COLLEGIATE BOARD RESOLUTION – RDC NO. 96 OF 17 DECEMBER 2008

Provides for advertising, publicity, information, and other practices, the objective of which is the dissemination or commercial promotion of medicinal products.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 11, item IV of the Brazilian Health Regulatory Agency Regulation approved by Decree no. 3,029 of 16 April 1999, and according to Article 11, item IV of the Internal Regulation approved under the terms of Annex I of Anvisa Ordinance no. 354 of 11 August 2006, republished in the Federal Official Gazette of 21 August 2006, as decided upon in a meeting held on 21 November 2008,

whereas the Federal Constitution of 1988;

whereas Law No. 6,360 of 23 September 1976;

whereas Decree No. 79,094 of 5 January 1977, which regulates Law No. 6,360 of 24 September 1976;

whereas Law No. 9,782 of 26 January 1999;

whereas Law No. 9,787 of 10 February 1999;

whereas Law No. 11,343 of 23 August 2006;

whereas Decree No. 78,992 of 21 December 1976, which regulates Law No. 6,368 of 21 October 1976;

whereas Law No. 6,437 of 20 August 1977, about health infractions;

whereas Law No. 9,294 of 15 July 1996;

whereas Decree No. 2,018 of 1 October 1996, which regulates Law No. 9,294 of 15 July 1996;

whereas Law No. 8,078 of 11 September 1990;

whereas Decree No. 2,181 of 20 March 1997;

whereas Law No. 8,069 of 13 July 1990;

whereas Law No. 10,742 of 6 October 2003;

whereas RDC No. 26 of 30 March 2007;

whereas Ordinance No. 3,916 of 30 October 1998, which defines the Brazilian Policy for Medicinal Products;

whereas the publication by the Ministry of Health and the Brazilian Health Regulatory Agency entitled Comparative Study – Regulation of Advertising of Medicinal Products (*Estudo Comparado – Regulamentação da Propaganda de Medicamentos*);

whereas the necessity to update the Technical Regulation about Advertising, Publicity, Promotion of, and Information on Medicinal Products;

adopts the following Collegiate Board Resolution and I, Director-President, determine its publication.

Article 1. The Regulation attached to this Resolution applies to advertising, publicity, information, and other practices, the objective of which is the dissemination or commercial promotion of medicinal products, whether produced nationally or internationally, regardless of the forms and means of their broadcasting, including those transmitted during the normal programming of radio and television stations.

Article 2. This Collegiate Board Resolution becomes effective 180 (one hundred and eighty) days from the date of its publication.

Dirceu Raposo de Mello

ATTACHMENT

REGULATION

Article 1. This Regulation applies to advertising, publicity, information, and other practices, the objective of which is the dissemination or commercial promotion of medicinal products, whether produced nationally or internationally, regardless of the forms and means of their broadcasting, including those transmitted during the normal programming of radio and television stations.

TITLE I

GENERAL REQUIREMENTS

Article 2. For the purposes of this Regulation, the following definitions are adopted:

BRAZILIAN COMMON NAME/DCB – Name of the medicine or pharmacologically active ingredient approved by the federal agency responsible for health surveillance.

INTERNATIONAL NONPROPRIETARY NAME/INN – Name of the medicine or pharmacologically active ingredient recommended by the World Health Organization.

COMPANY – A legal entity, governed by public or private law, whose main or subsidiary activity is the production, manipulation, trade, supply, distribution, and dissemination of medicines, pharmaceutical ingredients, and other products that are advertised as medicinal products.

WORD TRADEMARK – A trademark consisting of one or more words in the broad sense of the Roman alphabet, also including neologisms and combinations of letters and/or Roman and/or Arabic numerals.

FIGURATIVE TRADEMARK – A trademark consisting of a drawing, figure, or any stylized form of a letter or number, separately.

MIXED TRADEMARK – A trademark consisting of a combination of word and figurative elements or word elements with stylized spelling.

SCIENTIFIC MATERIAL – Published scientific articles and technical books.

VISUAL AID MATERIAL – Advertising material used exclusively by sales representatives to present medications to prescribing and dispensing professionals with information and language standardized by the company.

BIOLOGICAL MEDICATION – A biological medication that contains a molecule with known biological activity and has passed all manufacturing stages (formulation, bottling,

lyophilization, labeling, packaging, storage, quality control, and batch release of the biological product for use).

CORRECTIVE MESSAGE – A message designed to clarify and correct errors and misunderstandings caused by misleading and/or abusive advertising, and/or advertising that presents incorrect and incomplete information and is therefore capable of directly or indirectly misleading consumers, so they may make mistakes and engage in behavior that is detrimental to their health and safety.

MONOGRAPH – Material prepared through a compilation of technical and scientific information from published studies, technical books, and information contained in the registration documentation submitted to Anvisa, aiming to provide healthcare professionals with a variety of information about a given medication, presenting summaries with balanced information—that is, satisfactory and unsatisfactory results—and conclusions that are faithful to the original one.

