NOTIFICATION

Addendum

The following communication, received on 28 September 2018, is being circulated at the request of the Delegation of Brazil.

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| ANVISA Resolution - RDC nº 244, 17 August 2018 |
| The Draft Resolution number 397/2017, notified through G/SPS/N/BRA/1303, was adopted as a final text, published as ANVISA Resolution - RDC n.º 244, 17 August 2018.  The full text is available only in Portugues and can be downloaded at:  <http://portal.anvisa.gov.br/documents/10181/3484594/RDC_244_2018_.pdf/b432fe7b-88f1-4f96-9ed0-fa41fa655dd4> |
| **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:** |
| Coordenação de Articulação Internacional e Convergência Regulatória -CCREG  Tel: +(55 61) 3462 5402/5404/5406  E-mail: [rel@anvisa.gov.br](mailto: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:** |
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