

**Resolution - RDC no. 104, of May 31<sup>st</sup>, 2001(\*)**

The Collegiate Direction of the National Agency of Sanitary Surveillance (ANVISA), in the use of the attribution conferred by article 11, incised IV, of the ANVISA's Regulation approved by Decree no. 3,029, of April 16<sup>th</sup>, 1999, § 1 of article 111, incised I, sub-heading "b", of the Internal Regiment approved by the Ruling no. 593, of August 25<sup>th</sup>, 2000, republished in the Official Gazette (D.O.U.) of December 22<sup>nd</sup>, 2000, in a meeting held on May 30<sup>th</sup>, 2001,

considering the dispositions of the Law no. 9,294, of July 15<sup>th</sup>, 1996;

considering the disposed in the Law no. 9,782, of January 26<sup>th</sup>, 1999, that determines the regulation, control and inspection of products and services involving risk to the public health;

considering the dispositions of the Federal Law no. 10,167, of December 27<sup>th</sup>, 2000;

considering the dispositions of the Resolution no. 46, of March 28<sup>th</sup>, 2001;

considering the dispositions of the Provisional Measurement no. 2,134-33, of July 21<sup>st</sup>, 2001;

adopted the following Collegiate Direction Resolution (RDC), applicable to smoking tobacco products, commercialized in the domestic territory, produced internally or imported, and I, Head-Director, determine its re-publication:

**Art. 1** All smoking tobacco products must embody on the package and advertising, warning labels to consumers, about the harms associated to the use of these products.

**§ 1** It is understood by package, the packet, wallets or box, packs, cans, mallets and any another device to hold the product aimed to consumers.

**§ 2** It is understood by advertising, posters, billboards and placards displayed in-stores.

**Art. 2** All smoking tobacco products, must display the warnings labels transcribed bellow, simultaneously or sequentially rotating (in the last case, it should change at every five months at most), legibly and ostensibly noticeable. Warnings must be accompanied by images, and should be introduced by the statement "The Health Ministry Warns":

1. Smoking causes bad breath, teeth loss and cancer of mouth.
2. Smoking causes lung cancer
3. Smoking causes heart attack
4. Smokers are always short of breath
5. Smoking during pregnancy is harmful for the baby
6. Cigarette smoking during pregnancy leads to premature delivery, lowbirthweight babies and children prone to asthma
7. Children start smoking when seeing adults smoking
8. Nicotine is a drug and causes dependence
9. Smoking causes impotence

**Of The Packing**

**Art. 3** For the cigarette packages, denominated "packs" or "box", the warning, image, logo and Stop Smoking hotline number, must be printed, in the largest side visible to the consumer, as the standard image available through ANVISA's home page ([www.anvisa.gov.br](http://www.anvisa.gov.br)) or headquarters.

§ 1 For any package of smoking tobacco products of equal size to the one above mentioned, the warning, image, logo and Stop Smoking hotline number, must obey all the graphical features and be displayed in the largest side visible to the consumer, as the standard image available through ANVISA.

§ 2 For any package of smoking tobacco products smaller than the one above mentioned, it is responsibility of the manufacturer or importer, to make the adjustments to keep the proportions of the standard ANVISA's image, without changing its graphical features, to be displayed in the largest side visible to the consumer.

§ 3 For any packages of smoking tobacco products greater than the one above mentioned, the warning, image, logo and Stop Smoking hotline number, must obey all the graphical features and be displayed in the largest side visible to the consumer, as the standard image available through ANVISA.

Art. 4 For the fulfillment of the disposed in article 3 of ANVISA's Resolution no. 46, of March 28<sup>th</sup>, 2001, tar, nicotine and carbon monoxide levels, followed by the sentence: "there isn't safe levels for consumption of these substances", must be printed, in 2/3 of the length and all the extension of the width of one of the cigarette packages laterals, with white letters, on a black rectangle.

§ 1 The parameters for disclosure of levels and the additional information will be available through the National Agency of Sanitary Surveillance home page ([www.anvisa.gov.br](http://www.anvisa.gov.br)). In no way they can be modified.

#### Of The Advertising

Art.5 For commercial advertising of the products related in article 1, using posters, billboards and placards in-stores, the warning, as well as the logo and the Stop Smoking hotline number, should be printed with white, Univers 65 Bold letters, on a black rectangle with one fine white line, as frame, in order to assure its visibility. The minimum dimensions bellow should be observed:

|                   |         |
|-------------------|---------|
| 0 the 250 cm2     | Body 20 |
| 251 the 500 cm2   | Body 24 |
| 501 the 1000 cm2  | Body 26 |
| 1001 the 1500 cm2 | Body 30 |
| 1501 the 2000 cm2 | Body 36 |
| 2001 the 3000 cm2 | Body 40 |
| 3001 the 4000 cm2 | Body 48 |
| 4001 the 5000 cm2 | Body 52 |

§ 1 In other advertising pieces greater than the specified above, the messages must be in proportion, using as basis the area of 1000 cm2.

#### Of The General Dispositions

Art. 6 When the package is made of material that makes impracticable or difficult to print the warnings, respective images, as well as logo and Stop Smoking hotline number, a sticker can be used.

§ 1 The sticker must follow the standard ANVISA's image, keeping the graphical features and should not be inserted in the external wrap that involves the package.

§ 2 The disposed in this article applies to imported cigarettes and other smoking tobacco products.

§ 3 The disposed in this article does not apply to cigarettes manufactured or packed in the country.

Art.7 It is prohibited, the use of any type of wrap or device that hinders or difficult the visualization of the warnings, image, as well as of the logo and Stop Smoking hotline number in the package of the products mentioned in this Resolution.

Only paragraph. The Internal Revenue Office control stamp can not be placed in a way to hidden or difficult the visualization of the warnings.

#### Of The Time Limit

Art. 8 It is established the date of January 31<sup>st</sup>, 2002, for the fulfillment of the disposed in this Resolution. Special colors should be used in place of traditional polychrome for printing the warnings, image, logo, and Stop Smoking Hotline number.

Only paragraph. Products manufactured and distributed prior to the date established in this article could be commercialized until the date specified in the Internal Revenue Office control stamp.

Art. 9 Industries should comply until January 31<sup>st</sup>, 2002, to the disposed in incised 1, § 1 of article 1, only paragraph of article 2, and § 3 of article 3 of ANVISA's Resolution no. 46, of March 28<sup>th</sup>, 2001.

Art. 10 All non-observance of the disposed in this Resolution constitutes infraction of sanitary nature, subjecting the infringer to the penalties foreseen in the Law in the 6,437, of August 20<sup>th</sup>, 1977 and in the Federal Law no. 9,294 of July 15<sup>th</sup>, 1996.

Art.11. The National Agency of Sanitary Surveillance, through it's Management of Smoking Products can establish normative instructions for situations not foreseen in this Resolution.

Art.12. This Collegiate Direction Resolution enters in effect in the date of its publication.

GONZALO VECINA NETO

(\*) Republished due to errs in the original, on the Official Gazzette (D.O) no. 106-E, of June 1, 2001, Section 1, page 98.