

National Health Surveillance Agency

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Public Consultation No. 366 of July 13, 2017 DOU 07/07/2017

The Board of the National Health Surveillance Agency, in the use of Attributions conferred by articles 7, III and IV, 15, III and IV of Law No. 9,782, of January 26, 1999, art. 53, III, §§ 1 and 3 of the Internal Regulations approved in accordance with Annex I of Resolution of the Collegiate Board of Directors - RDC nº 61, of February 3, 2016, resolves to submit to the Public consultation, for comments and suggestions from the general public, draft legislative act In the Annex, as resolved at a meeting held on July 4, 2017, and I, President, I determine its publication.

Art. 1 The deadline of 30 (thirty) days for sending comments and Suggestions to the text of the amendment and inclusion of labeling of personal hygiene products, Cosmetics and perfumes, and establishes the rules for coexistence of more than one final art For the same product, according to Annex.

Single paragraph. The period covered by this article will begin 7 (seven) days after the date of Publication of this Public Consultation in the Official Gazette of the Union.

Art. 2 The proposal for a normative act will be available in full on the Anvisa website at And the suggestions should be sent electronically by completing form specific, available at the Address: [Http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=32938](http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=32938).

Paragraph 1 The contributions received are considered public and will be available to Anyone interested by means of tools contained in the electronic form, in the menu "Outcome", including during the consultation process.

§2. Upon completion of the electronic form, it will be made available to the Concerned the protocol number of the registration of its participation, being dispensed the sending Postcard or face-to-face protocol of physical documents with the Agency.

Paragraph 3. In case of limitation of access of the citizen to computerized resources will be allowed The sending and receipt of written suggestions, in physical environment, during the consultation period, To the following address: National Sanitary Surveillance Agency / Cosmetics Management - GECOS, SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

§4. Exceptionally, international contributions may be The following address: National Health Surveillance Agency / International Affairs - AINTE, SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

Article 3. After the deadline stipulated in art. 1st, the National Health Surveillance Agency The analysis of the contributions and, at the end, it will publish the result of the public

The Agency's website.

Single paragraph. The Agency may, as necessary and for reasons of convenience and Opportunities, to articulate with agencies and entities involved with the subject, as well as Those who have expressed an interest in the matter, to support subsequent discussions And the final deliberation of the Collegiate Board.

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JARBAS BARBOSA DA SILVA JR.

PROPOSAL IN PUBLIC CONSULTATION

Process n°: 25351.394977 / 2016-55

Subject: Proposal to amend and include labeling of personal hygiene products, Cosmetics and perfumes, and establishing rules for the coexistence of more than one art For the same product.

Regulatory Agenda 2015-2016: Not Agenda item.

Procedural Regime: Common

Responsible area: GECOS

Rapporteur: Jarbas Barbosa da Silva Júnior

MINUTES OF RESOLUTION

RESOLUTION OF THE BOARD OF DIRECTORS - RDC N ° XX, XX OF XXXXXXXX OF 2017

Provides for the amendment and inclusion of labeling of
Personal hygiene products, cosmetics and perfumes, and
Establishes the rules for coexistence of more than one
Final art for the same product.

The Board of the National Health Surveillance Agency, in the use of Attribution conferred by art. 15, III and IV allied to art. 7, III and IV, of Law 9,782, of June 26, January 1999, art. 53, V, §§ 1 and 3 of the Internal Regulations approved in accordance with Annex I Resolution of the Collegiate Board of Directors - RDC n° 61, of February 3, 2016, decides to adopt the Resolution of the Collegiate Board of Directors, as resolved at a meeting held in XX Of XX of 2017, and I, the Chief Executive Officer, determine its publication.

Art. 1 The present Resolution aims to establish procedures for the alteration and inclusion of Labeling of personal care products, cosmetics and perfumes, hereinafter referred to as Products, and rules for the coexistence of more than one final art for the same product.

