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# OFFICIAL FEDERAL GAZETTE

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Agency: Ministry of Health/Brazilian Health Regulatory Agency/Collegiate Board of Directors

## RESOLUTION - RDC No. 763, OF NOVEMBER 25, 2022(\*)

Amends the Resolution of the Collegiate Board of Directors - RDC No. 205, of December 28, 2017.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, by the powers granted to it by art. 15, III and IV, along with art. 7, III and IV, of Law No. 9,782, of January 26, 1999, and art. 187, VI, paragraph 1 of the Internal Regulations approved by Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, decides to adopt the following Resolution, as decided at a meeting held on November 23, 2022, and I, Director-President, determine its publication.

Art. 1 The Resolution of the Collegiate Board of Directors - RDC No. 205, of December 28, 2017, becomes effective with the following changes:

“Art. 10.....

I - request for a pre-submission meeting, if the interested party deems it necessary, for the submission of the DDCM, specific clinical trial dossier or substantial modification due to protocol inclusion;

II - hold a pre-submission meeting, if the interested party deems it necessary, for the submission of the DDCM, specific clinical trial dossier or substantial modification due to protocol inclusion, up to sixty days after the request by the interested party;

.....”(NR)

Art. 2 This Resolution becomes effective as of December 1st, 2022.

**ANTONIO BARRA TORRES**

Director-President

(CODOU N.) Republished because it published in the DOU on 1/Dec/2022, Section 1, page 120 with incorrecction.

This content does not replace the certified version.



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