EVIDENCE LEVEL I – Study Level I: Randomized clinical trials with clinically relevant outcomes and magnitude of effects, corresponding to the main hypothesis in thesis, with adequate power and minimal possibility of alpha error. Meta-analyses of comparable Level II clinical trials with internal validity, with adequate final power and minimal possibility of alpha error.

EVIDENCE LEVEL II – Study Level II: Randomized clinical trials that do not meet the Level I criteria. Analysis of secondary hypotheses of Level I studies.

SPONSORSHIP – Full or partial funding for the production of material, radio or television programs, events, community projects, cultural, artistic, sports, research, or scientific update activities, provided as a marketing strategy, as well as funding for participants in the aforementioned activities.

ADVERTISING PIECE – Each of the elements produced for an advertising or sales promotion campaign, with its own functions and characteristics, which follow the specificity and language of each medium. Examples: advertisement, insert, film, spot, jingle, poster, billboard, sign, display, folder, banner, mobile, outdoor advertising, bus door, visual aid, etc.

INDIVIDUAL – Any person who, directly or indirectly, is responsible for activities related to the production, handling, sale, supply, distribution, and promotion of medicines, pharmaceutical ingredients, and other products advertised as medicinal products.

MASTERAL PREPARATION – Any product prepared in a pharmacy, individually, to be dispensed according to a prescription from a qualified professional, in compliance with current legislation, which establishes its composition, pharmaceutical form, dosage, and instructions for use.

OFFICIAL PREPARATION – This is a preparation prepared in a pharmacy, whose formula is registered in pharmacopoeias, compendia, or formularies recognized by the Ministry of Health.

LOYALTY PROGRAMS – These are programs run by pharmacies and drugstores, which, with the intention of building customer loyalty, allow customers, in exchange for purchasing products, to participate in sweepstakes, win prizes, or discounts on product purchases, among other benefits.

ADVERTISING/PUBLICITY – A set of information and persuasion techniques and activities aimed at disseminating knowledge, increasing the awareness and/or prestige of a given product or brand, and influencing the public through actions aimed at promoting and/or inducing the prescription, dispensing, purchase, and use of medicinal products.

ABUSIVE ADVERTISING/PUBLICITY – The one that incites discrimination of any nature, violence, exploits fear or superstitions, takes advantage of a child's lack of judgment and experience, disrespects environmental values, or is capable of inducing users to behave in a way that is harmful or dangerous to their health or safety.

MISLEADING ADVERTISING/PUBLICITY – Any form of information or communication of an advertising nature, whether wholly or partially false, or which, in any other way, even by omitting essential product information, is capable of misleading consumers regarding the nature, characteristics, quality, quantity, properties, origin, price, and any other information about products and services.

INDIRECT ADVERTISING/PUBLICITY – Any advertising that, without mentioning the name of the products, uses brands, symbols, designations, and/or indications capable of identifying them and/or cites the existence of some type of treatment for a specific health condition.

BIBLIOGRAPHIC REFERENCE – A standardized set of descriptive elements that allows the identification of documents used, enabling their location and direct access by an interested reader.

ACTIVE SUBSTANCE – Any substance that has pharmacological activity or another direct effect on diagnosis, such as cure, relief, treatment, or prevention of diseases; or affects any function of the human body.

VACCINES – Biological products containing one or more antigenic substances that, when inoculated, can induce active specific immunity and protect against the disease caused by the infectious agent that originated the antigen.

Article 3. Advertising or publicity is only permitted for medicinal products regularized with Anvisa.

Paragraph 1. Advertising or publicity must come from companies regularized by the competent health agency, when required by law, even if the advertising material complies with these Regulations.

Paragraph 2. All claims contained in the advertising material regarding the medication's action, indications, dosage, instructions for use, adverse reactions, efficacy, safety,

quality, and other characteristics of the medicinal product must be consistent with the information registered with Anvisa.

Paragraph 3. Bibliographic references cited in medication advertising or publicity must be available to the Consumer Service Center and to professionals who prescribe and dispense medicinal products.

Article 4. Misleading, abusive, and/or indirect advertising or publicity is not permitted.

Sole paragraph – It is prohibited to use communication techniques that allow the broadcasting of images and/or mention of any active substance or brand of medicinal products, in a manner that is not declared advertising, directly or indirectly, in editorial spaces on television; in the scenic context of soap operas; theatrical performances; films; radio messages or programs; among other types of electronic or printed media.

Article 5. Companies may not grant, offer, promise, or distribute gifts, benefits, and advantages to prescribing or dispensing professionals, those engaged in direct sales to consumers, or the general public.

Article 6. The information required by this Regulation, when displayed in written language, must be presented in colors that contrast with the advertisement's background, must be arranged in the predominant direction of reading of the advertisement, and must allow for immediate visualization, maintaining the appropriate distances between them, essential for legibility and prominence.

