COLLEGIATE BOARD RESOLUTION – RDC NO. 243 OF 26 JULY 2018

Provides for the health requirements for dietary supplements.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item V, paragraphs 1 and 3 of Article 53 of the Internal Regulation approved in the terms of Annex I of the Collegiate Board Resolution – RDC no. 61 of 3 February 2016, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 17 July 2018, and I, Deputy Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Scope of Application

Article 1. This Resolution provides for composition, quality, safety, and labeling requirements for dietary supplements and for the update of lists of nutrients, bioactive substances, enzymes, and probiotics, use limits, claims, and complementary labeling of such products.

Article 2. This Resolution does not apply to foods for special dietary uses and conventional foods, including those added with nutrients, bioactive substances, enzymes, or probiotics.

Section II

Definitions

Article 3. For the purposes of this Resolution, the following definitions shall apply:

I – constituent: probiotics and ingredients used in the composition of dietary supplements with the purpose of providing nutrients, bioactive substances, or enzymes;

II – enzyme: protein capable of catalyzing biochemical reactions, increasing its speed, and which has a specific metabolic or physiological action on the human body;

III – ingredient: all substance, including food additives, which is used in the production or preparation of foods, and which is present in the final product in its original or altered form;

IV – nutrient: chemical substance normally consumed as a component of foods, which provides the energy necessary for growth, development, and for maintaining health and sustaining life, or the lack of which results in characteristic chemical or physiological changes;

V – probiotic: live microorganism that, when administered in adequate quantities, confers a benefit to one's health;

VI – bioactive substance: nutrient or non-nutrient normally consumed as a component of a food, which has a specific metabolic or physiological action on the human body;

VII – dietary supplement: product for oral ingestion, presented in pharmaceutical forms, intended to supplement the diet of healthy individuals with nutrients, bioactive substances, enzymes, or probiotics, either isolated or combined.

CHAPTER II

COMPOSITION, QUALITY, AND SAFETY REQUIREMENTS

Article 4. The constituents authorized for use in the composition of dietary supplements are restricted to those provided for in Annexes I and II of Normative Instruction no. 28 of 26 July 2018, which establishes the lists of constituents, limits of use, claims, and complementary labeling of dietary supplements.

Paragraph 1. Until Annexes I and II of Normative Instruction no. 28 of 26 July 2018 are updated, the constituents approved by the Resolution (RE) resulting from the analysis of safety and efficacy assessment request, provided for in Article 20, may be used.

Paragraph 2. The constituents provided for in the caption of this article may be used either isolated or combined, as long as there is no restriction described in the approved conditions.

Article 5. Food additives and processing agents authorized for use in dietary supplements are restricted to those provided for in Resolution RDC no. 239 of 26 July 2018, which establishes the food additives and processing agents authorized for use in dietary supplements.

Article 6. Other ingredients may be used in the elaboration of dietary supplements to provide flavor, color, or aroma, or to dissolve, dilute, disperse, or alter its consistency or form, as long as they comply with the following requirements:

I – they are traditionally used in the elaboration of foods;

II – they comply with the respective identity and quality standards;

III – they are not classified as food additives or processing agents;

IV – they are not classified as new foods or new ingredients, according to Resolution no. 16 of 30 April 1999, which approves the technical regulation of procedures for the marketing authorization of foods and/ or new ingredients;

V – they are not ingredients that are source of amino acids, vitamins, minerals, bioactive substances, enzymes, or probiotics, according to Annexes I and II of Normative Instruction no. 28 of 26 July 2018;

VI – they do not alter the purpose of use or the presentation form of the product as dietary supplement; and

VII – they are not object of any claim on the label or advertisement suggesting the ingredient is a source of nutrients, bioactive substances, enzymes, or probiotics.

Sole paragraph. If the ingredients provided for in the caption of this article are also featured as sources of proteins, carbohydrates, dietary fibers, or lipids in Annexes I and II of

Normative Instruction no. 28 of 26 July 2018, which establishes the lists of constituents, limits of use, claims, and complementary labeling of dietary supplements, the minimum limits required in Article 9 of this Resolution are not applied.

Article 7. The following are not allowed in the composition of dietary supplements:

I – substances considered as doping by the World Antidoping Agency;

II – substances subject to special control, in accordance with Administrative Rule no. 344 of 12 May 1998, which approves the technical regulation on substances and drug products subject to special control, and its updates;

III – substances obtained from the species that cannot be used in the composition of traditional herbal medicinal products, in accordance with Annex I of Resolution – RDC no. 26 of 13 May 2014, which provides for the marketing authorization of herbal medicinal products and the marketing authorization and notification of traditional herbal medicinal products; and

IV – partially hydrogenated oils and fats.

