTIFICATION

Addendum

The following communication, dated July 17th, 2019, is being circulated at the request of the delegation of Brazil.

The Resolution - RDC nº 293, July 15th, 2019, changes article 19 of the RDC nº 205, December 28th, 2017, notified through G/TBT/N/BRA/784 – that establishes special procedure for approval of clinical trials, good manufacturing practices certification and registration of new medicines for treatment, diagnosis or prevention of rare diseases.

From: "The companies that submit a requirement of market authorization for new medicines according to the criteria of this resolution must submit the dossier for definition of maximum price concomitant with the protocol of the solicitation of market authorization"

To: "The companies that submit a requirement of market authorization for new medicines according to the criteria of this resolution will have a deadline of 30 days to submit the dossier for definition of maximum price from the first business day after the publication of the market authorization of the medicine".

This resolution enters into force in the date its publication.

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

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=515&pagina=41&data=17/07/2019

http://portal.anvisa.gov.br/documents/10181/5457360/RDC_293_2019_.pdf/8c805184-fb4a-47dc-9c0f-a24312de2779
