



NOTIFICATION

Addendum

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

Title: Draft resolution 1206, 02 October 2023

| Reason for Addendum: | |
|-------------------------------------|---|
| <input type="checkbox"/> | Comment period changed - date: |
| <input checked="" type="checkbox"/> | Notified measure adopted - date: 17 June 2024 |
| <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 | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: |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 type="checkbox"/> | Content or scope of notified measure changed and text available from ¹ : New deadline for comments (if applicable): |
| <input type="checkbox"/> | Interpretive guidance issued and text available from ¹ : |
| <input type="checkbox"/> | Other: |

Description: Draft resolution 1206, 02 October 2023 - previously notified through G/TBT/N/BRA/1504 - which contains provisions on complementary on the registration of biosimilars through the Comparability Development Pathway, was adopted as Resolution 875, 28 May 2024.

The final text is available only in Portuguese and can be downloaded at:

http://antigo.anvisa.gov.br/documents/10181/6511806/RDC_875_2024_.pdf/dc748631-5245-4a22-be6d-0df49b9a46f2

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