Article 8. The ingredients that are source of nutrients, bioactive substances, and enzymes, provided for in Article 4 of this Resolution, must fully comply with the identity, purity, and composition specifications established in, at least, one of the following references:

I – Brazilian Pharmacopeia;

II – Officially acknowledged pharmacopeias, in accordance with Resolution – RDC no. 37 of 6 July 2009, which provides on the admissibility of foreign pharmacopeias, and its updates;

III – Codex Alimentarius;

IV – Joint FAO/WHO Expert Committee on Food Additives – JECFA;

V – Food Chemicals Codex – FCC;

VI – USP Dietary Supplement Compendium – DSC; or

VII – European Food Safety Authority – EFSA.

Sole paragraph. The ingredients whose specifications are approved by Anvisa are excepted from the provisions in the caption of this article.

Article 9. The quantities of nutrients, bioactive substances, enzymes, and probiotics contained in dietary supplements must comply with the minimum and maximum limits of use established in Annexes III and IV of Normative Instruction no. 28 of 26 July 2018.

Paragraph 1. The minimum and maximum limits must be complied with in the daily recommended consumption for the respective population groups indicated by the manufacturer.

Paragraph 2. The minimum and maximum limits provided for in the caption of this article do not apply to the dietary supplements intended exclusively for Public Health Programs of the Ministry of Health.

Article 10. Dietary supplements must be developed and produced in a way to ensure their characteristics are maintained until the end of their shelf life, considering the manufacturer's package instructions.

Paragraph 1. The conditions established in the caption of this article must be ensured through stability and quality control studies.

Paragraph 2. Overdose is allowed, as long as the product, as displayed for sale, does not exceed the maximum amounts established in Annex IV of Normative Instruction no. 28 of 26 July 2018.

Article 11. The documentation related to the compliance with the requirements provided for in this Resolution must be available for consultation by the competent authority.

Sole paragraph. The documentation provided for in the caption of this article must be submitted to Anvisa for the purposes of marketing authorization of the dietary supplements subject to compulsory health marketing authorization, in accordance with Annex II of Resolution – RDC no. 27 of 6 August 2010, which provides for the categories of foods and packages exempted from and subjected to compulsory health marketing authorization.

CHAPTER III

LABELING REQUIREMENTS

Article 12. The products provided for in this Resolution must be designated as "Dietary Supplement" added with its pharmaceutical form.

Paragraph 1. The designation of products may be complemented with the following information:

I – individual names of nutrients, bioactive substances, or enzymes;

II – names of the categories of nutrients, bioactive substances, or enzymes;

III – name of the source where the nutrient, bioactive substance, or enzyme was extracted from; or

IV – lineage identification or brand name of the microorganism, in the case of dietary supplements containing probiotics.

Paragraph 2. The specific dietary supplement designation requirements provided for in Annexes V or VI of Normative Instruction no. 28 of 26 July 2018 must be complied with.

Article 13. The designation must be declared next to the product's brand name and with legible characters that comply with the following declaration requirements:

I – upper case;

II – bold;

III – color contrasting the label background; and

IV – minimum size equivalent to 1/3 (one third) of the size of the largest font used for the product's brand name and never lower than the minimum limits established in the Annex of this Resolution.

Article 14. Without prejudice to the requirements provided for in Resolution – RDC no. 259 of 20 September 2002, which approves the technical regulations for the labeling of packaged foods, the labeling of dietary supplements must present the following information:

I – recommendation of use, including the following information grouped in the same location on the label:

a) the population groups of Annexes III and IV of Normative Instruction no. 28 of 26 July 2018, which the product is indicated for, including age range in the case of children;

b) the amount and frequency of consumption for each one of the population groups indicated on the label;

c) highlighted warning in bold "This product is not a medicinal product";

d) highlighted warning in bold "Do not exceed the daily recommended consumption indicated on the package"; and

e) highlighted warning in bold "Keep away from children's reach".

II – conservation instructions, also after the package is open; and

III – species identification of each lineage, in accordance with the latest binomial nomenclature, in the list of ingredients of dietary supplements containing probiotics.

Paragraph 1. The information required in letter a of item I may be complemented with indications for specific genders and age ranges and for physical activity practitioners and athletes within each population group indicated on the label.

Paragraph 2. The complementary labeling requirements for dietary supplements established in Annex VI of Normative Instruction no. 28 of 26 July 2018 must be complied with.