Sole paragraph: In the case of advertising or publicity broadcast on television, when the written information is not voiced, it must be displayed for sufficient time to be read.

Article 7. Information about medicinal products must be scientifically proven.

Article 8. The following are prohibited in medicine advertising or publicity:

I – encouraging and/or inducing the indiscriminate use of medicinal products;

II – suggesting or encouraging diagnoses to the general public;

III – including images of people using the medicinal product;

IV – advertising a medicinal product as new, after two years from the date it began to be commercialized in Brazil;

V – including seals, word trademarks, figurative marks, or mixed marks of government institutions, philanthropic entities, foundations, associations and/or medical societies, non-governmental organizations, associations representing the interests of consumers or healthcare professionals, and/or quality certification seals;

VI – suggesting that the medicinal product has pleasant organoleptic characteristics, such as: "tasty," "delicious," or equivalent expressions; as well as the inclusion of images or figures that refer to the medication's flavor;

VII – using imperatives that directly induce medication consumption, such as: "have," "take," "use," "try";

VIII – advertising or publicizing medicinal products and/or companies anywhere on prescription pads;

IX – creating sales expectations;

X – promoting as generic medicinal products compounded or manufactured medications that are not generic, pursuant to Law No. 9,787/99;

XI – using expressions or images that may suggest that a person's health may be affected by not using the medicinal product.

Article 9. The following are permitted in advertising or publicity of medicinal products:

I – using anatomical figures to guide healthcare professionals or patients on the correct use of the product;

II – describing the medication's flavor;

III – using expressions such as "safe," "effective," and "quality," in combination or alone, as long as they are complemented by phrases that justify the veracity of the information, which must be taken from studies published in scientific publications and must be properly referenced;

IV – using expressions such as "absolute," "excellent," "maximum," "optimal," "perfect," and "total" related to the efficacy and safety of the medicinal product, when faithfully reproduced from studies published in scientific publications and properly referenced;

V – when included among the properties approved in the medicinal product's marketing authorization with Anvisa, stating that the medication can be used by anyone, of any age group, including through images;

VI – when determined by Anvisa, publishing messages such as: "Approved," "Recommended by a specialist," "Most frequently recommended," or "Advertising Approved by the Health Regulatory Agency," by the "Ministry of Health," or similar messages referring to a similar state, municipal, or Federal District agency;

VII – mentioning the number of countries where the medicinal product is marketed and/or manufactured, provided that the countries are identified in the advertising material.

Article 10. Loyalty programs run in pharmacies and drugstores, aimed at consumers, may not include medicinal products as items for points, exchanges, raffles, or prizes.

Sole paragraph. All advertising material and regulations for loyalty programs must inform consumers of the restrictions set forth in the caption of this article.

Article 11. Price comparisons directed at consumers may only be made between medications that are interchangeable in accordance with Law No. 9,787/99.

Paragraph 1. Only prescribing professionals are permitted to compare prices between medicinal products that are not interchangeable, based on market information, provided they have the same active ingredient.

Paragraph 2. The comparison must be made between treatment costs or, in the case of medicinal products for continuous use, between the defined daily doses.

Paragraph 3. Advertising or publicity for biological medications, classified as such according to specific regulations, may not present price comparisons, even if they have the same indication.

Paragraph 4. When a percentage discount and/or promotional price for a medicinal product is stated, the full price charged by the pharmacy or drugstore must also be informed.

Paragraph 5. When pharmacies and drugstores advertise discounts for medicinal products, whether through advertisements on television, radio, printed means, banners, or any other means, they must have a list of medicinal products advertised at the reduced price available in a publicly visible location, in accordance with Article 18 of this Resolution.

Article 12. It is permitted to offer prescribers and dispensers material containing a list of generic medicinal products that includes the Anvisa marketing authorization number, the name of the marketing authorization holder, the presentation, including concentration, pharmaceutical form and quantity, the name of the reference medicinal product, and the respective marketing authorization holder, with the information in Articles 22, 23, and 27 of this Resolution being waived.

Article 13. Only medicinal product distributors, pharmacies, and drugstores are permitted to receive product catalogs containing the following information: the commercial name of the medicinal products, including those subject to prescription retention; the active ingredient according to the DCB/INN; the presentation, including concentration, dosage form, and quantity; the marketing authorization number with the Brazilian Health Regulatory Agency; and the respective price, with the information in articles 22, 23, and 27 being waived.

Article 14. Medicinal product advertising or publicity may not use designations, symbols, figures, or other graphic representations, or any indications that may render the information false, incorrect, or that allow for false interpretation, misunderstanding, error, and/or confusion regarding the true nature, composition, origin, quality, method of use, purpose, and/or characteristics of the product.

Article 15. Direct or indirect comparisons between any medications, whether over the counter or not, must be based on information extracted from comparative studies published in scientific publications, preferably with levels of evidence I or II, and must specify complete bibliographic reference.

