WORLD TRADE ORGANIZATION

G/TBT/N/

Date

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Committee on Technical Barriers to Trade Original:

1.1. notification

Addendum

The following communication, dated November 7th, 2019, is being circulated at the request of the delegation of Brazil.

The Draft Resolution 453, 28 December 2017 – previously notified through G/TBT/N/BRA/780 – which establishes the criteria for carrying out Stability Studies of active pharmaceutical inputs (IFAs), and of new, generic, similar, dynamized, specific, simplified notification, herbal and radiopharmaceutical medicines, other than biological, and makes other arrangements, was adopted as Resolution 318, 6 November 2019.

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

http://portal.anvisa.gov.br/documents/10181/3898778/RDC_318_2019_.pdf/72014894-122d-433e-97b0-2c48bfb4ab54
