WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Specific medicines
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution Nº 460, December 28th, 2017 (12 page(s), in Portuguese)
6.	**Description of content:** This Draft Resolution changes the Resolution RDC No. 24, dated 14 June 2011, Resolution - RDC No. 107, dated 5 September 2016 and the Normative Instruction - IN No. 11, dated 29 September 2016, and regulates the registration of vitamins, minerals, amino acids and proteins for oral use, classified as specific medicines. Paragraph 3 of Article 3 of Resolution RDC No. 24 of 14 June 2011 shall become effective with the following wording: "§3 This Resolution does not apply to food supplements, contemplated in the scope of RDC XXX of XXX, which can not be registered as specific medicines." Section XII of Article 5 of Resolution RDC No. 24 of 14 June 2011 shall become effective with the following wording: "XII - medicines based on vitamins and / or minerals and / or amino acids and / or proteins isolated or associated with each other, for oral use, with well-established therapeutic indications and different from the claims authorized for food supplements in Resolution - RDC No. XX, XX of XXXXXX of 20XX"; Article 6 of Resolution No. RDC No. 24 of 14 June 2011 shall become effective with the following wording: "Art. 6 Isolated or associated vitamins, minerals and amino acids, registered as specific medicinal products for oral or injectable use, are classified as medicines for sale under medical prescription." Holders of specific medicine products based on vitamins and / or minerals and / or amino acids and / or proteins isolated or associated with each other for oral use shall have a

	period of 24 (twenty four) months from the date of entry into force of this Resolution, for the adequacy of the registration as follows: I - In case they are classified as dietary supplements, registry holders must comply with the procedures for registration and exemption from registration established in Resolution No. 23 of 15 March 2000 and Resolution No. RDC No. 27 of 6 August 2010; or II - If they remain classified as specific medicines, they must submit, by means of a specific petition, evidence of efficacy and safety for therapeutic indication as established at the Resolution RDC No. 24, dated 14 June 2011. Holders of specific medicines registration may request their revalidation as a specific drug in up to 24 (twenty four) months, as of the validity of this Resolution, but they can not fail to observe the final deadline established in the caput of this article for regularization of products as food supplements. Specific medicines that are classified as food supplements and that are not regularized within 24 (twenty four) months from the entry into force of this Resolution will have their records canceled. This Resolution revokes: - I. subsection XIV of Article 4; - the sole paragraph of Article 6; - paragraphs 1 and 2 of Article 31; - paragraphs I and III of Article 33 of Resolution - RDC n ° 24 of 14 June 2011, which provides for registration of specific drugs;
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** RDC nº 107/2016; RDC nº 24/2011; RDC nº 27/2017; RDC nº 23/2000; IN Nº 11/2016.
9.	**Proposed date of adoption:** On the date of its publication. **Proposed date of entry into force:** On the date of its publication.
10.	**Final date for comments:** 9 April 2018
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://portal.anvisa.gov.br/documents/10181/3898888/CONSULTA+P%C3%9ABLICA+N+460+GGMED.pdf/e6920b20-9db9-4199-8f51-7cd1e80f9117