Sole paragraph. Comparisons related to bioavailability and bioequivalence of active ingredients may be made based on studies issued by official laboratories and approved by Anvisa, provided they are duly referenced and available on the company's website and customer service.

Article 16. In the case of generic medicinal products, in accordance with Law No. 9,787/99 and its regulations, advertising must include the phrase: "Generic Medicinal product – Law No. 9,787/99."

Article 17. Advertising for medicinal products that have sedative and/or drowsy effects, according to the product's package insert granted marketing authorization by Anvisa, must include the warning: "(trade name of the medicinal product or, in the case of generic medicinal products, the active ingredient) is a medicine. While using it, do not drive vehicles or operate machinery, as your agility and attention may be impaired." The warning in Article 23 of this Resolution is waived.

Sole paragraph. The warning referred to in the caption of this article must comply with the criteria set forth in Article 23.

Article 18. Medicinal products prices, when disclosed to the general public, must be indicated through lists that should include only the product's trade name; active ingredient, according to the DCB/INN; presentation, including concentration, dosage form, and quantity; the marketing authorization number with the Brazilian Health Regulatory Agency; the name of the marketing authorization holder; and the price of the listed medications.

Sole paragraph. In the case of over-the-counter medications, forms of communication other than lists are permitted, provided they include the other information required by this Resolution.

Article 19. When pharmacies and drugstores use phrases to advertise price reductions for groups of medications, such as "discount on contraceptives" or "generics with a 30% discount," other advertising arguments may not be used.

Article 20. In advertising or publicity directed at professionals authorized to dispense or prescribe medications, information regarding the maximum consumer price must mention the respective source, as well as the presentation, including concentration, dosage form, and quantity of the medication.

Article 21. In the specific case where the name and/or image of a healthcare professional is presented as support for the advertised properties of the medicine, the advertising message must clearly state the name of the professional involved and their registration number with the respective Council or other professional registration body.

TITLE II

REQUIREMENTS FOR ADVERTISING OR PUBLICITY OF NON-PRESCRIPTION MANUFACTURED MEDICINAL PRODUCTS

Article 22. Advertising or publicity for non-prescription medicinal products must comply with general requirements, without prejudice to specific requirements for certain types of medicinal products, and must include the following information:

I – The medicinal product's trade name, if applicable;

II – The name of the active ingredient according to the DCB and, in its absence, the INN or botanical nomenclature, which must be at least 50% the size of the trade name;

III – Anvisa marketing authorization number, containing at least nine digits, except for advertisements broadcast on radio;

IV – For medicinal products with simplified notification, the following phrase: "MEDICINAL PRODUCT WITH SIMPLIFIED NOTIFICATION RDC Anvisa No...../2006. AFE. No.: .....", except for advertisements broadcast on radio;

V – Indications;

VI – Printing date of the advertisements;

VII – The warning: "IF SYMPTOMS PERSIST, A DOCTOR SHOULD BE CONSULTED", which must comply with Article 6.

a) The requirements of items "II", "V", "VI", and "VII" apply to officinal formulations, based on technical and scientific data based on national and international literature, officially recognized and listed in Annex II of this Resolution.

b) The radio station, upon sale of the promotional space, must make available to consumers and the health authority information on the marketing authorization number or, in the case of simplified notification medicinal products, the Resolution authorizing the manufacture, import, and/or sale of the medicinal product.

c) When directed to the general public, the technical terms in advertising or publicity for over-the-counter medicinal products must be written in a manner that facilitates public understanding.

Article 23. Advertising or publicity for over-the-counter medicinal products must also carry a warning related to the medicinal product's active ingredient, in accordance with the table in Annex III.

Sole paragraph. If an active substance or combination is not listed in the table in Annex III, the advertisement or publicity must carry the following warning: "(trade name of the medicinal product or, in the case of generic medicinal products, the active substance) IS A MEDICATION. ITS USE MAY CARRY RISKS. SEEK A DOCTOR AND PHARMACIST. READ THE PACKAGE INSERT."

Article 24. The warning referred to in Article 23 must be contextualized in the advertising piece, so that it is spoken by the main character when broadcast on television; delivered by the same announcer when broadcast on radio; and, when printed, it must have the same visual impact as the other information contained in the advertising piece, presented in at least 35% of the size of the largest font used.

I – The voiceover of the warnings referred to in the caption of this article must be rhythmic, paused, and perfectly audible.

II – If the television advertisement or publicity does not feature a main character, the warnings must meet the following requirements:

a) after the end of the advertising message, the warning will be displayed on a single card, with a blue background, in white letters, allowing perfect legibility and visibility, remaining still in the video;

b) the voiceover must be distinct, paced, paused, and perfectly audible;

c) the card must follow the RTV filming template in the standard size of 36.5cm x 27cm (thirty-six and a half centimeters by twenty-seven centimeters);

d) the lettering on the card will be in the Humanist 777 Bold or Frutiger 55 Bold typeface, size 38, all caps.