Article 15. The nutrition labeling of dietary supplements must comply with the provisions in Resolution – RDC no. 360 of 23 December 2003, which approves the technical regulations on the nutrition labeling of packaged foods, with the following specificities:

I – the portion declared in the nutrition information must be the daily amount recommended by the manufacturer, for each one of the specific population groups and age ranges indicated on the label;

II – the nutrition information must include the amounts of all nutrients, bioactive substances, enzymes, and probiotics supplied by the product, declared in the measurement units provided for in Annexes III and IV of Normative Instruction no. 28 of 26 July 2018; and

III – the percentage of daily values (%DV) must be declared for each one of the specific population groups indicated on the label, based on the reference daily intake values provided for in Resolution – RDC no. 269 of 22 September 2005, which approves the technical regulations on the reference daily intake (RDI) of protein, vitamins, and minerals, when established.

Article 16. The claims authorized for use in dietary supplements are restricted to those provided for in Annex V of Normative Instruction no. 28 of 26 July 2018, as long as the respective requirements are complied with.

Paragraph 1. Text variations of the authorized claims are not allowed, except when:

I – the claims for a single substance are written together in a single phrase; or

II – identical claims for different substances are written together in a single phrase.

Paragraph 2. The use of claims is optional, except for dietary supplements with probiotics or with enzymes.

Paragraph 3. Claims related to contents and properties of food additives and processing agents, and related to properties of the ingredients referred to in Article 6 of this Resolution are not allowed, except for the cases provided for in legislation.

Article 17. Without prejudice to the requirements provided for in Decree-Law no. 986 of 21 October 1969, which establishes basic rules on foods, and the requirements provided

for in Resolution – RDC no. 259 of 2002, the labeling of dietary supplements cannot present words, brands, images, or any other graphic representation, including in other languages, that state, suggest, or imply, either expressively or in an implicit way, that:

I – the product has medicinal or therapeutic purposes;

II – the product contains unauthorized or prohibited substances;

III – feeding is not capable of providing the components needed for health; or

IV – the product is comparable or superior to conventional foods.

Article 18. The dietary supplements indicated for breastfeeding women and infants must comply with the provisions in Law no. 11,265 of 3 January 2006, which regulates the commercialization of foods for breastfeeding women and infants, and also of correlated childcare products, and its regulations.

Article 19. Resolution – RDC no. 54 of 12 November 2012, which provides on the technical regulation on complementary nutrition information, does not apply to dietary supplements.

CHAPTER IV

REQUIREMENTS FOR THE UPDATE OF LISTS OF CONSTITUENTS, LIMITS OF USE, CLAIMS, AND COMPLEMENTARY LABELING

Article 20. The update of lists of constituents, limits of use, claims, and complementary labeling of Normative Instruction no. 28 of 26 July 2018 must be requested by the companies through a specific petition for safety and efficacy analysis, containing documentation that proves the following requirements are complied with:

I – in the case of nutrients, bioactive substances, and enzymes, the constituents must:

a) be provenly safe for human consumption, in accordance with Resolution no. 17 of 30 April 1999, which approves the technical regulation that establishes the basic directives for food risk and safety assessment;

b) comply with the provisions in Article 8 of this Resolution;

c) have minimum limits established, whenever possible, in a way to ensure a significant ingestion based on the scientific evidence related to daily needs or the metabolic or physiological effect;

d) have maximum limits established in a way to reduce the risk of excessive consumption, considering the scientific evidences related to upper safety limits, the specificities of the population group they are intended for, and the amounts consumed through other food sources;

e) have the efficacy of its claims proven, in accordance with Resolution no. 18 of 30 April 1999, which approves the technical regulation that establishes the basic directives for analysis and confirmation of functional and/ or health properties claimed in food labeling.

II – in the case of probiotics, the requirements in Resolution – RDC no. 241 of 26 July 2018, which provides for the requirements to confirm safety and health benefits of probiotics for use in foods, must be complied with.

Sole paragraph. The result from the assessment of the petition referred to in the caption of this article shall be published through a Resolution (RE), and the use of constituent, limit of use, claim, and complementary labeling is allowed in the approved conditions, until the lists contained in Normative Instruction no. 28 of 26 July 2018 are updated.

Article 21. The decisions on petitions of marketing authorization of dietary supplements subject to compulsory health marketing authorization, in accordance with Annex II of Resolution – RDC no. 27 of 2010, submitted after the publication of this Resolution, shall be bound to the previous decision on the safety and efficacy assessment petition, according to the procedure provided for in Article 20.

CHAPTER V

FINAL AND TRANSITIONAL PROVISIONS

Article 22. This Resolution establishes the period of up to 60 (sixty) months for the adequacy of products regularized within the Brazilian Health Surveillance System on the date this Resolution is published.

Paragraph 1. The adequacy of products referred to in the caption of this article must be done completely, in a single act.

Paragraph 2. The products manufactured and imported during the adequacy period may be commercialized until the end of their shelf lives.

Article 23. The products that are no longer subject to compulsory marketing authorization in the dietary supplement category, in accordance with Resolution – RDC no. 27 of 2010, may be manufactured and imported in the conditions approved in their marketing authorization until the end of the adequacy period established in Article 22 of this Resolution, even if their respective marketing authorizations expire.

