

**(Translator's Note:** I have kept the translation as close as possible to the original in Portuguese so as to show how complicated this legislation has been drafted. In the final text adopted, the word 'advertising' was replaced by 'commercial promotion', which is not quite the same. That creates confusion that shows up in subsequent articles and paragraphs. Art 4 prohibits all 'commercial promotion' but then goes on to limit what that is, and the subsequent articles describe and restrict specific forms of 'commercial promotion', i.e. advertising.

The description of products covered is not the same as that in the Code. That may be a Brazilian particularity, but it complicates the labelling rules. Monitors and health authorities will have a hard time checking that each of the detailed labelling provisions for different foods are applied correctly.

Jean-Pierre Allain, 14 Nov 2015)

## **Decree No 8552 of 3 November 2015**

### **Regulating Law No 11265 of 3 January 2006 on marketing of foods for infants and young children and related childcare products**

**THE PRESIDENT OF THE REPUBLIC**, in the exercise of the powers vested in her by Art. 84, Caput, Para IV, of the Constitution, and in view of Art. 29 of Law 11265 of 3 January 2006,

#### **DECREES:**

**Art. 1:** This Decree shall regulate implementation of Law No 11265 of 3 January 2006 covering the marketing of foods for infants and young children and related childcare products.

### **CHAPTER I**

#### **GENERAL PROVISIONS**

**Art. 2:** This Decree shall apply to the marketing, advertising and related practices, to quality and information on use of the following products, whether manufactured in the country or imported:

I – **Weaning foods and cereal-based foods** appropriate for infants or young children, and other foods and beverages, milk-based or not, when they are marketed or presented as appropriate to feed infants and young children;

II – **Nutrient formulas presented or indicated for high-risk newborns;**

III – **Follow-on formulas for young children;**

IV – **Infant formulas and follow-on formulas for infants;**

V – **Infant formulas for specific dietary or therapeutic needs;**

VI -- **Liquid or powdered milks, modified milks or similar vegetable-based milks;** and

VII – **Feeding bottles, teats and pacifiers.**

**Art. 3:** For purposes of this Decree, the following definitions shall apply:

I - **Breastmilk substitute:** any food marketed or otherwise represented as a partial or total replacement for breastmilk.

II – **Weaning foods for infants and young children:** ready-for use manufactured food or home-made preparation used as a complement to breastfeeding or to infant formula, introduced into the feeding of infants and young children to promote gradual adaptation to common foods and to promote an adequate and balanced diet suitable for their age, taking into account their physiological maturity and their neuro-psychomotor development.

III – **Cereal-based foods for infants and young children:** any cereal-based food adapted to feed infants after their sixth month and young children, respecting their physiological maturity and their neuro-psychomotor development.

IV – **Sample:** a unit of a product provided free of charge, one single time.

V – **Special presentation:** Any form of presenting a product for purposes of commercial promotion with the aim of inducing its purchase or sale, such as promotional packaging, decorative packing, or joint presentation of a product together with other products not covered by this Decree.

VI – **Health authority:** Any person who carries out health-related activities, in a public or official position.

VII – **Monitoring authority:** A health authority or entity, part of the National Health Control System, or part of a public consumer protection agency, whether at federal, state, district or municipal level.

VIII – **Teat:** An object presented or prescribed for the process of suction feeding, with the purpose of administering or providing foods or liquids from a container (to the infant) or onto the (mother's) nipple.

IX – **Kit or set:** A collection of products of different brands, shapes or sizes, fitted into a single package.

X – **Child:** A person up to the age of twelve years.

XI – **Young child** (in Portuguese also called “child in the first childhood”): A child from twelve months to three years of age.

XII – **Pacifier:** A suction gadget without the purpose to administer foods, medications or liquids.

XIII – **Highlight:** A graphic or sound message to highlight a specific warning, sentence or text.

XIV – **Donation:** Free gift of a product in a quantity greater than a sample.

XV – **Distributor:** Any person or entity, in the public or private sector, directly or indirectly involved in the sale or import, wholesale or retail, of one or more products covered by this Decree.

XVI - **Special exhibit:** Any way to expose a product in a manner to distinguish it from others in the shop, such as a showcase, at the tip of a gondola, in an island or a stack of products pyramid-shaped, on crates, via shelf decoration or any other way, as defined in the National Health Monitoring Agency (ANVISA) regulations.

