NOTIFICATION

Addendum

The following communication, received on 17 December 2020, is being circulated at the request of the Delegation of Brazil.

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| Resolution RDC number 441, 2 December 2020 |
| The Draft Resolution number 613, 28 February 2019, previously notified through G/SPS/N/BRA/1487, was adopted as Resolution RDC number 441, 2 December 2020, and will entry into force on 4 January 2021.The full text is available only in Portuguese, and can be downloaded at: <http://antigo.anvisa.gov.br/documents/10181/5344168/RDC_441_2020_.pdf/e6ea1928-7ab3-4712-8b19-f9dbd3c0e46c>. |
| **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.)*** |
| [ ] Sixty days from the date of circulation of the addendum to the notification and/or *(dd/mm/yy)*: Not applicable |
| **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 - AINTEInternational Affairs OfficeAgência Nacional de Vigilância Sanitária - AnvisaBrazilian Health Regulatory AgencyTel: +(55 61) 3462 5402/5404/5406E-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 - AINTEInternational Affairs OfficeAgência Nacional de Vigilância Sanitária - AnvisaBrazilian Health Regulatory AgencyTel: +(55 61) 3462 5402/5404/5406E-mail: rel@anvisa.gov.br  |

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