



NOTIFICATION

Addendum

The following communication dated [date], is being circulated at the request of the delegation of Brazil.

Title: Amendment of the Collegiate Board Resolution - RDC No. 346 of March 12, 2020.

Reason for Addendum:	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from ¹ :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input checked="" 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 ¹ :
<input checked="" type="checkbox"/>	Other: https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-419-de-1-de-setembro-de-2020-275655953

Description: Resolution – RDC number 346, 1 March 2020 – previously notified through [G/TBT/N/BRA/984](https://www.in.gov.br/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-419-de-1-de-setembro-de-2020-275655953) – which establishes extraordinary and temporary criteria and procedure for Good Manufacture Practice Guidelines for market authorization and post-market registration amendments of Active Pharmaceutical Ingredients, medicines, and healthcare products due to the international public health emergency of the new coronavirus (Covid-19), was changed by the Resolution – RDC number 419, 1 September 2020.

¹ This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final measure and/or interpretive guidance can be obtained.