XVII – **Packaging:** Any container, package or wrapper used to ensure the conservation and ease of transport and handling of products.

XVIII – **Nationally recognized association:** Any association that brings together at least fifty per cent of the doctors and nutritionists in all regions of Brazil.

XIX - **Teaching and research scientific organization:** Any university, college, integrated college, high school or centre of technological education, recognized by the Ministry of Education.

XX – **Manufacturer:** Any private or public entity involved in manufacturing products covered by this Decree.

XXI - **Humanized figure or illustration:** Any photo, drawing or depiction of children's characters, living or inanimate, stylized or not, with physical or behavioural characteristics peculiar to humans.

XXII - **Infant formula for infants:** A product in liquid or powder form intended for the feeding of infants up to six months, upon prescription, as a full or partial replacement of breast milk, to satisfy their nutritional needs.

XXIII - **Infant formula for specific dietetic needs:** A product whose composition has been modified to meet the specific needs arising from temporary or permanent physiological or pathological changes, not included in the specific technical regulation of infant formula.

XXIV - **Infant follow-up formula for infants:** A product in liquid or powder form, used upon recommendation of a qualified professional, as a substitute for breastmilk, from the sixth month of age of an infant.

XXV – **Infant follow-up formula for young children:** A product in liquid or powder form used as a breastmilk substitute for young children.

XXVI - **Nutrient formula for infants at high risk:** A compound of nutrients presented or indicated as suitable for feeding infants at high risk.

XXVII – **Importer:** A legal entity that imports products covered by this Decree.

XXVIII – **Infant:** A child up to the age of eleven months and twenty-nine days.

XXIX – **Milk:** A liquid or powdered product, obtained from the complete uninterrupted milking, in clean conditions, of healthy, well-fed and rested animals of all species.

XXX – **Modified milk:** Liquid or powdered milk whose composition has been modified by extracting or by adding components.

XXXI – **Feeding bottle:** A container to administer a liquid or semi-liquid product to children. It is made of a teat and a container that may have a ring to keep the two attached.

XXXII - **Educational materials:** Written or audio-visual material for the public to guide on the feeding of infants and young children or about the proper use of products intended for infants and young children, such as brochures, books, articles in layman journals, cassettes, videotapes, electronic information system and others.

XXXIII - **Technical and scientific materials:** Material with proven information about products or related to nutrition and paediatrics, aimed at professionals and health personnel.

XXXIV - **Main panel or front panel:** The easily visible area (of a label), under normal exposure conditions, on which are written in a clear and relevant way, the product description, the brand and the logo.

XXV – **Sponsorship:** Funding of all or a part of the costs of materials, of a radio or television show, of internet pages or internet content and of content of other media, of an event, a community project, a cultural, artistic or sport activity, of research or scientific update, or direct or indirect funding of health care professionals to participate in activities or any kind of enticement to encourage them.

XXXVI - **Commercial promotion:** Information and persuasion activities by companies that produce, process, distribute or sell products covered by this Decree, including information via visual, auditory and audio-visual means, aimed at inducing the purchase or sale of a product.

XXXVII – **High-risk newborn:** An infant who:

- a) Was born prematurely, with less than thirty-four weeks of gestational age;
- b) Was born weighing less than one thousand five hundred grams; or
- c) Presents pathology that requires intensive treatment soon after birth.

XXXVIII - **Sales representative:** Any seller, promoter, demonstrator, company or sales representative or any other paid professional, who is directly or indirectly employed by manufacturers, suppliers or importers of the products covered by this Decree.

XXXIX – **Label:** Any inscription, legend, image, descriptive matter or graphic that is written, printed, stamped, engraved, embossed, lithographed, glued or fused onto the surface of the container, of the product or its packaging.

XL – **Similar of vegetable origin:** Any food, in liquid or powder form, containing vegetable protein, marketed or presented as alternative to milk.

XLI - **Similar of mixed vegetable origin:** A food of plant origin that includes in its composition a non-plant protein.

## CHAPTER II – MARKETING AND ADVERTISING

**Art. 4:** Commercial promotion of products listed in sections II, IV and VII of Art. 2, in any media, including the indirect or hidden advertising and disclosure by electronic, written, audio and visual means, shall be prohibited.

