

Date

(00-0000) Page: 1/1

Committee on Technical Barriers to Trade

Original:

NOTIFICATION

Addendum

The following communication, dated August 22nd, 2019, is being circulated at the request of the delegation of $\underline{\text{Brazil}}$.

The draft normative instruction regarding Complementary guidelines to the manufacture of investigational medicinal products of the draft resolution number 653, May 24^{th} , 2019 – previously notified through $\underline{\text{G/TBT/N/BRA/870}}$ - was adopted as a final text, published as Normative Instruction number 45, August 21st, 2019.

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

http://portal.anvisa.gov.br/documents/10181/5389382/IN 45 2019 .pdf/5c8b3b4c-f138-4e47-96fa-ca945452ecac