NOTIFICATION

Addendum

The following communication, dated 11 June 2020, is being circulated at the request of the delegation of Brazil.

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The Resolution – RDC number 346, 12 March 2020 – previously notified through [G/TBT/N/BRA/984](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?MetaCollection=WTO&SymbolList=%22G%2fTBT%2fN%2fBRA%2f984%22+OR+%22G%2fTBT%2fN%2fBRA%2f984%2f*%22&Serial=&IssuingDateFrom=&IssuingDateTo=&CATTITLE=&ConcernedCountryList=%22Brazil%22&OtherCountryList=&SubjectList=&TypeList=&FullTextHash=371857150&ProductList=&BodyList=&OrganizationList=&ArticleList=&Contents=&CollectionList=&RestrictionTypeName=&PostingDateFrom=&PostingDateTo=&DerestrictionDateFrom=&DerestrictionDateTo=&ReferenceList=&Language=ENGLISH&SearchPage=FE_S_S001&ActiveTabIndex=0&HSClassificationList=&ServicesClassificationList=&EnvironmentClassificationList=&ICSClassificationList=&ICSClassificationDescList:EnvironmentClassificationDescList:ServicesClassificationDescList:HSClassificationDescList=&languageUIChanged=true) – which establishes extraordinary and temporary criteria and procedure for Good Manufacture Practice Guidelines for market authorization and post-market registration amendments of Active Pharmaceutical Ingredients, medicines, and healthcare products due to the international public health emergency of the new coronavirus (Covid-19), was changed by the Resolution – RDC number 385, 12 May 2020.

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

<http://portal.anvisa.gov.br/documents/10181/5809525/RDC_385_2020_.pdf/d2868bf9-e33c-4107-80f0-1ba983ee5332>

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