**Single paragraph.** The ban on commercial promotion in the first sentence applies to promotional strategies, such as special displays and price discounts, discount coupons, prizes, gifts, sales tied to the purchase of products not subject to the provisions of this Decree, special presentations or any other methods established in ANVISA regulations.

**Art. 5:** The commercial promotion of infant foods mentioned in paragraphs I, III and VI of Art. 2 shall include the following words, with visual or auditory highlight, depending on the means of transmission:

I - For products listed in paragraphs III and VI of Art. 2: *"The Ministry of Health states: Breastfeeding avoids infections and allergies and is recommended up to two (2) years or more";*

II - For products referred to in paragraph I of Art. 2: *"The Ministry of Health recommends: After six (6) months of age, continue breast-feeding your child and offer new foods."*

§ 1 - Words conveyed in writing shall be readable, in capital letters, next to the products (they qualify), in the same direction as other informative texts, when available.

§ 2 - The characters mentioned in § 1 must in capital letters, bold and be at least twenty per cent of the size of letters used in the commercial promotion, with a minimum size of two millimetres.

§ 3 - Audio highlights shall be presented in a paused, clear and audible manner.

**Art. 6:** Sales representatives shall not perform duties in health care facilities, except for the communication of technical-scientific aspects of the products to paediatricians and nutritionists.

**Single paragraph.** It shall be the duty of manufacturers, distributors or importers to inform their sales representatives and advertising agencies about the provisions of this Decree.

**Art. 7:** Manufacturers, distributors and importers may provide samples of the products listed in items I, III, IV and VI of Art. 2 to paediatricians and nutritionists only at the launch of a product, subject to the provisions of Art. 17.

§ 1. For the purposes of this Decree, the national launch (of a product) in all of Brazil shall be made within a period eighteen months maximum.

§ 2. The starting point for calculating the period referred to in § 1 shall be set in specific ANVISA regulations.

§ 3. The distribution of samples when a product is relaunched or when a brand is changed, without substantial modification of the nutritional composition of said product, shall be banned.

§ 4. In order to avoid the ban provided for in § 3 above, the manufacturer, distributor or importer of a product shall prove to the competent monitoring agency that there has been a substantial modification of the nutritional composition of said product.

§ 5. The distribution of samples of bottles, teats, pacifiers and nutrient formula for infants at high risk shall be banned.

§ 6. Samples of infant formula for infants shall be offered only if requested by a paediatrician or a nutritionist and shall be accompanied by a company delivery form, with a copy to the requesting health professional.

**Art. 8:** Manufacturers, importers and distributors of products covered by this Decree may only provide sponsorship to teaching and research scientific institutions or to nationally recognized professional associations and shall be banned from sponsoring individuals.

§ 1. Associations affiliated to nationally recognized professional associations that may receive sponsorship as mentioned in the heading of this article, may do so only after they have been approved by the nationally recognized professional association.

§ 2. The beneficiary entities shall not allow the companies referred to in this article to perform commercial promotion of their products in sponsored events.

§ 3. The sponsoring companies shall be restricted to the distribution of technical and scientific material during a sponsored event.

§ 4. The sponsored events shall include the following highlighted text in any promotional materials: *"This event received sponsorship from private companies in accordance with Law No. 11265 of 3 January 2006"*.

**Art. 9:** Donations or reduced price sales of products covered by this Decree, to hospitals and institutions providing childcare, shall be prohibited.

§ 1. This prohibition does not apply to donations or sales at reduced price in situations of exceptional individual or collective need, at the discretion of the supervisory authority.

§ 2. When the donation or sale at a reduced price has been authorized, as provided for in § 1, the supply shall be maintained continuously for as long as the recipient infants needs it.

§ 3. For purposes of § 1, the donor or vendor of the product shall be allowed to print his name or logo, but any product advertising shall be banned.

§ 4. Donations of products for research purposes shall be allowed only upon presentation of a research protocol approved by the Ethics Committee of the institution to which the professional in charge of the research is linked, in compliance with the standards established by the National Board of Health and ANVISA.

§ 5. Products donated for research shall bear on the front panel, highlighted, the words *"Donation for research, according to Law No. 11265 of 3 January 2006"*.