III – On the internet, the warning must be permanently and visibly displayed, inserted in a rectangle with a white background, framed by an internal border, in black letters, Humanist 777 Bold or Frutiger 55 Bold, capitalized, respecting the proportion of two-tenths of the total advertising space.

Article 25. The broadcasting of advertisements or publicity for medications on television during breaks in programs aimed at children or adolescents, as classified by the Child and Adolescent Statute, is prohibited, as well as in magazines with content dedicated to such audience.

Article 26. In advertisements or publicity for over-the-counter medications, the following are prohibited:

I – Using expressions such as: "Demonstrated in clinical trials," "Scientifically proven";

II – Suggesting that the medication is the only treatment alternative, leading one to believe that healthy lifestyle habits and/or a visit to a doctor are superfluous;

III – Presenting the name, image, and/or voice of a person not skilled in medicine or pharmacy, whose characteristics are easily recognized by the public due to their celebrity, stating or suggesting that they use the medication or recommending its use;

IV – Using direct or indirect language linking the use of medication to excessive alcohol or food consumption;

V – Using direct or indirect language linking the use of medication to a person's physical, intellectual, emotional, sexual performance, or beauty, except when these properties are approved by Anvisa;

VI – Presenting abusive, misleading, or frightening visual representations of changes in the human body caused by illness or injury;

VII – Including messages, symbols, and images of any nature directed at children or adolescents, as classified by the Child and Adolescent Statute.

TITLE III

REQUIREMENTS FOR ADVERTISING OR PUBLICITY OF PRESCRIPTION-BASED MEDICINAL PRODUCTS

Article 27. Advertising or publicity for prescription medicinal products must comply with general requirements, without prejudice to specific requirements for certain types of medicinal products and is restricted to communication channels intended exclusively for healthcare professionals authorized to prescribe or dispense such products. They must include essential information regarding:

I – The medicinal product's trade name, if applicable;

II – The name of the active ingredient according to the DCB and, in its absence, the INN or botanical nomenclature, which must be at least 50% the size of the trade name;

III – Anvisa marketing authorization number, including at least nine digits;

IV – Indications;

V – Contraindications;

VI – Precautions and warnings (including adverse reactions and interactions with medicinal products, food, and alcohol);

VII – Dosage;

VIII – The medicinal product's classification in relation to prescription and dispensing;

IX – The printing date of printed advertising materials.

Paragraph 1. The information required by this article must be presented in a font size of at least two millimeters.

Paragraph 2. Vaccine advertisements or publicity must also include information on the number of doses required for complete immunization.

Article 28. In advertisements or publicity for prescription medicinal products, when the benefits of the medicinal product are highlighted in the text of the advertisement, at least one contraindication and one of the most common medicinal product interactions must be highlighted, among those required in Article 27, items V and VI, creating a visual impact on the reader and complying with the proportionality of 20% of the size of the largest font used.

Article 29. Advertisements or publicity for prescription medicinal products published online must be accessible exclusively to professionals authorized to prescribe or dispense medications, through an electronic registration system, and a disclaimer must be presented informing of the legal restriction on access.

Sole paragraph. Prescription medicinal product package inserts posted online, without restricted access, must be up-to-date, faithfully reproduce those approved by Anvisa, and may not contain designations, symbols, figures, drawings, images, slogans, or any advertising arguments related to the medicinal products.

Article 30. Any statements, citations, tables, or illustrations related to scientific information must be taken from clinical studies published in scientific publications, preferably with levels of evidence I or II.

Paragraph 1. The statements, citations, tables, or other illustrations referred to in the caption of this article must be faithfully reproduced and the bibliographic reference must be specified.

Paragraph 2. The creation of graphs, charts, tables, and illustrations of mechanisms of action to convey information that is not represented in scientific studies must accurately reflect the veracity of the information and specify the complete bibliographic reference.

Paragraph 3. The graphs, tables, and illustrations of mechanisms of action covered by this article must be truthful, accurate, complete, and unbiased, and must not be presented in a manner that could lead to error or confusion regarding the characteristics of the medication through visual impact.

Article 31. Statements related to the bioavailability and bioequivalence of active ingredients may be made based on studies issued by laboratories accredited and approved by Anvisa, provided they are duly referenced and available on the company's website and in the Customer Service Center.

Article 32. Advertising or publicity for medications under special control, subject to prescription, prescription notification, or prescription retention, in addition to complying

with the provisions of this technical regulation, may only be carried out in journals with exclusively technical content, relating to pathologies and medications, and aimed directly and solely at healthcare professionals authorized to prescribe and/or dispense medications.

Paragraph 1. Journals mentioned in the caption of this article are excluded from those containing material of a sociocultural nature and other material that is not technical-scientific.

