

title: Resolution RDC num. 32, of May 29, 2008

amendment: Amends provisions of Resolution - RDC 90, of December 27, 2007, which concerns the registration of identifying data of tobacco derivative smoking products.

publication: D.O.U. - Diário Oficial da União; Executive Branch, of May 30, 2008

issuing body: ANVISA - National Agency of Sanitary Oversight

scope of ruling: Federal – Brazil

area of application: Smoking products

Relationship (s):

amends:

- Resolution RDC num. 90, of December 27, 2007 concerning (**Republished version - 28.03.2008**)

RESOLUTION OF THE COLLEGIATE DIRECTORATE - RDC Num. 32, OF MAY 29, 2008

Amends the provisions of Resolution - RDC 90, December 27, 2007, concerning the registration of identifying data for tobacco derivative smoking products.

The Collegiate Directorate of the National Agency of Sanitary Oversight (ANVISA), in the exercise of the powers vested in it by sub-paragraph IV of Art. 11 of the Regulation approved by Decree num. 3.029, April 16, 1999, and taking into account what is set forth in sub-paragraph II and §§ 1 and 3 of Art. 54 of the Internal Regimen approved pursuant to the terms of Annex I of Statute num. 354 of ANVISA, dated August 11, 2006, republished in the DOU on August 21, 2006, at a meeting held on May 13, 2008,

in light of what is set forth in Law n.º 9.782, of January 26, 1999, as amended by Provisional Measure num. 2190-34 of August 23, 2001, which determines the regulation, control and enforcement for products and services involving a risk to public health;

in light of what is set forth in Art. 8, sub-paragraph X and paragraph 4, of Law n.º 9.782, of 1999, as amended by PM (Provisional Measure) num.. 2.190-34, of 2001;

in light of what is set forth in Law num.. 9.782, of 1999, as amended by PM num.. 2.190-34, of 2001, concerning the nomenclature "registration, revalidation or renewal of registration of smoking products,"

in light of the need for amendments to RDC 90/2007 on the registration of smoking products as a result of the

adoption of the new electronic system for registration application,

Hereby adopts the following Resolution and I, Director-President, order its publication:

Art 1. Sub-paragraphs IV, V and X of Art. 2 of RDC 90, of December 27, 2007, republished in the D.O.U. on March 28, 2008 are to take effect with the following text:

"Art. 2.....

IV – Brand Name: the name, whether or not it is accompanied by a descriptor placed on a product, which will be recognized by the consumer as a way of distinguishing the product from others of the same nature. Sub-brands will be considered brands;

V - Descriptor: word, number and color of the packaging.

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X - Additive: any substance or compound that is not tobacco or water, used in the processing, manufacture and packaging of a smoking product;" (NR)

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Art 2. §7 of Art. 4 of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 is to take effect with the following text:

"Art. 4

§ 7 For purposes of registration, the brand name contained in the initial application will be considered the brand name, and any request for an alteration of the brand name must be submitted in an application for Renewal of Registration of the brand." (NR)

Art 3. The headings of Articles 5, 6, 8 and 19 of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 are to take effect with the following text:

"Art. 5 Any change to be made by the company in the packaging submitted for the registration of identifying data, except for a change of brand name, must be subject to the analysis of ANVISA, through a Memorandum, which will be analyzed within a period of up to 30 days." (NR)

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"Art. 6 Once the analysis is completed, if there is no requirement to be satisfied, applications for Registration of Identifying Data will be approved, and notification of such approval will be given via publication in the bulletin Diário Oficial da União of the specific brand, company name and CNPJ." (NR)

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"Art. 8 Once the analysis is completed, if there is no requirement to be satisfied, applications for Renewal of Identifying Data will be approved, and notification of such approval will be given via publication in the bulletin Diário Oficial da União of the specific brand, company name and CNPJ." (NR)

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"Art. 19 Approval of the application for Registration of Identifying Data or its renewal will be granted to brands for smoking products that meet the requirements of this resolution, and notification of such approval will be given via publication in the bulletin Diário Oficial da União of the specific brand, company name and CNPJ." (NR)

Art 4. Art. 7 of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 is to take effect with the addition of the following paragraph:

"Art. 7

§ 6 If there is a change of brand name, an authenticated copy must be submitted of the registered communication to the SRF if the approval (ADE) has not yet been published in the DOU." (NR)

Art 5. Art. 13 of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 is to take effect with the following amendments and the addition of paragraph 3:

"Art. 13 Applications for registration of identifying data of brands of tobacco derivative smoking products can be processed by ANVISA at any time of the year.

§ 1 Applications for the registration mentioned in the heading will be analyzed in up to 45 days following their intake at ANVISA, and if there is no requirement for the company to fulfill, the analysis will be completed, the application for registration approved and published in the Diário Oficial da União.

§ 2 Sale of a brand can only begin after approval of the registration application and the publication in the Diário Oficial da União of the specific brand name, the company name and CNPJ.

§ 3 After publication of the approval of the application in the Diário Oficial da União, the brand name will be included in the Listing of Brands of Smoking Products made available at the website of ANVISA." (NR)

Art 6. Articles 27 and 28 of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 are to take effect with the addition of the following paragraphs:

"Art. 27

Sole paragraph. For successive renewals of the registrations mentioned in the heading, the annual deadline of June 30 is hereby established." (NR)

"Art. 28

For successive renewals of the registrations mentioned in the heading, the annual deadline of March 31 is hereby established." (NR)

Art 7. Items II and III of Annex II of RDC 90, of December 27, 2007, republished in the D.O.U. of March 28, 2008 are to take effect with the following texts:

"II.....

6. List of Additives used in the product:

- Names of Additives
- Categories of additives: Sugar, Adhesive, Agglutinating Agent, Combustion Agent, Ameliorating Agent, Process Auxiliary, Flavoring, Fungicide, Preservatives, Dye and Moisturizer;
- Places of application: in the Tobacco mixture, in the wrapping, in the filter, in the filter paper, in the paper of the tip, in the packaging." (NR)

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"III -

6. List of Additives used in the product:

- Names of Additives;
- Categories of additives: Sugar, Adhesive, Agglutinating Agent, Combustion Agent, Ameliorating Agent, Process Auxiliary, Flavoring, Fungicide, Preservatives, Dye and Moisturizer;
- Places of application: in the Tobacco mixture, in the wrapping, in the filter, in the filter paper, in the paper of the tip, in the packaging;" (NR)

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Art. 8 This Resolution enters into force on the date of its publication.

DIRCEU RAPOSO DE MELLO