§ 6. The text mentioned in § 5 shall be legible, in bold capital letters, in the same direction of informational text and be at least fifty percent of the font size of the largest font used in the informative text, excluding the trademark, provided that the minimum size of two millimeters is respected.

### CHAPTER III – LABELLING

**Art. 10:** Packaging or labels of infant formula for infants and of follow-up formula for infants shall not:

I – Use photos, pictures or graphic representations that are not necessary to illustrate the method of preparation or the use of the product, apart from the brand or logo of the product, and not use pictures of infants, young children or other humanised figures or illustrations.

II – Use names or phrases that may suggest a strong resemblance of the product to breastmilk, such as "humanised milk", "maternalised milk", "breastmilk substitute" or any others that may be determined by ANVISA regulations.

III – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

IV – Use expressions or names that identify the product as the most suitable to feed infants, such as "baby", "kids", "ideal for baby", "first growth" or any others that may be determined by ANVISA regulations.

V – Use information that may lead to the use of the product under a false pretext of advantage or safety.

VI – Use phrases or expressions that suggest health conditions for which the product is purported to be appropriate.

VII – Promote the manufacturer's products or those of another company.

§ 1. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *“IMPORTANT NOTICE: This product must be used only to feed infants under 1 (one) year old, upon the express recommendation of a doctor or nutritionist. Breastfeeding prevents infections and allergies and strengthens the mother-to-child bond.”*

§ 2. Labels shall highlight a warning about the risks of improper preparation, with instructions on the correct preparation of the product, on measures of cleanliness that must be observed and on the correct dilution, when appropriate, as per ANVISA regulations.

**Art. 11:** Packaging or labels of follow-up formula for young children shall not:

I - Use photos, pictures or graphic representations that are not necessary to illustrate the method of preparation or the use of the product, apart from the brand or logo of the product, and not use pictures of infants, young children or other humanised figures or illustrations.

II – Use names or phrases that may suggest a strong resemblance of the product to breastmilk, such as “humanised milk”, “maternalised milk”, “breastmilk substitute” or any others that may be determined by ANVISA regulations.

III – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

IV – Use expressions or names that identify the product as the most suitable to feed infants, such as “baby”, “kids”, “ideal for baby”, “first growth” or any others that may be determined by ANVISA regulations.

V – Use information that may lead to the use of the product under a false pretext of advantage or safety.

VI – Use sequential brands in follow-up formulas for young children.

VII - Promote the manufacturer’s products or those of another company.

§ 1. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *“IMPORTANT NOTICE: This product must be used only to feed infants under 1 (one) year old, upon the express recommendation of a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to the age of 2 (two) years or more.”*

§ 2. Labels shall highlight a warning about the risks of improper preparation, with instructions on the correct preparation of the product, on measures of cleanliness that must be observed and on the correct dilution, when appropriate, and not use pictures of feeding bottles, as per ANVISA regulations.

**Art. 12:** Packaging and labels of infant formula for specific dietetic needs shall contain information on the specific nature of the food and shall not indicate any health conditions for which the product may be used.

Single paragraph: The provisions of Art. 10 shall apply to the products mentioned in this article.

**Art. 13:** Packaging and labels of liquid or powdered milk, modified milks and similar vegetable-based milks shall not:

I - Use photos, pictures or graphic representations that are not necessary to illustrate the method of preparation or the use of the product, apart from the brand or logo of the product, and not use pictures of

infants, young children or other humanised figures or illustrations nor any other that may induce to the use of the product for those age groups.

II – Use names or phrases that may suggest a strong resemblance of the product to breastmilk, such as “humanised milk”, “maternalised milk”, “breastmilk substitute” or any others that may be determined by ANVISA regulations.

III – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

IV – Use expressions or names that identify the product as the most suitable to feed infants, such as “baby”, “kids”, “ideal for baby”, “first growth” or any others that may be determined by ANVISA regulations.

V – Use information that may lead to the use of the product under a false pretext of advantage or safety.

VI – Use sequential brands in follow-up formulas for young children.

VII - Promote the manufacturer’s products or those of another company intended for infants.

