WORLD TRADE ORGANIZATION

G/TBT/N/BRA/770

5 January 2018

(18-0091)

Page: 1/2

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
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):** Industrialized Allergen Products. Pharmaceutics (ICS 11.120).
5.	**Title, number of pages and language(s) of the notified document:** Resolution - RDC n. 194, December 12th, 2017. (22 page(s) in English)
6.	**Description of content:** This Resolution provides for registration and post-registration changes of Industrialized Allergen Products, and makes other arrangements. This Resolution applies to Industrialized Allergen Products to be submitted for analysis for marketing authorization (registration) and post-registration alterations, as well as regulates the products Allergenic Nominal Patient Vaccine, Allergen Vaccine for Use by Professional Enabled and Allergenic Product for use by Qualified Professional. Industrialized Allergen Product: industrialized finished medicinal product, manufactured by authorized pharmaceutical industry, and can be an Industrialized Allergen Extract, an Industrialized Allergen Vaccine or an Industrialized Allergen Product for Diagnosis. Industrialized Allergen Products may only be marketed and distributed in Brazil if registered in Anvisa and manufactured or imported by a company whose operation is authorized by this Agency, and duly licensed by the competent local health authority. All companies involved in the manufacture of Industrialized Allergen Product, from the extraction stage, must comply with good manufacturing practices, and present the certificate of good manufacturing practices issued by Anvisa. Industrialized Allergen Products must be registered by Anvisa as a biological product, according to specific petition procedures. The registration of Industrialized Allergen Products manufactured in other countries can only be granted by Anvisa if the product is registered and released for use in its country of manufacture. In cases where the country of origin does not register Industrialized Allergen Products, the manufacturing authorization must be presented, in accordance with the local requirements, and the proof of commercialization. All therapeutic or diagnostic allegations claimed in the registration application must be documented in the reports of the clinical studies in the product registration dossier. The studies mentioned in the caput of this article must have

	been conducted with the Industrialized Allergenic Product presented for registration. The clinical studies carried out must have been approved by the sanitary authority of the country where the clinical research was carried out. All clinical investigations conducted in Brazil with the Industrialized Allergen Product must have prior authorization from Anvisa, as provided for in the Resolution of the Collegiate Board of Directors - RDC No. 9 of February 20, 2015, and its updates. At the moment of applying for registration, the requesting company must present documentation regarding the validation of the transport chain, with the presentation of the operation qualification and performance qualification of the system to be used for the transport of the product. This Resolution establishes the necessary or required documentation concerning the quality, safety and efficacy of the product to be registered. The absence of any document required by this Resolution shall be justified and scientifically based. This Resolution revokes the Resolution RDC nº 233, 17 August 2005.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Resolution RDC nº 55, December 16th, 2010; Resolution RDC nº 9, February 20th, 2015; Resolution RDC nº 68, March 28th, 2003; Resolution RDC nº 47, September 8th 2009; Resolution RDC nº 71, December 22th, 2009; Resolution RDC nº 166. July 24th, 2017; Resolution RDC nº 50, September 20th, 2011; Resolution RDC nº 49, September 20th, 2011
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** 90 (ninety) days after the date of its publication
10.	**Final date for comments:** No final date for comments
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/10181/3426936/RDC_194_2017_.pdf/bd1080ca-1e76-432e-8601-47b687c148ba