Paragraph 2. Advertising or publicity for the medicinal products mentioned in the caption of this article is permitted in the form of a faithful copy of a technical-scientific article referring to the active substance of the medicinal product advertised and published in the journals mentioned in the caption, specifying the complete bibliographic reference, as well as in visual aid material for the exclusive use of the advertiser and monographs of the medicinal product.

TITLE IV

REQUIREMENTS FOR FREE SAMPLES

Article 33. Companies may only distribute free medicinal product samples to prescribing professionals in outpatient clinics, hospitals, and medical and dental offices.

Paragraph 1. The distribution of free samples of biological medicinal products is prohibited.

Paragraph 2. The distribution of free samples of compounding preparations is prohibited.

Paragraph 3. The distribution of free samples of over-the-counter medicinal products is prohibited.

Article 34. Free samples of prescription medicinal products must contain 50% of the contents of the original presentation granted marketing authorization by Anvisa and marketed by the company, with the exception of antibiotics, which must contain a sufficient quantity for the treatment of one patient, and contraceptives and continuous-use medications, which must contain 100% of the contents of the original presentation granted marketing authorization by Anvisa and marketed by the company.

Article 35. Free sample packaging must contain the non-removable expression "FREE SAMPLE."

Paragraph 1. Secondary packaging for free samples may not display names, symbols, figures, images, drawings, slogans, or any advertising material, except when approved by Anvisa, to be included on the original packaging.

Paragraph 2. The labeling and layout of free samples not covered by this article, as well as package inserts, labels, and leaflets, must be identical to those approved for inclusion on the original packaging.

Paragraph 3. The marketing authorization number on the free sample must contain the thirteen digits corresponding to the original, granted marketing authorization, and marketed packaging from which the sample was taken.

Paragraph 4. The batch number must be included on the free sample labeling, and the company must keep the sample distribution chart updated and available to the Brazilian Health Regulatory Agency for a minimum period of two years.

Paragraph 5. The distribution of free samples of medications containing substances subject to special control shall also be carried out in accordance with the provisions regulated by current health legislation.

TITLE V

REQUIREMENTS FOR INFORMATION MATERIAL ON COMPOUNDED MEDICINES

Article 36. For the dissemination of information on compounded medications, pharmacies are authorized to provide, exclusively to professionals authorized to prescribe medications, informational material containing only the names of the active substances used in compounding compounded formulas, according to their Brazilian Common Name or, in its absence, the International Nonproprietary Name or botanical nomenclature, as well as their respective therapeutic indications, accurately extracted from specialized literature and scientific publications, duly referenced.

Sole paragraph. The information material referred to in the caption of this article may not contain the trade name, price, designations, symbols, figures, images, drawings, slogans, or any advertising arguments related to the active substance.

Article 37. Advertising or publicity for companies on prescription pads is prohibited.

TITLE VI

REQUIREMENTS FOR VISIT BY ADVERTISERS

Article 38. When technical information about manufactured and compounded medications is provided to prescribing or dispensing professionals through company representatives, it must be transmitted with the intent of promoting the prescription and dispensing of the medication appropriately and in accordance with the Brazilian Medication Policy.

Paragraph 1. In their advertising or publicity efforts, representatives must limit themselves to the scientific information and characteristics of the medication granted marketing authorization by Anvisa.

Paragraph 2. Visits by representatives cannot interfere with pharmaceutical services or patient care, nor can they be conducted in the presence of patients and their companions. Regulating visits by representatives is at the discretion of healthcare institutions.

TITLE VII

REQUIREMENTS FOR ADVERTISING OR PUBLICITY IN SCIENTIFIC EVENTS

Article 39. At scientific events, scientific material containing the brand name of the medicinal product, the active ingredient, and the company name may be distributed to healthcare professionals not qualified to prescribe or dispense medications and to healthcare students.

Article 40. Marketing or advertising material for medicinal products must be distributed to event participants who have their professional category identification clearly visible on their badges.

Article 41. The identification of spaces in the exhibition area and inside auditoriums and similar spaces may display the brand name of the medicinal product, when applicable, along with the respective active ingredient and/or the company name. The figurative or mixed brand of the product present on the packaging approved by Anvisa may be used.

Article 42. Any support or sponsorship, total or partial, to healthcare professionals for participation in national or international scientific events must not be conditional on the prescription, dispensing, and/or advertising of any type of medication.

Paragraph 1. Sponsorship by one or more companies of any events, symposia, congresses, meetings, conferences, and similar events, whether public or private, whether partial or complete, must be clearly disclosed upon participant registration and in the proceedings, where applicable.

Paragraph 2. Speakers at any scientific session who establish relationships with pharmaceutical laboratories or have any other financial or commercial interest must disclose any potential conflict of interest to the conference organizers, duly indicated in the official event program and at the beginning of their presentation, as well as in the proceedings, where applicable.

Article 43. Organizers of scientific events that permit the advertising or publicity of medicinal products must inform Anvisa three months in advance of any regional, national, or international scientific events, including location and date, as well as the categories of participating professionals.