§ 1. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning:

I – For skimmed or semi-skimmed milks, with or without addition of essential nutrients:

*“IMPORTANT NOTICE: This product must not be used to feed children, except when expressly recommended by a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to the age of 2 (two) years or more.”*

II – For whole milks or similar vegetable-based or mixed milks, enriched or not: *“IMPORTANT NOTICE: This product must be used only to feed infants under 1 (one) year old, upon the express recommendation of a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to the age of 2 (two) years or more.”*

III – For modified milks: *“IMPORTANT NOTICE: This product must not be used to feed infants under 1 (one) year old. Breastfeeding prevents infections and allergies and is recommended up to the age of 2 (two) years or more.”*

§ 2. Condensed milks and/or flavoured milks shall not be recommended, by any means, for feeding infants and young children.

**Art. 14:** Packaging and labels of weaning foods, cereal-based foods indicated for infants and young children, and of foods or milks, whether milk-based or not, when marketed or presented as suitable for feeding infants and young children, shall not:

I - Use photos, pictures or graphic representations of young children.

II – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

III – Use expressions or names that identify the product as suitable or preferred to feed infants under six months age, such as “baby”, “kids”, “ideal for baby”, “first growth” or any others that may be determined by ANVISA regulations.

IV – Use information that may lead to the use of the product under a false pretext of advantage or safety.

V – Promote infant formulas, milks, milk-based products and cereals that can be fed by feeding bottle.

§ 1. The age from which the products can be used shall appear on the front panel of labels.



§ 2. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *“The Ministry of Health warns: This product must not be used to feed infants under 6 (six) months old, except if expressly recommended by a doctor or nutritionist. Breastfeeding prevents infections and allergies and is recommended up to the age of 2 (two) years or more.”*

**Art. 15:** Packaging or labels of nutrient formulas for high-risk newborns shall not:

I - Use photos, pictures or graphic representations that are not necessary to illustrate the method of preparation or the use of the product, apart from the brand or logo of the product, and not use pictures of infants, young children or other humanised figures or illustrations.

II – Use names or phrases that suggest the need for complements, supplements or enrichment of breastmilk.

III – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

IV – Use expressions or names that identify the product as the most suitable to feed infants, such as “baby”, “kids”, “ideal for baby”, “first growth” or any others that may be determined by ANVISA regulations.

V – Use information that may lead to the use of the product under a false pretext of advantage or safety.

VI - Promote the manufacturer’s products or those of another company.

§ 1. Labels shall bear on the front panel the following warning: *“IMPORTANT NOTICE: This product must only be used to supplement the feeding of a high-risk newborn when prescribed by a doctor and shall be used exclusively in hospitals.”*

§ 2. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *“The Ministry of Health warns: Breastmilk contains the essential nutrients for your child’s growth and development during the first years of life.”*

§ 3. Labels shall highlight a warning about the risks of improper preparation, with instructions on the correct preparation of the product, on measures of cleanliness that must be observed and on the correct dilution, when appropriate, as per ANVISA regulations.

§ 4. The product referred to in this article (TN: nutrient formulas for high-risk newborns) shall be used exclusively in hospitals. It’s marketing outside health services shall be banned.

**Art. 16:** Packaging or labels of bottles, teats and pacifiers shall not:

I - Use photos or pictures of infants, young children or humanised figures or illustrations.

II – Use phrases or expressions that put in doubt the ability of mothers to breastfeed their children.

III – Use phrases, expressions or illustrations that suggest there is similarity between these products and the human breast or nipple.

IV – Use expressions or names that identify the product as the most suitable to use for infants, such as “baby”, “kids”, “ideal for baby”, “first growth” or any others that may be determined by ANVISA regulations.

V – Use information that may lead to the use of the product under a false pretext of advantage or safety.

VI - Promote the manufacturer's products or those of another company.

§ 1. Labels shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *"The Ministry of Health warns: A breastfed child does not need a feeding bottle, teats or pacifiers. The use of feeding bottle, teats or pacifiers is harmful to breastfeeding."*

§ 2. The use of packaging and labels on bottles, teats and pacifiers, with instructions for use, as per ANVISA regulations, shall be compulsory.

