



Title: **RDC Resolution nº 46, of August 28, 2009.**

Summary: Prohibits sale, importation and advertising for any kind of electronic smoking device, known as electronic cigarettes.

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Issuing body: ANVISA - *Agência Nacional de Vigilância Sanitária* ('National Agency of Health Oversight')

Scope of act: Federal - Brazil

Area treated: Smoking

Relation(s):

Amends:

RESOLUTION OF THE COLLEGIATE DIRECTORY – RDC Nº. 46 of August 28, 2009

Published in the DOU.

Prohibits the sale, importation and advertising for any kind of electronic smoking device, known as electronic cigarettes.

The Collegiate Directory of the National Agency of Health Oversight (ANVISA - *Agência Nacional de Vigilância Sanitária*), in the exercise of the attributions conferred upon it by sub-paragraph IV of Art. 11 and Art. 35 of the Regulations of ANVISA, as approved by Decree nº 3.029, of April 16, 1999, and bearing in mind what is set forth in sub-paragraph and items §§ 1 and 2 of Art. 54 of the Internal Regimen approved pursuant to the terms of Annex I of Edict nº 354, 11 August 11, 2006, republished in the DOU of August 21, 2006, at a meeting held on August 25, 2009, adopts the following Resolution, and I, Chief Executive Officer, order its publication:

In light of Law nº 9782 of January 26, 1999, especially Arts. 6 and 8, § 1, sub-paragraph X, which confers upon ANVISA the institutional purpose of promoting the protection of public health, with the competence to regulate, monitor and oversee products and services involving a risk to public health, including cigarettes, cigarillos, cigars and any other kind of smoking product, whether or not it is a tobacco derivative;

In light of Law nº 6437 of August 20, 1977, which sets forth infractions of federal health law and establishes the respective sanctions;

In light of the Framework Convention on Tobacco Control, promulgated through Decree 5.658 of January 2, 2006;

In light of the lack of scientific data that proves the efficiency, efficacy and safety



of the use and handling of any electronic smoking devices, known as electronic cigarettes, in view of the application of the Precaution Principle, resolves:

Art. 1. The sale, importation and advertising for any electronic smoking devices, known as electronic cigarettes, e-cigarettes, e-ciggy, ecigar, among other names, especially those that claim to be a substitute for cigarettes, cigarillos, cigars, pipes and the like associated with the smoking habit, or to be an alternative for treating tobacco addiction, are prohibited.

Sole paragraph. Any accessories or refills intended for use in any electronic smoking device fall within the prohibition set forth in the heading of this article.

Art. 2. ANVISA's acceptance of applications to the Register of Registration Data for any electronic smoking device, especially those intended for the treatment of tobacco addiction, or as a substitute for cigarettes, cigarillos, cigars, pipes and the like associated with the smoking habit, shall depend upon the submission of toxicological studies and specific scientific tests that substantiate the purposes alleged.

§1. The toxicological study and tests mentioned in the heading of this article must be conducted in accordance with internationally recognized and accepted scientific protocols and methods, accompanied by an assessment of the risk of causing user health to deteriorate, and proof of non-contamination of the environment with toxic compounds.

§2. All of the results of the toxicological studies and tests mentioned in the heading of this article shall be subject to technical analysis and approval by ANVISA.

§3. Even if the Registration discussed in the heading of Article 2 is approved, the sale or provision, even free of charge, or the administering or delivery in any form of any sort of electronic smoking device to children or adolescents is prohibited.

Art. 3. Violation of what is set forth in this Resolution shall subject those responsible to the sanctions set forth in Law 6437, of August 20, [1977].

Art. 4. This Resolution shall enter into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO