

RESOLUTION OF THE COLLEGIAL DIRECTORATE - RDC N° 54, AUGUST 6, 2008

Amends RDC n° 335, of November 21, 2003, that regulates packaging of tobacco derivative smoking products.

The Collegial Directorate of the National Agency of Health Oversight in the exercise of the duty conferred upon it by Article 11, Section IV of the Regulation approved by Decree n° 3.029, of April 16, 1999, and taking into consideration the provisions of Article 54, Section II, and §§ 1 and 3 of Article 54 of the Internal Regimen approved pursuant to Annex I of ANVISA Statute n° 354, of August 11, 2006, republished in the Official Diary of the Union (DOU) on August 21, 2006, in a meeting held on August 5, 2008, and

In light of the provisions of Law n.º 9.782, of January 26, 1999, which determines the regulation, control and inspection of products and services that pose risks to public health;

In light of the provisions of Law n.º 9.294, of July 15, 1996 and its subsequent amendments;

In light of the need to renew images and warnings on packaging for tobacco derivative products,

Adopts the following Resolution of the Collegial Directorate and I, the Director-President, call for its publication:

Art. 1º The heading of Art. 2º of RDC 335, of November 21, 2003 shall take effect and come to read as follows:

"Art. 2º For tobacco derivative smoking products, the warnings transcribed below are to be used simultaneously or in a rotating sequence, and in the latter case they should change every five months, and be in a legible form prominently displayed, and are to be accompanied by images that are available at the site:

<http://www.anvisa.gov.br/tabaco/embalagem.htm>, with all warnings preceded by the statement "The Ministry of Health warns."

1. VICTIM OF THIS PRODUCT – This product poisons mother and child, causing premature birth and death.
2. GANGRENE – The use of this product obstructs arteries and hinders circulation of the blood.
3. DEATH - The use of this product leads to death by lung cancer and emphysema.
4. HEART ATTACK - The use of this product causes death by heart disease.

5. TOXIC SMOKE – Breathing the smoke of this product causes pneumonia and bronchitis.
6. HORROR – This product causes early aging of the skin.
7. SUFFERING – Nicotine addiction causes sadness, pain and death.
8. TOXIC PRODUCT – This product contains toxic substances that lead to sickness and death
9. DANGER – The risk of stroke is greater with the use of this product.
10. IMPOTENCE – The use of this product diminishes, hinders or impedes erection.
(NR)

Art. 2º A period of 9 months is established, counting from the date of publication of this resolution, for manufacturers and importers to supply to retail sellers packaging of tobacco derivatives and publicity materials that are duly in compliance with the changes indicated in the foregoing article.

§ 1º At the end of the period mentioned in the heading, only packaging and advertising materials that are in accordance with this resolution can be supplied to retail sellers.

§ 2º Products manufactured or imported prior to the period established in the heading and that do not meet the requirements of this resolution can be sold for up to 12 months after the publication of this resolution.

§ 3º The periods indicated above apply to all tobacco derivative smoking products without exception, including cigars, cigarillos, clove cigarettes, Kretek cigarettes and others.

Art. 3º This Resolution of the Collegial Directorate enters into effect on the date of its publication.

DIRCEU RAPOSO DE MELLO