

NOTIFICATION

Addendum

The following communication, dated 6 January 2021, is being circulated at the request of the delegation of Brazil.

Title: Good Manufacturing Practices for dietoherapeutic formulas

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input checked="" type="checkbox"/>	Notified measure published - date: 23 December 2020
<input checked="" type="checkbox"/>	Notified measure enters into force - date: 23 December 2020
<input checked="" type="checkbox"/>	Text of final measure available from ¹ : http://antigo.anvisa.gov.br/documents/10181/5917696/IN_82_2020_.pdf/53f83bbd-b868-49cd-8bf7-aaf5a95d13f0
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input type="checkbox"/>	Content or scope of notified measure changed New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from:
<input type="checkbox"/>	Other:

Description:

The Draft Normative Instruction number 820, 9 June 2020 - previously notified through G/TBT/N/BRA/1027 - which establishes good manufacturing practices for dietary formulas destined for inborn errors of metabolism, was adopted as Normative Instruction number 82, 17 December 17 2020.

This regulation will be also notified to the SPS 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