Art. 2 It is allowed the coexistence of more than one final art of labeling approved in one Product registration process or registration-free product notification, provided that the

The requirements of this Resolution.

Art. 3 All final gear that the company intends to commercialize must be included in the process Product registration or product registration notification.

Art. 4 New registration procedures and new notifications of products exempt from registrations May contain more than one final art of labeling provided that the differences are Exclusively those provided for in art. 7th.

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Article 5. For products subject to registration already registered or exempted from registration already notified, the Company may include, by means of a request for inclusion of labeling, a new final artwork Authorized, provided that the differences are exclusively those provided for in Art. 7th.

Paragraph 1 - Petitions for the inclusion of labeling for registered or notified products dealing with the Capability are possible to be implemented immediately after protocol in Anvisa or its inclusion in the System of notification by the company, respectively.

§ 2 The immediate implementation provided for in paragraph 1 of this article does not prevent the analysis, at any Time, of documentation, and may be ratified or canceled.

Paragraph 3. In the event of cancellation provided for in paragraph 2 of this article, the manufacture of the product Labeling shall be discontinued until the necessary And Anvisa shall inform the possibility of exhaustion of inventory or necessity Of the products on the market.

Article 6 The labeling changes referring only to changes in the established elements In art. 7 can be implemented immediately after protocol in the petition Anvisa Specific for that purpose or its inclusion in the system of notification by the company, respectively.

§ 1 For changes in elements not provided for in art. 7th in products subject to registration at Company must file a petition to change the labeling and wait for publication of Deferment.

§ 2 Once a petition to change the labeling of immediate implementation in the Terms of the caput of this article or deferred the petition for a change of labeling pursuant to § 1, the labels previously approved for the product are invalid.

§ 3 The immediate implementation provided for in the caput of this article does not prevent the analysis, at any Time, of documentation, and may be ratified or canceled.

Paragraph 4. In the event of cancellation provided for in paragraph 2 of this article, the manufacture of the product with

Labeling shall be discontinued until the necessary
And Anvisa shall inform the possibility of exhaustion of inventory or necessity
Of the products on the market.

Art. 7 The elements of the labeling that may differ in more than one final art for the same
Product or that can be changed with immediate implementation are:

I - colors;

II - figures and images that do not have technical specifications, suggestion of use or suggestion of
Properties of the product;

III - references to commemorative dates;

IV - proper names that do not change the name of the product;

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V - promotional statements;

VI - Manufacturer data and technical responsible; and

VII - final arts that specifically attend programs of the Ministry of Health.

Art. 8 The presence of the elements described in art. 7th should not cause false interpretation, error
Or confusion as to the quality, purpose or character of the product.

Article 9 - Changes in labeling not provided for in art. 7 and due to the publication of new
Regulations shall be enforced by petition for a change in
Specific guidance in this respect.

Article 10. For the following changes in labeling it is not necessary to
Amendment or inclusion of labeling:

I - company logo;

II - address of the holder of the registration;

III - business name of the holder of the registration;

IV - address of the manufacturer (s);

V - the business name of the manufacturer (s);

VI - technical responsible; and

VII - quantitative indication of the content.

§ 1° In the situation provided for in item I of this article, the company must report the change of
Its labels to Anvisa through a single office, with the presentation of the new logo.

§ 2 In the situations provided for in items II, III, IV, V and VI, the registration must be updated

Before the responsible area, according to the Resolution of the Collegiate Board of Directors - RDC n° 16, April 2014 and its updates.

Article 11. Non-compliance with what is established in this Resolution constitutes a sanitary infraction, in Pursuant to Law No. 6,437, of August 20, 1977, without prejudice to civil liabilities, Administrative and penal sanctions.

Art. 12. The Resolution of the Collegiate Board of Directors - RDC n ° 131, of December 5, 2016.

Art. 13. This Resolution shall enter into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR.
CEO