TITLE VIII

REQUIREMENTS FOR SOCIAL CAMPAIGNS

Article 44. The sole purpose of publicizing a social campaign must be to inform people about the company's social responsibility actions, and there may be no mention of the names of medications or advertising for these products, just as no advertising or publicity for medicinal products may refer to the company's social campaign actions.

TITLE IX

GENERAL PROVISIONS

Article 45. Companies and individuals responsible for advertising, publicity, information, and other practices aimed at publicizing, promoting, or marketing medicinal products are hereby established a period of 180 (one hundred and eighty) days from the date of publication of this Resolution to adapt to the new provisions of this regulation.

Sole paragraph. Free samples are exempt from the period established in the caption of this article, which must be adapted within 360 (three hundred and sixty) days from the date of publication of this Resolution.

Article 46. The granting of a reduction in the price of medicinal products, as well as their free acquisition subject to the submission of coupons, cards, or any other means or material, or the provision of any data that allows the identification of the patient, the prescribing professional, the institution to which the professional is affiliated, or the place of prescription, is subject to regulation by the Medication Regulatory Chamber.

Article 47. The materials referred to in articles 12, 13, the captions of articles 18, 39, and 41 may not use designations, symbols, figures, images, drawings, figurative or mixed marks, slogans, or any advertising arguments related to medicinal products.

Article 48. After the publication of the ruling imposing the sanction of a corrective message, the responsible party will be notified to present the media plan for the advertisement or publicity broadcast irregularly and a proposed corrective message with the respective provisional media plan.

Paragraph 1. The corrective message must include:

I – A declaration that the company or individual was ordered in an administrative health proceeding, instituted by Anvisa and/or a local health authority, to publish a corrective and clarification message to compensate for advertising or publicity for a product subject to health surveillance that was broadcast in noncompliance with federal health legislation;

II – List the irregularities identified in the advertisement and analyzed in the administrative health process, which culminated in the application of the corrective

message, clarifying the errors, mistakes, and misunderstandings caused and providing correct and complete information about the advertised product;

III – In the case of over-the-counter medicinal products, display the following warning: "All medications also pose risks. To avoid harm to your health, inform yourself."

IV – In the case of prescription medications, provide information on the contraindications, precautions, warnings, adverse reactions, and medication interactions of the medicinal product, as well as the following warning: "Balanced and carefully evaluated information is essential for the prescription and rational use of medications."

Paragraph 2. The provisional media plan may be modified and/or adapted, and other requirements may be imposed that consider the type of product advertised, the health risk, and the targeted audience.

Article 49. The dissemination of the corrective message must meet the following requirements:

I – On television, the rectifying message must be broadcast in text written on a green background, without images, in white letters, Humanist 777 or Frutiger 55 standard, ascending in a character list, with voice-over, cadenced, without background music and perfectly audible.

II – On radio, the rectifying message must be read without background music and with cadenced and perfectly audible voice-over.

III – In newspapers, magazines, outdoor media, and similar media, the rectifying message must be published on a white background, framed by an internal border, and in black lettering, Humanist 777 or Frutiger 55 standard.

IV – On the Internet, the rectifying message must be placed on a white background, framed by an internal border, and in black lettering, Humanist 777 or Frutiger 55 standard.

V – If advertising space is sufficient, the message must be displayed on a single poster, with the letters in a legible size. If this is not sufficient, the message must be displayed sequentially and in a perfectly legible manner.

VI – The responsible party may be notified to submit, within ten days of receipt of the notification, extendable once for the same period, modifications to the rectifying message and media plan presented to adapt them to the requirements imposed in accordance with the standards established in this Resolution.

Article 50. Once all requirements are met, the responsible party will be notified to proceed with disseminating the corrective message in the media, and must then demonstrate full execution of the media plan as follows:

I – For corrective messages broadcast on television and radio, a detailed invoice must be attached to the case file, proving that the message was disseminated in the media, at the

times and frequencies specified in the media plan, as well as a recording of the message broadcast;

II – For corrective messages broadcast in newspapers and magazines, a copy of each publication in which the message was disseminated must be attached to the case file;

III – For corrective messages broadcast in outdoor and similar media, in addition to the detailed invoice, proving that the message was disseminated as provided in the media plan, photos with negatives of the message inserted in the respective media must be attached to the case file;

IV – Regarding corrective messages posted on the Internet, a document proving that the message was posted on the websites specified in the media plan, as well as a printout of the page containing the date, must be attached to the case file.

Paragraph 1. After the corrective message is posted, followed by proof of full execution of the media plan, an order will be issued attesting to the proper compliance with the sanction, resulting in the termination of the administrative health proceeding.

Paragraph 2. In the event of non-compliance with the sanction for a corrective message, the responsible party will be subject to the consequences and penalties provided for in health legislation.

Article 51. During the investigation of the offense, when it involves advertising, publicity, or information that poses an imminent risk to public health, the health entity may, as a precautionary measure, order the suspension of the broadcast of the advertising or informational material, for the period necessary to conduct analyses or other required measures.

