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Agency: Ministry of Health/National Health Surveillance Agency/Collegiate Board

## RESOLUTION Nº 902, OF SEPTEMBER 6, 2024

Provides for the inclusion of a statement about a new formula in the labeling of products subject to health surveillance when their composition is changed.

THE COLLEGIATE BOARD OF DIRECTORS OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in exercise of the power conferred upon it by Articles 7, paragraph III, and 15, paragraphs III and IV, of Law No. 9,782, of January 26, 1999, and considering the provisions of Article 187, paragraph VI and §§ 1º and 3º of the Internal Regulations, approved by Resolution of the Collegiate Board - RDC No. 585, of December 10, 2021, resolves to adopt the following Resolution of the Collegiate Board, as deliberated at a meeting held on September 4, 2024, and I, the Chief Executive Officer, determine its publication.

Art. 1 This Resolution provides for the inclusion of a statement about a new formula in the labeling of products subject to health surveillance when their composition is changed, in compliance with the decision handed down by the Court of the 2nd Federal Court of the Judicial Section of Sergipe and final in the records of Process No. 0001185-30.2008.4.05.8500.

Art. 2 The provisions contained in this Resolution apply to products subject to surveillance.  
sanitary classified as:

- I - drugs reported as low risk;
- II - traditional herbal products;
- III - cannabis products;
- IV - food;
- V - medical devices;
- VI - pesticides and similar;
- VII - sanitizing agents;
- VIII - personal hygiene products, including disposable ones;
- IX - cosmetics and perfumes; and
- X - smoking products derived from tobacco.

Sole paragraph. This Resolution does not apply to medicines covered by the Collegiate Board Resolution - RDC No. 768, of December 12, 2022, and its updates.

Art. 3 Products subject to health surveillance that undergo changes in their composition or formulation must bear the statement "NEW FORMULA" or equivalent expression.

Art. 4 The declaration required in art. 3 must be presented on the label of products subject to health surveillance covered by this Resolution in an obvious, unequivocal, clear, legible and visible manner.  
to the consumer.

Sole paragraph. The statement referred to in the caput may be inserted into the packaging by means of adhesive affixation, provided that the integrity of the colors and the material from which the adhesive is made is guaranteed, so as to prevent the adhesive from being partially or totally removed.

Art. 5 The specific requirements for detailing the rules and procedures necessary for the effective implementation of the obligation to declare a new formula on the labeling of products covered by this Resolution will be established in the following regulations and their respective updates:

I - Normative Instruction No. 68, of September 1, 2020, which provides for the inclusion of a statement about a new formula in the labeling of medical devices when changing their composition;

II - Normative Instruction No. 71, of September 1, 2020, which provides for the inclusion of a statement on a new formula in the labeling of notified low-risk medicines, traditional herbal products and cannabis products when their composition is changed;

III - Normative Instruction No. 72, of September 1, 2020, which provides for the inclusion of information on changes to ingredients on the packaging of tobacco-derived smoking products;

IV - Normative Instruction No. 73, of September 1, 2020, which provides for the inclusion of a declaration on a new formula in the labeling of pesticides and similar products when their composition is changed;

V - Resolution of the Collegiate Board - RDC No. 727, of July 1, 2022, which provides for the labeling of packaged foods;

VI - Normative Instruction No. 242, of August 4, 2023, which provides for the inclusion of a declaration of a new formula in the labeling of personal hygiene products, including disposables, cosmetics and perfumes when the formula is modified; and

VII - Normative Instruction No. 243, of August 9, 2023, which provides for the declaration of new formula on the labeling of sanitizing products, when changing the formula.

Sole paragraph. The rules referred to in items I to VII of the caput define requirements relating to:

I - scope, including situations of applicability and non-applicability, when necessary;

II - types of changes in composition or formulation that will give rise to the obligation of affixing a declaration to the label;

III - text of the declaration on the label;

IV - legibility characteristics of the declaration on the label;

V - period of time during which the declaration remains on the label;

VI - maximum deadlines for adapting the labeling of products that undergo changes in their formulation or composition; and

VII - other requirements necessary for implementing the obligation to include a declaration about new formulation or composition on the label.

Art. 6 Failure to comply with the provisions contained in this Resolution constitutes a health infraction subject to the penalties provided for in Laws No. 9,294 of July 2, 1996, and No. 6,437 of August 20, 1977, without prejudice to applicable civil or criminal sanctions.

Art. 7º The following are revoked:

I - the Resolution of the Collegiate Board - RDC No. 421, of September 1, 2020, published in Official Gazette of the Union No. 170, of September 3, 2020, Section 1, page 74; and

II - art. 3 of the Collegiate Board Resolution - RDC No. 729, of July 1, 2022, published in the Official Gazette of the Union No. 126, of July 6, 2022, Section 1, pages 222 and 223.

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

**ANTONIO BARRA TORRES**  
CEO

This content does not replace that published in the certified version.