WORLD TRADE ORGANIZATION

G/TBT/N/BRA/601.Add2

12 December 2016

(xx-xxxx)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 12 December 2016, is being circulated at the request of the delegation of the Brazil.

This addendum aims to inform that the Brazilian Health Regulatory Agency (ANVISA), issued the Draft Resolution Nº 282, 9 December 2016, regarding inspection procedures on Good Clinical Practices on clinical trials of medical devices.

This Draft Resolution establishes a Normative Instruction to adopt inspection procedures to harmonize, guide and verify the compliance of Good Clinical Practices on clinical trials of medical devices, according to ANVISA's Resolution RDC 10, February 20 2015 notified as G/TBT/N/BRA/601/Add.1.

The full text of this proposal is available in Portuguese and can be downloaded at:

http://portal.anvisa.gov.br/documents/10181/2822620/CONSULTA+P%C3%9ABLICA+N+282+GGTPS.pdf/90de8e11-5714-409b-8747-de3025c9571c