Article 52. Companies must inform all their medicinal product commercialization and marketing personnel, including advertising agencies, about this Technical Regulation and their responsibilities for compliance.

Article 53. Anvisa may, at any time, issue regulatory acts related to this matter, with the purpose of updating the regulations on advertising, publicity, promotion, and information for products subject to health surveillance.

Article 54. RDC 102/2000, RDC 199/2004, RDC 197/2004, and other Resolutions that provide otherwise are expressly revoked.

Article 54. RDC 102 of 30 November 2000, published in the DOU No. 231 – E, Section 1, page 28, of 1 December 2000, RDC 199 of 17 August 2004, published in the DOU No. 159, Section 1, page 82, of 18 August 2004, republished in the DOU No. 164, Section 1, page 47, of 25 August 2004, Article 90 of SVS/MS Ordinance No. 344 of 12 May 1998, published in the DOU No. 91 - E, Section 1, page 3, of 15 May 1998, republished in the DOU of 1 February 1999 and other rules that provide otherwise are expressly revoked. (Amended by the Federal Official Gazette No. 157 of 17 August 2010, section 1, page 41)

ANNEX I

OFFICIALLY RECOGNIZED NATIONAL AND INTERNATIONAL LITERATURE

BRAZILIAN PHARMACOPOEIA

GERMAN PHARMACOPOEIA

BRITISH PHARMACOPOEIA

EUROPEAN PHARMACOPOEIA

NORDIC PHARMACOPOEIA

JAPANESE PHARMACOPOEIA

FRENCH PHARMACOPOEIA

AMERICAN PHARMACOPOEIA AND ITS NATIONAL FORMULA

MEXICAN PHARMACOPOEIA

USP NATIONAL FORMULARY

MARTINDALE, WILLIAN

EXTRA PHARMACOPOEIA

VIDAL DICTIONARY

EDITIONS DU VIDAL

REMINGTON PHARMACY

PAN-AMERICAN MEDICAL EDITORIAL

USP MEDICINAL PRODUCT INFORMATION

USP PHARMACISTS' PHARMACOPOEIA

NATIONAL FORMULA

HOMEOPATHIE – PHARMACOTECHNIE ET MONOGRAPHIES DES MEDICAMENTES COURANTS VOLUME I AND II

HOMOEPATHIC PHARMACOPEIA OF INDIA

PHARMACOPÉE FRANÇAISE AND COMPLEMENTS

THE HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES AND COMPLEMENTS

ANNEX II

(TABLE)

	ACTIVE INGREDIENT	**WARNINGS FOR USE IN ADVERTISING**
1.	Acetylsalicylic acid	*Do not use this medicine if you are pregnant, have gastritis or stomach ulcers, or if you suspect you have dengue fever or chickenpox.*
2.	Ascorbic acid (vitamin C)	*Do not use this medicine if you have severe kidney disease.*
3.	Baking soda	*Do not use this medicine if you have restricted salt intake, kidney, heart, or liver failure.*
4.	Bisacodyl	*Do not use this medicine in case of severe intestinal diseases.*
5.	Camphor	*Do not use this medicine in children under two years old.*
6.	Calcium Carbonate	*Do not use this medicine if you have kidney disease.*
7.	Charcoal	*Do not use this medicine in children with acute and persistent diarrhea.*
8.	Ambroxol hydrochloride	*Do not use this medicine in children under two years old.*
9.	Phenylephrine hydrochloride	*Do not use this medicine if you have heart disease, high blood pressure, or glaucoma.*
10.	Dipyrone sodium	*Do not use this medicine during pregnancy or in children under three months old.*
11.	Dropropizine	*Do not use this medicine in case of coughing secretion and in children under two years old.*
12.	Aluminum hydroxide	*Do not use this medicine in case of kidney disease and acute abdominal pain.*
13.	Magnesium hydroxide	*Do not use this medicine if you have kidney disease.*

14.	Ibuprofen	*Do not use this medicine in cases of ulcers, gastritis, kidney disease, or if you have ever had an allergic reaction to anti-inflammatory medicinal products.*
15.	Mebendazole	*Do not use this medicine in children under one year old.*
16.	Naproxen	*Do not use this medicine in cases of ulcers, gastritis, kidney disease, or if you have ever had an allergic reaction to anti-inflammatory medicinal products.*
17.	Nicotine	*Do not use this medicine if you are a smoker with heart problems.*
18.	Paracetamol	*Do not use this medicine with other medicinal products containing paracetamol, with alcohol, or in case of severe liver disease.*
19.	Sodium picosulfate	*Do not use this medicine in case of severe intestinal diseases.*
20.	Plantago ovata Forsk	*Do not use this medicine in case of severe intestinal diseases.*
21.	Ferrous sulfate	*Do not use this medicine if you have gastrointestinal problems.*