NOTIFICATION

Addendum

The following communication, received on 14 January 2021, is being circulated at the request of the Delegation of Brazil.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
| Normative Instruction number 82, 17 December 2020 |
| The Draft Normative Instruction number 820, 9 June 2020 - previously notified through G/SPS/N/BRA/1682 - which establishes good manufacturing practices for dietary formulas destined for inborn errors of metabolism, was adopted as Normative Instruction number 82, 17 December 2020.This regulation will be also notified to the TBT Committee.The final text is available only in Portuguese and can be downloaded at:<http://antigo.anvisa.gov.br/documents/10181/5917696/IN_82_2020_.pdf/53f83bbd-b868-49cd-8bf7-aaf5a95d13f0> |
| **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  |

**\_\_\_\_\_\_\_\_\_\_**