



NOTIFICATION

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved:
2. Agency responsible: Brazilian Health Regulatory Agency (ANVISA)
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): HS Code(s): 2106, 29, 2936, 2937, 2941, 3303, 3304, 3305, 3306, 3307, 340111, 340130, 3402, 340119, 340120, 330290, 9616, 9619; ICS Code(s): 13, 65
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Resolution number 805, 27 March 2020. Language(s): Portuguese. Number of pages: 9 Draft: http://portal.anvisa.gov.br/documents/10181/5833170/CP+805.pdf/ab194b8c-fb14-473d-aa00-9035b6ad93a7 Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=54824
6. Description of content: This resolution establishes administrative procedure for the concession of Good Manufacturing Practices Certification for medicines, medical devices, personal hygiene products, cosmetics, perfumes, sanitizers, active pharmaceutical ingredients, and food; and Good Practices of Storage and Distribution Certification for medicines, medical devices, and active pharmaceutical ingredients.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, describe, whenever possible, how and why it deviates from the international standard:

9.	Other relevant documents and language(s) in which these are available:
10.	Proposed date of adoption (dd/mm/yy): In the date of its publication. Proposed date of publication (dd/mm/yy): To be determined after the consultation period.
11.	Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): In the date of its publication. <input type="checkbox"/> Trade facilitating measure
12.	Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 5 August 2020 Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: Assessoria de Assuntos Internacionais - AINTE International Affairs Office Agência Nacional de Vigilância Sanitária - Anvisa Brazilian Health Regulatory Agency Tel: +(5561) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br
13.	Text(s) available from: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: Assessoria de Assuntos Internacionais - AINTE International Affairs Office Agência Nacional de Vigilância Sanitária - Anvisa Brazilian Health Regulatory Agency Tel: +(5561) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br