NOTIFICATION

Addendum

The following communication, received on 3 June 2019, is being circulated at the request of the Delegation of Brazil.

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| ANVISA Resolution - RDC nº 285, 17 May 2019 |
| The draft resolution (Consulta Pública) number 583, 21 December 2018, notifiedf through G/SPS/N/BRA/1465, was adopted as a final text, published as ANVISA Resolution - RDC Nº 285, 17 May 2019. The fulll text is available only in Portuguese and can be downloaded at: <http://portal.anvisa.gov.br/documents/10181/5141616/RDC_285_2019_.pdf/ab2c802a-6841-49ff-8266-0c842a5f1fab>. |
| **This addendum concerns a:** |
| [ ] Modification of final date for comments |
| [**X**] Notification of adoption, publication or entry into force of regulation |
| [ ] Modification of content and/or scope of previously notified draft regulation |
| [ ] Withdrawal of proposed regulation |
| [ ] Change in proposed date of adoption, publication or date of entry into force |
| [ ] Other: |
| **Comment period: *(If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)*** |
| [**X**] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: 3 August 2019 |
| **Agency or authority designated to handle comments: [ ]****National Notification Authority, [****X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** |
| Assessoria de Assuntos Internacionais - AINTE  International Affairs Office  Agência Nacional de Vigilância Sanitária - Anvisa  Brazilian Health Regulatory Agency  Tel: +(55 61) 3462 5402/5404/5406  E-mail: rel@anvisa.gov.br |
| **Text(s) available from: [ ]****National Notification Authority, [****X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:** |
| Assessoria de Assuntos Internacionais - AINTE  International Affairs Office  Agência Nacional de Vigilância Sanitária - Anvisa  Brazilian Health Regulatory Agency  Tel: +(55 61) 3462 5402/5404/5406  E-mail: rel@anvisa.gov.br |

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