**Art. 17:** Labels of samples of products covered by this Decree shall exhibit on the main panel, in block letters, in a legible manner, horizontally, easily visible and in contrasting colours and in letters of at least two millimetres height, highlighted, the following warning: *"Free sample for professional evaluation. Shall not be distributed to mothers, pregnant women and families."*

#### **CHAPTER IV – EDUCATION AND PUBLIC INFORMATION**

**Art. 18:** Public health institutions, education and research institutions and associations of paediatricians and nutritionists shall participate in the process of dissemination of information on infant and young child feeding, as well as in training of people.

**Art. 19:** Educational, technical and scientific materials on infant and young child feeding and on products referred to in article 2, shall abide by the provisions of this Decree and include explicit, clear, legible and understandable information on:

I - The benefits of breastfeeding and its superiority compared to breastmilk substitutes.

II – Guidance on appropriate feeding of pregnant and nursing mothers, stressing preparation and maintenance of breastfeeding up to two years of age or more.

III – The negative impacts of using bottles, teats or pacifiers on breastfeeding, particularly the difficulty of getting back to breastfeeding and the inconvenience of preparation of foods and cleanliness and sterilization of those products.

IV – The financial implications of choosing to feed breastmilk substitutes.

V – The harm caused to infant health by the unnecessary or inappropriate use of artificial foods.

VI – The importance of developing (in the infant) education and cultural habits that encourage the consumption of family diet foods.

§ 1. Educational, technical and scientific materials, including those for health professionals and for health authorities, shall not contain any pictures or text that recommend or that could lead to the use of feeding bottles, teats and nipples or to the use of breastmilk substitutes.

§ 2. Educational materials about infant feeding shall not be produced nor sponsored by distributors, suppliers, importers or manufacturers of products within the scope of this Decree.

**Art. 20:** Institutions responsible for the training of health professional shall include (in their curricula) the dissemination (of this Decree) and strategies to comply with its provisions, as part of program content in subjects dealing with infant feeding.

**Art. 21:** Health professionals shall disseminate and encourage the practice of exclusive breastfeeding up to six months and continued breastfeeding up to two years or more.

**Art. 22:** Primary and middle education institutions shall disseminate and promote the content of this Decree.

## **CHAPTER V – FINAL PROVISIONS**

**Art. 23.** It shall be incumbent upon public agencies and entities at the federal, state, county and municipal level, together with civil society organisations and under the guidance of the Ministry of Health and ANVISA, to ensure the dissemination, implementation and monitoring of compliance with the provisions of this Decree.

Single paragraph. Public agencies and entities at the federal, state, county and municipal level, shall work together with civil society organisation, with a view to publicise this Decree and to ensure compliance with its provisions.

**Art. 24.** Foods for infants shall meet the quality standards established in ANVISA resolution.

**Art. 25.** Bottles, teats and pacifiers shall not contain more than ten parts per billion of any N-nitrosamine, nor more than twenty parts per billion of more than one of these substances together.

§ 1. ANVISA shall establish, where appropriate, prohibitions or restrictions on substances harmful to the health of infants and young children.

§ 2. The provisions in this article shall be monitored through the network of public health laboratories created in accordance with paragraph b of section III of article 16 of Law No. 8080, of 19 September 1990.

§ 3. ANVISA shall be authorized to accredit laboratories to act in a manner complementary to the network referred to in § 2.

**Art. 26:** ANVISA may establish new product categories and regulate their production, marketing and commercial promotion, with the aim to achieve the objective set out in Article 1 of Law No. 11265 of 2006.

**Art. 27:** Violations of the provisions of Law No. 11265 of 2006 or of the provisions of this Decree shall subject violators to the penalties provided for in Law No. 6437 of 20 August 1977.

Single paragraph. The provisions of Law No. 8078 of 11 September 1990, of Decree-Law No. 986 of 21 October 1969, of Law No. 8069 of 13 July 1990, and other regulations issued by the agencies and the competent public authorities shall apply to situations governed by this Decree, as applicable.

**Art. 28.** This Decree shall enter into force on the date of its publication.

§ 1. Companies shall have a period of one year from the date of publication of this Decree to adapt the labelling of their products to the provisions of this Decree.

§ 2. Products manufactured up to the end of the period mentioned in § 1 may be marketed until the end of their period of validity.

Brasília, 3 November 2015; 194<sup>o</sup> Year of Independence and 127<sup>o</sup> Year of the Republic.

DILMA ROUSSEFF (President)

Marcelo Costa e Castro (Minister of Health)