Paragraph 1. The products referred to in the caption of this article shall not be liable to post-marketing authorization alterations, except for title transfer.

Paragraph 2. The products referred to in the caption of this article shall be exempted from the compulsory marketing authorization, and also exempted from the need to inform on the production start to the health authority of the State, the Federal District, or the Municipality until the end of the adequacy period established in Article 22 of this Resolution.

Article 24. The marketing authorization of products, granted until the date this Resolution is published, shall remain in force until the end of the period established when granted.

Paragraph 1. The adequacy of products that remain subject to the compulsory health marketing authorization in the dietary supplement category, in accordance with Resolution – RDC no. 27 of 2010, must be effected through a post-marketing authorization petition submission.

Paragraph 2. Until the end of the adequacy period established in Article 22 of this Resolution, the products that remain subject to the compulsory health marketing authorization in the dietary supplement category may have their marketing authorizations revalidated, as long as they maintain the conditions approved in their marketing authorization.

Article 25. The marketing authorization and post-marketing authorization petitions of products that become exempted from the compulsory marketing authorization in the dietary supplement category, in accordance with Resolution – RDC no. 27 of 2010, pending Anvisa's

decision by the date this Resolution is published, shall be rejected due to loss of object, except if the responsible companies, duly notified by the Agency, expressly state they withdraw their application in the period of 30 (thirty) days from the date of the notification.

Article 26. The marketing authorization petitions for products containing probiotics or enzymes that enter the category of dietary supplements, and the safety and efficacy assessment petitions for new ingredients, enzymes, or probiotics for use in dietary supplements, which have not been decided by Anvisa by the date this Resolution is published, shall be assessed in compliance with the requirements and procedures established in this Resolution, and they may be rejected due to non-compliance with such requirements, except if the responsible companies, duly notified, expressly state, in the period of 30 (thirty) days from the date of the notification, their interest in:

I – withdraw the petition;

II – amend the petition, in accordance with the provisions approved in this Resolution; or

III – inform that the documents related to the safety and efficacy assessment of the enzyme or probiotic present in the product that is the object of the marketing authorization petition will be submitted in a specific safety and efficacy assessment petition.

Paragraph 1. The amendment referred to in item II must be effected in the period of up to three hundred sixty-five days from the date this Resolution is published, in a single act.

Paragraph 2. The safety and efficacy assessment petition for the enzyme or probiotic, provided for in item III, must be submitted in the period of up to three hundred sixty-five days from the date this Resolution is published.

Paragraph 3. For the companies that choose the situation provided for in item III, the decision on the marketing authorization petition shall be bound to the previous decision on the safety and efficacy assessment petition.

Paragraph 4. After the period established in paragraphs 1 and 2, the petition shall be analyzed regardless of the submission of safety and efficacy assessment petitions or the addition of complementary information to the marketing authorization.

Article 27. The failure to comply with the provisions in this Resolution constitutes a health infraction, in the terms of Law no. 6,437 of 20 August 1977 and its updates, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 28. The following provisions are hereby revoked:

I – Administrative Rule SVS/MS no. 32 of 13 January 1998, which approves the technical regulation for vitamin and/ or mineral supplements;

II – Administrative Rule SVS/MS no. 40 of 13 January 1998, which approves the regulation that establishes rules for the levels of daily dosages of vitamins and minerals in medicinal products;

III – Administrative Rule SVS/MS no. 222 of 24 March 1998, which approves the technical regulation related to foods for practitioners of physical activities;

IV – Administrative Rule SVS/MS no. 223 of 24 March 1998, which approves the technical regulation for fixation and quality of dietary complements for pregnant or breastfeeding women;

V – Resolution – RDC no. 2 of 7 January 2002, which approves the technical regulation for isolated bioactive substances and probiotics with claims of functional and/ or health properties;

VI – Resolution – RDC no. 18 of 27 April 2010, which provides for foods for athletes;

VII – item 4.2 of Resolution no. 16 of 30 April 1999, which approves the technical regulation for the Procedures for the marketing authorization of Foods and/ or New Ingredients; and

VIII – items 2.2.2 b), 2.2.3 b), and 4.2.2 of Administrative Rule SVS/MS no. 29 of 13 January 1998, which approves the technical regulation related to foods for special purposes.

Article 29. This Resolution enters into force on the date of its publication.

FERNANDO MENDES GARCIA NETO

ANNEX

Label main panel area (cm^2)	Minimum font (mm)
Smaller than 50	1
Larger than or equal to 50 and smaller than 170	2
Larger than or equal to 170 and smaller than 650	3
Larger than or equal to 650 and smaller than 2600	4.5
Larger than or equal to 2600	6

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